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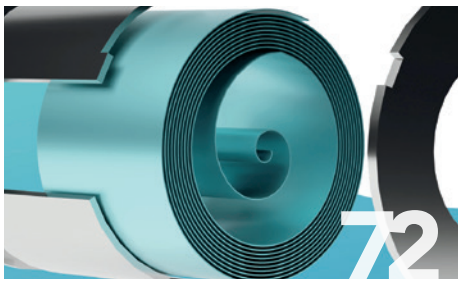

PREFILLED SYRINGES & INJECTION DEVICES

ONdrugDelivery Issue N° 182, January 19th, 2026

This edition is one in the ONdrugDelivery series of publications. Each issue focuses on a specific topic within the field of drug delivery, and is supported by industry leaders in that field.

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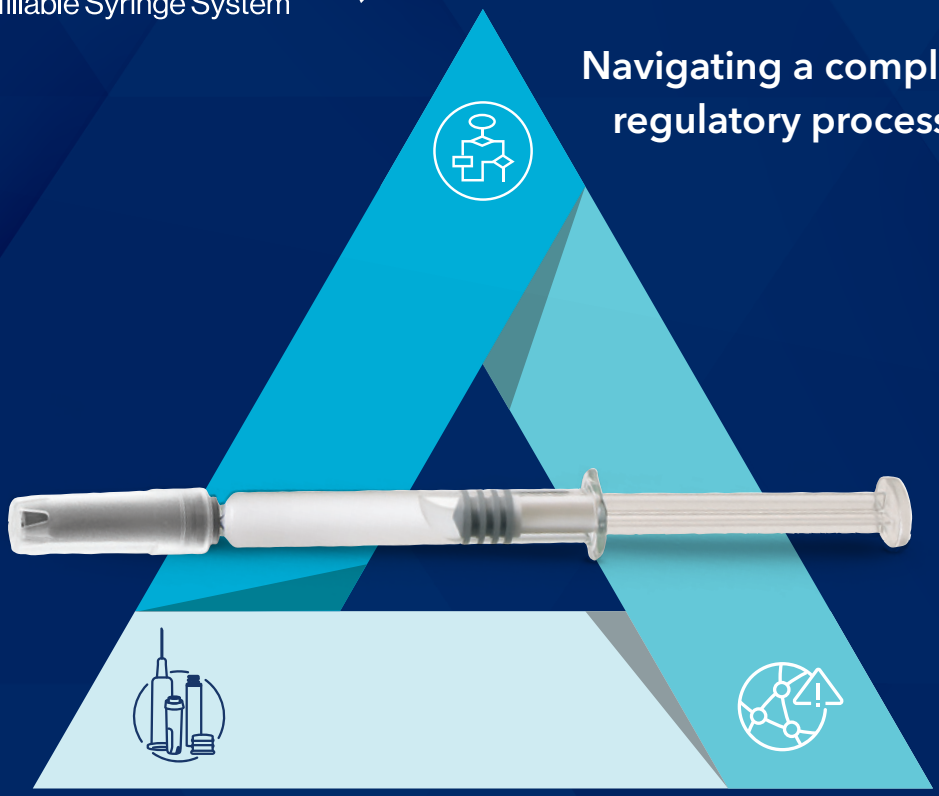

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An Evolving Sector: Innovation In Injection

As we enter 2026, ONdrugDelivery returns to Prefilled Syringes and Injection Devices for another bumper issue. The continued support for this issue topic, consistently our largest each year, is clear evidence that the injectables sector continues to march forwards, facing challenges and presenting new solutions. This issue comes just ahead of Pharmapack Europe in Paris (January 21–22, 2026) and contains a wealth of ideas and topics for discussion at one of the key events in the drug delivery calendar.

The issue kicks off with Outstanding Sponsor **West Pharmaceutical Services** introducing its new Synchrony™ PFS system (Page 12). Continuing with devices, **Ypsomed** discusses its CliniPilot® add-on device and Clear to Clinic™ programme (Page 16), **Gerresheimer** introduces its Gx InMonit™ connected add-on (Page 78) and **Daré Biosciences**, along with its partner **Cambridge Consultants**, provide insight into the groundbreaking implantable DARE Intelligent Drug Delivery System (Page 90).

Along with devices, this issue features multiple articles investigating the current state of the drug delivery industry and device development. Opening this discussion, **Sanner** provides an insightful look forwards at the trends for the coming year (Page 22) and **Informa**'s Sherma Ellis Daal, Brand Director of Pharmapack, considers the major industry themes that are to be discussed at the event (Page 32). Following on from this, **Paul Jansen** puts forward the case for a novel model for funding platform development (Page 38).

Focusing more specifically on device development, **Crux Product Design** discusses the role that *ex vivo* and *in silica* testing can play in tackling the challenges of high-volume and high-viscosity drug delivery (Page 42). Pivoting to another key aspect of drug delivery product development, **Nelipak** takes a closer look at secondary packaging (Page 54). Next, **EdgeOne Medical** turns attention to wearable injectors (Page 108) and **Jabil Healthcare** rounds out the discussion with a broader look at the pressures and influences at play in modern device development (Page 114).

As evidenced by the many co-authored articles that partners publish jointly in this and other issues of ONdrugDelivery, a prominent feature of the drug delivery industry today is the need for strong partnerships with experts and specialists across the value chain. Continuing on the subject of partnering, **BD** discusses how it is positioned to assist its pharma partners in handling USP <382> (Page 58), and **PCI Pharma Services** presents the benefits of its product service offering as an expert CDMO (Page 118).

Another substantive industry theme is automation and scale-up. **Instron** begins the discussion on this subject with a focus on automated device testing (Page 48), which is further explored by **ZwickRoell** later in the issue (Page 85). Broadening the topic to industrialisation, **Contexo** and **Probotec** discuss their joint approach to manufacturing and operational scale-up (Page 64) and **SMC** provides insights into the role of small-batch work cells in manufacturing strategy (Page 94).

Lastly, the issue considers the role that component design and manufacturing take in the wider drug delivery ecosystem. **Scherdel Medtec** considers how Design of Experiments methodologies can be used when designing power springs for drug delivery devices (Page 72). Finally, **BAUMANN Medical** discusses the critical value that having a global footprint and ready access to regional markets presents to component manufacturers (Page 101).

I look forward to another year of bringing our readers more excellent articles on the key topics across the drug delivery sector and, along with the ONdrugDelivery team, hope to see many of you at our stand in the Media Hub at Pharmapack, Paris, later in January.

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ARE YOU STILL PIECING TOGETHER YOUR PREFILLABLE SYRINGE SYSTEM OR ARE YOU ALREADY FILLING IT?

Dr Bettine Boltres of **West Pharmaceutical Services** introduces the West Synchrony™ prefillable syringe system, explaining how the device, as a single comprehensive package, minimises regulatory complications and delays.

Despite having been employed since the turn of the 20th century, it was not until after the Second World War that the term "supply chain" really started gaining traction in the world of manufacturing. By the 1980s, the phrase had moved from poetic metaphor to part of the lexicon. It neatly and somewhat simplistically presented the concept of co-dependent stakeholders linked in a continuous series, facilitating the efficient flow of materials and components towards their ultimate destination as a finished product.

Over time, this image has become increasingly intricate in line with the highly complex multi-supplier ecosystems that underpin product development and manufacture today. Evidence of this can be seen clearly in the pharmaceutical industry, and in drug delivery more specifically. Here, ever more sophisticated approaches are continually being explored and accommodated within supply chains to optimise the efficacy and quality of drug products, and to enhance convenience, safety and health outcomes for patients. More complex manufacturing solutions are accepted as the price of innovation and the cost of progress.

In a previous article, West Pharmaceutical Services highlighted prefillable syringe (PFS) system technology as the embodiment of this dilemma. Over time, PFS technology has grown into a global platform drug delivery system, both in terms of market volumes and its value to healthcare professionals and patients. Advances in engineering, design and

materials science mean that PFS systems have evolved to ensure that the quality of drug products, even sensitive biologics, remains protected, allowing patients to self-administer accurate doses within non-clinical settings, including the home. A recent publication even estimated significant cost savings for hospitals in using PFSs versus the traditional vial and syringe approach.[1] But bringing these products to market is the culmination of a lengthy, highly involved and tightly regulated process, which begins with product design and component specification while also encompassing compatibility testing, clinical and human factors studies, technology transfer and scale-up manufacture.

Currently, these various goals can only be achieved through the co-ordination of a sophisticated network of interlinked supply chain partners. This comes down to the fact that, in reality, PFSs are an aggregation of multiple components, each of which must be carefully combined to form a coherent whole. And for the growing number of emerging biotechnology companies targeting the launch of exciting new therapies, this represents a multifaceted manufacturing challenge where there are few opportunities to shortcut, bypass or accelerate the many stages involved.

Thankfully, this paradigm is now shifting. At CPHI Worldwide 2025 in Frankfurt, Germany, West unveiled the West Synchrony™ PFS system, marking the introduction of an entirely new model for the development of PFS drug delivery solutions.

Commercially available from January 2026, the West Synchrony PFS system will enable pharmaceutical partners to simplify and accelerate the development, manufacturing and regulatory approval of primary packaging for their drug. This is achieved through the provision of an integrated and fully design-verified PFS system, encompassing the syringe barrel, plunger and needle shield/tip cap, all from a single, robust, experienced and expert supplier. This integrated, system-based approach removes much of the difficulty and complexity associated with the sourcing, design verification and integration of individual components from separate providers.

"THE PRINCIPLE OF SIMPLIFYING COMPLEXITY MAKES THE WEST SYNCHRONY PFS SYSTEM IDEALLY SUITED TO BIOLOGIC APPLICATIONS, WHICH ARE OFTEN THE DOMAIN OF EMERGING BIOTECH COMPANIES."

The principle of simplifying complexity makes the West Synchrony PFS system ideally suited to biologic applications, which are often the domain of emerging biotech companies. While the emphasis for these newcomers is centred on progressing their molecules through to clinical trials to obtain funding for their projects and obtain marketing authorisation, difficult questions and important decisions must be addressed in relation to drug delivery as part of this process. For smaller companies, however, limitations are likely to exist in terms of their resource capacity and the depths of specialist component-level expertise available to them in-house, all of which intensifies the task of selecting the appropriate PFS.

Faced with this uphill struggle, companies must either rely on recommendations from their selected CDMOs or take it upon themselves to pursue a component-by-component approach to system design, often turning to external consultants and laboratory service organisations to fill in the relevant knowledge gaps. However, these organisations can only ever consult and recommend, with the final decisions solely in the domain of the biotech company. Within this process, the performance of each element and the combined packaging system as a whole must be understood in regulator-approved detail. This necessitates the pulling together of disparate data threads into a unified and robust Design & Development File to support the submission as an Electronic Common Technical Document and/or a Technical File for Notified Bodies in the EU.

In contrast, with the West Synchrony PFS system, all relevant drug-independent design verification testing of the PFS system comes in a complete data package, providing reassuring evidence of all required performance characteristics. A particular advantage is that it can remove an entire phase of scouting, decision making and testing, saving valuable costs and effort while enabling teams to progress directly to the clinical fill phase. Moreover, it also avoids the uncomfortable uncertainty that can arise when forced to interpret and mesh the findings from independent component-level tests.

Building confidence in the combination product development process is crucial when products are developed under the highly critical gaze of global regulatory bodies, which demand accuracy, depth and consistency within data submissions. However these qualities are difficult to guarantee as part of a multi-component approach, where documentation from separate parties must be standardised and compiled into a unified package. Further complications can also arise when regulators question the data provided, as this could trigger simultaneous information requests from different suppliers, as well as the need for collaboration to arrive at a consensus. If this is the case, commercial sensitivities can potentially introduce a demand for multiple three-way confidentiality disclosure agreements to be implemented to ensure that stakeholders are protected.

"BUILDING CONFIDENCE IN THE COMBINATION PRODUCT DEVELOPMENT PROCESS IS CRUCIAL WHEN PRODUCTS ARE DEVELOPED UNDER THE HIGHLY CRITICAL GAZE OF GLOBAL REGULATORY BODIES, WHICH DEMAND ACCURACY, DEPTH AND CONSISTENCY WITHIN DATA SUBMISSIONS."

Problem solving and challenge resolution are, of course, an accepted and expected part of the process when developing a regulated combination product. However, the scale of those problems and the speed and effort required to achieve resolution are critical risk factors in terms of the overall development schedule for a PFS product. If regulatory complications are not easily fixed or if data requests require further testing, development schedules can be delayed, milestones might be missed and launch timeframes become extended. All the while, costs inevitably escalate. Indeed, research from the Tufts Center for the Study of Drug Development (Boston, MA, US) suggests the cost of missing a single day in drug development equates to approximately US$500,000 (£375,000) in lost prescription drug or biologic sales, while approximately $40,000 is lost per day on Phase II and III trials.[2]

The West Synchrony PFS system reduces the risk of regulatory delays and complications by incorporating all relevant information into a single comprehensive regulatory package that has been compiled with the needs and expectations of regulators in mind. This system mindset is further emphasised with one Drug Master File that encompasses the entire PFS system. Furthermore, it comes with a system specification that it is tested against at each batch release. All of this provides pharmaceutical partners with a detailed evaluation of critical quality attributes and design inputs as guided by current GMP regulations across global territories, which include Part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals) and Part 820 (Quality Management System Regulation) of Title 21 of the Code of Federal Regulations in the United States (21 CFR Part 211 & 820) and the GMP guidelines in the EU.

Acting as a "single source of fact", content from the package can be directly transferred into the marketing authorisation submission, ensuring accuracy and consistency while generating significant savings in terms of time and effort. Rather than ownership of information being diluted across stakeholders, it is concentrated into the hands of the drug product owner, who need only liaise with one supplier in the form of West. The benefits of this simplified structure are further underlined when considering any future iterations to PFS components, with West having a robust change management process in place to proactively alert partners to any changes that might impact their filing and necessitate updates to be made with regulators.

As already highlighted, achieving consistency is a particular challenge when managing the flow of information from multiple suppliers. But the challenge of consistency extends beyond the regulatory submission process. Indeed, when it comes to the practicalities of managing product volumes, pharma and biotech companies face a difficult challenge in balancing the various forces of supply and demand in this highly volatile market.

Supply, in particular, can present many points of friction. The ideal scenario of on-demand ordering, as-needed volumes and just-in-time delivery is frequently replaced by significant mismatched minimum order quantities, long lead times and variation in delivery timeframes. Across multiple components, this can exacerbate pressure on cashflow and result in stock-holding issues or unnecessary product wastage.

The West Synchrony PFS system alleviates these pressures through a make-to-stock strategy of complete PFS systems in quantities that are more closely aligned with levels of demand. Inventory can, therefore, be managed more economically, more efficiently and more reactively, with shorter lead times allowing for supply to be matched to volatile market movements.

This security of supply is complemented by assurances of quality and accountability. In terms of quality, the West Synchrony PFS system has been tested at system level prior to distribution, which, by definition, cannot be said of any individual components, where the onus is placed on manufacturing facilities to conduct incoming inspections and system-level testing. Accountability is also improved in a single-supplier arrangement, whereas uncovering the root cause of a post-market issue becomes far more complicated when multiple suppliers are involved.

"THE WEST SYNCHRONY PFS SYSTEM TURNS THE IDEA THAT PROGRESS IN DRUG DELIVERY MUST CORRELATE WITH COMPLEXITY ON ITS HEAD."

In this context, taking a component-based approach to PFS design, if not unviable, is not advisable. It is simply difficult to justify applying additional layers of complexity to an already onerous task. Drug delivery is a sector driven by innovation, with new technologies, processes and approaches continually being implemented either to enhance manufacturing practices or improve patient outcomes. However, with every innovation, there is a risk to accepting another link added to an already complex supply chain.

The West Synchrony PFS system turns the idea that progress in drug delivery must correlate with complexity on its head. By merging several links in the PFS supply chain, it simplifies the primary packaging challenge facing developers of biologics and vaccines, bringing speed to the selection process, accelerating the pathway to clinical fill-finish and easing global regulatory submissions while also providing assurances of consistency in quality and supply. The notion of the supply chain has already witnessed evolution over the past century, and, with the West Synchrony PFS system, the drug delivery sector has an opportunity to rethink, reframe and redefine it once more.

Synchrony is a trademark of West Pharmaceutical Services, Inc.

Dr Bettine Boltres

Bettine Boltres, PhD, Director, Scientific Affairs, Integrated Systems at West Pharmaceutical Services is a recognised thought leader in the industry, fostering scientific exchange between West and the pharmaceutical sector. She possesses extensive knowledge in glass, polymer and rubber materials, which carries over in her expertise in combination products. Dr Boltres is the author of the book "When Glass Meets Pharma" and serves as an expert for the United States Pharmacopeia (USP), European Pharmacopoeia and various ISO working groups. Additionally, she plays an active role in the Parenteral Drug Association (PDA) and has served on the PDA Board of Directors since 2019.

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REFERENCES

1. *Borms M et al, "Improving Efficiency and Safety with Prefilled Syringes: A Model-Based Economic Evaluation for US Healthcare Settings". Clinicoecon Outcomes Res, 2025, Vol 17, pp 673–685.*
2. *Smith Z, DiMasi J, Getz K, "New Estimates on the Cost of a Delay Day in Drug Development". Ther Innov Regul Sci, 2024, Vol 58(5), pp 855–862.*

Interview: Enhancing Clinical Trials with CliniPilot® and Clear to Clinic™ Programme

In this exclusive interview, **Dr Carolina Canapè** and **Roger Lüscher** talk with ONdrugDelivery's Guy Furness about the application of connectivity in decentralised trials, and how **Ypsomed**'s CliniPilot and the company's range of clinic-ready autoinjectors support faster, more efficient and more effective clinical trials.

Q Today, pharma companies are aiming to accelerate clinical development for faster time to market without compromising on data quality or compliance. With that in mind, how is Ypsomed helping its partners achieve speed and reliability in their injection device programmes?

CC A key way that we're helping our partners achieve speed and quality is with CliniPilot (Figure 1), which is an add-on device that transforms YpsoMate autoinjectors into smart, connected devices that automatically capture injection data such as time, date and injection outcomes, then sync those data into electronic data capture systems via a companion app that can also be integrated into an ePRO app (Figure 2). Historically, it's been difficult for clinical trial sponsors to collect reliable objective data on injection, so with CliniPilot, we can massively reduce the need for manual data entry, reduce errors and enable real-time injection data capture.

This has many advantages, such as enabling early interventions if, for example, a patient takes their injection at the wrong time. CliniPilot not only improves data quality and trial outcomes but also provides valuable insights about patient behaviour and, critically, this is all done without adding burden to the patients or to the trial site. CliniPilot technology is based on Ypsomed's SmartPilot, a US FDA-cleared device, and it is suitable for traditional hybrid and decentralised clinical trials models, enabling patients to perform injections at home, minimising the number of necessary visits to the trial site.

Figure 1: CliniPilot smart add-on device for Ypsomate autoinjectors.

Q Next, could you provide an overview of Ypsomed's Clear to Clinic programme and describe what advantages it offers to pharma companies?

RL So far, Ypsomed has provided customised autoinjector devices for each of our pharma partners, each with its own individual development process – every autoinjector was developed from scratch, which used to take around 12 months. Now, with Clear to Clinic, we have clinic-ready devices that are already qualified and verified, making them

"WITH CLEAR TO CLINIC, WE HAVE CLINIC-READY DEVICES THAT ARE ALREADY QUALIFIED AND VERIFIED, MAKING THEM READY FOR USE BY PHARMA PARTNERS."

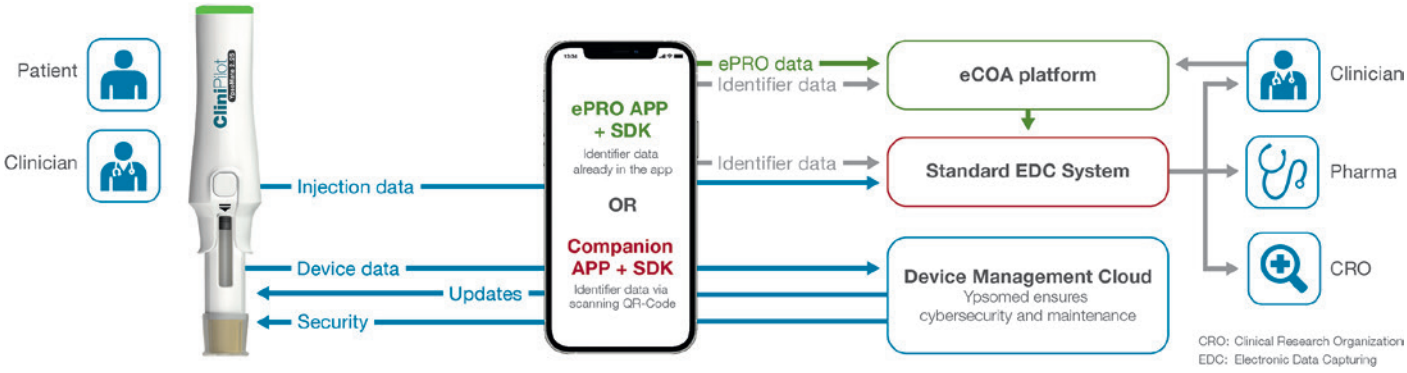

Figure 2: CliniPilot data collection and transfer.

Dr Carolina Canapè

Business Development Lead
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Carolina Canapè, PhD, is Business Development Lead Digital Health at Ypsomed with over 15 years of experience in medtech and digital health. She specialises in developing and executing global go-to-market strategies, integrating digital solutions and driving innovation across clinical and commercial environments. In her current role, she develops strategic partnerships and commercial initiatives for Ypsomed Digital Health solutions. Dr Canapè holds a PhD in Molecular Imaging and an MBA.

ready for use by pharma partners. This approach has reduced project durations to around six months, meaning that autoinjector development is no longer on the critical path in clinical development (Figure 3).

Under the traditional model, when autoinjectors are introduced to a clinical study during its later stages, pharma companies would need to conduct a pharmacokinetic (PK) bridging study to demonstrate equivalence between the autoinjector and the vial or safety syringe used in the early trial stages. By taking the pre-developed approach of Clear to Clinic, pharma partners can use autoinjectors in the early trial stages, enabling them to eliminate the PK bridging study and go to market sooner.

With our Clear to Clinic programme, both the autoinjector and the design verification are ready within three months of pharma preparing the clinical fill, which means that they no longer delay the clinical submission. As you know, Phase IIb and III studies are very expensive, so pharma partners want to avoid delays at all costs.

Importantly, our clinic-ready devices cover the full range of fill volumes and viscosities efficiently. This means that a pharma partner can enter a Phase IIb clinical study with a range of fill volumes and pick a device, or even several, to suit their needs. Also, if the fill volume changes from one study to the next, the impact on the device side is relatively minor compared to what it would be with custom device development – they can simply switch to another clinic-ready device.

The last point to make is that the Clear to Clinic programme has a prepared submission dossier that covers the regulatory requirements for early clinical studies. This dossier was put together using our extensive regulatory experience – Ypsomed has contributed to numerous successful combination product submissions over the years. Our regulatory and medical experts are there to provide device-related expertise to our pharma partners from the start of the study protocol through to submission.

Q In your experience, how is connectivity transforming the way clinical trials are designed, conducted and monitored?

CC The adoption of decentralised trial methodologies – combining technologies with in-person site visits – is accelerating across all types of clinical studies. Connected solutions like CliniPilot can be particularly valuable in scenarios where patients face challenges

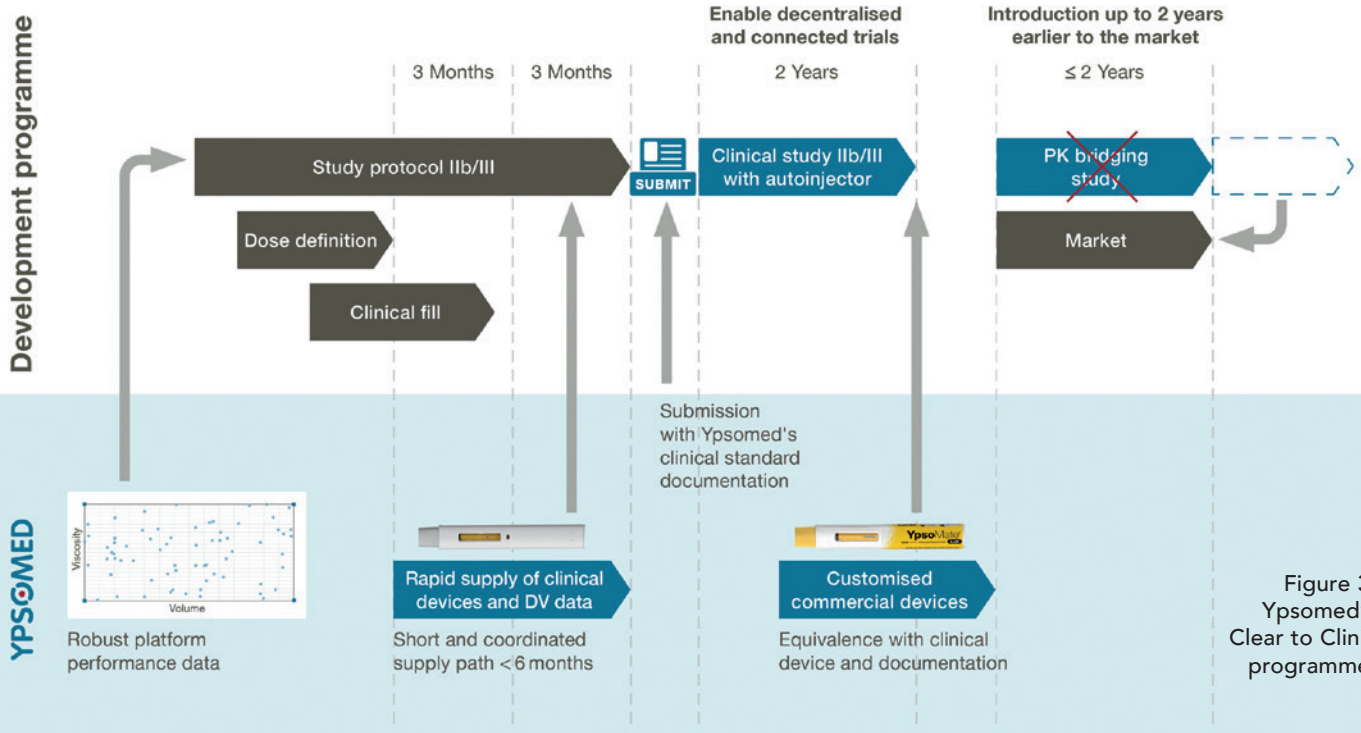

Figure 3: Ypsomed's Clear to Clinic programme.

Roger Lüscher

Project Manager for Autoinjectors

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Roger Lüscher is Project Manager for Autoinjectors at Ypsomed. With more than 14 years of experience in medtech product development, he specialises in managing mechanical and mechatronic product platform projects and has been with the company since 2017. In his current role, he supports the strategic positioning of the YpsoMate autoinjector by aligning business processes with pharmaceutical customer needs, advancing innovation in clinical and commercial settings and fostering strategic partnerships. Mr Lüscher holds an MSc in Industrial Management and Manufacturing from ETH Zurich.

travelling to trial sites. They also play a critical role in long-duration studies, such as those for chronic conditions, which often span multiple years. By enabling seamless connectivity and remote engagement, solutions like CliniPilot help improve patient access, retention and overall trial efficiency.

In summary, CliniPilot connected devices benefit all the stakeholders involved in clinical trials. The shift it enables towards at-home administration benefits patients especially, minimising site visits, eliminating the burden of data collection and improving injection confidence with step-by-step guidance, which has the added benefit of reducing the burden on the medical staff and helping to achieve better patient retention and recruitment. Last, but not least, for pharma, connectivity leads to better, higher quality data that can support faster and better regulatory submissions.

RL What comes to mind for me is an example of a big pharma company that was able to conduct a worldwide study across many patient populations. It would have been a logistical nightmare to perform all the injections within the clinic, so the patients being able to use autoinjectors at home was a major advantage.

Another interesting example to note is rare and orphan diseases. When there are very few patients for a disease, it can be very difficult to find participants for a clinical trial. But, if patients don't need to go to clinics to participate, it makes recruitment much easier – with at-home administration, the burden on them is much lower, allowing them to fit using the autoinjector in and around their regular lives.

Q How do CliniPilot and Clear to Clinic combine to make clinical trial execution faster and smarter?

CC Put simply, the combination reduces the overall time required for clinical trials. Clear to Clinic gets the autoinjector into clinics sooner and CliniPilot enables trial sponsors to collect objective injection data. On top of that, the data can support the management of the trial itself. For example, if patients are behaving in an unexpected way with self-administration of the drug, the real-time data enabled by connectivity allows clinical teams to intervene quickly and provide adequate support to patients.

Additionally, the data collected from CliniPilot can be linked with other data, such as patient-reported outcomes (ePRO) and clinician-reported outcomes (eCOA). This makes it easier to collect all the patient's data into a single place for the pharma sponsor, which enable a better, more holistic understanding of the trial data to gain better insights. Better data and better insights can then be taken forward, allowing sponsors to optimise future trials and, ultimately, the commercial launch.

RL CliniPilot works seamlessly with all our clinic-ready devices. All the devices share the same interface and the same colours, so they're really easy for patients to use and for pharma partners to set up, including for blind studies. Let's say that the viscosity of the drug and the placebo are different, so – to keep the trial truly blind – a different autoinjector can be used for each to keep the injection time similar. With our clinic-ready devices, that different autoinjector is already there, outwardly identical and ready to go.

Q Do you think that these approaches to clinical trials are carrying through to commercial products for regular patients?

RL In some ways, yes. For example, one of the advantages of our clinic-ready devices is that they can be used throughout the clinical studies, then the pharma partner can develop their own autoinjector for commercial use, with the full range of design options that our product portfolio provides.

There are several advantages for transitioning from the clinical to the commercial device. First, the user interface remains essentially the same. Second, the technical file of the clinical development can be reused and enriched for the commercial

"OVERALL, PHARMA PARTNERS CAN RELY ON ESTABLISHED AND PROVEN DOCUMENTATION FROM THE START OF DEVELOPMENT FOR AN EARLY CLINICAL STUDY UNTIL COMMERCIAL READINESS, WHICH INCREASES FAMILIARITY AND ENABLES A SMOOTH PROCESS AND COLLABORATION."

Figure 4: YpsoMate autoinjector.

submission. Third, the drug injection profile is comparable, which allows the integration of the performance data from the clinical device into the documentation of the commercial device. Overall, pharma partners can rely on established and proven documentation from the start of development for an early clinical study until commercial readiness, which increases familiarity and enables a smooth process and collaboration.

Q Looking beyond clinical trials, what is the value of real-world injection data and patient-use insights in a commercial setting?

CC Real-world injection data and patient-use insights provide critical evidence for improving adherence, shaping patient support programs, and demonstrating value to payers and providers, ultimately driving better outcomes and brand differentiation in the commercial market, as already demonstrated across a few use cases.

SmartPilot, our commercial-stage solution, is FDA-cleared; we received 510(k) clearance in early September. CliniPilot, on the other hand, is designed for clinical trial use and does not require 510(k) clearance. Because both solutions function as add-on devices, pharmaceutical companies can integrate them during clinical development, and in the commercial setting across multiple therapeutic areas without impacting the regulatory approval process for the drug-device combination product.

Q From a broader perspective, how does this connected clinical development approach reflect Ypsomed's long-term strategy in digital health and patient-centric innovation?

CC Our strategy is to scale connectivity on both the clinical development and the commercial side. Our goal is to enable pharma companies to collect more and better injection data to support clinical development and commercial launches. That's what we're focusing on for the near future. For the commercial setting, we're looking at how best to integrate SmartPilot within digital health ecosystems, which in most cases involves companion apps, and how we can support pharma in differentiating their products across the entire product lifecycle.

Q Are there any final comments that you'd like to add before we wrap up?

CC One extra thing I'd like to bring up regarding CliniPilot is that we've made it so that it can be integrated into existing clinical trial digital infrastructure. With multiple electronic data capture providers out there, we wanted to ensure that CliniPilot could easily be integrated into any solution that the trial's pharma sponsor might already have in place. We're committed to providing integration without disrupting the existing workflow.

RL There are already numerous successfully launched YpsoMate autoinjectors on the market (Figure 4). In addition, Ypsomed has demonstrated the performance of all its clinic-ready devices. The market-proven device, the performance data, as well as the support of Ypsomed device experts, help pharma partners to enter and derisk expensive early clinical studies with these devices.

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MAY Delivering Injectables: Devices & Formulations DEADLINE: **Apr 2, 2026**	**MAY/JUN** Oral Drug Delivery DEADLINE: **Apr 16, 2026**	**JUN** Connectivity in Drug Delivery DEADLINE: **May 7, 2026**
JUL Industrialising Drug Delivery DEADLINE: **May 21, 2026**	**SEP** Wearable Injectors DEADLINE: **Aug 6, 2026**	**SEP/OCT** Dual Chamber Delivery Systems DEADLINE: **Aug 20, 2026**
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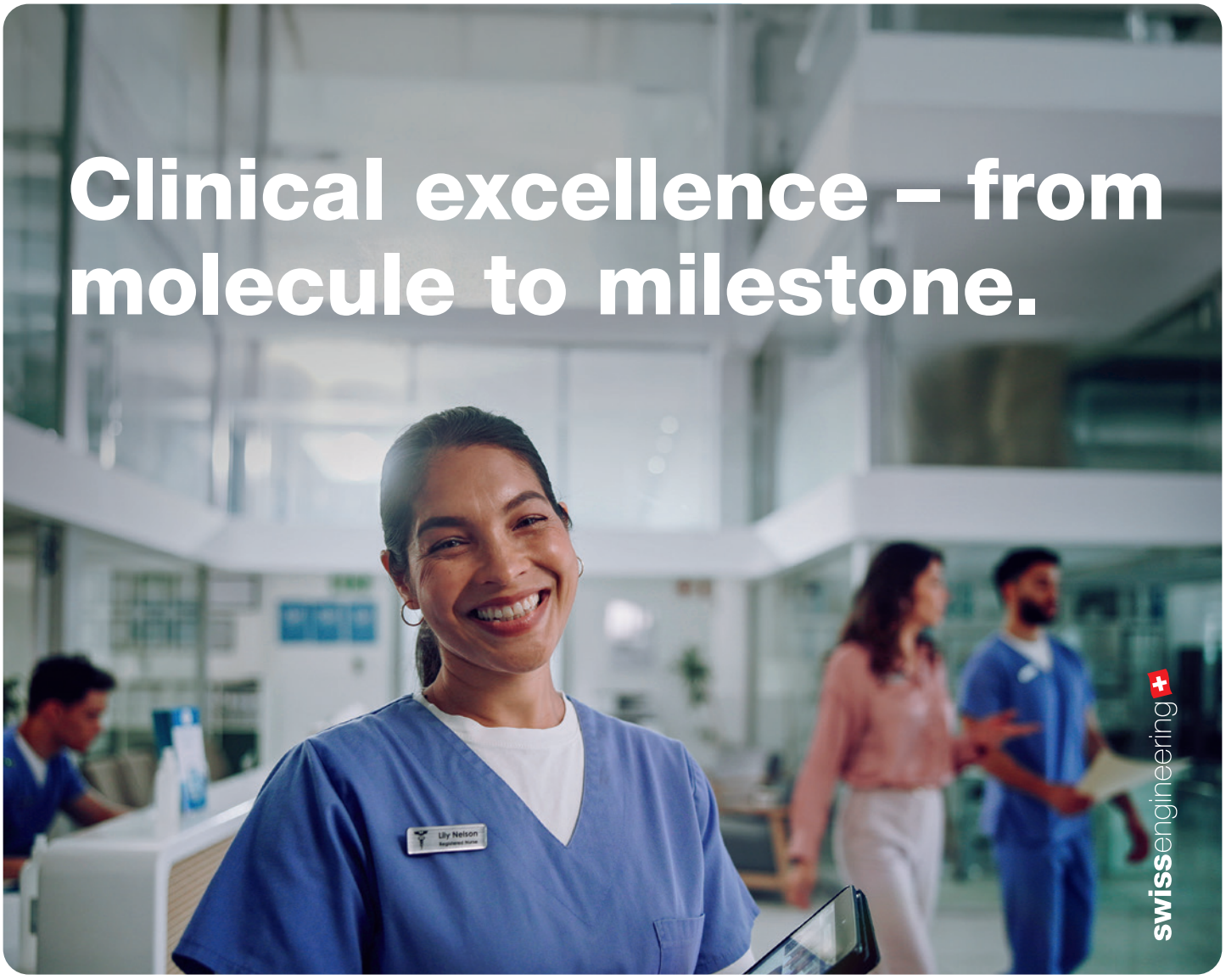

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Expert View

TRENDS FOR 2026

A new reality is forming as we enter 2026 – it will not be "business as usual". Geopolitical forces in the largest market for pharmaceuticals, the US, are likely to mean substantial changes. Here, **Tom Oakley** and **Alex Vasiev**, both of Sanner Group, cover those changes, the incretin juggernaut and the march of technical progress with "minitablet" dispensers, large-volume injectors and dual-chamber devices.

US POLICY CHANGES

The US accounts for around 45% of global pharmaceutical sales by value[1] and the majority of global pharmaceutical profits. President Trump has announced a policy of "Most Favoured Nation" pricing for pharmaceuticals, with the aim of aligning drug pricing for US residents with comparable G7 countries.

In addition, there is an "America first" policy regarding onshore pharmaceutical manufacturing. Major pharmaceutical companies have responded by announcing significant investments in US manufacturing sites.[2,3]

While pharmaceuticals were exempt from the tariffs announced on April 2, 2025, the US Bureau of Industry and Security, initiated a Section 232 national security investigation into pharmaceutical imports.[4] The White House subsequently stated that tariffs on pharmaceuticals entering the US will be introduced.[5] The UK has signed a trade deal to avoid tariffs on its pharmaceutical exports to the US in return for increased spending on drugs.[6]

Finally, the US FDA vaccine committee has been replaced by new appointees known to be sceptical of some vaccine technologies, such as messenger RNA vaccines.

Altogether, if these changes take effect before the next US administration enters office in 2029, they represent substantial changes to the way medicines are reimbursed, taxed and regulated, as well as where they are made. The same effects will be felt through the supply chain, affecting drug delivery device manufacturers, packaging suppliers, fill-finish partners and others. Companies throughout the drug delivery ecosystem need to consider multinational strategies or face significant disruption to their business and/or barriers to growth.

Figure 1: Example use of incretin agonist injector by celebrity (in this case Serena Williams).

"COMPANIES THROUGHOUT THE DRUG DELIVERY ECOSYSTEM NEED TO CONSIDER MULTINATIONAL STRATEGIES OR FACE SIGNIFICANT DISRUPTION TO THEIR BUSINESS AND/OR BARRIERS TO GROWTH."

THE INCRETIN JUGGERNAUT

Incretin receptor agonists, such as glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide, have proven to be clinically effective in managing Type 2 diabetes mellitus and obesity. The demand for incretin receptor agonists has led to a rapid growth in their use, with a 700% increase over four years in the US in the number of patients without diabetes starting treatment.[7]

Two phenomena have accelerated in the incretin boom. First, direct-to-consumer sales of injection devices have become "mainstream", with promotion by social media influencers and increased prominence in modern decentralised media. Celebrities such as Elon Musk, Oprah Winfrey, Sharon Osbourne and Serena Williams have spoken publicly about using incretins for weight management, which brings cultural acceptance and even advocacy (Figure 1).

Second, "compounding" pharmacies have become a far more prevalent part of the market.[8] Compounding pharmacies combine or alter ingredients to create a customised medication for an individual patient based on a licensed practitioner's prescription.[9] They use FDA-approved ingredients, but the resulting formulation is not FDA-approved.[10] Therefore, compounded medicines are regulated differently from the originator and may vary in quality. An example of a compounded formulation is the addition of vitamin B12 to semaglutide. Compounding pharmacies have manufactured large quantities of semaglutide since May 2023, when the FDA placed Novo Nordisk's Ozempic (semaglutide) and Wegovy (semaglutide) on their Drug Shortages List because demand outstripped the quantities that Novo Nordisk could supply to the US market.[11]

Semaglutide was removed from the Drug Shortage List in February 2025,[12] but the compounders have continued marketing semaglutide to the extent that the market for compounded semaglutide in the US is "roughly equal" in size to Novo Nordisk's sales of that drug in that market.[13] This is effectively generic/biosimilar competition before the originator patents expire, which significantly changes the economic viability for developing new medicines. However, compounding pharmacies typically cannot supply the same drug delivery device used by the originator.

Balancing pricing with cost pressures from both competitors and competitor generics can be a challenge, with CVS Caremark reportedly removing Eli Lilly's Zepbound (tirzepatide) from its formulary in July 2025 in a move to balance cost with access to these therapies.[14]

UK regulators uncovered an illicit supply of counterfeit Retatrutide (LY-3437943) – the AbbVie drug currently undergoing clinical trials – and tirzepatide being sold with pen-injector devices by entities on social media.[15] Despite the seizure of thousands of unlicensed pens and raw materials, sellers reportedly continue to promote these unregulated products online, driven directly by consumer demand for these products.

Looking ahead, the market may become increasingly stratified. Longer-acting formulations, including monthly or even quarterly dosing, have undergone animal trials.[16] A push towards multi-agonist "Triple G" parenteral therapies, such as Retatrutide, may also result in therapies that require devices to administer larger weekly injections of up to 1.0 mL.[17]

Equally, multiple oral dosage forms targeting the treatment of obesity, such as Lilly's Orforglipron (LY3502970), are now in development. While also offering lower cost and greater access, the availability of oral therapies provides a new option within the class for patients who are unable or unwilling to self-administer an injectable agent. The shorter half-lives may benefit patients who need to adjust their dosage to counteract side effects.

SMART DISPENSERS AND MINITABLETS

Many medicines have better efficacy and safety profiles (better outcomes with fewer side effects and adverse events) if they are personalised to the patient.[18] This can be particularly true where the patient population is inherently highly diverse, such as in paediatrics. Children vary greatly in their body weight, metabolism, tolerance and anatomy. Blanket age range recommendations can be undermined by the significantly different growth rates experienced by children.

"MANY MEDICINES HAVE BETTER EFFICACY AND SAFETY PROFILES (BETTER OUTCOMES WITH FEWER SIDE EFFECTS AND ADVERSE EVENTS) IF THEY ARE PERSONALISED TO THE PATIENT."

In addition, some patients find it difficult to swallow the pills and tablets used for many medicines. Sometimes compounding pharmacies are used to create alternative presentations of the drug substance, but there could be a case for formulating drugs as powders or minitablets to be metered at the point of use.

Finally, some medicines need to be "titrated", which means beginning with a low dose and gradually adjusting it upwards (or sometimes downwards) until the desired therapeutic effect is reached while minimising side effects. Reasons for titration include:

- **Safety**: Some drugs can cause serious side effects if started at full strength; titration gives the body time to adapt
- **Individual Variability**: Patients respond differently to the same drug depending on age, weight, metabolism, other medications and medical conditions
- **Therapeutic Window**: Some drugs have a narrow range between being effective and being toxic; titration helps to determine the "sweet spot"
- **Monitoring Response**: Doctors can observe how symptoms improve and adjust accordingly.

The drug delivery industry has long provided devices such as pen injectors to allow user-settable doses of injectable drugs such as insulin, GLP-1, growth hormone and so on.

Fine-increment user-settable dosing is less well established in oral drug delivery. Several devices are in development to meet the need for variable dosing. For example, Adare Pharma Solutions' (Philadelphia, PA, US) Diffucaps + AbbatiaLabs' (Payerne, Switzerland) POWDOSE is a combination system where the POWDOSE device dispenses the desired number of minitablets, and the Diffucaps polymer membrane encases the minitablets to control drug release and enhance solubility in the targeted gastrointestinal regions (Figure 2).[19]

OraFID by Sensidose (part of Navamedic, Oslo, Norway) is a prefilled, single-use container and dispenser where the user twists a counter counterclockwise, then clockwise and presses a button to dispense the desired number of minitablets.[20] The Mini-Tablet Dispenser by Phillips-Medisize (Hudson, WI, US) is a cap that fits onto a standard table bottle and helps the user to see the number of minitablets about to be dispensed.[21] Finally, OnDosis (an AstraZeneca spin-out in Gothenburg, Sweden) is an electromechanical minitablet dispenser with the option of syncing dispense data with a smartphone app.[22] This list gives some examples and is not intended to be exhaustive.

There are also developments in 3D-printed tablets and modular oral solid doses. Modular manufacturing means using standardised, flexible production units that can be scaled up or down depending on requirements. The aim is faster adaptation to different drug formulations, easier compliance with regulatory requirements and efficient production of multiple dosage forms in one facility.

CONTINUED GROWTH OF LARGE-VOLUME INJECTIONS

The market for large-volume autoinjectors and on-body delivery systems has expanded rapidly as injectable therapies become more complex and dose masses continue to increase. One driver for this is an industry trend toward reformulating intravenous therapies for subcutaneous delivery, particularly in oncology and immunology.[23] Well-known examples such as Keytruda (pembrolizumab, Merck & Co), Darzalex (daratumumab, Janssen Pharmaceutical), Rituxan (rituximab, Genentech), Herceptin (trastuzumab, Roche) and Skyrizi (risankizumab, Abbvie) illustrate this shift, driven by patient convenience, reduced healthcare burden and improved access.

Figure 2: POWDOSE device.

"THE MARKET FOR LARGE-VOLUME AUTOINJECTORS AND ON-BODY DELIVERY SYSTEMS HAS EXPANDED RAPIDLY AS INJECTABLE THERAPIES BECOME MORE COMPLEX AND DOSE MASSES CONTINUE TO INCREASE."

For biologics, particularly monoclonal antibodies, high dosage mass often translates into either highly viscous formulations, large-injection volumes or both. These physical properties place significant demands on delivery devices, driving innovation, as devices increasingly need higher power (Table 1) or longer and slower delivery times, which favour on-body devices.

The increasing power requirements of large-volume and high-viscosity injections have led many companies to explore gas pressure as a means of driving the delivery mechanism. Gas-powered actuation is not new, but it addresses several inherent limitations of traditional spring-driven autoinjector designs.

One key limitation of springs is the dynamic impact associated with releasing large amounts of stored mechanical energy, which can generate force peaks and increase the risk of glass breakage. Gas-based systems can deliver high power in a more controlled and progressive manner using valving or expansion chambers, avoiding the sharp force transients that occur when a spring impacts the plunger stopper. Managing high internal pressures remains challenging when working with glass primary packaging, and one approach taken by Aktiv (Broomfield, CO, US) in its PenPal device is to use the outer casing as a pressure chamber, pressurising both the inside and outside of the primary container (Figure 3). This reduces pressure differential across the glass wall and mitigates hoop stress.

Product	Manufacturer	Power Source	Primary Packaging	Delivery Progress Indication	Development Status	Maximum Delivered Volume (mL)
Aerio platform	Kaleo	Gas	Cartridge or prefilled syringe	Visual and audible	Development with low-volume variant on market	10
ArQ-Bios	SMC	Gas	Prefilled syringe	Visual, audible at start and end	Development	5
HVAI	Halozyme/ Antares	Spring	Prefilled syringe	Visual and audible (undisclosed)	Clinic[24]	10
LVDC	Windgap Medical	Gas	Cartridge	Undisclosed	Development	10
Maggie 5.0	SHL Medical	Spring	Cartridge	Visual, continuous audible	Development	5
PenPal	Aktiv Medical Systems	Gas	Cartridge	Undisclosed	Development	5.5
YpsoMate 5.5	Ypsomed	Torsion spring	Prefilled syringe	Visual, continuous audible	Development	5.5

Table 1: Overview of large-volume autoinjector technologies.

Figure 3: PenPal by Aktiv Medical Systems.

Compared with spring-driven mechanisms, gas-powered systems can also deliver a much flatter force profile throughout the injection. This improves control of the delivery rate and is particularly important for concentrated biologics and long-acting injectables, which often exhibit non-Newtonian behaviour and therefore an apparent viscosity that varies with applied pressure.

Windgap Medical (Watertown, MA, US) has demonstrated that gas actuation can also enable reciprocal motion, making it well suited to applications such as automated reconstitution and multidose delivery, where pausing, restarting or cyclic movement may be required.

From a platform perspective, gas-powered systems offer a high degree of flexibility and adaptability. Delivery performance can often be tuned by adjusting the gas fill, measured gravimetrically in production, rather than requiring a redesign of the spring. Common propellants include gases such as argon and nitrogen, which are relatively insensitive to environmental variability and capable of delivering very high pressures, as well as gases stored in a liquid phase, such as carbon dioxide and hydrofluoroalkanes. These provide lower pressures but a consistent force profile, subject to stable ambient temperature and pressure.

> "FROM A PLATFORM PERSPECTIVE, GAS-POWERED SYSTEMS OFFER A HIGH DEGREE OF FLEXIBILITY AND ADAPTABILITY."

Given the growing interest in large-dose subcutaneous administration, this segment can be expected to develop. Tolerability of large injections remains a significant challenge, although this may be partially addressed using adjuvants such as hyaluronidase. In this context, the inclusion of a 10 mL autoinjector from Halozyme (San Diego, CA, US) should be viewed as a strong signal of the company's confidence in the viability of this as a delivery approach.

DUAL-CHAMBER INJECTORS

Dual-chamber technologies have traditionally been developed to support lyophilised drug products, where the drug is reconstituted with a diluent prior to injection. The dual-chamber format is well established and widely accepted because it simplifies preparation while maintaining stability during storage. However, dual

chambers are not well suited to liquid-liquid co-delivery because they commonly rely on the compression of a significant air volume before the stopper reaches the bypass that connects the two chambers. The need for this air volume limits compatibility with larger liquid-liquid fills, and standard fill-finish processes.

Several solutions are being developed to support therapies that require the controlled delivery or mixing of two liquid components immediately prior to injection. This need arises where liquid-liquid stability is limited or unproven; where an excipient, buffer or stabiliser must be introduced shortly before administration; or where formulations benefit from remaining physically separated until the point of use. There is a split between the development of new dual-chamber primary packaging or devices that use standard primary packaging, achieving sequential delivery from two separate containers.

Kindeva's (Woodbury, MN, US) DuoDote® is a commercialised example of a dual-liquid delivery system. Used for the emergency treatment of nerve agent poisoning, the device contains atropine and pralidoxime chloride in two separate chambers and delivers them sequentially through a single needle in one activation. The product is FDA-approved and, in early 2025, Kindeva Drug Delivery's Meridian Medical Technologies division secured a significant contract to supply DuoDote® to the US Strategic National Stockpile.[25]

Windgap Medical has developed dual-liquid autoinjector platforms based on separate reservoirs rather than a single dual-chamber syringe with a mechanical bypass. This approach enables controlled sequential or co-ordinated delivery of two liquids through a single needle. The architecture is particularly well suited to molecules that need to be isolated because of specific fill-finish or packaging requirements, large-volume and high-viscosity applications. It can also be used to perform reconstitution.

Credence MedSystems'[26] (Menlo Park, CA, US) Dual Chamber Syringe System enables multiple liquids to be delivered in sequence with a single press of the plunger rod. The system also features a proprietary passive needle retraction system and has recently been adapted into a new autoinjector concept (Figure 4).

Figure 4: Credence Medical autoinjector concept, which includes Credence's Sequential Dual Chamber System.

Capa Valve[27] (Hertfordshire, UK) has developed a patented valve system that can be installed into standard syringes to create dual-chamber functionality without needing bespoke primary packaging. The valve technology allows two liquids (or a liquid and a diluent/powder) to be stored separately and then dispensed sequentially through a single syringe. This approach uses established infrastructure, minimising manufacturing complexity.

BD has explored dual-liquid syringe concepts that maintain compatibility with standard prefillable syringe formats.[28] They recently published a white paper on the BD Dual-Injection Valve, which similarly keeps two liquid components separate within a single primary container.

This is an interesting area of innovation that may see growth as drug-drug and drug-biologic combination therapies become more prevalent due to their enhanced effectiveness, ability to tackle complex diseases such as cancer and chronic conditions, and facilitate personalised medicine where the combination is adjusted to a specific sub-set of the population.[29]

CONCLUSIONS

As we enter 2026, the pharmaceutical and drug delivery landscape is entering a period of fundamental change. Geopolitical developments are reshaping how medicines are priced, regulated, manufactured and supplied, with effects that will be felt globally. For companies across the drug delivery ecosystem, these shifts demand a reassessment of their long-term strategy.

The continued rapid expansion of the incretin receptor agonist market has reshaped not only pricing strategies but

"GEOPOLITICAL DEVELOPMENTS ARE RESHAPING HOW MEDICINES ARE PRICED, REGULATED, MANUFACTURED AND SUPPLIED, WITH EFFECTS THAT WILL BE FELT GLOBALLY. FOR COMPANIES ACROSS THE DRUG DELIVERY ECOSYSTEM, THESE SHIFTS DEMAND A REASSESSMENT OF THEIR LONG-TERM STRATEGY."

also patient expectations and the nature of competition. The emergence of early generic-like competition and counterfeit products adds further complexity, while longer-acting injectables, multi-agonist therapies and oral alternatives point to sustained innovation in this therapeutic area for many years to come.

Device technologies are evolving to meet future needs. Variable dosing systems, smart dispensers and minitablet-based approaches address the growing requirement for personalisation, particularly for diverse or vulnerable patient populations. Dual-chamber liquid-liquid injection further expands the available toolkit for drug developers, enabling the delivery of more complex and potentially personalised therapies. At the same time, the continued growth of large-volume subcutaneous delivery is driving innovation in high-power autoinjectors as an alternative to on-body systems, although the tolerability of such injections remains an open question.

Taken together, these trends suggest that innovation remains strong across the industry, yet there is no one-size-fits-all solution. Instead, success is increasingly defined by adaptability to the needs of patients, pharmaceutical companies, payers and regulatory authorities.

ABOUT THE COMPANY

Sanner is a global manufacturing company that develops and produces plastic packaging and drug delivery systems for pharmaceutical, medical and healthcare customers. Sanner specialises in desiccants and effervescent tablet packaging.

REFERENCES

1. *"U.S. Pharmaceutical Statistics". Magnet ABA Therapy, Mar 2017.*
2. *Jack S, Mitchell A, "UK pharma boss says US is the best country to invest in." BBC News, Dec 11, 2025.*
3. *Kansteiner F, "Pharmas have promised $370B in US investments amid 2025's onshoring boom: DPR." Fierce Pharma, Dec 2, 2025.*
4. *Bond D, "Trump Administration Initiates Section 232 Investigations on Pharmaceuticals and Semiconductors". White & Case, Apr 16, 2025.*
5. *Chia O, Edwards C, "Trump announces new tariffs on drugs, trucks and kitchen cabinets". BBC News, Sep 26, 2025.*
6. *"Landmark UK-US pharmaceuticals deal to safeguard medicines access and drive vital investment for UK patients and businesses". Press Release, Gov.UK, Dec 1, 2025.*
7. *Mahase E, "GLP-1 agonists: US sees 700% increase over four years in number of patients without diabetes starting treatment", BMJ, 2024, Vol 386, q1645.*
8. *Kansteiner F, "After Novo and Lilly resolved GLP-1 shortages, where does the compounding industry stand? Experts weigh in", Fierce Pharma, Jun 27, 2025.*
9. *Mountain J, "Compounded Weight Loss Medications: What are They and What are Their Risks?". BROWN Health University, Mar 18, 2025.*
10. *"Compounding and the FDA: Questions and Answers". US FDA, Sep 2025.*
11. *Spencer-Jolliffe N, "Compounding pharmacies caught in counterfeit controversy". Pharmaceutical*

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Technology, Sep 27, 2024.
12. *Choi J, "Ozempic and Wegovy officially moved off FDA's drug shortage list". The Hill, Feb 21, 2025.*
13. *"Financial report for the period 1 January 2025 to 30 June 2025". Novo Nordisk, accessed Dec 2025.*
14. *"Impact of the CVS GLP-1 formulary change: Trends in prescribing". Truveta, Sep 5, 2025.*
15. *"MHRA smashes major illicit weight loss medicine production facility in record seizure". Press Release, UK MHRA, Oct 24, 2025.*
16. *D'Aquino A et al, "Sustained Delivery of GLP-1 Receptor Agonists from Injectable Biomimetic Hydrogels Improves Treatment of Diabetes". bioRxiv [Preprint], 2023: 2023.01.28.526057.*
17. *Jastreboff A et al, "Triple–Hormone-Receptor Agonist Retatrutide for Obesity — A Phase 2 Trial". N Engl J Med, 2023, Vol 389(6), pp 514–526.*
18. *Al-Metwali B, Mulla H, "Personalised dosing of medicines for children". J Pharm Pharmacol, 2017, Vol 69(5), pp 514–524.*
19. *Jomini T, Baronnet S, van den Anker J, "Enhancing Personalised Medicine: POWDOSE and Diffucaps for Precise Oral Solid Dosing". ONdrugDelivery, Issue 173 (May/Jun 2025), pp 28–32.*
20. *"OraFID". Web Page, Navamedic. Accessed Dec 2025.*
21. *"Mini-tablet Dispenser". Web Page, Phillips Medisize, Accessed Dec 2025.*
22. *"OnDosis". Web Page, OnDosis, Accessed Dec 2025.*
23. *Harvin A et al, "The Shifting to Subcutaneous Oncology: Recent FDA Approvals". AJMC, Jun 11, 2025.*
24. *Kang D et al, "A phase I clinical study to evaluate rapid, high-volume, subcutaneous auto-injector tolerability with recombinant human hyaluronidase". Drug Deliv Transl Res, 2026, Vol 16(1), pp 95–107.*
25. *"Kindeva Drug Delivery awarded up to $129 million to supply DuoDote® autoinjectors to the Strategic National Stockpile". Press Release, Kindeva, Jan 16, 2025.*
26. *"Enabling Delivery of Challenging Drug Products". Web Page, Credence Medsystems, Accessed Dec 2025.*
27. *"Award Winning Dual-Chamber Drug Delivery Platform Technology". Web Page, Capa Valve, Accessed Dec 2025.*
28. *Flippe M, Lelias S, "Reimagining Dual-Chamber Injection: De-Risking a Novel Valve Component for Use with Standard Syringe Systems". ONdrugDelivery, Issue 177 (Sep/Oct 2025), pp 54–61.*
29. *Gao J et al, "The Future of Drug Delivery". Chem Mater, 2023, Vol 35(2), pp 359–363.*

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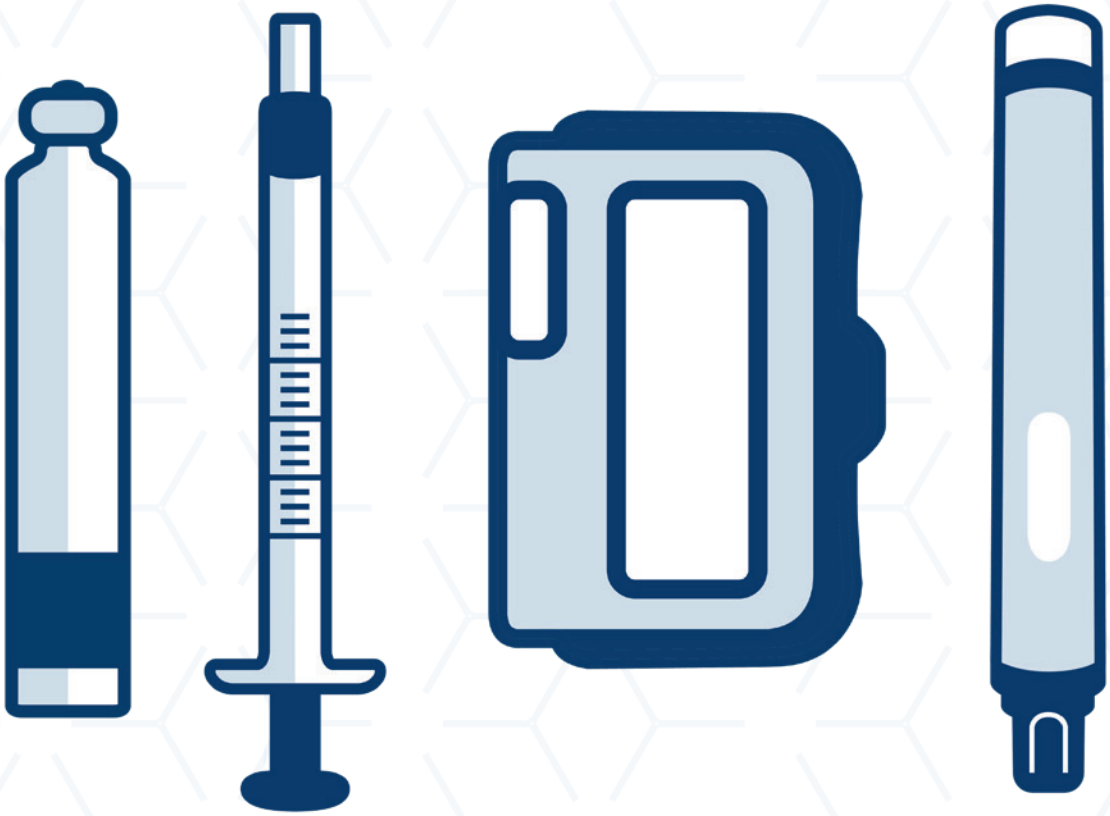

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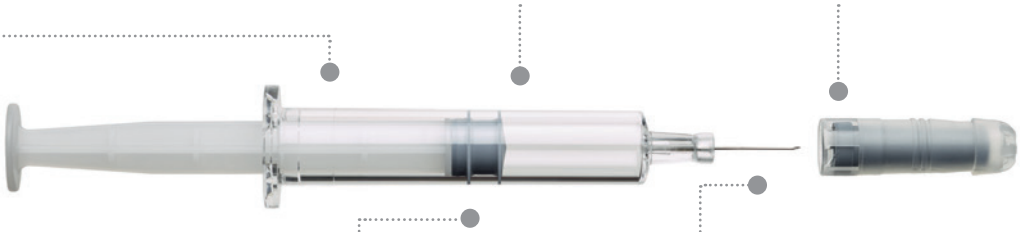

A simple formula for biotech success

PM-08754

REDEFINING THE ROLE OF PACKAGING IN A DEMANDING PHARMACEUTICAL LANDSCAPE

PHARMAPACK by informa

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Ahead of this year's Pharmapack Europe conference on Jan 21–22, 2026, **Sherma Ellis Daal** of **Informa Markets** discusses the role of packaging and drug delivery systems in the wider pharmaceutical industry, offering insights on how key trends and pressures are changing thinking and redefining what makes a successful project.

As the pharmaceutical industry enters 2026, packaging and drug delivery systems have moved decisively from being a developmental afterthought to a strategic focus. What was once treated as a downstream execution challenge is now recognised as a key factor for patient experience, sustainability performance, regulatory readiness and supply chain resilience. This shift has been driven by several pressures that have intensified simultaneously – the increase of complex biologics and chronic therapies in the pharmaceutical pipeline, tightening environmental regulations, the digitalisation of healthcare and rising expectations for usability and access.

The conversations taking place across the sector suggest a growing maturity with less emphasis on statements of ambition and greater scrutiny of whether or not innovation can be delivered at scale, within regulatory constraints and with measurable outcomes. This transition from intent to impact marks a defining moment for pharmaceutical packaging.

A SECTOR DEFINED BY CAUTIOUS OPTIMISM

The prevailing mood across the pharmaceutical packaging and drug delivery industry is characterised by cautious optimism. Companies now recognise that the challenges they face, whether environmental, regulatory or logistical, are systemic rather than temporary. At the same time, there is confidence

"AGAINST THIS BACKDROP OF CAUTIOUS OPTIMISM, PHARMACEUTICAL PACKAGING AND DRUG DELIVERY TEAMS ARE OPERATING UNDER UNPRECEDENTED PRESSURE."

that solutions are emerging, driven by advances in materials science, device engineering, digital tools and cross-industry collaboration.

This mindset reflects a broader change underway in the wider life sciences sector. After several years of disruption, from pandemic-era volatility to geopolitical instability and supply-chain stress, the industry is placing greater value on resilience and long-term viability. Packaging decisions are increasingly evaluated not just on cost or speed to market, but also on their ability to withstand regulatory change, support global distribution and meet sustainability expectations throughout the product lifecycle. In this context, optimism comes from the recognition that progress is being made incrementally, pragmatically and often through collaboration rather than competition.

HOW THE ROLE OF PACKAGING IS CHANGING

Against this backdrop of cautious optimism, pharmaceutical packaging and drug delivery teams are operating under unprecedented pressure. Their role is expanding well beyond execution, as they are increasingly required to balance sustainability goals, innovation expectations, patient needs, regulatory complexity and supply chain resilience – often simultaneously – with limited room for compromise.

Rather than responding to isolated challenges, developers and manufacturers are now navigating a convergence of trends that are reshaping how packaging and delivery systems are designed, approved and deployed. These trends overlap, reinforce one another and, at times, pull in competing directions. Understanding how they interact is becoming a core competency for organisations seeking to future-proof their portfolios.

A Sharpened Focus on Sustainability

Sustainability has moved decisively from a peripheral consideration to a defining constraint in pharmaceutical packaging. What distinguishes the current phase from earlier efforts is the level of accountability now attached to environmental claims. Packaging decisions are increasingly expected to stand up to regulatory scrutiny, investor expectations and internal governance, all of which demand evidence rather than merely stated intent.

This shift is elevating environmental measurement from a specialist exercise to a strategic requirement. Lifecycle assessments and product carbon footprinting are no longer confined to pilot projects or sustainability teams; they are becoming central inputs into packaging design, supplier selection and portfolio planning. For packaging teams, this represents a fundamental change in how success is defined, as environmental performance must now be assessed alongside cost, manufacturability and compliance.

Regulatory developments are accelerating this transition, particularly in Europe, where new requirements around recyclability, material reduction and waste management are forcing concrete design choices. These rules rarely align neatly with pharmaceutical safety and quality frameworks, increasing the complexity of implementation. In many cases, the challenge is in the uncertainty around how far innovation can go without compromising product protections or inviting regulatory risk.

Crucially, sustainability is no longer framed solely as a materials challenge. While advances in polymers, monomaterial formats and barrier technologies remain essential, attention is shifting towards systems-level thinking. Logistics optimisation, pack-size rationalisation, reuse or take-back models, and end-of-life pathways are all coming under scrutiny. This broader perspective reflects a growing recognition that meaningful environmental gains often lie beyond individual components, requiring co-ordination across packaging, operations and supply chain functions.

Embracing Innovation Under Constraints

Innovation in pharmaceutical packaging and drug delivery continues at pace, but the environment in which it must succeed is becoming increasingly demanding. Novel technologies are no longer evaluated primarily on ingenuity; they are judged on their ability to deliver tangible value under real-world conditions.

The rise of complex biologics and chronic therapies is driving demand for more sophisticated delivery systems that combine precision, usability and reliability. At the same time, interest in smart packaging and connected devices reflects a broader push towards data-enabled healthcare, where packaging plays a role in adherence, monitoring and traceability rather than serving solely as a means of containment.

However, adoption remains uneven. Digital functionality introduces new layers of complexity, including data governance, cybersecurity, interoperability with healthcare systems and regulatory approval pathways. Similarly, material and format innovations must demonstrate consistency at scale, compatibility with existing manufacturing infrastructure and resilience under global distribution conditions. The bar for success is high.

As a result, innovation is increasingly constrained by the realities of implementation. The question facing many organisations is not whether innovation is possible, but whether it can be deployed responsibly, cost-effectively and at scale. This has led to a more pragmatic

"THE RISE OF COMPLEX BIOLOGICS AND CHRONIC THERAPIES IS DRIVING DEMAND FOR MORE SOPHISTICATED DELIVERY SYSTEMS THAT COMBINE PRECISION, USABILITY AND RELIABILITY."

approach, where incremental improvements and integration with existing systems often take precedence over radical redesign.

A Growing Demand for Patient Centricity

Patient-centric design has become a central expectation in pharmaceutical packaging and device development, reflecting the continued shift towards self-administration and long-term disease management. However, the industry's understanding of patient centricity is evolving.

Design teams are being challenged to move beyond assumptions about a "typical" user and instead account for a wide range of patient capabilities and contexts. Ageing populations, reduced dexterity, visual impairment and varying levels of health literacy all influence how packaging and devices are used in practice. In this context, usability is directly linked to adherence, safety and therapeutic outcomes.

This expanded definition of patient centricity introduces additional complexity. Packaging and device solutions must balance ease of use with regulatory requirements, manufacturing constraints and cost pressures. Demonstrating usability across diverse patient populations requires early and rigorous human-factors engineering, often involving iterative testing and cross-functional input.

As healthcare systems place greater emphasis on outcomes and value, the role of packaging and delivery systems in supporting correct use of the drugs they contain is coming under closer scrutiny. Poorly designed packaging can undermine even the most effective therapy, with one-third of reported medication incidents stemming from confusion over packaging and labelling.[1] Meanwhile, an intuitive, accessible design can improve patient confidence and compliance, as shown in medication adherence rising from 63% to 71% when packaging interventions such as blister packs and pill organisers are used.[2] These findings have elevated patient centricity from a design principle to a strategic consideration.

Escalating Regulatory Complexity

Regulation remains one of the most influential forces shaping pharmaceutical packaging, and its impact is intensifying. Environmental legislation is increasingly intersecting with established pharmaceutical regulatory frameworks, often without full alignment, creating new areas of ambiguity and risk.

Packaging teams must now interpret and reconcile requirements related to safety, quality and sterility with emerging rules on recyclability, material composition and waste. These frameworks were developed with different objectives in mind, and navigating the overlap between them requires careful judgement, as late-stage changes to address regulatory misalignment can be costly, disruptive and time-consuming.

As a result, regulatory intelligence and foresight are becoming critical capabilities. Organisations that integrate regulatory considerations early in the development process are better positioned to make informed trade-offs and avoid reworks. Rather than simplifying decision-making, regulation is forcing teams to document their rationales more rigorously and defend their choices in detail.

Those that treat regulation as a downstream hurdle risk delays and non-compliance. In contrast, companies that embed regulatory expertise into their packaging strategy are more likely to adapt effectively as requirements continue to evolve.

Persistent Supply Chain Challenges

Supply-chain resilience continues to shape packaging strategy, influenced by geopolitical uncertainty, material availability and manufacturing capacities. Recent disruptions have exposed vulnerabilities in global sourcing models, prompting renewed interest in alternative materials, regional suppliers and dual-sourcing strategies.

However, building supply-chain resilience is rarely straightforward. Changes to suppliers or materials can trigger regulatory revalidation, impact quality systems and alter cost structures. As a result, supply-chain decisions are increasingly intertwined with sustainability and regulatory considerations, rather than being addressed in isolation.

Digital tools and data analytics are beginning to support more proactive supply chain management, offering greater visibility into risk and performance. Yet technology alone is not sufficient. Effective use depends on organisational readiness, data quality and cross-functional co-ordination between procurement, packaging, regulatory and operations teams. For many organisations, the challenge lies in balancing flexibility with stability, building supply chains that can adapt to disruption without introducing unnecessary complexity or risk.

LEADERSHIP AND ACCOUNTABILITY

One of the most significant shifts underway is at the leadership level. Sustainability, patient centricity and supply-chain resilience cannot be delivered through isolated teams or pilot projects alone. They require sustained commitment, investment and accountability from senior management. There is increasing recognition that packaging and delivery decisions have long-term strategic implications, influencing brand reputation, market access and risk exposure. As a result, these topics are moving higher up the organisational agenda, with greater involvement from executives across R&D, operations, regulatory and commercial functions.

This leadership engagement is essential for overcoming internal silos and aligning incentives. Without it, even well-designed initiatives risk stalling at the implementation stage. Conversely, organisations that embed sustainability and patient focus into governance and performance metrics are better positioned to deliver consistent progress.

"RECENT DISRUPTIONS HAVE EXPOSED VULNERABILITIES IN GLOBAL SOURCING MODELS, PROMPTING RENEWED INTEREST IN ALTERNATIVE MATERIALS, REGIONAL SUPPLIERS AND DUAL-SOURCING STRATEGIES."

COLLABORATION AS A COMPETITIVE ADVANTAGE

As challenges grow more complex, collaboration across the pharmaceutical packaging value chain is becoming less optional and more strategic. No single organisation holds all the expertise required to address sustainability, regulatory change, technological innovation and patient needs simultaneously.

Pharmaceutical companies, device developers, packaging suppliers, material innovators and consultancies are increasingly working together earlier in the development process. This shift reflects a recognition that late-stage optimisation is often too slow and too costly to meet emerging requirements.

Cross-industry collaboration also plays a critical role in standardisation, whether in sustainability metrics, digital interfaces or regulatory interpretation. Without shared frameworks, there is a significant risk of fragmentation, duplication of effort and slower progress. Collaborative platforms are helping to align expectations and accelerate learning, particularly in areas such as circularity and environmental measurement.

Start-ups and scale-ups are an essential part of this ecosystem. They often bring specialised technologies or fresh perspectives that larger organisations may lack, but they also face barriers to adoption, including validation, scale-up and regulatory acceptance. Creating pathways for emerging companies to engage with established players is therefore essential for translating innovation into impact.

AN INFLECTION POINT FOR THE INDUSTRY

Taken together, these developments suggest that pharmaceutical packaging and drug delivery are approaching an inflection point. The industry is moving beyond broad commitments and isolated innovations towards a more integrated, accountable approach. The path forward is unlikely to be linear; trade-offs between performance, safety, cost and environmental impact will persist, and not all solutions will scale as expected. However, the direction of travel is clear – packaging and delivery systems are being redefined as strategic assets that must deliver value across multiple dimensions.

For industry leaders, the challenge is to build the organisational capability to evaluate, implement and refine them over time. This requires investment in data, collaboration and skills, as well as a willingness to engage with complexity rather than seek simplistic answers. As the sector enters 2026, the most meaningful progress is likely to come from those organisations that treat packaging and drug delivery as integral components of a broader commitment to sustainable, patient-centric healthcare.

*Industry experts will further discuss these themes, challenges and more at **Pharmapack Europe** on 21–22 January in Paris, France.*

Sherma Ellis Daal

Sherma Ellis Daal is the Brand Director of Pharmapack Europe, where she leads the strategic growth and evolution of one of the pharmaceutical packaging industry's most influential platforms. With a strong focus on brand acceleration, community building and long-term value creation, she has played a key role in shaping Pharmapack's positioning and industry engagement. She is a graduate of Hampton University (VA, US) and holds an MSc from Vrije Universiteit (Amsterdam, the Netherlands). Having worked on and off the Pharmapack brand for over eight years, she brings deep institutional knowledge and a forward-looking perspective to driving innovation, connection and growth across the global pharma packaging ecosystem.

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"THE DIRECTION OF TRAVEL IS CLEAR – PACKAGING AND DELIVERY SYSTEMS ARE BEING REDEFINED AS STRATEGIC ASSETS THAT MUST DELIVER VALUE ACROSS MULTIPLE DIMENSIONS."

REFERENCES

1. *Aceves-Gonzalez C et al, "Estimating the impact of label design on reducing the risk of medication errors by applying HEART in drug administration". Eur J Clin Pharmacol, 2024, Vol 80(4), pp 575–588.*
2. *Conn VS et al, "Packaging interventions to increase medication adherence: systematic review and meta-analysis". Curr Med Res Opin, 2014, Vol 31(1), pp 145–460.*

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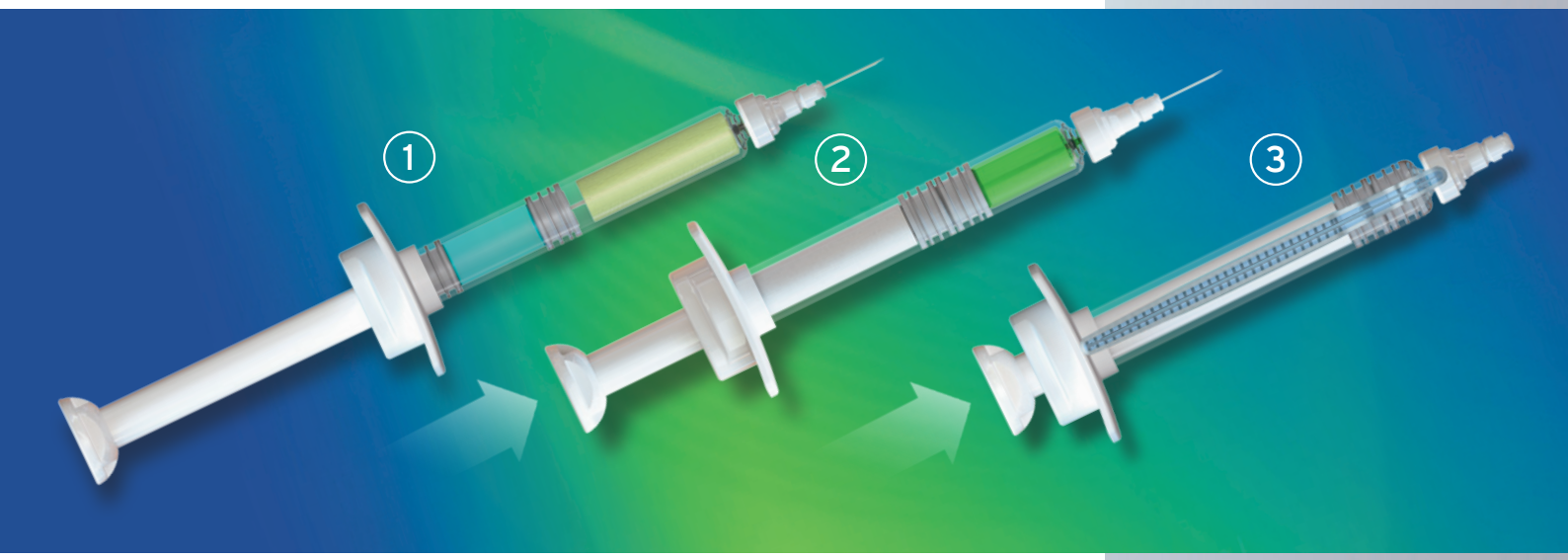

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Expert View

FRACTIONAL INVESTMENT IN DEVICE PLATFORMS – A NEW FUNDING PARADIGM

Drawing on his extensive experience in the drug delivery device industry, **Paul Jansen** considers how funding for delivery device development has shifted over the years, from the pre-platform model to currently accepted practice and looks forward to how it may further evolve to support the development of novel devices in the biologics space and beyond.

"MOST DEVICES WERE CONSIDERED AS SECONDARY PACKAGING. EACH DRUG HAD A BESPOKE DEVICE DEVELOPED FOR IT AND, FOR THE MOST PART, COST WAS NOT CONSIDERED – ALL THAT MATTERED WAS SPEED TO MARKET."

Drug delivery and device development used to be a very different world. In particular, project funding was very different to today. While, funding has evolved over the years, another new opportunity remains to be considered.

THE RISE OF PLATFORMS

In the early days of what is now known as combination product development, each device was bespoke. When the pharma R&D department had a new drug, they would work with the marketing department to decide how best to sell the product. For parenteral products developed in the 1980s, this usually meant subcutaneous or intramuscular delivery. The marketing department would then come to the manufacturing packaging team, which, in some companies, had expertise in designing drug delivery devices, and request a device to deliver the drug. Most devices were considered as secondary packaging. Each drug had a bespoke device developed for it and, for the most part, cost was not considered – all that mattered was speed to market.

Eventually, however, cost became more important and pharma companies began developing and creating technology platforms. Perhaps one of the first was the SoloStar® (Sanofi) pen platform launched in 2007. While the original design was specifically for Lantus (insulin glargine), the technology used in SoloStar has since been repurposed for more than a dozen different drugs. Other platforms followed – Ypsomed's (Burgdorf, Switzerland) YpsoMate autoinjector platform and SHL's (Zug, Switzerland) Molly autoinjector platform both have multiple devices launched with more planned. And there are others. The platform model is now a standard way of developing drug delivery devices.

The platform concept offers many benefits for pharmaceutical companies. As the base technology is already developed, the risk of using the technology with another drug is significantly reduced. There is much less concern about the reliability of the device, especially if it is already on the market and well-understood. Also, compared with designing a new device from scratch, less time is required to iterate a platform device for a new use case and the development costs are lower. In practice, the regulatory agencies that had already approved the SoloStar Lantus combination product were comfortable using an already approved device for another drug. Finally, there is much less risk for patent infringement litigation. All in all, having a platform was a great step forward for the pharmaceutical companies.

As the same time CMOs that had been satisfied making pharma-funded and, in many cases, pharma-designed devices realised that they could develop their own technology platforms, which would allow the CMO a better chance to secure manufacturing contracts. If the CMO developed the product, they would naturally have a good technical understanding of the device. The subsequent technical transfer from development to manufacturing and manufacturing scale up would be easier, faster and involve less risk.

FUNDING PLATFORM DEVICES

The first attempts at CMO-developed platform devices were funded in a variety of ways. Both the CMOs and pharma wanted to manage risk. In the perfect (for

"WHAT THEREFORE EXISTED WAS THIS ODD, DIFFICULT DANCE BETWEEN TWO PARTNERS BOTH TRYING TO MINIMISE THEIR FINANCIAL EXPOSURE WHILE SIMULTANEOUSLY DESPERATELY WANTING TO MINIMISE THEIR PROJECT RISK EXPOSURE."

the CMO) scenario, the CMO provided a proof-of-concept model (although many of the early designs were nothing more than a fancy PowerPoint slide presentation) that the pharma company then agreed to develop and fund fully. The CMOs, not being entirely sure that their technology would work or that anyone would buy it if they made it, wanted to carefully manage their financial exposure; thus, the funding provided by the CMO was the minimum required to convince the pharma company to buy the design and fund the remainder, which was, in fact, the majority of the development and scale-up. Moulds and automation were generally funded by the pharma company.

While, on the one hand, pharma required CMOs to make their devices, they were wary of the risk associated with the failure of the CMO and thus retained ownership of key manufacturing equipment, such as moulds, automation and packaging. What therefore existed was this odd, difficult dance between two partners both trying to minimise their financial exposure while simultaneously desperately wanting to minimise their project risk exposure.

As with any new ideas, after some trial and error, both parties started to get comfortable with letting go. Pharma understood the value of letting a competent CMO develop, validate and scale the required device. The CMOs gained experience and competence in their designs, processes and capabilities. With this experience, the CMOs gained traction and started developing and promoting their platforms, which were now developed all the way through validation and with fully validated and automated assembly in place. All pharma had to do was determine their specific use case product specifications and the CMO would iterate their platform product to meet those requirements.

At this point, it became possible for many pharma companies to have devices based on the same platform but with their own specific variations, such as colour and shape. This model has now been in place for pen injectors, autoinjectors and wearable injectors for years. Over the past five to seven years, this concept has become firmly entrenched, now even with some companies that never previously outsourced device development starting to do so.

THE CHALLENGE OF FUNDING INNOVATION

However, as is often the case, market dynamics have changed again. Money is tighter than ever, so funding has become noticeably harder to come by. There is downward pressure on pricing and increased pressure on sustainability. This has had a particularly acute effect on smaller device technology companies.

While the existing funding model works well for established device formats, such as pens, autoinjectors and wearable injectors, it is less so for the new technologies being developed to satisfy the needs of novel biotech therapies with larger delivery volumes and higher viscosities. There are many new smaller device start-ups with great technology that require funding to take their product from proof of concept to commercialisation, yet their novelty has made financing device development challenging. These small companies typically need a first customer to make their product credible and, very often, no one wants to be the first customer – everyone wants to be a fast follower for the technology. This leaves development funding in question.

This dilemma has caused new ideas on funding to emerge. There are some models where a CMO and pharma partner agree to share the cost of development. In so doing, they share the risk and reward. Some companies have gone as far as to share savings generated by continuous improvement programmes equally between the CMO and the pharma company.

THE SHARED INVESTMENT APPROACH

Recently, a few companies have taken the risk-cost sharing concept one step further. In debating this model with them, it has become clear that this is a positive approach that smaller companies with new technology platforms should consider using to fund their developments.

The concept is a development model based on shared investment. One way to think of the concept is as "fractional development financing". Similar to fractional housing, where a fixed number of people own a single home, multiple pharma companies contribute money to develop a single platform that is then accessible to all of them for specific customisation. While, in principle, the approach is quite straightforward, the devil is in the details.

There are three options that have been discussed. There are certainly more variants possible, but these three help to illustrate the concept:

1. Fund the company that is developing the technology with an up-front understanding of what rights the investment gives each company.
2. Draft a single master development agreement that serves as a governing document for all participants, defining intellectual property (IP) ownership, milestones for device development, funding and governance.

"THESE SMALL COMPANIES TYPICALLY NEED A FIRST CUSTOMER TO MAKE THEIR PRODUCT CREDIBLE AND, VERY OFTEN, NO ONE WANTS TO BE THE FIRST CUSTOMER – EVERYONE WANTS TO BE A FAST FOLLOWER FOR THE TECHNOLOGY."

3. Parallel statements of work where each participating company would have a separate development contract and all deliverables and timelines are aligned by the technology company.

In each of these scenarios there are multiple other considerations. A steering committee needs to be established with representation from each of the participating pharma companies that can make key decisions. There should be a mechanism in place to manage a company wanting out of their fractional investment due to changing needs, strategy or circumstances. Data management is another key concern – specifically pharma company data on molecules must be kept strictly confidential.

Since the pharma companies will be making investments in new technology IP, data rights must be defined and understood. The core platform technology IP should remain with the technology company. It may be developed further with the fractional investments from pharma, but the rights should be retained by the technology company. The pharma companies' molecule-specific IP, data and device-platform-specific customisations should remain private and the property of their respective pharma company. Jointly developed improvements would be available to all the fractional investors but would be assigned to the technology company, although there could be optional exclusive rights granted to investors on specific configurations for an additional investment.

Walking Through a Hypothetical Example

As an example, consider a hypothetical fractional investment concept for Technology Company A, with Pharma Company B, C and D investors. Pharma Company B, C and D will work with Technology Company A to define what development activities they will fund; for example, up to design validation testing, providing clinical samples and manufacturing capabilities. Together, they will define milestones for the development activities; for example, being validated platform configuration complete, clinical use assemblies becoming available, draft documentation for regulatory use becoming available and completing test method validation.

Based on the development activities and milestones that have been defined, the funding model is then agreed upon. The model could be an equal cost share model. The total cost for the agreed-to activities is US$21 million (£15.6 million). Each company would then contribute $7 million. Each of Pharma Company B, C and D share equally in the non-custom deliverables that they have agreed to fund.

Alternatively, the funding model could be a tiered participation model. Tier One could be defined at $14 million. Tier Two would then be set at $7 million. The Tier One participant would have priority input, early access to prototypes and clinical samples and other agreed upon benefits. There are many variations that one could think of, so the details would be dependent upon the fractional investment partner companies. However, the core concept is that greater fractional investment brings extra rights with it.

Regardless of the model agreed upon, there still remain a number of considerations that the fractional investors and the technology company need to think through and decide on. How are costs controlled and reported? Is it possible for one fractional investor company to purchase further priority or exclusivity over other investors?

FUTURE OUTLOOK

While the idea is yet to be tested in real life with a real product platform and real fractional investors, the concept is viable. The key messages to take away from this idea are:

1. Pharma and technology companies need not go it alone when developing a new device platform – be creative and think out of the box
2. Shared risk equals shared speed, shared leverage and reduced financial burden
3. Fractional investment de-risks the development of a validated device platform from a time and cost perspective
4. The concept supports the generally accepted best practices – one platform device for many drugs.

It is my hope that the reader will be provoked to think more about this, develop the concept further and perhaps lead the charge to try it.

Paul Jansen

Paul Jansen currently works as a drug device development consultant. He is a member of the Kymanox Executive Advisory Board, as well as serving on the Advisory Boards of Evoleen & Windgap Medical. He was formerly Associate Vice-President, Medical Device Development, at Sanofi until his retirement in January 2017. Mr Jansen is a Professional Engineer with more than 30 years of experience in medical devices. He completed his degree in mechanical engineering and has completed graduate work in biomedical engineering at the University of Toronto (Canada).

Mr Jansen has extensive experience in the design, development, manufacturing and lifecycle management of medical devices, including multiple patents to his name and deep experience in the creation and management of IP portfolios. He has successfully led teams that have developed and launched several award-winning devices, including Lantus SoloStar. Additionally, he has expertise in the design and development of injection-moulding systems and electronic components. Mr Jansen was a long-time member of the ISO, serving as Working Group Convenor and Expert on many work groups responsible for standards related to injection devices. Until January 2022, he was the Chair of Technical Committee 84, Devices for the administration of Medicinal Products and Catheters.

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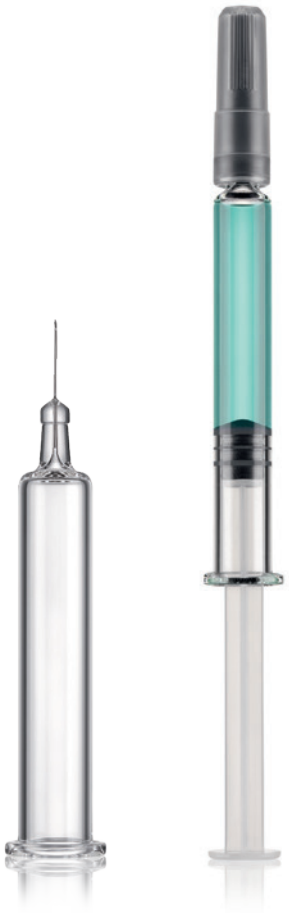

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Expert View

THE PLATFORM PARADOX: DEVICE DEVELOPMENT CHALLENGES WITHIN FAST EVOLVING DRUG DISCOVERY PIPELINES

Tim Quigg, **Mariam Al-Amari** and **Joel Gresham** of Crux Product Design discuss how to enable high-dose delivery for novel biologics, using *ex vivo* and *in silico* approaches to accelerate drug-device development and improve device performance, thus de-risking projects and saving costs.

There are a number of unmistakable factors that have propelled the success of platform devices. The ubiquitous push for at-home drug delivery has provided a clear and compelling business case for recalibrating drug discovery pipelines. Where biologic drugs were once almost exclusively delivered intravenously (IV), it is hard to ignore the increasing prevalence of subcutaneous (SC) assets across pharmaceutical pipelines. SC dosing regimens are now not only being developed in parallel to IV dosing, but increasingly being prioritised as the primary or standalone dosing option.

As many pharmaceutical companies normalise expansive pipelines with 100+ assets progressing through clinical milestones, the appeal of platform devices is clear; amortised device investments, with multiple assets benefitting from the same delivery device technology. While this "one-size-fits-all" elevator pitch is compelling, it may be in direct contrast to trends within large-dose biologics development.

Large-dose administration has seen the industry continue to challenge on-market precedents, incrementally pushing the perceived limits of acceptable drug volumes, viscosities and delivery times. Furthermore, many large-dose assets exhibit highly complex rheological behaviours (Figure 1). At one extreme, ultra-high concentrations are breaching the 200 mg/mL precedents that have been established over the last decade, even reaching beyond 500 mg/mL. These trends have coincided with the development of non-aqueous suspensions, where a small modification in formulation chemistry can result in significant changes to syringeability, drug delivery and even pharmacokinetic (PK) performance.

Conversely, at the other edge of the design space, the industry is seeing comparably large doses being achieved with higher volumes (Figure 2). Whilst 2 mL autoinjector administrations have become the norm in recent years, pipelines are pushing far beyond this theoretical limit, with the advent of large-volume autoinjectors and on-body injectors proving to be a catalyst for this change. De-risking device development and

"DE-RISKING DEVICE DEVELOPMENT AND SELECTION WHILST WORKING WITHIN THIS EVER-CHANGING FORMULATION DESIGN SPACE HAS BECOME A KEY CHALLENGE FOR COMBINATION PRODUCT TEAMS."

High Concentration	High Volume
Viscosity-reducing agents	High-volume (3 mL) autoinjectors
Ultra-concentrated suspensions	Hyaluronidase for >3 mL
Autoinjectors with powerful drive systems suitable for >20 cP viscosities	Injection pumps

Figure 1: Opportunities for high-dose delivery are commonly segmented into opposing formulation strategies – high concentration and high volume.[1]

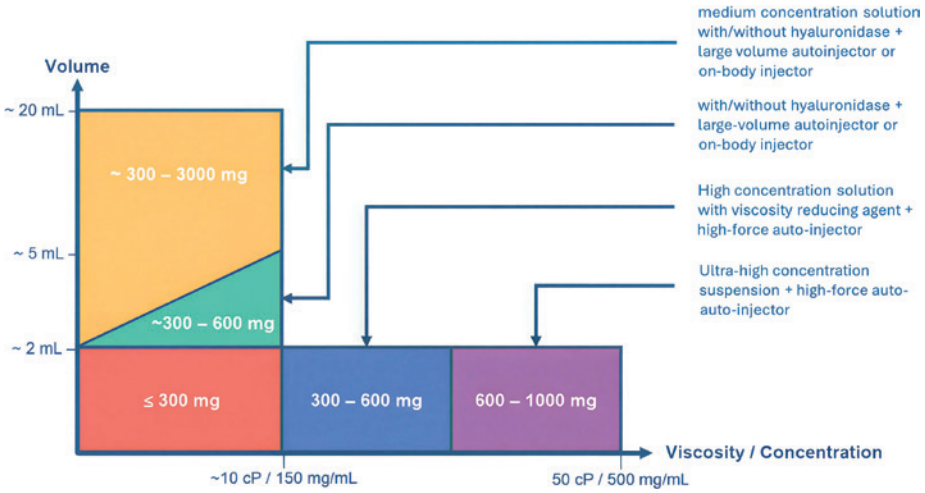

Figure 2: The high-dose design space is diverse, encompassing both higher volume and high concentration formulations, challenging a "one-device-fits-all" platform strategy.[1]

"CURRENT DEVICE PROGRAMMES CAN BENEFIT FROM SUPPLEMENTARY *EX VIVO* TISSUE TESTING, FRONT-LOADING THE CURRENT UNDERSTANDING OF DRUG-DEVICE-TISSUE INTERACTIONS PRIOR TO PRECLINICAL AND CLINICAL STUDIES."

selection whilst working within this ever-changing formulation design space has become a key challenge for combination product teams.

This can be described as "the platform paradox". As off-the-shelf devices converge towards standardisation, next-generation biologics are pushing boundaries and allowing for increasingly unique, diverse design spaces. Thus, navigating this platform paradox requires novel research and development approaches, leveraging state-of-the-art analytical tools to make informed device decisions.

ENABLING HIGH-VOLUME DELIVERY

A variable that often remains unknown during device development is the behaviour of the injectate following injection. With the device landscape historically dominated by 1–2 mL or 1 cP prefilled syringes and spring-driven autoinjectors, it is no surprise that delivery profiles have often been overlooked. A 1 mL injection yields negligible skin distention and therefore characterising bolus formation is rarely deemed essential for traditional SC delivery. However, when going beyond the traditional design space – expanding delivery volumes up to 20 mL and considering high-viscosity formulation technologies – the dynamic behaviours of SC bolus formation become significant.

Most biologics are absorbed into the vascular or lymphatic capillaries prior to ending up in systemic circulation. As there are multiple biological barriers to cross before reaching systemic circulation, and due to their size, some biologics show unfavourable bioavailability profiles after SC injection. For instance, some studies have shown that needle depth upon administration affects absolute bioavailability and PK parameters for biologics.[2] Therefore, this must be considered when developing injection devices for the SC route (Figure 3).

As bolus formation and PK performance become salient questions, traditional evaluation methods can prove both limited and costly. Preclinical and PK studies may be inevitable as a pipeline asset progresses towards market, but significant value can be derived through the adoption of *ex vivo* testing and advanced imaging. Where historic development programmes relied heavily on injections into air to demonstrate credible delivery times, current device programmes can benefit from supplementary *ex vivo* tissue testing, front-loading the current understanding of drug-device-tissue interactions prior to preclinical and clinical studies.

Despite traditional verification testing standards not requiring *ex vivo* evaluations, it is crucial to visualise depot formation and drug dispersion post injection. This, alongside measurement of tissue back-pressure, can help to guide device design (e.g. injection rate, needle selection, injection depth, push-on-skin pressure) and de-risk projects progressing towards the clinic.

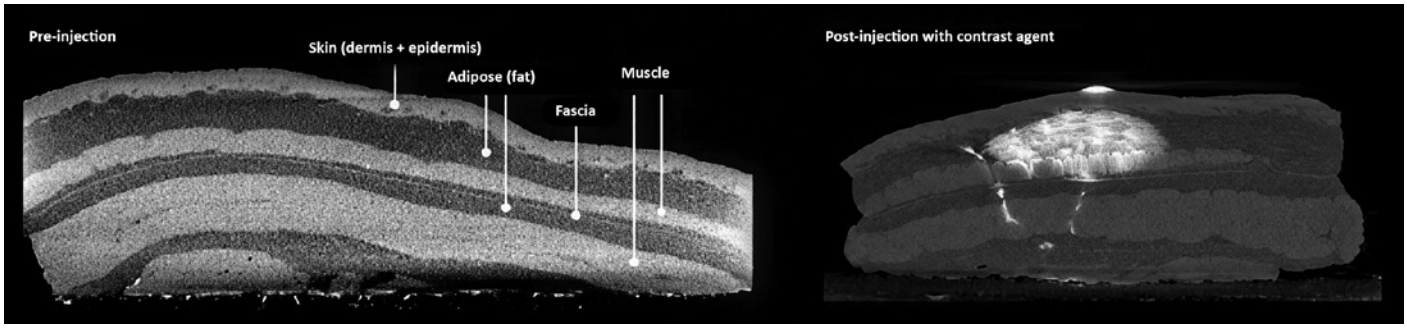

Figure 3: The SC region consists of adipose fat tissue, sometimes separated from muscle by the presence of fascia.

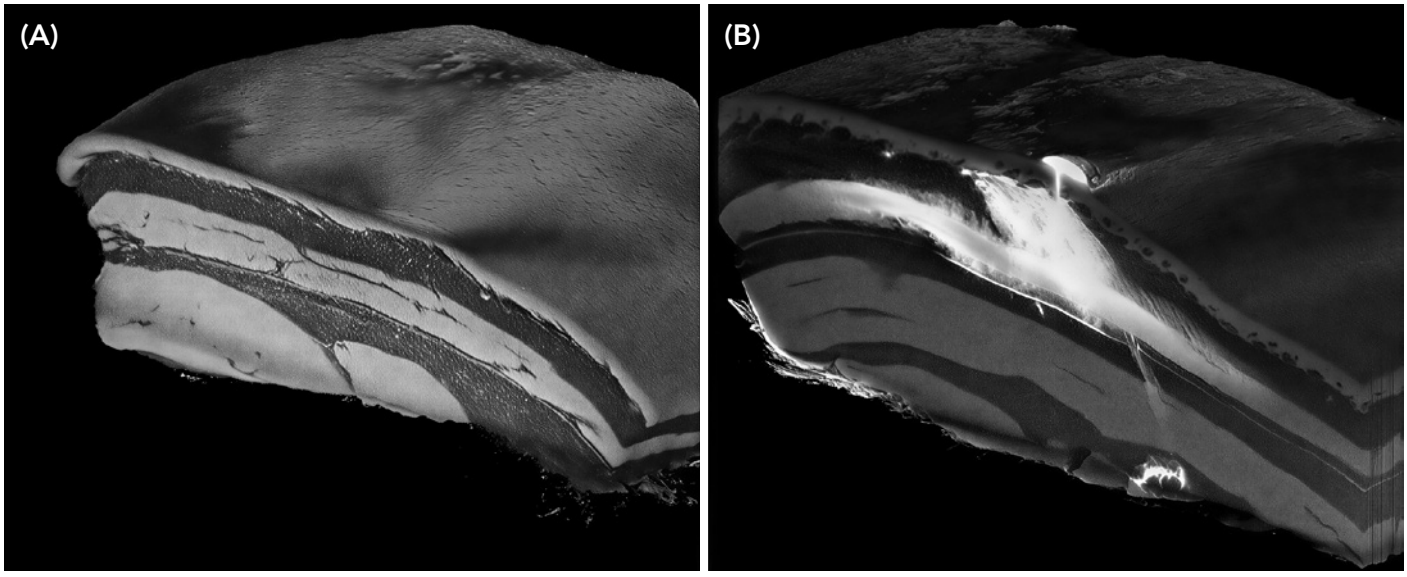

Figure 4: 5 mL bolus in *ex vivo* tissue, showing partial intramuscular penetration below the intended SC layer and significant leakage from the injection site. (A) Before injection. (B) After injection.

Public domain literature presents the results of *ex vivo* testing on porcine abdominal tissue, leveraging micro-CT scanning technology.[3] The porcine model was selected for its translational relevance to human tissue, with resemblant skin thickness and skin tissue architecture. While *ex vivo* tissue does not account for full injectate absorption due to its lack of lymphatic drainage and wider physiological behaviours, it is recognised that minimal fluid removal occurs within the first 20 minutes post injection, enabling an accurate study of injectate dispersion in SC tissue immediately after injection.[3]

A 3D injected bolus volume can be derived following injection, providing datasets that can be interrogated to identify statistically significant variables (Figure 4). Data from these 3D images can be used to assess industry-wide areas of uncertainty, from predicting bioavailability changes as delivered volumes increase, to how bolus morphology may influence patient tolerability and pain.

Early-stage studies began as qualitative, comparative evaluations of in-development formulations. Today, this approach has matured, with refined test protocols, tissue handling frameworks, imaging procedures and data processing for investigating bolus spread, injection site reactions, leakage and skin distention. With advancing research, it has been found that this data can feed directly into device development programmes to:

- Inform optimal injection sites for different patient populations, which has an immediate effect on drug PK
- Study pain and tolerability as a function of bleb formation and size to design injection devices that may improve patient adherence
- Evaluate how injection rate and viscosity can influence leakage after needle removal, resulting in injectate loss, which influences how long the injection duration should be
- Assess device-skin interactions and how large-volume administration may affect tissue backpressure.

"DATA FROM THESE 3D IMAGES CAN BE USED TO ASSESS INDUSTRY-WIDE AREAS OF UNCERTAINTY, FROM PREDICTING BIOAVAILABILITY CHANGES AS DELIVERED VOLUMES INCREASE, TO HOW BOLUS MORPHOLOGY MAY INFLUENCE PATIENT TOLERABILITY AND PAIN."

Combining the data derived from micro-CT imaging to visualise the injectate dispersion post injection has proven to be a valuable method to enhance due-diligence processes and inform the design space for in-development combination products.

MODELLING THE HIGH-CONCENTRATION DESIGN SPACE

In silico modelling and simulation technologies can be used to inform and establish the design space for high-dose SC biotherapeutics. The high-concentration domain remains poorly defined due to the novelty of high-dose biotherapeutic formulations and a historical focus on small molecules. These typically do not exceed 2 mL dose sizes and remain below a concentration of 250 mg/mL. As formulation technologies mature, so too must analytical techniques.

Advanced simulation approaches using finite element analysis and computational fluid dynamics (CFD) can be deployed to create a digital twin to simulate the complex mechanics, material behaviours and fluid interactions of high-concentration therapies. Digital twins are already acknowledged for their ability to predict complex device functionality, though their utility may be extended to include drug-device interactions. This enables device engineers to collaborate

closely with formulation teams, evaluating how in-development drug assets may perform with available platform devices. Further challenging the platform paradox, these digital approaches can be leveraged to define clear device performance limits across the emerging formulation design space.

Amongst today's high-dose formulation technologies, suspensions remain prevalent. Whilst overall viscosities may be kept relatively low, suspension-based formulations are not without complexity when integrating them with platform devices. The most pertinent risk relates to poor syringeability (drawing into a syringe from a vial) and injectability (delivering out of a syringe into tissue) due to particle-induced needle occlusion. These issues stem largely from inter-particle interactions, including sedimentation and agglomeration. Whilst a fully mixed suspension avoids needle clogging, the risk is increased when a formulation is not fully reconstituted or resuspended before use (Figure 5).

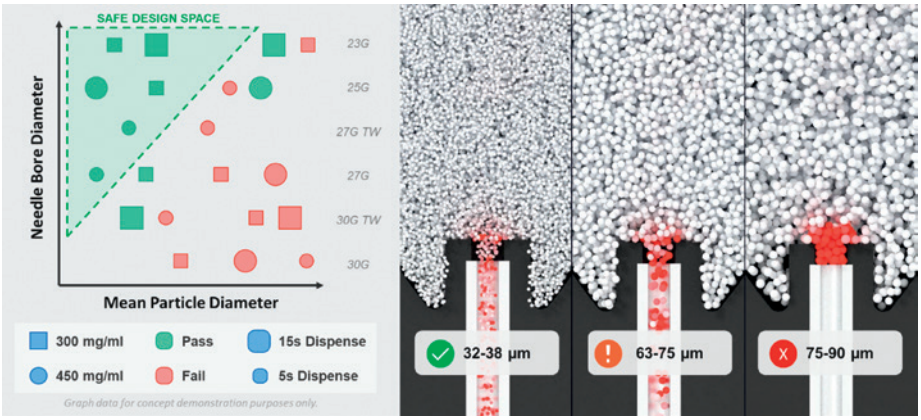

Figure 5: CFD and discrete element modelling to optimise drug particle and needle size specifications.

Addressing the significant complexity of biologics, with a diverse range of formulation variables, by conducting a comprehensive design-space investigation into needle occlusion would be costly and time-consuming. In contrast, a large virtual design-space study can be completed in a matter of weeks by leveraging computational models and high-performance computing. Hundreds of simulations can be run in parallel, exploring thousands of device-formulation combinations to inform development strategies. Such models can evaluate how factors such as particle morphology, cohesivity and vehicle rheology can directly influence needle occlusion. Combining these studies with

the variability observed across the device landscape (e.g. needle size and inlet geometry) provides unparalleled insight into drug-device interactions when changing formulation properties.

ABOUT THE COMPANY

Crux Product Design is a technology-driven consultancy specialising in drug delivery and healthcare innovation. The company partners with leading pharmaceutical companies to develop inhalers, injection devices, wearables and novel delivery systems. Crux's multidisciplinary team combines engineering, sciences, human factors and design expertise to turn complex challenges into successful products. Certified to ISO 13485, ISO 9001, and ISO 14001, with an Ecovadis Gold rating, Crux is trusted by the world's top pharma companies. Based in Bristol, UK and Cambridge, MA, US, Crux delivers evidence-based innovation that drives the future of drug delivery.

REFERENCES

1. *Bruin G et al, "An industry perspective on clinical development and regulatory strategies for subcutaneously administered high-dose biologics". J Control Release, 2025, Vol 386, art 114156.*
2. *Hu P et al, "Systematic review of device parameters and design of studies bridging biologic-device combination products using prefilled syringes and autoinjectors". AAPS J, 2020, Vol 22(2), art 52.*
3. *Gresham J et al, "Visualisation and quantification of subcutaneous injections of different volumes, viscosities and injection rates: An ex-vivo micro-CT study". J Pharm Sci, 2024, Vol 113(12), pp 3447–3456.*

"HUNDREDS OF SIMULATIONS CAN BE RUN IN PARALLEL, EXPLORING THOUSANDS OF DEVICE-FORMULATION COMBINATIONS TO INFORM DEVELOPMENT STRATEGIES."

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Tim Quigg, Development Director at Crux Product Design, supports development strategy and novel problem solving across drug delivery device development programmes. Crux collaborates with 18 of the top 20 pharmaceutical companies, providing Mr Quigg with foresight into cross-industry challenges. With a master's in Mechanical Engineering and a career spanning both combination product and medical device development, Mr Quigg champions front-loading of technical understanding, leveraging emerging tools to de-risk design, development and commercialisation.

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BUILDING STRATEGIC PARTNERSHIPS FOR EARLY-STAGE DRUG DELIVERY DEVICE TESTING

Landon Goldfarb of **Instron** considers the importance of relationships between formulation and delivery teams for pharmaceutical innovation, highlighting a framework to differentiate between an equipment supplier and a testing partner, outlining the system capabilities and organisational competencies required to create effective early device-development teams.

The pace of pharmaceutical innovation is growing exponentially, driven by novel mechanisms of action and AI-powered drug discovery, which leads to robust drug pipelines. This pace has thrust organisational excellence in drug delivery systems into the spotlight, as many newer formulations have characteristics such as higher viscosities or lyophilised products that can challenge traditional delivery devices. This, along with consumer expectations for self-injection devices, means that drug developers need to investigate delivery devices earlier and more often, creating dedicated teams to assess the current landscape of devices to meet their existing and future pipeline.

These early-stage functional groups require testing equipment that provides both modularity for various device form factors and user experiences built around intuitive method development. Understanding the critical requirements for this equipment can allow early device teams to adapt to potential formulations with agility and evaluate a wider range of device technologies.

THE RISE OF DEVICEABILITY FUNCTIONS

The chasm between the formulation and delivery teams has begun to slowly narrow, as project success is much more closely linked to the choice and subsequent performance of the drug delivery system. To build these crosslinks, communication between these teams is happening earlier and more frequently, allowing for discussion of pipeline strategy over longer timescales.

Restructuring occurs on different scales depending on the size of the pharmaceutical organisation. For major players, this has involved expanding core competencies to develop new functional groups, while for smaller players, this can mean being more deliberate in identifying contract partners to support their device development needs. In either case, a common intention around device strategy has created both benefits and challenges for these organisations.

Holistically, this cross-functional effort can make both sides more successful. A stronger shared understanding of formulation and subsequent delivery platforms can help to identify potential issues earlier and create more effective feedback loops. As an example, biological formulations typically require cold storage, with some messenger RNA therapies requiring ultra-cold storage below -80°C. These conditions can have a major impact on device performance and container closure integrity. In an ideal scenario, deviceability teams will have performed preliminary investigations and studies to identify the performance characteristics of different platforms, providing insights into syringe barrel siliconisation, elastomeric components and break-loose and glide forces.

Such insights can circumvent time spent evaluating different devices or, more crucially, going down the wrong path. Furthermore, performing preliminary device testing can provide data that can supplement design verification for the combination product. This advanced development approach can streamline the selection process and ultimately shorten time to market.

The inherent downside is simply the novelty of these functions for some organisations. In many cases, the supply of device-oriented engineers cannot meet the demand. Particularly among smaller companies, more analytically focused talent is being moved into the device space, often using unfamiliar equipment. This disconnect highlights the importance of selecting a partner that understands the unique needs of the drug delivery space and can offer equipment designed for usability. Building a talent pool capable of developing robust device evaluation protocols is critical for ensuring that there are vetted devices ready to support current and future drug pipelines.

Figure 1: Instron Autoinjector Testing System, capable of full functionality testing for needle shield and button-activated devices, as well as safety syringes.

SELECTING THE RIGHT EQUIPMENT PARTNER

Identifying the right partner requires evaluating both their physical equipment capabilities and their organisational experience within the drug delivery space. A partner with both will be best poised to support an expanding deviceability team, with considerations towards long-term needs including design verification and transfer to production. These long-term considerations can help avoid roadblocks associated with method transfer between systems, functional groups or sites and more quickly identify potential device issues earlier in development (Figure 1).

Compatibility With Platform Devices

The use of autoinjectors has become normalised for many patient populations, spurred by the rise of glucagon-like peptide-1 and other chronic therapies. In many cases, automated drug delivery systems are an expectation from the market rather than an additional feature. This expectation has led to unprecedented growth for makers of platform devices, such as Ypsomed's (Burgdorf, Switzerland) YpsoMate® or SHL Medical's (Zug, Switzerland) Molly™, which have built global infrastructures designed to support production ramp-ups and have significant clinical data to de-risk their implementation. These factors have led many pharmaceutical organisations to pursue platform strategies, choosing to standardise on a platform for multiple assets. This allows for preliminary testing that can then be bridged into later phases of the development process.

Considering the risk-averse nature of the pharmaceutical industry, it is likely that platform devices with considerable time on the market will be the initial contenders for deviceability groups. Ideally, testing equipment will be automatically configured to support the most common platform devices on the market, while minimising the amount of physical and method setup required to perform device evaluations. Reducing the complexity of changeovers and the number of interchangeable parts

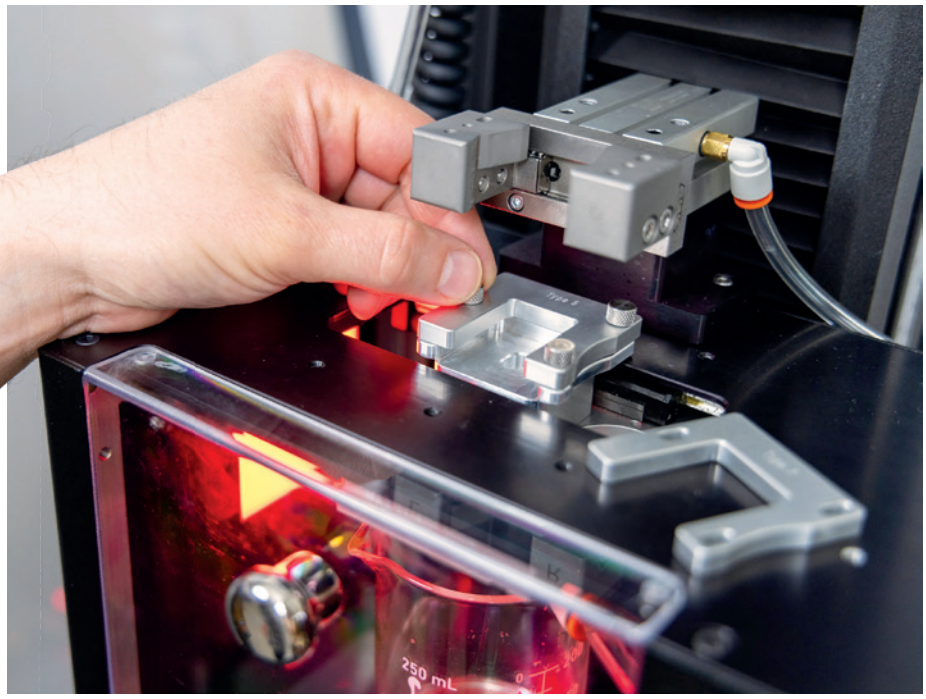

Figure 2: Example cap adapter used to switch between testing different platform devices on Instron's Autoinjector Testing System.

helps to reduce equipment setup time and training required for operators. Figure 2 shows an example cap adapter, which allows for seamless transition between platform devices with a single change part. Collaboration between the two means that the test system has been specifically designed with these platform devices in mind, ensuring proper fit and function of the system.

Beyond physical integration, method development is another area where an expert partner can add value. Alignment of test protocols between the device manufacturer and the pharmaceutical company can help to avoid measured performance outside of the expected specification. When these issues arise, the root cause analysis can be time intensive and require significant collaboration between both parties. In many cases, the equipment supplier is expected to assist, helping to isolate variables in the test procedure that could result in a discrepancy. These issues can be mitigated if the equipment supplier has channels of communication with the device manufacturer and insight into their internal procedures. With that connection, methods can be delivered directly to the customer that align more closely with those of the manufacturer – removing problematic variables and leading to faster solutions. Additionally, this relationship can ensure that test equipment capabilities align with device manufacturers' future product roadmap, limiting the time needed to support newly released devices.

Supporting Novel Device Requirements

Today's drug delivery device landscape is ever growing and changing, driven by patient needs, drug pipelines and industry trends. Serving unique patient populations, paired with increased emphasis on human factors as an organisational competency, is directly impacting the functionality and form factor of devices on the market. For example, devices are using novel feedback mechanisms, shifting from individual auditory clicks to continuous clicks throughout the injection, developed after studies of patient reaction time.

"IN THIS INDUSTRY, SUSTAINABILITY IS PARAMOUNT AND, IN MANY CASES, DIRECTLY SHAPES THE DEVICE FORM FACTOR."

New modalities being brought to market require delivery via lyophilised solutions and reconstitution, necessitating devices with additional patient interactions and capabilities. In this industry, sustainability is paramount and, in many cases, directly shapes the device form factor. An example of this is using a reusable body with interchangeable cassettes loaded with the primary container. These factors are spurring the development and commercialisation of innovative devices, each with the potential for unique testing requirements. Many of these devices are being developed by smaller manufacturers because they can be more agile in response to industry needs, or with the intention of addressing a specific use case. For this reason, many organisations are broadening the scope of devices they are investigating.

As an example, many devices designed for lyophilised drug products require additional patient input for the reconstitution process. Unlike most platform devices, this can involve a rotation in addition to push-pull actions. This additional axis needs to be evaluated to discern the torque necessary to engage the mechanism, which adds complexity to the testing process. Test systems need to be expanded to include the measurement of torque and angular displacement in addition to the standard functional assessment. To guarantee reliable results, the system should allow for programmable rotational rates and a rotary encoder to plot the torque profile in relation to the angle. This level of modularity is crucial for enabling highly capable test programmes and should be a prerequisite for selecting a potential system manufacturer (Figure 3).

Another example has resulted from changing international standards for testing injectable drug delivery devices. As these devices become more commonplace, standards are updated accordingly to better reflect the landscape of devices on the market and their essential performance requirements. ISO 23908 outlines the requirements for sharps protection features on drug delivery devices. The most recent update in 2024 saw increased scrutiny when testing access to a device while in safe mode. For autoinjectors, this specifically refers to when the needle shield is locked out. Traditionally, this has been done through

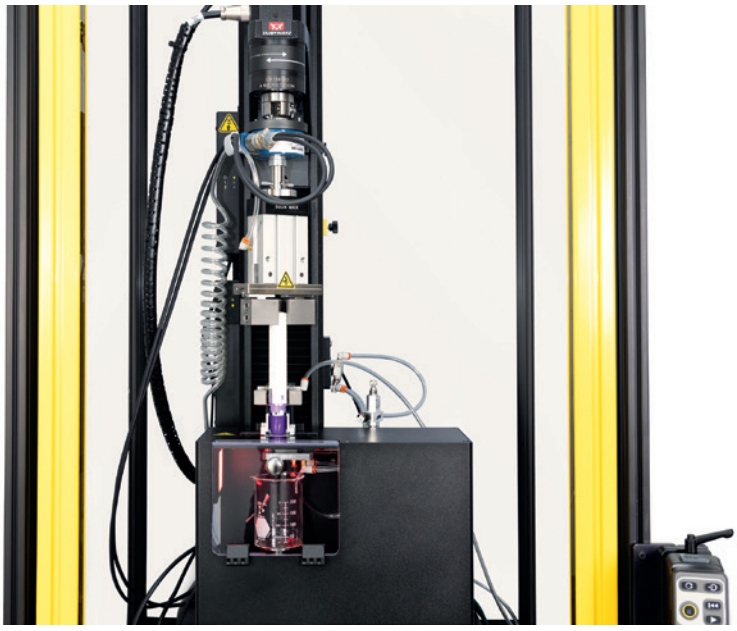

Figure 3: Modular torsion add-on enables biaxial testing capabilities.

dimensional stack-up analysis and finite element analysis. Physical tests are increasingly preferred, especially when performed as a variable test. This reduces the total number of samples needed, a critical efficiency gain in early-stage programmes when devices can be scarce. Needle safe distance, or the measurement of the distance between the needle tip and the needle shield in the locked-out position, is another common modular add-on.

Mechanical test equipment should allow for modularity, supporting additional test capabilities as needed. Beyond available add-ons, an equipment partner should have in-house design teams with a competency around developing custom modifications. When using the equipment, manufacturer-provided concepts offer additional benefits – including method development support, traceability and simplified transfer to production.

Scalability for the Future

Investing in test equipment in the early device evaluation stages does not need to be a trade-off with considerations for later-stage objectives. Regulatory compliance should be discussed early and often with equipment manufacturers, assessing the system's ability to be used in good manufacturing practice environments. Performing daily checks on equipment is an essential capability to ensure measurement devices are operating within specification before collecting data and instilling confidence in the results produced by the system. Using system-integrated daily check devices removes the guesswork for organisations. Additionally, built-in software workflows can reduce documentation burdens, integrating the operator sign-offs and daily check reports directly into the system audit trail. Moving towards digital documentation and automatic prompting for daily checks minimises errors in data collection and ensures traceability (Figure 4).

"REGULATORY COMPLIANCE SHOULD BE DISCUSSED EARLY AND OFTEN WITH EQUIPMENT MANUFACTURERS, ASSESSING THE SYSTEM'S ABILITY TO BE USED IN GOOD MANUFACTURING PRACTICE ENVIRONMENTS."

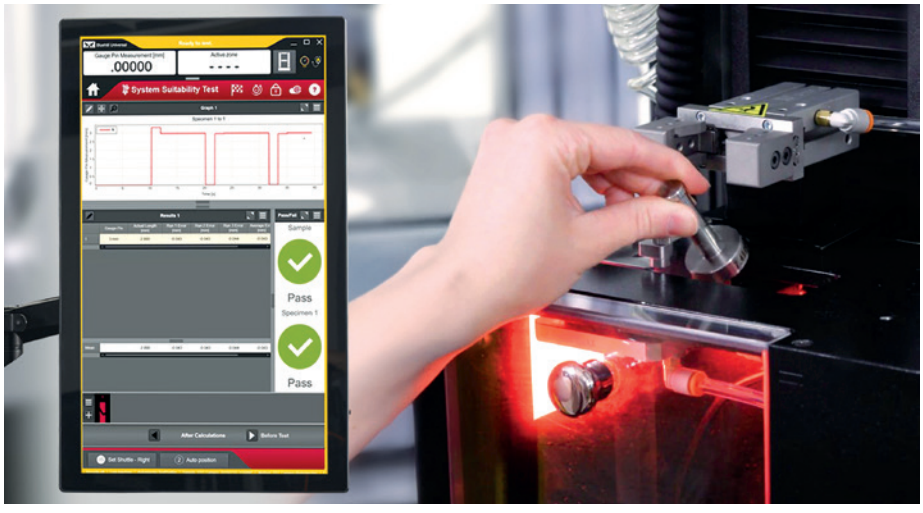

Figure 4: System suitability testing ensures measurement devices are operating within specification before collecting data.

Method development will often begin with the early device teams – with their work being the foundation for design verification – followed by production environments. Enabling change management of test methods and the ability to transfer methods across different functions, can remove uncertainty related to method selection and prevent accidental modifications to validated methods. Enterprise software platforms are scalable with pharmaceutical organisations and can connect test systems across sites – unifying method databases and user permissions, and restricting operator actions to avoid errors.

Instron's Bluehill Central lab management software enables remote management of connected testing systems, allowing for the creation of teams, each with their own dedicated permissions and

file repositories – meaning data can be siloed according to function and asset programme, then transferred when necessary. Systems capable of supporting these software platforms allow for seamless hand-offs across the development process and should be a key metric for selecting a partner.

Finally, when looking towards higher-volume, more standardised test environments, it is important to consider automation capabilities. Automation serves to reduce opportunities for operator error and variability in the data. In most autoinjector-specific cases, automation will not actually reduce the total test time, so it is important to identify automation designed to reduce requirements for system setup and device changeovers. The level of reliance on equipment manufacturers can be prohibitive, especially in work environments where employee turnover is an issue. System flexibility and usability are paramount in evaluating automation partners.

These criteria provide a framework for differentiating between an equipment supplier and a testing partner, identifying the system capabilities and organisational competencies necessary to assist in building effective early device-development teams and, subsequently, to navigate the entire development process.

Landon Goldfarb

Landon Goldfarb is Biomedical Product & Market Manager at Instron, driving innovation in mechanical testing for pharmaceutical and medical device companies. With extensive expertise in highly regulated industries, he helps global organisations implement and automate advanced testing solutions across R&D and production. Collaborating closely with engineering teams, Mr Goldfarb shapes next-generation products tailored to the evolving biomedical landscape. As a trusted industry voice, he contributes to standards development and shares actionable insights through technical publications and conference presentations – sharing best practices and driving innovation in biomedical testing worldwide.

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Expert View

DESIGNING SUSTAINABLE DRUG DELIVERY DEVICE PACKAGING: TRENDS, CHALLENGES AND REGULATORY IMPLICATIONS

Angela Shotton and **Nic Hunt**, both of Nelipak Healthcare Packaging, look at the evolving landscape of the pharmaceutical packaging landscape and consider how the industry is meeting sustainability and regulatory requirements.

"SUSTAINABILITY IS NO LONGER OPTIONAL – IT HAS BECOME A KEY CONSIDERATION IN PHARMACEUTICAL PACKAGING, WITH COMPANIES EMBEDDING PACKAGING INTO THEIR CORPORATE DECARBONISATION AND SCOPE 3 EMISSIONS STRATEGIES."

The pharmaceutical packaging landscape is changing quickly. With more drugs on the market, including a growing share of biologics and a shift towards home-based therapies, packaging demands are becoming increasingly complex. At the same time, sustainability and regulatory pressures are pushing the industry to rethink materials, formats and design approaches.

Today, packaging needs to do more than just protect a product in transit. It also has to work with automated systems, meet evolving regulatory requirements, reduce environmental impact and support patients managing their own care at home.

MARKET TRENDS DRIVING PACKAGING INNOVATION

The market for devices has grown significantly in recent years. Biologics now make up a larger proportion of prescriptions, and inhalers, autoinjectors, prefilled syringes and wearable devices are becoming more common across a variety of therapies.

This growth has increased the demand for durable transport trays, inserts and secondary packaging that can handle high-speed automation, protect sensitive components and support efficient handling in both clinical and home environments. CDMOs and pharmaceutical companies are exploring ways to optimise packaging for volume, automation and environmental performance. Initiatives such as the Pharmaceutical Supply Chain Initiative are also influencing packaging strategies, aligning pharmaceutical companies' supplier requirements to encourage a reduction in energy use and emissions. Packaging suppliers are working closely with manufacturers to create thermoformed trays and packaging that meet these needs.

SUSTAINABILITY DRIVERS

Sustainability is no longer optional – it has become a key consideration in pharmaceutical packaging, with companies embedding packaging into their corporate decarbonisation and Scope 3 emissions strategies. Regulations such as the EU Packaging and Packaging Waste Regulation (PPWR) are reinforcing this, requiring that, by 2030, packaging not in direct contact with the pharmaceutical product contains defined quantities of post-consumer recycled (PCR) content.

Implementing sustainable packaging is a process. It starts with setting clear sustainability goals, developing design concepts and involving key stakeholders early. Rapid prototyping and proof-of-concept sampling can help to ensure that requirements are met before full production begins. Involving product stewardship helps to ensure that the benefits of sustainability are shared across the supply chain.

There are four key areas driving sustainable manufacturing in drug delivery device packaging:

1. **Material Circularity:** Choosing the right materials can make a big difference. Many companies are moving towards mono-material trays and inserts, which are easier to collect and recycle, and avoiding materials of concern. Third-party certifications can confirm recyclability readiness. Some suppliers

"EARLY COLLABORATION BETWEEN PACKAGING ENGINEERS, AUTOMATION SPECIALISTS AND DEVICE TEAMS IS ESSENTIAL."

are developing mono-material packaging solutions that offer sufficient strength and functionality while supporting circularity.

2. **Recycled Content**: Compliance with PPWR requires non-contact packaging to include a minimum PCR content, with the amount varying depending on the type of materials. Manufacturers are currently reviewing material specifications to ensure reliable PCR availability and compatibility with required standards. Close collaboration across the supply chain is also key to ensuring stable supply of selected materials.

3. **Size Optimisation**: Right-sizing trays and packs reduces material use, shipping volume, storage space and carbon footprint, while keeping contact materials unchanged. Digital simulation tools and pallet load studies can help to visualise and optimise tray density. This kind of dimensional optimisation can reduce waste by 10–15% in high-volume lines and improve distribution efficiency.

4. **Design for Circularity**: Durable, reusable trays can replace single-use equivalents, lower carbon dioxide footprints and support circular approaches. Design considerations include durability, cleanability and traceability. Many CDMOs are exploring circular tray programmes, often in collaboration with packaging suppliers, to make sustainability practical and measurable.

DESIGN AND AUTOMATION CONSIDERATIONS

Automation plays a big role in modern packaging. High-speed assembly and filling lines all depend on trays and inserts that are dimensionally stable and compatible with robotic systems. Poorly designed trays can cause line stoppages, misalignment and extra labour.

Early collaboration between packaging engineers, automation specialists and device teams is essential. Modelling tray orientation, optimising pick points and testing prototypes can prevent costly delays. Digital simulations and pallet load studies can enable teams to understand automation efficiency and shipping density before production. It is important to use structured product requirement specification (PRS) processes to align device, automation and packaging requirements early in the design phase.

Fully integrated design services can align device protection, automation compatibility and user requirements within a single, structured process. Effective transit tray development often involves multiple stakeholders – from design authorities and consultants to pharmaceutical companies, device manufacturers and automation partners. Working with an established PRS framework can capture and reconcile all functional and technical needs before tray design begins. Designers translate the initial technical brief into detailed digital concepts that address critical considerations, such as device orientation, protection of sensitive features and handling requirements, including gripper access for automated systems. Sustainability should be embedded throughout the design lifecycle, with a team collaborating closely with stakeholders to support environmental objectives through options such as *in silico* design tools, tray take-back programmes, recycled content, recycle-ready materials and lifecycle analyses.

REGULATORY AND COMPLIANCE IMPLICATIONS

Regulations such as PPWR highlight the importance of integrating sustainability and material selection into packaging design from the start. Items that were once considered operational, such as transit trays and secondary packaging, are now classified as packaging and must meet compliance requirements. Companies need to consider material chemistries, recycled content, supply chain resilience, sterilisation compatibility and validation requirements. Early engagement with suppliers and CDMOs is critical for regulatory and operational readiness.

HUMAN FACTORS AND PATIENT-CENTRED PACKAGING

As some therapies move from hospital to home, packaging must be intuitive, safe and easy to use. Considerations should include device removal, ergonomics for older patients or those with limited dexterity and compatibility with digital adherence tools. Packaging that is difficult to use can negatively affect adherence and therapeutic outcomes.

Many manufacturers are adopting intuitive tray designs and combination packs that guide patients through setup and administration. Packaging is increasingly a key part of the therapeutic experience. It is important that packaging suppliers work closely with manufacturers to integrate human factors into packaging early in the design process.

PRACTICAL STEPS FOR MANUFACTURERS

Pharmaceutical and device manufacturers can take several practical steps to prepare for sustainability and regulatory requirements. They can assess current packaging for material efficiency, size optimisation and recyclability. Opportunities to integrate mono-materials or PCR content should be explored. Collaborating with suppliers

"IT IS IMPORTANT THAT PACKAGING SUPPLIERS WORK CLOSELY WITH MANUFACTURERS TO INTEGRATE HUMAN FACTORS INTO PACKAGING EARLY IN THE DESIGN PROCESS."

and CDMOs early can help to model tray performance, automation compatibility and lifecycle impacts. Rapid prototyping and digital simulation can validate design choices before full production. Aligning packaging changes with sustainability goals and regulatory timelines can ensure smooth compliance.

Angela Shotton

Angela Shotton is Sales Director Pharma & Drug Delivery at Nelipak Healthcare Packaging with 30 years of industry experience, working alongside CDMO and pharma/drug delivery customers. Ms Shotton specialises in complex, multiparty projects, delivering value to each stakeholder with best-in-class, sustainable packaging solutions.

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These practices are already being adopted across the industry. Early collaboration between suppliers and CDMOs accelerates decision-making, reduces risk and supports sustainability goals.

CONCLUSION

Sustainable packaging for devices has become a must, affecting regulatory compliance, environmental performance, manufacturing efficiency and the patient experience. By considering material circularity, recycled content, right-sizing, reusability, automation compatibility, human factors and product stewardship early in the design process, manufacturers can create packaging that meets both commercial and environmental goals.

Leading suppliers and CDMOs are adapting by exploring new materials, reusable formats and design practices in preparation and anticipation of upcoming regulations. Companies that engage early and work collaboratively will be in the best position to meet the sustainability and regulatory challenges of the next decade while delivering safe, effective and patient-friendly therapies.

ABOUT THE COMPANY

Nelipak is a global provider of healthcare packaging solutions, including rigid and flexible sterile-barrier packaging for medical device, diagnostic, pharmaceutical drug delivery and other demanding applications. To support the development of innovative sustainable packaging solutions, Nelipak offers in-house design, prototyping, tooling, simulation, validation, laboratory and other value-added services as well as a line of tray-sealing equipment.

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Interview: New But Not News – A Smooth Transition to USP <382> with Established Expertise

In this interview, **Dr Aurélie Rebuffet** of **BD Medical – Pharmaceutical Systems** and **Virginie Jeymond** of **ZebraSci**, a BD company, discuss the new requirements set out in the US Pharmacopeia (USP) Chapter <382>, including the shift towards assessing the drug-device combination product as a holistic whole and how ZebraSci and BD can support pharma companies in complying with USP <382>.

Q To begin, can you give us an overview of USP <382>, why it is being implemented and how it differs from the current regulations in USP <381>?

"USP <382> TAKES A MORE HOLISTIC APPROACH, ASSESSING THE ELASTOMERIC COMPONENTS AS PART OF THE FULL DRUG DELIVERY COMBINATION PRODUCT."

AR USP <382> is a new chapter of the USP covering elastomeric components for injectables, including vials, cartridges and prefilled syringes (PFSs). Previously, USP regulations assessed the elastomeric components of a combination product individually, with USP <381> setting out the necessary tests and requirements and focusing primarily on the chemical characterisation of the elastomers. USP <382> takes a more holistic approach, assessing the elastomeric components as part of the full drug delivery combination product.

This change in focus is representative of a change in approach that is taking hold across the drug delivery industry. Over the past several years, an increasing emphasis has been placed on user centricity, considering patients, healthcare practitioners and caretakers. This has led developers and regulators to view the entire drug-device combination product as a single entity, rather than a collection of individual components. This change of focus acknowledges the potential interactions between the drug and its primary container, bringing these considerations into the development process to deliver better products that are safer for patients and users.

In practical terms, USP <382> requires more tests for injectable combination products, some of which were previously covered by ISO standards and are now being formally brought under the USP. These new tests cover aspects such as container closure integrity (CCI); needle and spike access functionality for vial stoppers; functional performance metrics for PFS plungers, including activation and extrusion forces; and tip cap and needle shield functionality. Critically, these tests must now be performed on assembled devices filled with the actual drug product or a fully validated proxy, thereby ensuring that the results reflect real-world performance.

As a PFS and component expert, BD has long been prepared for USP <382> and is fully ready to support pharma customers with the changes it requires. Our role in this transition is to accompany drug developers and pharma partners in navigating these regulatory changes to support them in successfully bringing new injectable

Dr Aurélie Rebuffet

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Aurélie Rebuffet, PharmD, is a Senior Staff Specialist in Regulatory Affairs at BD Medical – Pharmaceutical Systems. In her role, she defines and implements regulatory strategies, leads complex cross-functional initiatives and represents Regulatory Affairs in strategic projects and international forums. Her work ensures compliance excellence while creating value-driven solutions for clients and the organisation. Dr Rebuffet began her career in Regulatory Affairs at Sanofi Pasteur, before joining BD in 2016. She holds a Doctorate in Pharmacy from Grenoble Pharmacy University (France), a Civil Engineering degree from École des Mines de Saint-Étienne (France), and a master's degree in Regulatory Affairs from Paris-Sud Pharmacy University (France).

Virginie Jeymond

Senior Global Marketing Manager

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Virginie Jeymond is a Senior Global Marketing Manager at BD Medical – Pharmaceutical Systems. In her role, she defines marketing and go-to-market strategies for several combination product support services, including lab testing services under the ZebraSci brand, and collaborates with various cross-functional stakeholders to implement these strategies globally and within the regions. Ms Jeymond began her career in Global Marketing at Fresenius Kabi and Baxter before joining BD in 2021. She holds a master's degree in marketing from Grenoble Ecole de Management (France), and an engineer's degree in IT Methodologies Applied to Company Management from Grenoble University (France).

therapies to market with a minimum of hassle, so that patients can receive treatments that are safer and more effective.

Q What does USP <382> mean for players in the PFS space?

AR The two headline changes that come with USP <382> are new tests required for injectable systems and the necessity for these tests to be performed with the final drug product, which entails that pharma partners can no longer fully rely on existing data available from components manufacturers.

A key consideration of USP <382> is that the combination product must be shown to be "fit for purpose". Specifically, this means that the complete system must show that it can maintain sterility and prevent contamination throughout its shelf life, and facilitate safe and effective administration of the drug product by fulfilling mechanical and functional criteria under real-use conditions. The thinking behind this "fit for purpose" approach is once again to ensure that patient outcomes are kept at the centre of drug development.

Regarding CCI, the new requirements focus on a full-system evaluation. Importantly, the new regulations prescribe deterministic testing methods rather than the probabilistic approach previously required. Probabilistic tests, such as bubble tests or dye ingress, are heavily reliant on visual inspection, which leads to greater variability and inconsistency in the results. In contrast, deterministic tests, such as vacuum decay and helium leak testing, provide precise, reproducible results. The more rigorous, science-based approach offered by deterministic testing methods aligns with USP <382>'s emphasis on full-system testing and produces results that are true to real-world use.

Another key requirement for PFSs in USP <382> is that device characteristics such as activation and extrusion forces, as well as tip cap and rigid needle shield (RNS) removal forces, need to be appropriate for the device's target demographic. For example, under USP <382>, if a PFS combination product is targeted towards self-administration by elderly patients, whose grip strength will likely be lower. The drug developer will need to show that the PFS enables those patients to remove the RNS and depress the plunger successfully and consistently.

While these tests are new to the USP, they aren't new to us – we've been conducting CCI, activation and extrusion force, and tip cap and RNS removal force tests on fully assembled systems for years as part of our standard design verification process. A key emphasis of USP <382> is the holistic approach to testing, meaning that the entire combination product – drug and device – must be tested as a whole for results to account for the specific interaction of the drug and its delivery system while being representative of real-world use. And that means data cannot simply be provided by the device manufacturer.

Q Who is responsible for ensuring that the regulations in USP <382> are followed?

AR USP <382> is a critical change for the industry. Previously, under USP <381> the device manufacturer could conduct the necessary tests on their devices and pass that data on to pharma partners for the regulatory submission. With USP <382>, the pharma company must provide test results conducted with their final drug product and carries the responsibility for ensuring that these tests were performed as required.

The reason for this change is simple – only the pharma company has direct access to all elements of the complete combination product. USP <382> considers both the drug and device as a holistic whole, mandating that tests be carried out on a fully assembled and filled system. While this is step forward in ensuring that test results are truer to real-world performance, it does mean that we as device developers can't perform the necessary tests on our own, as we're missing a key part of the picture: the drug.

"WHILE THESE TESTS ARE NEW TO THE USP, THEY AREN'T NEW TO US – WE'VE BEEN CONDUCTING CCI, ACTIVATION AND EXTRUSION FORCE, AND TIP CAP AND RNS REMOVAL FORCE TESTS ON FULLY ASSEMBLED SYSTEMS FOR YEARS AS PART OF OUR STANDARD DESIGN VERIFICATION PROCESS."

The fact that pharma partners cannot fully rely on readily available data generated by device manufacturers further emphasizes their responsibility to regulatory authorities, which may seem daunting. But it doesn't have to be. Some companies may already have the capabilities and expertise required to handle these tests in-house, while smaller players in the sector, such as biotech startups, will likely need assistance in meeting the requirements set by USP <382>.

"IN PARTICULAR, AS A BD COMPANY, ZEBRASCI SPECIALISES IN DEVICES FOR PARENTERAL INJECTION AND IS A SPECIALIST IN PFSs, NEEDLE SAFETY SYSTEMS AND ON-BODY INJECTORS."

Fortunately, we have been building up experience in full-system testing for a long time and, with ZebraSci, are now able to make that expertise as a service to our pharma partners.

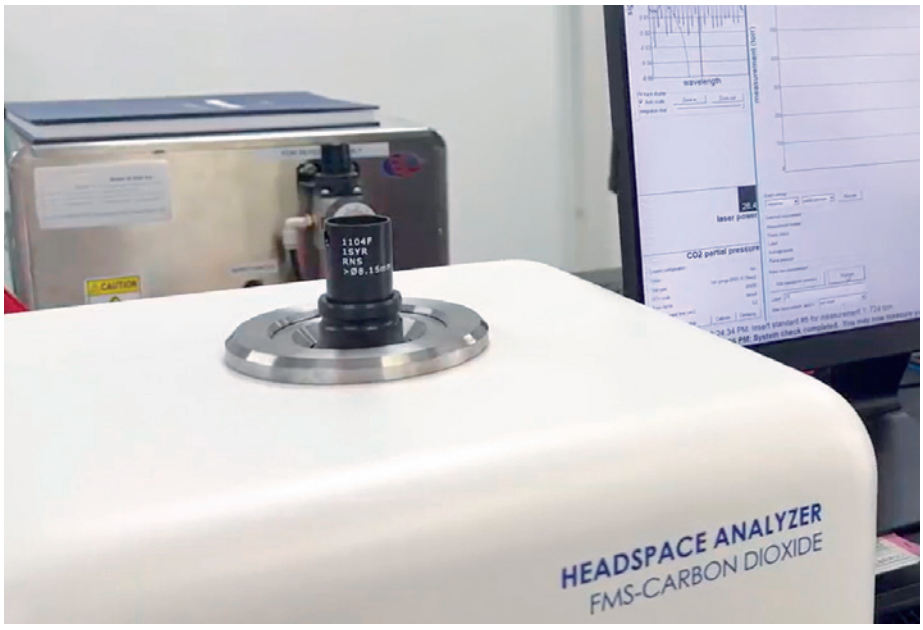

Figure 1: A laser headspace analyser at ZebraSci.

Q Who is ZebraSci and how are they positioned to support pharma companies in implementing USP <382>?

VJ Where BD offers our pharma partners an extensive portfolio of full prefillable systems, including the glass barrel, rubber closure, plastic components and secondary devices for parenteral injection, ZebraSci's focus is on combination product development consulting and validation testing, including developing methodologies, specifically tailored to support the pharmaceutical, biotech and medical device sectors. Our extensive experience, in-house expertise and tight focus make us a leading expert in drug-device combination product validation testing. In particular, as a BD company, ZebraSci specialises in devices for parenteral injection such as PFSs, autoinjectors, needle safety systems and on-body injectors.

ZebraSci is fully prepared to perform the full-system testing required by USP <382> within our GMP laboratories (Figure 1). We operate sites in France, New Jersey

(US), California (US) and China, giving us a global presence that enables us to reach our partners locally, all around the world. Additionally, we have small-scale fill-finish and assembly capabilities in-house, so we can assemble prefillable syringes on site with drug product provided by our pharma partners, with a unique ability to customise silicone levels for testing purposes.

As a brief, non-exhaustive overview of our testing capabilities, we're able to perform both probabilistic and deterministic CCI testing, extractables and leachables testing, toxicological risk assessments, siliconisation analysis, sub-visible particle analysis and a full range of performance testing – including break-loose and glide force testing. In summary, we're well prepared to help pharma partners perform all the necessary testing for USP <382>.

However, it's important to point out that our services aren't limited to validation testing. ZebraSci is equipped to support customers throughout development, with expertise spanning from early-stage design through to regulatory submission. When it comes to USP <382>, on top of testing services, we're able to support our partners with regulatory expertise, assisting them in putting together their submissions, including custom protocol development for regulatory filings. Additionally, all our labs are GMP-compliant and have ISO 17025 and 13485 certifications.

We are fully capable of working with any drug delivery system in-house – we do not subcontract testing services to external partners. This means that we've built a depth of knowledge and expertise with combination products and have a thorough understanding of project timelines. As a BD company, we're deeply integrated with BD and have a wealth of experience with BD's product portfolio, which enables us to act as an integrated solution provider when advising on and working with BD products.

"ALL OF OUR PRODUCTS ARE VALIDATED USING A RIGOROUS DESIGN VERIFICATION PROCEDURE, INCLUDING CCI, LEAK TESTING AND GLIDE AND BREAK-LOOSE FORCES."

Figure 2: BD provides complete injection systems to its pharma partners.

Q ZebraSci offers extensive support for combination product validation. What about early-stage selection of the primary packaging?

AR For years now – since before the announcement of USP <382> – BD has emphasised testing its products as complete systems, with a view to preparing datasets of system performance. All our products are developed using a rigorous design verification procedure, including CCI, leak testing and glide and break-loose forces. As you'll note, these are the key aspects covered by USP <382>.

This procedure was refined and reinforced during the development of the BD Neopak™ and BD Hypak™ Glass Prefillable syringe for biologics (Figure 2). We also put significant effort into generating a wealth of system data to demonstrate the performance capabilities of these products as complete systems, including in combination with BD SCF™ PremiumCoat® and BD SCF™ Flurotec® Plunger Stopper.

While this wealth of data may not be directly used for regulatory filings under USP <382> – as BD's tests are conducted using model solvents – it provides a valuable benchmark that informs early-stage decision making and derisk combination product development. Additionally, this approach has helped BD develop robust, in-house experience that can be made available to pharma partners to help in their own combination product developments.

Along with ZebraSci, BD provides recommendations for primary packaging selection and regulatory support to our pharma partners, including personalised support to help them navigate the intricacies of combination product requirements and derisk their development process. When it comes to USP <382>, BD is well prepared and will continue to alleviate the responsibility associated with combination product testing for our partners and ensure that their development journeys are as smooth as possible, all to bring better, safer therapies to the most important stakeholder – the patient.

FluroTec® is a registered trademark of West Pharmaceutical Services, Inc, and PremiumCoat® is a registered trademark of Aptar Pharma.

2026 Event Calendar

PharmaED RESOURCES, INC

Connected Devices & Digital Health 2026
April 8-9, Providence, RI

Extractables and Leachables 2026
April 22-23, Providence, RI

Combination Products Summit 2026
May 27-28, Providence, RI

Microneedle & Transdermal Delivery Forum 2026
September 16-17, Philadelphia, PA

Aseptic Processing Summit 2026
October 27-28, Philadelphia, PA

Extractables & Leachables West 2026
November 4-5, La Jolla, CA

Pre-filled Syringes & Injection Devices 2026
December 9-10, La Jolla, CA

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Every small detail is essential to de-risk your next big breakthrough in biologics

Meet our advanced biologics prefillable syringe system offerings

BD offers an integrated Prefillable Syringe system approach, backed by a comprehensive portfolio of syringes, stoppers and other drug delivery solutions.

The BD Neopak™ Glass Prefillable Syringe platform is designed to address key development needs for biologic drugs, such as enabling drug-container and autoinjector compatibility and accommodate a range of viscosities and sensitive drug formulations.[1,2,3,4] It is available in both 1mlL and 2.25mL formats.

The latest addition to the BD Neopak™ Glass Prefillable Syringe platform is our BD Neopak™ XtraFlow™ Glass Prefillable Syringe.

Featuring a shorter (8mm) needle length and thinner wall cannula, the BD Neopak™ XtraFlow™ Glass Prefillable syringe has been designed to optimize subcutaneous delivery of higher viscosity drug formulations >15cP.[3,*]

The BD Neopak™ Glass Prefillable Syringe Platform can be leveraged with our BD SCF™ PremiumCoat® Plunger Stopper, available in 1mlL and 1-3mL sizes.

BD SCF™ PremiumCoat® supports:

- Improved functional performance due to reduced glide force and glide force variability**[5,6]
- Container Closure Integrity with guarantee of no ribs not touching[7,8]
- Integration into combination products through a robust system data package[9,10]

Developing new biologics is complex, choosing the right partner is not.

Partner with BD today.

*When compared to 12.7 mm special thin wall (STW) needle
**When compared to the BD SCF™ FluroTec® Plunger Stopper. Results are based on a sample of 100 pieces of BD Flurotec® and BD SCF™ PremiumCoat®. Variables compared were Mean (glide force reduction) and standard deviation (glide force variability)
¥ Gliding test performed at nominal design space, in BD Neopak™ Glass Prefillable Syringe 2.25mL 27G filled with WFI

1. BD Neopak™ 1mlL customer quality specification, Le Pont-de-Claix, France; Becton, Dickinson, 2017 **2.** BD Neopak™ and BD Neopak™ XSi™ 2.25 mL customer quality specifi cation, Le Pont-de-Claix, France; Becton, Dickinson, 2020 **3.** Injection time and ejection force calculation [internal study], Le Pont-de-Claix, France; Becton, Dickinson and Company, 2021 **4.** Depaz et al. Cross-Linked Silicone Coating: A Novel Prefilled Syringe Technology That Reduces Subvisible Particles and Maintains Compatibility with Biologics JOURNAL OF PHARMACEUTICAL SCIENCES 103:1384–1393, 2014 **5.** DVTR20192507_DV data BD SCF™ PremiumCoat® 1 mlL R&D data [internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **6.** TR20234488 Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024 **7.** BD SCF™ PremiumCoat® Plunger Stopper 1mlL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2022. **8.** BD SCF™ PremiumCoat® Plunger Stopper 1-3mL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **9.** Design Control Evidence BD SCF™ Premiumcoat® 1mlL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2021 **10.** Design Control Evidence BD SCF™ Premiumcoat® 1-3mL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024

FROM CONCEPT TO SERIES PRODUCTION – ACCELERATING INDUSTRIALISATION IN MEDTECH

Matthias Müller of **Contexo** and **Sven Müller** of **Probotec** discuss the two companies' combined approach to scaling drug-device combination products from laboratory prototypes to fully validated GMP commercial-scale production lines.

The journey from a laboratory concept to a fully validated, high-volume medical device production line has always been one of the biggest challenges faced by the drug delivery industry. The path is steep – prototypes must become reproducible products, pilot lines must evolve into stable serial production and every step must comply with strict regulatory frameworks, including GMP, ISO and the US FDA. For many manufacturers, this process takes far too much time – time that can decide whether a product reaches the market early or is overtaken by competitors.

In a sector where time-to-market is as critical as product quality, industrialisation speed has become a decisive competitive factor. However, acceleration cannot come at the cost of validation, especially in drug-device products or precision delivery systems, every process step – from component feeding to final packaging – must be proven, documented and repeatable under production conditions.

This is where the partnership between Contexo, a specialist in mechanical engineering and process automation (Figure 1), and Probotec, an expert in GMP-compliant production and operations, comes in. Together, these two companies have developed a seamless industrialisation approach that compresses the path from concept to series production – often by several months – without compromising regulatory compliance or technical depth.

Figure 1: Mechanical engineering and process automation.

THE INDUSTRIALISATION BOTTLENECK

Medical device developers often reach a critical point once prototypes have demonstrated functionality. At this stage, the focus shifts from product design to manufacturability, and the following questions need to be answered:

- Can the process be automated without sacrificing flexibility?
- How can validation be achieved quickly and efficiently?
- How can production be scaled once market demand increases?

Traditionally, these phases have been sequential; first comes machine design, then process definition and finally the setup of the production environment. Every interface, between design and production and between automation and operation, introduces potential delays, misunderstandings and risks.

"CONTEXO AND PROBOTEC CHALLENGE THIS PARADIGM WITH AN INTEGRATED, CONCURRENT APPROACH – INSTEAD OF ISOLATED PROJECT STAGES, THEY DEVELOP THE MACHINE, PROCESS AND PRODUCTION ENVIRONMENT IN PARALLEL."

Contexo and Probotec challenge this paradigm with an integrated, concurrent approach – instead of isolated project stages, they develop the machine, process and production environment in parallel. The result is a validated, fully documented production system ready for operation within months.

TIME-TO-MARKET MEETS VALIDATION: THE CONTEXO & PROBOTEC MODEL

Customers no longer need PowerPoint concepts; they need functioning production systems. By synchronising engineering, validation and operation, Contexo and Probotec can eliminate waiting times and interface losses (Figure 2). At the core of the companies' collaboration lies the idea of "One Flow", wherein machine and process design, qualification and production start-up are all treated as a single, tightly integrated workflow.

END-TO-END PROCESS DESIGN

Contexo develops complete process architectures, from feeding to palletising. Every detail – part handling, sorting, dosing, laser welding, ultrasonic sealing, vision inspection, traceability and final packaging – is simulated, verified and

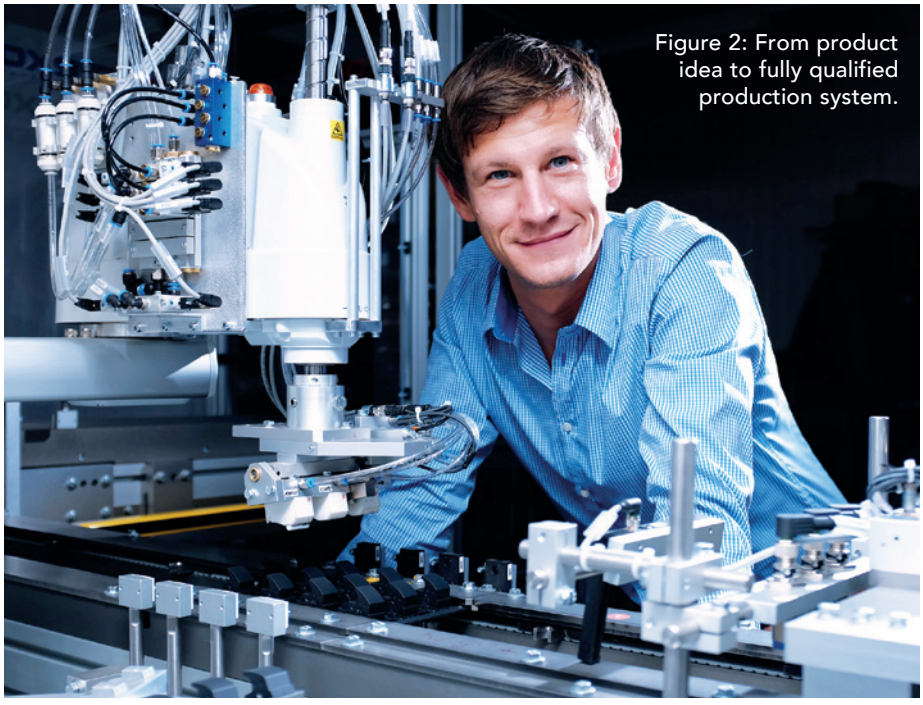

Figure 2: From product idea to fully qualified production system.

documented (Figure 3). Meanwhile, in parallel, Probotec establishes the production environment, from layout design to infrastructure and cleanroom qualification, up to full GMP certification.

SIMULTANEOUS BUILD-UP AND TESTING

While machines are being built and tested at Contexo, Probotec prepares the production site, including logistics and operational quality systems. This parallel validation concept enables joint factory and site acceptance tests (FAT/SAT) under real production conditions. The outcome is a verified and audit-ready production line that meets all technical and regulatory requirements from day one.

RAPID RAMP-UP AND CONTINUOUS IMPROVEMENT

Once production starts, the joint team monitors efficiency, yield and quality in real time. Inline monitoring, statistical process control (SPC) and predictive maintenance are integrated from the outset. Adjustments and process optimisations occur without downtime, forming a continuous improvement loop. The result is that products reach the market earlier, in higher volumes and with consistent quality – all under full GMP documentation.

BRIDGING THE GAP BETWEEN DEVELOPMENT AND PRODUCTION

Many medtech companies approach industrialisation with incomplete specifications. Contexo and Probotec often start with a basic concept and a product idea and, after about eight months, the customer leaves with a fully qualified production system, complete

Figure 3: Contexo and Probotec develop all necessary process steps.

"CONTEXO AND PROBOTEC OFTEN START WITH A BASIC CONCEPT AND A PRODUCT IDEA AND, AFTER ABOUT EIGHT MONTHS, THE CUSTOMER LEAVES WITH A FULLY QUALIFIED PRODUCTION SYSTEM, COMPLETE DOCUMENTATION AND AN OPERATIONAL PRODUCTION LINE."

documentation and an operational production line. This is possible because the two companies cover the full value chain – from engineering to operation:

- **Contexo – Machinery**: Feeding, sorting, handling, dosing, welding, crimping, assembly, pressing, vision-inspection, laser marking, packaging concepts and palletising
- **Probotec – Operations**: Material flow, logistics, traceability, process operation, quality control, inline monitoring, SPC, data analytics, storage, dispatch and documentation.

The combination of the two creates a direct transfer of know-how with no media breaks, no interpretation gaps and no redundant validation cycles. Each process step is verified in the exact environment that it will later operate in. This eliminates the common scale-up surprises that often occur when moving from laboratory automation to industrial throughput.

MODULARITY ENABLES SPEED AND FLEXIBILITY

For medical device and combination product manufacturers, flexibility is key. Market demands and design changes can occur even during late-stage development. Contexo's modular machine platforms are designed to absorb such changes without major redesigns. Whether a customer needs half a million or 200 million units per year, Contexo can scale the system accordingly, as the company's mechanical and software architecture enables quick expansion while maintaining validated performance.

SCALING UP WITHOUT LOSING CONTROL

Once products enter the market, the challenge shifts to scaling production. Here, the Contexo and Probotec model ensures that growth does not compromise compliance or cost efficiency. Probotec takes responsibility for line operation, preventive maintenance and process monitoring. Data are collected from every machine and analysed in real time, enabling predictive maintenance and continuous yield optimisation. Simultaneously, Contexo provides the engineering backbone for technical upgrades and capacity expansion. Both partners ensure that every change, update or extension remains fully documented and validated.

Figure 4: Integrated supply chain and logistics.

INTEGRATED SUPPLY CHAIN AND LOGISTICS

Beyond machinery and process control, Probotec integrates procurement, warehousing and material flow management (Figure 4). This holistic approach ensures that the production line not only operates efficiently but also stays supplied and compliant throughout the entire product lifecycle.

The packaging and dispatch process is likewise automated – from unit labelling and serialisation to palletising and shipping documentation – everything is designed to meet international traceability standards.

VALIDATION FROM THE START – NOT AS AN AFTERTHOUGHT

One of the major advantages of the Contexo and Probotec approach lies in its validation philosophy.

Rather than treating qualification and documentation as separate project stages, validation is built into every step of development. Each component, process parameter and test sequence is logged and traceable from the first prototype.

This design-for-validation mindset ensures audit readiness at every milestone. The system documentation is generated automatically, covering GMP, hazard analysis and critical control point (HACCP) and ISO requirements. When authorities or notified bodies audit the production line, every record is consistent, verifiable and electronically archived. This approach saves weeks of preparation during regulatory submissions and supports faster approval processes – a crucial factor for drug-device manufacturers entering multiple global markets simultaneously.

COST AND PERFORMANCE GUARANTEES

Industrialisation in medtech is not only about compliance – it is also about economic reliability. Both Contexo and Probotec offer performance guarantees:

- **Cost Guarantee:** Stable production costs through standardised, optimised processes
- **Availability Guarantee:** Defined output and uptime levels secured by predictive maintenance and spare-part management.

These contractual guarantees provide transparency and planning security, which is especially valuable for start-ups and scale-ups with investor-backed milestones.

INTELLIGENT AI AUTOMATION

Contexo has taken a decisive step in its digital evolution with the integration of OperAID (LEAD Digitalisierung, Winterbach, Germany) – an artificial intelligence (AI) automation platform engineered to support the manufacturing of medical devices, diagnostic components and primary packaging systems (Figure 5).

"INDUSTRIALISATION IN MEDTECH IS NOT ONLY ABOUT COMPLIANCE – IT IS ALSO ABOUT ECONOMIC RELIABILITY."

OperAID systematically captures, structures and automates process and machine knowledge across complex assembly and inspection systems. By applying advanced AI algorithms, the platform transforms raw machine and process data into actionable insights that support predictive maintenance, process optimisation and quality control.

Through the integration of data from multiple sources, OperAID enables consistent information flow throughout production environments. This digital connectivity facilitates automated documentation, reduces manual intervention and strengthens traceability and compliance – critical requirements in regulated medical and pharmaceutical manufacturing.

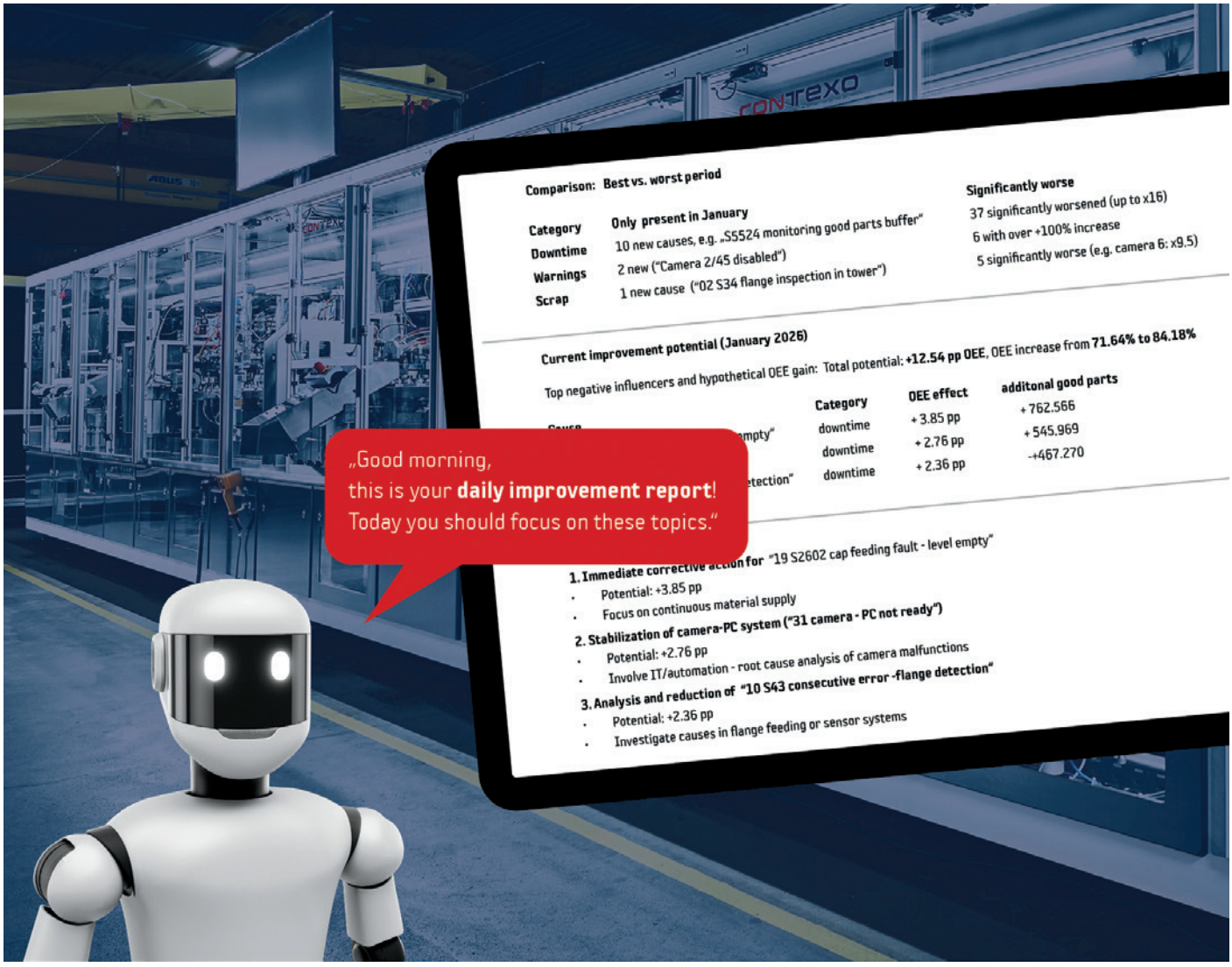

Figure 5: Intelligent AI automation to support the manufacturing process.

FROM PILOT TO 24/7 PRODUCTION

In one recent project, a European medical device manufacturer sought to scale its drug delivery component production from a pilot line to full-scale, GMP-compliant serial manufacturing.

Within eight months, Contexo and Probotec delivered a fully validated system with:

- Simultaneous engineering and qualification of machines and cleanroom environments
- Integrated FAT/SAT with complete documentation package
- Production ramp-up to continuous operation
- Scale-up capability without the need for a layout redesign.

The client achieved market launch nearly half a year earlier than planned – a competitive advantage that translated directly into higher market share and earlier revenue generation.

COLLABORATION AS A SUCCESS FACTOR

What makes this model particularly effective is not only the technology but the organisational integration. Both companies work as one interdisciplinary team, sharing responsibility for process performance and regulatory compliance. This "One Team – One Flow – One Result" philosophy replaces traditional supplier-customer relationships with genuine partnership. Communication barriers disappear and projects progress with clear accountability and mutual transparency.

TOWARDS ADAPTIVE MANUFACTURING IN MEDTECH

The acceleration of industrialisation processes in medtech is part of a broader trend towards adaptive manufacturing – the ability to modify and scale production quickly while remaining within validated boundaries. With modular platforms and concurrent validation, the Contexo and Probotec approach aligns perfectly with this vision. It enables manufacturers to respond flexibly to design updates, new product variants or changing regulatory requirements, without restarting qualification from scratch. As medical devices become more complex, such agile, validation-oriented production concepts will be indispensable.

"THE ACCELERATION OF INDUSTRIALISATION PROCESSES IN MEDTECH IS PART OF A BROADER TREND TOWARDS ADAPTIVE MANUFACTURING – THE ABILITY TO MODIFY AND SCALE PRODUCTION QUICKLY WHILE REMAINING WITHIN VALIDATED BOUNDARIES."

EIGHT MONTHS AHEAD

In an industry where every week counts, shortening the path from concept to series production by months is a decisive edge. By merging machine building, process automation and GMP-compliant operations into a unified development stream, Contexo and Probotec have redefined what industrialisation speed and validation can mean for the medtech sector. Faster market entry, validated quality from day one and scalable production without risk – this is the promise of their approach.

Matthias Müller

Matthias Müller is the Chief Commercial Officer of Contexo, which he runs together with his two brothers. His father founded the company in 1975 and the brothers took over the management together in 2011.

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Sven Müller

Sven Müller is the Managing Director of Probotec and the driving force behind the company's development. After building the business from the ground up, he has been steering it since 2015 with a clear focus on high-quality contract assembly. Drawing on a deep expertise in mechanical engineering and production, he shapes Probotec's strategic direction and ensures a strong technical foundation. Together with his team, he designs and implements customised production solutions that help clients optimise processes, increase efficiency and achieve long-term success.

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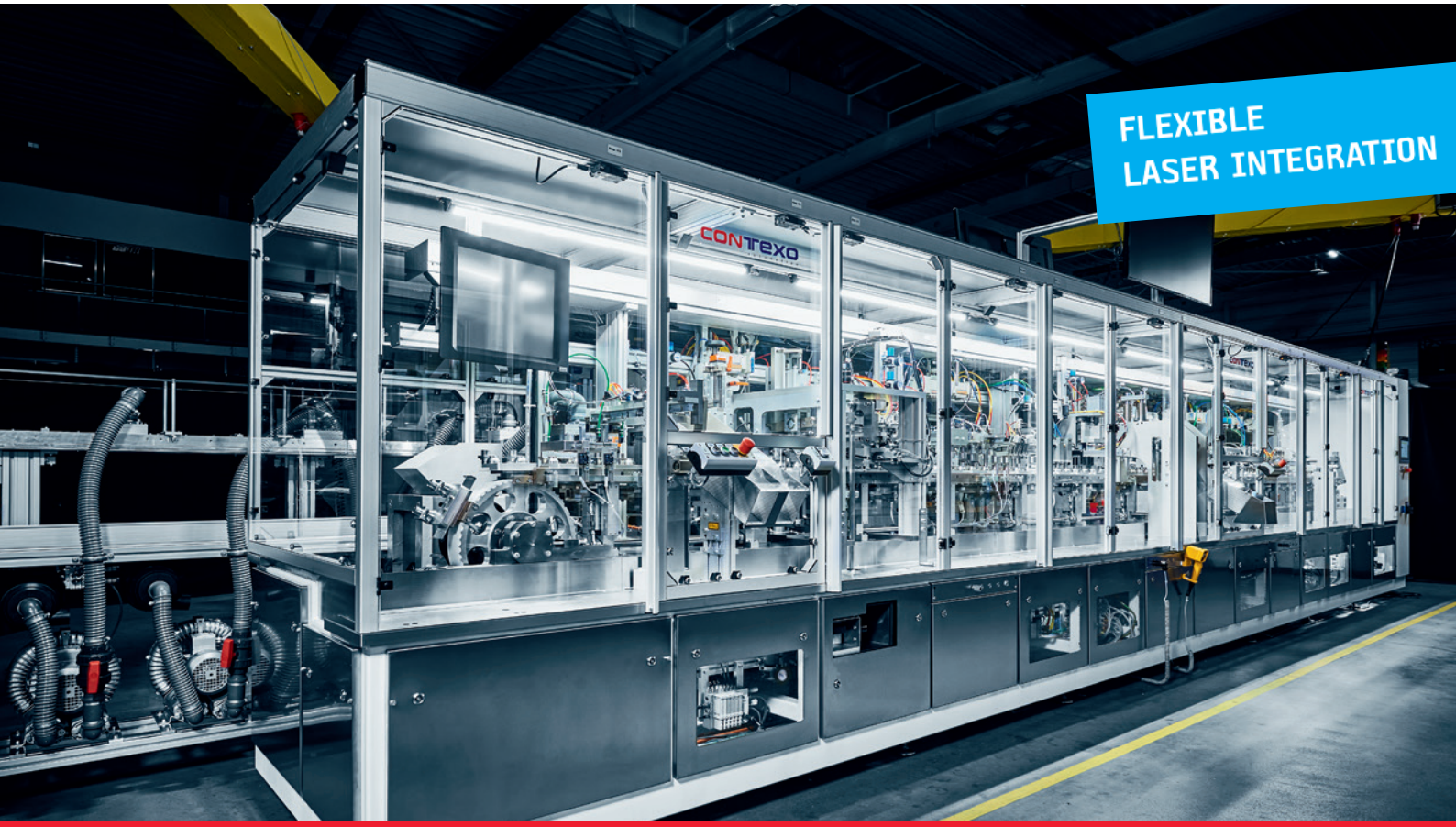

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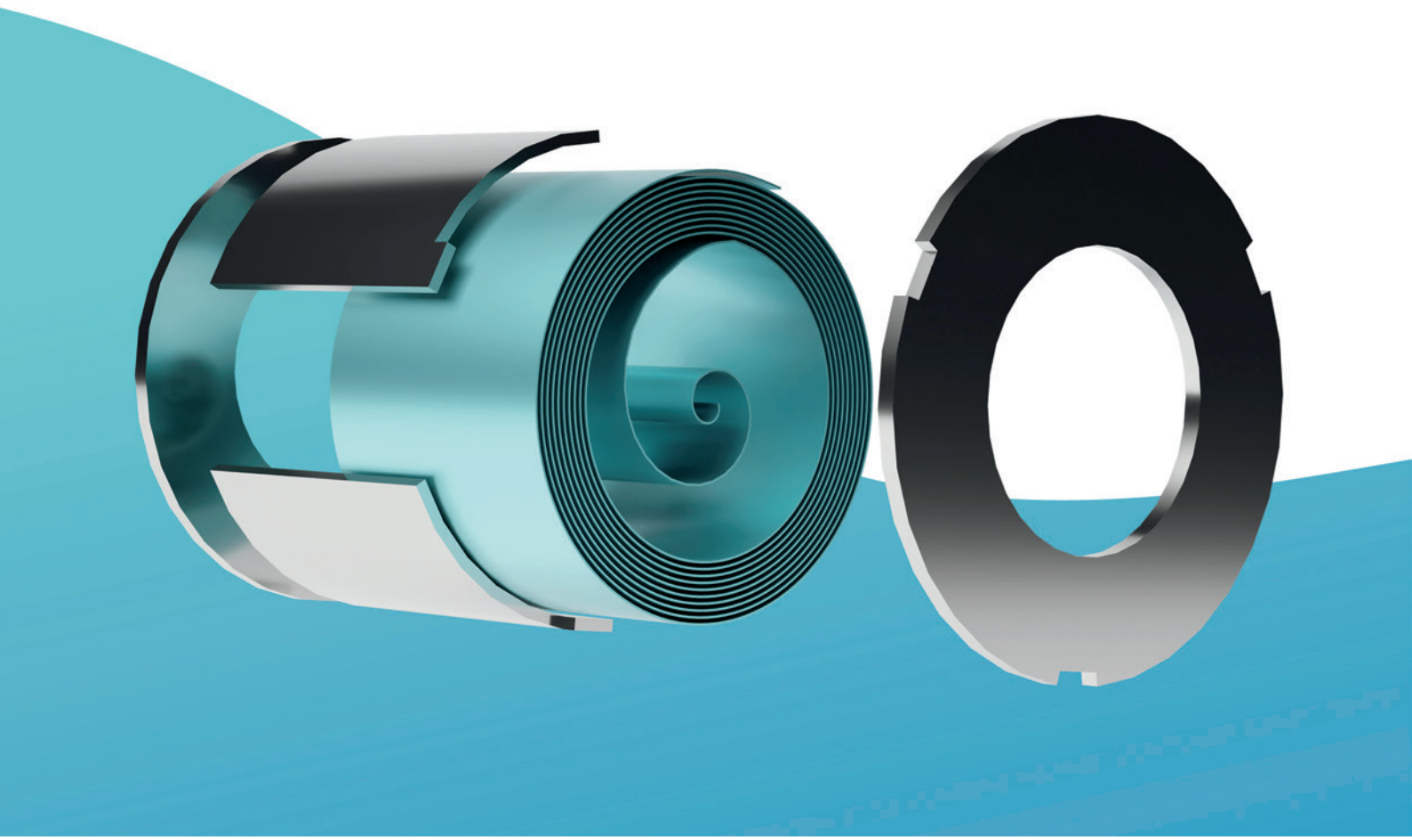

SAFETY BY DESIGN FOR DRUG DELIVERY DEVICES

Professor Stefan Schreiber of **Technische Hochschule Würzburg-Schweinfurt**, **Dr Theo Wember** of **camLine** and **Sebastian Block** of **Scherdel Medtec** discuss how using Design of Experiments methodology can provide insights into the manufacturing process of power springs that can enable manufacturers to more robustly control variables and produce more consistent outputs.

Scherdel Medtec is an expert in metal components for drug delivery devices, manufacturing precision parts for the drive and dosing systems used in autoinjectors, pen injectors and inhalers, where ensuring correct and safe functionality is essential for patient safety. For this reason, Scherdel places a strong emphasis on product quality. Potential influences on functional performance can be evaluated at an early stage using a Design of Experiments (DoE) methodology, including for effects originating from material suppliers. This enables an optimal process setup and a clearly defined set of process parameters that can reliably prevent deviations from product specifications.

POWER SPRINGS

Developing a power spring is a demanding, multistep process. Experienced development engineers can easily identify 20 or more parameters that influence key performance characteristics. However, not all of these parameters – particularly those derived from material properties – can be controlled during manufacturing. Understanding the interactions between these factors is

> "EXPERIENCED DEVELOPMENT ENGINEERS CAN EASILY IDENTIFY 20 OR MORE PARAMETERS THAT INFLUENCE KEY PERFORMANCE CHARACTERISTICS."

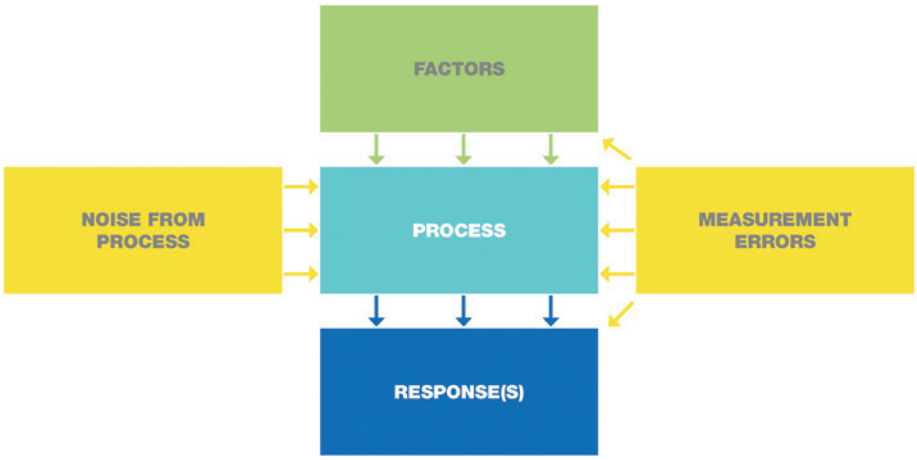

Figure 1: Process model.

therefore essential to achieving consistent and optimal product quality. This is where DoE provides significant value.

Figure 1 shows the process model used throughout the DoE framework. In this model, the manufacturing process is ideally influenced by controllable factors (green), which lead to the desired responses (blue). Noise effects (yellow) represent stochastic influences originating from upstream processes or the measurement system. DoE provides objective evidence of how production is affected by noise and how robust process windows can be established to maintain consistent performance.

Winding Process Manufacturing

Before applying DoE, it is necessary to understand the many aspects of the manufacturing process. Although the fundamental theory behind power springs is widely accessible, the complexity of the manufacturing sequence makes it impractical to create a comprehensive analytical model of the entire process. In particular, friction between loaded and unloaded coils cannot be represented by analytical equations reliably.

Power springs are typically manufactured through a winding process using an austenitic stainless-steel strip of specified width and thickness. Several factors influence the quality, function and reliability of the final product. Key steps of the process include:

1. **Supplied Materials**: For this type of spring, Scherdel typically uses cold-rolled steel strips with predetermined technological parameters, such as tensile strength, chemical composition and geometric properties, all defined in close co-ordination with suppliers.

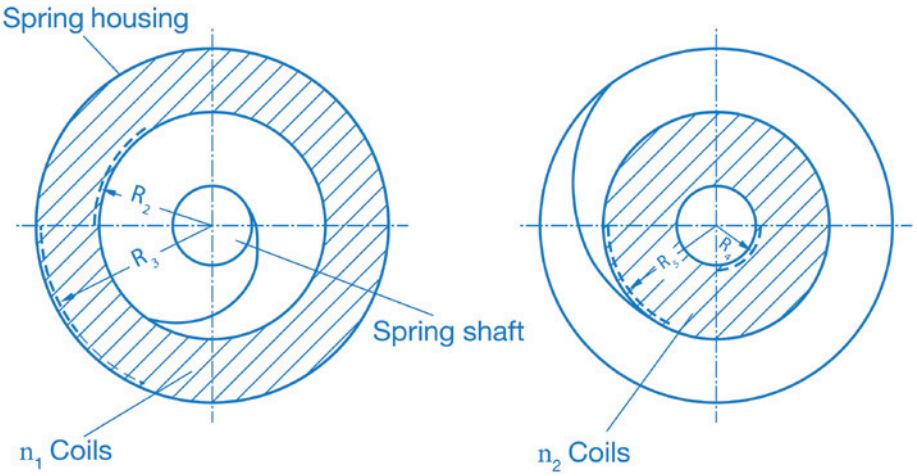

Figure 2: Geometry of a power spring.

2. **Cold-Forming**: Various spring designs used in medical devices, such as torsion springs or power springs, are formed using dedicated cold-forming machinery. Relevant factors include machine-specific settings and the condition of tooling (predictive maintenance).

3. **Heat Treatment**: Heat treatment affects cold-setting behaviour and tensile strength. Important parameters include oven temperature, tempering duration and possible positional effects within the oven.

4. **Assembly**: Depending on the specific spring design, an assembly step may be required. Scherdel can provide complete drive systems, including housing, directly to customers.

5. **Quality Control**: Customers typically specify the required force or torque values. Additional dimensional or functional requirements may also apply. Scherdel treats measurements as its own process and works to minimise measurement variation to ensure the highest possible consistency.

The Equations Behind Power Springs

According to the established "spring manual" (available upon request from Scherdel Medtec), the torque M_T of a power spring without coil clearance is defined as:

$$M_T = \frac{E \cdot b \cdot t^3 \pi (n_2 - n_0)}{6\, l_w}$$

- **E**: Young's modulus of the material
- **b, t**: Width and thickness of the strip
- **n_0, n_2**: Number of coils in the spring's released and fully loaded status
- **l_w**: Spring length is defined as:

$$l_w = (R_2 + R_3)\pi \cdot n_1 = (R_4 + R_5)\pi \cdot n_2$$

With n_1 as the number of coils in an intermediate loading and R_2 to R_5 as the radii defined in Figure 2.

Figure 3 presents a simulated torque-angle curve illustrating an exemplary requirement of 35 Nmm at the beginning and 30 Nmm at the end of use over 10 revolutions (3600°). The torque drops to zero in the 11th revolution, indicating full release. The complexity of this

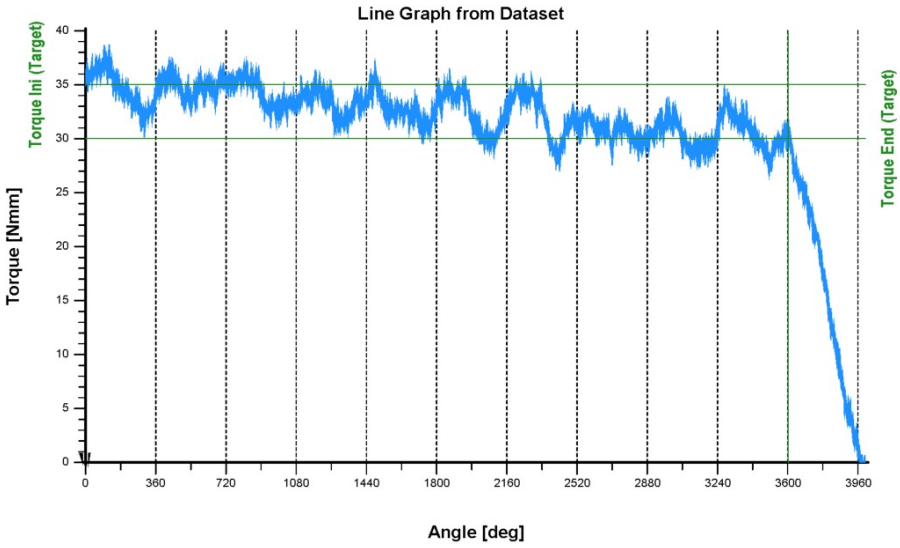

Figure 3: Exemplary simulated torque versus angle diagram of a power spring used in the DoE analyses.

behaviour and the many interactions within the production process demonstrate the necessity of a structured DoE approach.

DESIGN OF EXPERIMENTS

From more than 20 possible identified factors, six were selected for the study. Three factors and their respective ranges are disclosed, while the further three (x_4 to x_6) remain confidential (Table 1). The investigation focused on the winding process. The responses reflect the initial torque, end torque and one additional undisclosed parameter (Table 2). The DoE methodology is a tried and tested sequence of preparatory works and in-depth mathematical analyses beyond the scope of this text, so only a rough sketch is covered here.

Factors	Symbol	Min	Max	Units
Coil Thickness	Thickness	95	105	µm
Tempering Temperature	Tempering Temp	340	420	°C
Tempering Time	Tempering Time	30	40	min
-undisclosed-	x_4			
-undisclosed-	x_5			
-undisclosed-	x_6			

Table 1: List of factors.

Responses	Symbol	Goal	Low	High	Target	Units
Initial Torque	Torque Ini	Target	30	40	35	Nmm
End Torque	Torque End	Target	25	35	30	Nmm
-undisclosed-		Maximise				

Table 2: List of responses.

Using engineering reasoning and the theoretical background of power spring behaviour, a polynomial model was created linking all six factors to the three responses. The model contained 26 coefficients, representing the minimum number of required experiments. The full "design space" of the six factors would require 324 experiments. Using a D-optimal design, a practical subset of 32 experiments was selected.

Each experiment was carried out ten times, resulting in a total of 320 observations. While this number is only slightly less than the aforementioned 324 experiments, repeating a single experiment ten times only requires a fraction of the effort of performing 10 different experiments. After the experiments were executed and analysed, the model for the response "Initial Torque" achieved an adjusted $R^2 = 0.89$, indicating that 89% of the observed variation is explained by the model – an excellent result.

One of the most notable findings was the interaction between coil thickness and factor x_5, shown in Figure 4. Although coil thickness was a controlled factor in the experimental setup, it becomes an uncontrolled noise factor during real production because it is defined by the supplier. The interaction plot shows that at the minimum level of x_5, the impact of coil thickness variation is significantly reduced and the curve becomes flatter. Thus, the process becomes more robust. This is a key principle of Taguchi's robust design strategy[1] – use controllable factors to minimise the influence of uncontrollable ones.

"THIS IS A KEY PRINCIPLE OF TAGUCHI'S ROBUST DESIGN STRATEGY – USE CONTROLLABLE FACTORS TO MINIMISE THE INFLUENCE OF UNCONTROLLABLE ONES."

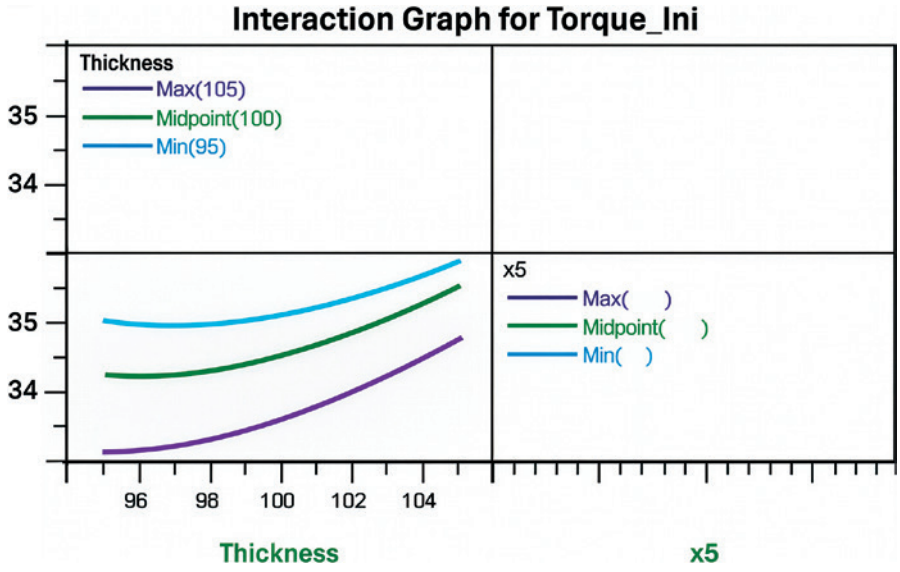

Figure 4: Interaction Graph for initial torque.

After this investigation, the statistically proven models for all three responses constitute the ultimate toolset for finding good process parameters and identifying appropriate corrective measures in case of process deviations.

A MATTER OF DESIGN

As in many production processes, the large number of controllable and uncontrollable factors presents both opportunities and challenges. To achieve stable production while meeting stringent quality requirements, all contributing factors must be understood and controlled. The authors strongly recommend implementing a rigorous quality-assurance strategy based on DoE. As demonstrated, DoE reveals valuable insights into system performance – insights that would otherwise remain hidden. When beneficial interactions such as the one between coil thickness and factor x_5 are identified, the resulting improvements in process robustness can be substantial.

> "FOR SAFETY-CRITICAL COMPONENTS, ESPECIALLY THOSE USED IN DRUG DELIVERY DEVICES, SAFETY MUST BE A MATTER OF DESIGN, NOT A MATTER OF CHANCE."

Such findings would rarely be discovered without a systematic approach. For safety-critical components, especially those used in drug delivery devices, safety must be a matter of design, not a matter of chance. DoE offers a powerful methodology to reduce costs and accelerate time-to-market using a minimal number of trials while maximising insights.

REFERENCE

1. *Taguchi G, "Introduction to Quality Engineering: Designing Quality into Products and Processes". Asian Productivity Organization, Jun 1986.*

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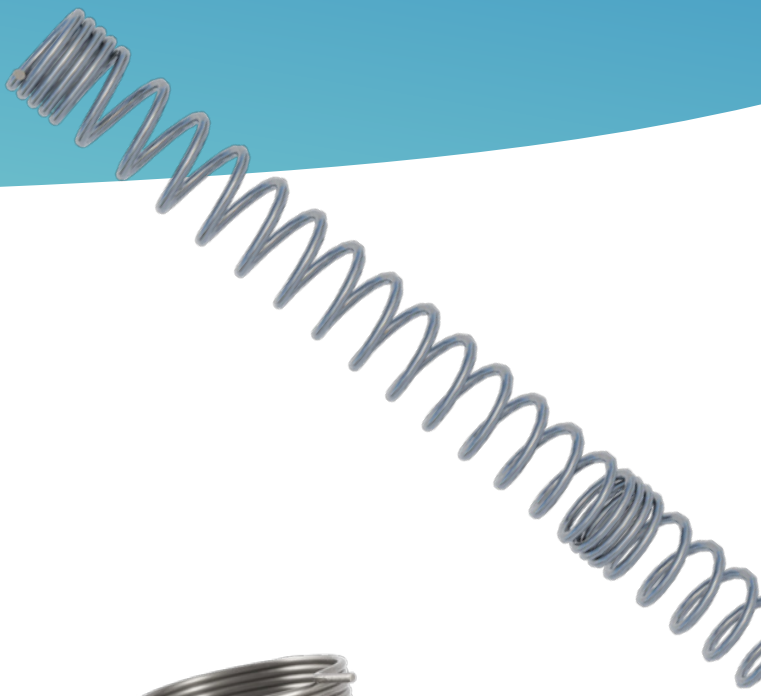

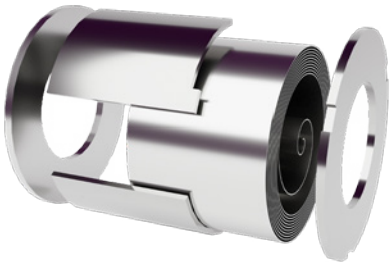

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FRICTIONLESS ENGAGEMENT: HOW GX INMONIT™ CAN SIMPLIFY SELF-INJECTION AND STRENGTHENS PATIENT ADHERENCE

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innovating for a better life

Dr Giacomo Bruno and **Simon Buerdel** of **Gerresheimer** consider the causes of patient non-adherence and its subsequent effects on healthcare systems, going on to present the solutions created by Gerresheimer to address the patient experience across treatment types.

Digital health interventions have emerged as a promising strategy for improving patient drug adherence in self-administration.[1–5] The combination of mobile health apps and connected devices can remind, motivate and monitor patients. For example, a recent trial investigating severe mental illness showed that a digital medication system increased the proportion of patients adhering to treatment from 21% to 78%, helping to reduce complications and hospitalisations.[1,6]

However, creating a closed loop with Bluetooth-based connected devices remains limited due to technological limitations, security and poor user experience.[7–9] Additionally, traditional app-based solutions can suffer from poor patient engagement and retention.[10,11] Some patients are reluctant to download yet another smartphone app to manage their therapy or to go through complex device setups, leading to high dropout rates.[12] Thus the critical challenge is to deliver a holistic adherence support solution that can be integrated with minimal friction into the everyday routines of patients.

CHALLENGES OF SUBCUTANEOUS SELF-ADMINISTRATION

According to a WHO report, non-adherence can account for up to 50% of treatment failures, around 125,000 deaths and up to 25% of hospitalisations each year in the US.[13] First understood over 20 years ago, recent studies are still looking for a paradigm shift to address the issue of non-adherence.[14–16]

"THE CRITICAL CHALLENGE IS TO DELIVER A HOLISTIC ADHERENCE SUPPORT SOLUTION THAT CAN BE INTEGRATED WITH MINIMAL FRICTION INTO THE EVERYDAY ROUTINES OF PATIENTS."

The consequences are significant – worsened clinical outcomes, increased hospitalisation rates, avoidable disease progression and a substantial waste of healthcare resources.[14]

Although at-home self-administration with an autoinjector can enhance patient independence while reducing the burden on healthcare systems, it can also add further procedural complexity. Outside of clinical supervision, patients must manage the entire sequence themselves – preparing the device, selecting the injection site, performing the injection and confirming completion. This often heightens anxiety and uncertainty, introducing a cognitive and emotional burden that may negatively affect confidence and consistency.[17]

Notable challenges of self-administration include:

- **Patient Discomfort**: High injection forces can increase discomfort, which may impact adherence and require engineering solutions.[18]
- **Adherence**: Extended injection times and multistep handling may impact adherence, particularly among patients with limited dexterity.
- **Efficacy**: Complete dosing within an acceptable timeframe is essential for therapeutic performance and is especially challenging for high-viscosity biologic formulations.[19]
- **Engagement with Digital Applications**: Despite strong evidence, real-world adoption often stalls due to cumbersome onboarding processes and difficulty scaling engagement beyond controlled pilot studies.[20]
- **Emotional Considerations**: Many individuals experience fear of pain, hesitation about performing an injection correctly (particularly with expensive medications) or uncertainty about whether the full dose has been delivered.[17] Others may feel overwhelmed by instructions, concerned about side effects or unsure how to integrate injections into their lives.
- **Lack of Real-World Evidence**: With self-administration outside of a healthcare environment, pharma companies and healthcare providers (HCPs) lack objective insights into patient use, adherence and adverse events.[21]
- **Instructions for Use (IFU) Unread or Misunderstood**: Studies have shown that less than a third of patients read and understand a drug's IFU – a particular concern for long-term therapies.[22,23]

Together, these factors highlight the need for solutions that ease cognitive load, support patients before, during and after self-injection, and provide guidance in a way that feels intuitive, familiar and effortless.

OVERCOMING THE CHALLENGES OF SUBCUTANEOUS SELF-ADMINISTRATION

User-Centric Autoinjector Design

The Gx Inbeneo® autoinjector is designed to overcome many of the usability, emotional and procedural challenges associated with self-administration. Its cartridge-based architecture and optimised double-ended needle system enable highly viscous formulations to be delivered in less time. Intuitive handling with simple two-step administration and a unique visual indicator supports usability and injection tracking.[24]

While such an innovative, user-centric autoinjector design concept already represents a significant step, there are additional factors that affect the patient before and after the injection, such as psychological blocks, forgetfulness, side effects and pain management. A survey conducted by Gerresheimer with a cohort of 57 participants self-injecting a prescribed medicine for a long-term condition reported that confidence substantially increased over time. However, the data also indicated a persistent subgroup with low confidence: despite overall improvement, approximately 16% of participants continued to rate themselves as unsure or very unsure when injecting.

Patient Guidance at the Moment of Injection

To address potential patient anxiety with self-injection, Gerresheimer has developed Gx InMonit, a reusable smart add-on designed to be mounted on top of an autoinjector such as the Gx Inbeneo (Figure 1). It features a large, high-contrast, easy-to-read AMOLED display that guides the patient step-by-step through injection preparation, initiation, progress and confirmation of completion. Real-time detection of injection start, stop, premature removal or potential injection failure using motion sensors provides the reassurance that many patients seek.

Gx InMonit also incorporates temperature monitoring and verification of the device, drug and dose by scanning a near-field communication (NFC) tag under the label of the autoinjector.

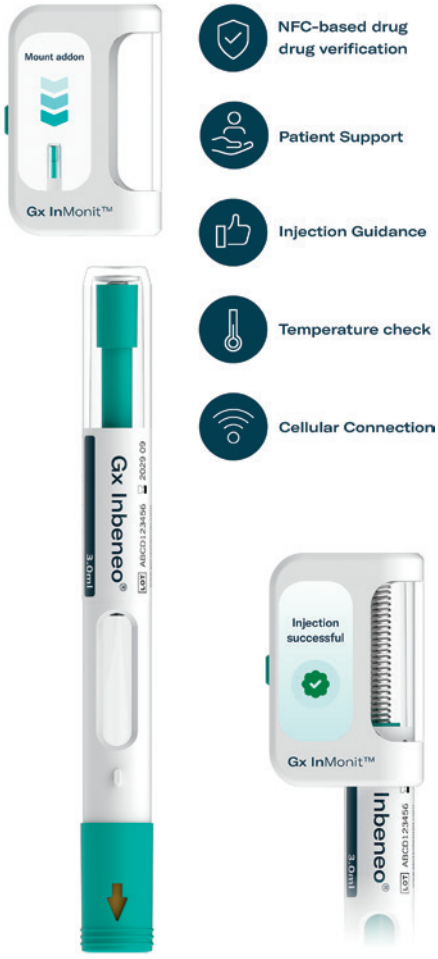

Figure 1: The Gx InMonit smart add-on assembled on top of a 3 mL Gx Inbeneo autoinjector.

This combination of features can reduce uncertainty and ensure that patients conduct injections with authentic devices correctly and in alignment with the prescribed care plan. The Gx InMonit device needs no additional user actions such as pairing, app installation or manual data upload; data are transmitted automatically to the cloud through its embedded cellular module, allowing patients to remain fully focused on their therapy.

Agentic AI-Driven Actionable Patient Support

While Gx InMonit provides guidance and captures accurate data at the point of self-administration, patients can also benefit from support before and after injections (Figure 2). Gerresheimer is developing an artificial intelligence (AI)-driven, two-way messaging application, Gx AdheraLink™, to complement Gx InMonit and provide a combined ecosystem that further enhances patient support.

Before a scheduled injection, Gx AdheraLink can provide timely reminders and gentle prompts, also known as nudges, which helps patients to mentally prepare for the upcoming injection and may, in turn, reduce anxiety and strengthen routine formation. Such methods have been shown to significantly improve patients' self-management for chronic conditions.[25] After the injection, the system follows up with positive reinforcement in the form of encouraging messages, based on cognitive behavioural therapy methods. It subtly collects information about the injection experience, injection location, pain level, overall experience and side effects, which can then be used for reporting and monitoring by an HCP.

"GERRESHEIMER IS DEVELOPING AN AI-DRIVEN, TWO-WAY MESSAGING APPLICATION, GX ADHERALINK, TO COMPLEMENT GX INMONIT AND PROVIDE A COMBINED ECOSYSTEM THAT FURTHER ENHANCES PATIENT SUPPORT."

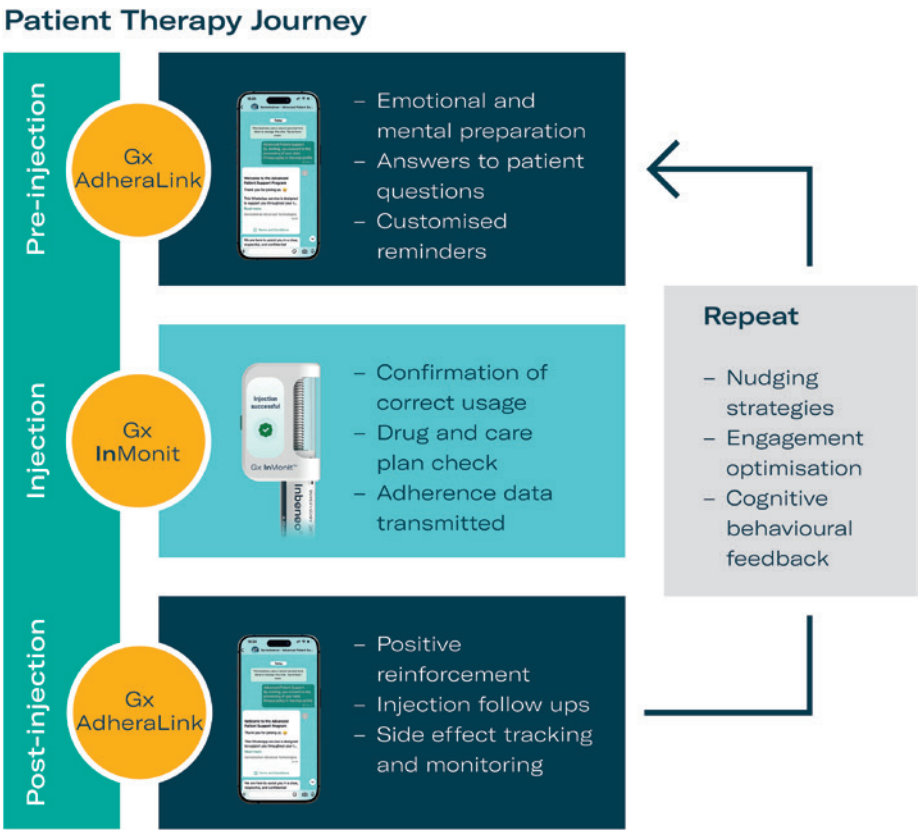

Figure 2: Benefits for patients and pharma of the Gx InMonit combined ecosystem providing a closed-loop patient support strategy.

To achieve this support, Gx AdheraLink uses agentic AI that interacts with patients on an instant messaging application, such as WhatsApp or iMessage, that most will already have installed on their phones. By employing a preferred app that is already integrated into a patient's everyday life, Gx AdheraLink can create two-way communications that are personalised, smart and immediate. User friction is reduced, as there is no need to install a new app, learn a new interface or navigate additional accounts. The solution also offers the possibility of using multimedia-rich conversations such as a video-based IFU.

Together, Gx InMonit and Gx AdheraLink form a unified ecosystem designed to reduce patient burden, improve engagement and support therapy outcomes with objective data. As the two solutions operate across the full therapy journey, they create a dynamic feedback loop that transforms them into a self-regulated system. Each interaction generates behavioural signals that feed back into the platform, allowing different nudging and engagement strategies to be evaluated. Those that are most effective can then be progressively reinforced to create a tailored approach for each patient. Over time the platform evolves into a personalised cognitive-behavioural companion: it reinforces correct patient actions, gradually builds confidence and lays the groundwork for effective future injections.

CONFIRMATION OF PATIENT NEED AND INTEREST

Qualitative User Study Reveals Pain Points

The development of any Gerresheimer solution starts with gathering input from users and stakeholders. In this case, the first step was to conduct qualitative user research with 12 US patients dealing with various autoimmune diseases. The user research was divided into two cohorts with six patients each. The goal was to

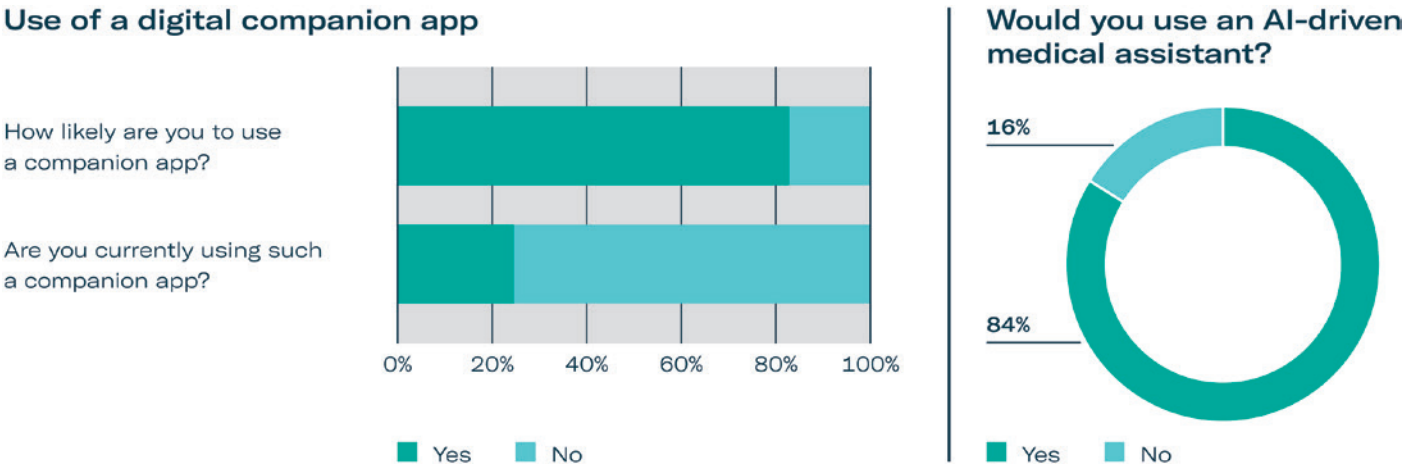

Figure 3: Interest in a digital solution to help manage therapy from 90 respondents to a user survey of patients regularly performing self-injections for chronic conditions (excluded diabetes and weight management).

"83% OF THE PATIENTS BELIEVED THAT AN ADD-ON DEVICE AND AN APP COULD INCREASE THEIR CONFIDENCE WHEN SELF-INJECTING."

understand the user's perspective when self-administering recurring monthly injections with an autoinjector, in order to evaluate the utility of the Gx InMonit add-on device and Gx AdheraLink digital support.

Participants reported anxiety towards self-injecting and fear of making mistakes with drugs, even when this has been their routine for several years. Subjective feedback on a potential add-on device highlighted the value of real-time guidance, sensing the temperature of the injection device and additional information on delivery success or error. The interview with the first cohort revealed that 83% of the patients believed that an add-on device and an app could increase their confidence when self-injecting. All the participants from the second cohort rated a digital companion app as useful (33%) or very useful (67%) for reminders, injection and symptom tracking, guidance on injection errors and communication with HCPs.

The study revealed that an add-on and companion solution complement each other, highlighting that users place strong value on receiving reminders for injection schedules, feedback on drug temperature, and additional audible and visual real-time feedback on injection progress that align with existing self-management techniques.

Gathering Deeper User Insights

After the initial assessment of challenges faced by patients, a further survey was implemented. Of the 90 respondents from the US who self-injected regularly to treat conditions other than diabetes and weight management, 83% expressed a desire for a digital solution that could support their therapy journey. However, a solution capable of tracking injections, sending reminders and providing drug information, was being used by less than a quarter (24%) of the interviewed population (Figure 3). When asked if they would use an AI-driven medical assistant, over 80% of the respondents said yes (Figure 3). This survey revealed a positive attitude towards a smart digital support solution among participants and highlighted that the use of AI was also viewed positively.

Based on user research and market evaluation, Gerresheimer developed the ecosystem of Gx InMonit and Gx AdheraLink. At this stage of development, a third user research study was conducted with 57 individuals with similar profiles and injection frequencies, ranging from once per week to twice per year. The response to such a combined solution was overwhelmingly positive: 90% would consider using a connected digital companion to support their therapy journey. When asked how they would prefer to receive this support, the majority (74%) selected instant messaging as their preferred channel, far surpassing the interest in a dedicated app (14%) or a web-based application (12%), as shown in

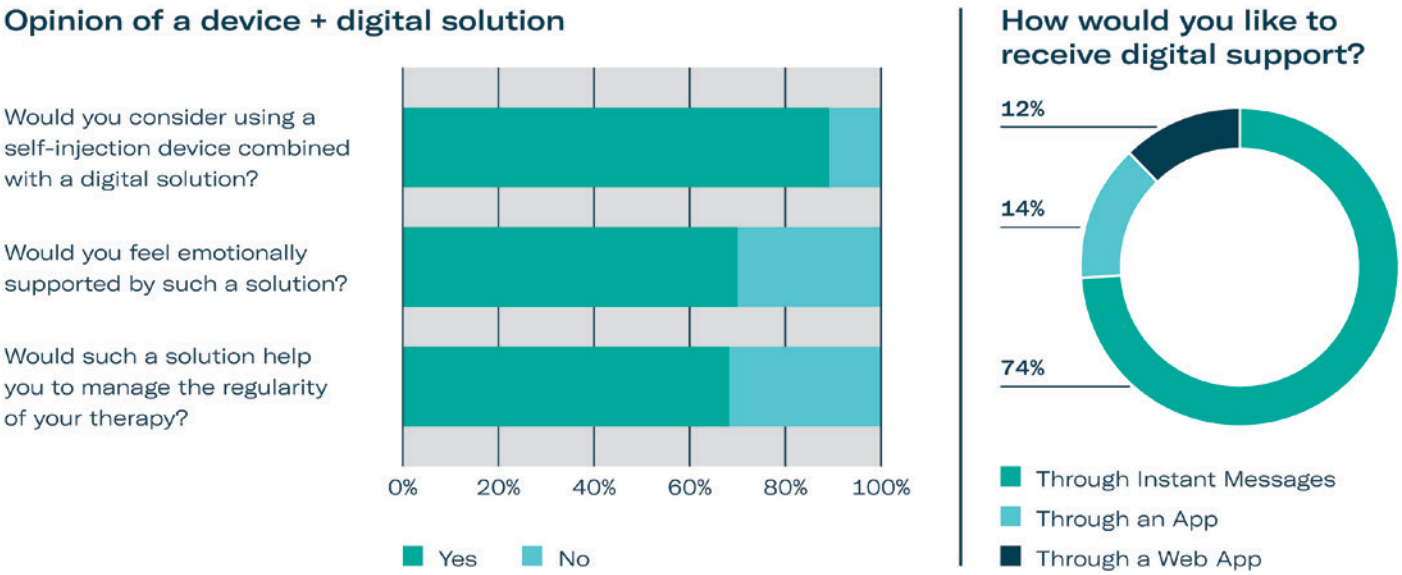

Figure 4: Interest in a device + digital solution from 90 respondents to a user survey of patients regularly performing self-injections for chronic conditions (excluding diabetes and weight management).

Figure 4. Notably, approximately 70% of participants also believed that such a solution would help them emotionally and make it easier to take their medication more consistently.

BENEFITS OF THE COMBINED GERRESHEIMER ECOSYSTEM FOR STAKEHOLDERS

Addressing Non-Adherence

The Gx InMonit–Gx AdheraLink ecosystem tackles the core problem of non-adherence by supporting patients before, during and after each injection, with the goal of achieving more consistent dosing, higher therapy persistence and optimal therapy outcomes. For pharma, this could translate into stronger therapeutic performance and more reliable real-world evidence.

Scalability Across Markets

The solution is easy to deploy globally because Gx AdheraLink uses messaging apps already installed on patients' phones and Gx InMonit functions as a reusable add-on, without requiring additional gateways or dedicated apps.

Value-Based Healthcare Models for HCPs

Gx InMonit gives clinicians direct visibility into patient behaviour without adding extra workload, making it easy to identify missed or incomplete doses and intervene early on. Gx AdheraLink enriches this view with patient-reported information, such as pain, fatigue or side effects, which supports more personalised clinical decisions. This combined insight helps strengthen continuity of care, especially for chronic conditions where consistent self-administration is essential.

Traceability and Real-World Evidence

Gx InMonit generates objective real-world evidence through automated, reliable injection data, supporting pharmacovigilance, value-based care models and outcome analysis. Integrated drug-identification and anti-counterfeiting capabilities ensure that medication type, batch number and expiry date are captured and verified securely, enhancing supply chain integrity and enabling advanced monitoring strategies.

CONCLUSION

Improving adherence is a multifaceted endeavour requiring innovation in both human factors and technology. The Gx Inbeneo autoinjector from Gerresheimer, combined with a smart and connected add-on, demonstrates a promising model of "digital + device" synergy that benefits all stakeholders: patients could receive a patient-focused treatment experience that potentially leads to a better outcome, while pharma could gather more relevant evidence to prove the value of their therapies. Such an integrated approach transforms the act of self-injection from a solitary, often uncertain task into a guided, connected experience that integrates the patient into a supportive network. As healthcare systems globally continue shifting towards outcome-based models, connectivity solutions help to confirm that medications can deliver on their promised real-world benefits.

REFERENCES

1. *Zhou J et al, "Randomized clinical trial of a digital medication system to enhance adherence in patients with severe mental disorders". npj Digital Medicine, 2025, Vol 88(1), p 333.*
2. *Lanke V et al, "Evaluating the Effectiveness of Mobile Apps on Medication Adherence for Chronic Conditions: Systematic Review and Meta-Analysis". JMIR, 2024, Vol 27, art e60822.*
3. *"Komodo Health analysis finds Medisafe's digital drug companions improve medication adherence and extends persistence". PDF, Medisafe, 2022.*
4. *"IQVIA Study Proves Medisafe Digital Companion". PDF, Medisafe, 2019.*
5. *"IQVIA Study Proves Medisafe Digital Companion". PDF, Medisafe, 2020.*
6. *Kim SK et al, "Effectiveness of*

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Mobile Health Intervention in Medication Adherence: a Systematic Review and Meta-Analysis". J Med Syst, 2025, Vol 49(1), p 13.
7. *Lonzetta AM et al, "Security Vulnerabilities in Bluetooth Technology as Used in IoT". J Sens Actuator Netw, 2018, Vol 7(3), p 28.*
8. *"Seventy-Six Percent of People With Diabetes Have Issues Transmitting Their Reading Using Bluetooth® Glucose Meters". Business Wire, Nov 2024.*
9. *Pidgeon A, "Smart Enough: Designing Drug Delivery Devices that Put Patients First". ONdrugDelivery, Issue 174 (Jun 2025), pp 12–15.*
10. *Helander E et al, "Factors related to sustained use of a free mobile app for dietary self-monitoring with photography and peer feedback: retrospective cohort study". J Med Internet Res, 2014, Vol 16(4), art e109.*
11. *Wang Y et al, "A systematic review of application and effectiveness of mHealth interventions for obesity and diabetes treatment and self-management". Adv Nutr, 2017, Vol 8(3), pp 449–462.*
12. *Meyerowitz-Katz G et al, "Rates of Attrition and Dropout in App-Based Interventions for Chronic Disease: Systematic Review and Meta-Analysis". J Med Internet Res, 2020, Vol 22(9), art e20283.*
13. *"Adherence to long-term therapies: evidence for action". World Health Organization, 2003.*
14. *Bosworth HB et al, "Medication Adherence: A Call for Action". Am Heart J, 2011, Vol 162(3), pp 412–424.*
15. *Kim J et al, "Medication Adherence: The Elephant in the Room". US Pharmacist, 2018, Vol 43(1), pp 30–34.*
16. *Kardas P et al, "Medication non-adherence: reflecting on two decades since WHO adherence report and setting goals for the next twenty years". Front Pharmacol, 2024, Vol 15, art 1444012.*
17. *Coyne M, "Impact of Routines and Rituals on Burden of Treatment, Patient Training, Cognitive Load, and Anxiety in Self-Injected Biologic Therapy". Patient Prefer Adherence, 2022, Vol 16, pp 2593–2607.*
18. *Pager A, Duinat B, Alves B, "How Shorter Needles with Thinner Walls are Set to Improve the Injection Experience in Chronic Care". ONdrugDelivery, Issue 107 (May 2020), pp 37–42*
19. *Mathaes R et al, "Subcutaneous Injection Volume of Biopharmaceuticals-Pushing the Boundaries," J Pharm Sci, 2016, Vol 105(8), pp 2255–2259.*
20. *''Pharmaceutical Mobile App Usage and Engagement Strategies". PDF, IntuitionLabs, Jan 2025.*
21. *Dunbar-Jacob J and Zhao J, "Medication Adherence Measurement in Chronic Diseases: A State-of-the-Art Review of the Literature". Nurs. Rep, 2025, Vol 15(10), p 370.*
22. *Raynor DK et al, "How do patients use medicine information leaflets in the UK?". IJPP, 2007, Vol 15(3), pp 209–218.*
23. *"Disposing of the paper leaflet: The challenges with Patient Information Leaflets". Blog, Datapharm, Mar 2023.*
24. *Primavessy D, Saaler-Reinhardt S, Maksymowicz K, Stockton M, "Gx Inbeneo® – Developing an Autoinjector that Responds to the Challenges of Biologics". ONdrugDelivery, Issue 152 (Oct 2023), pp 32–36.*
25. *Möllenkamp M et al, "The effectiveness of nudges in improving the self-management of patients with chronic diseases: A systematic literature review". Health Policy, 2019, Vol 123(12), pp 1199–1209.*

Giacomo Bruno

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TESTING AUTOINJECTORS ACCORDING TO ISO 11608-5 TO INCREASE RELIABILITY AND BOOST EFFICIENCY

Zwick / Roell

Wolfgang Moersch of **ZwickRoell** discusses the role of automation in testing injection devices – including autoinjectors, pen injectors and on-body injectors – and how advanced testing software and robotics solutions can provide more accurate and consistent testing results.

Autoinjectors and advanced injection systems play a central role in the modern drug delivery landscape, particularly for biologics and self-administration therapies. As these combination products become more complex – handling higher viscosities, larger volumes and increasingly diverse patient needs – the demands on testing strategies have grown significantly. Robust, reproducible and traceable testing is no longer limited to late-stage quality control; it is now essential across the entire product lifecycle, from early development through to commercialisation.

TESTING CHALLENGES IN A GLOBAL REGULATORY ENVIRONMENT

Bringing an autoinjector to market requires alignment between device design, drug formulation, regulatory expectations and manufacturing realities. Pharmaceutical companies and CDMOs must manage parallel development paths – design

> "BRINGING AN AUTOINJECTOR TO MARKET REQUIRES ALIGNMENT BETWEEN DEVICE DESIGN, DRUG FORMULATION, REGULATORY EXPECTATIONS AND MANUFACTURING REALITIES."

verification on the one hand and process validation and scale-up on the other. At each milestone, from design freeze and submission through to validation and routine production, testing data must be verifiable, comparable and fully documented.

The correct injection technique and proper dose of medicine are vital to achieve therapeutic success. Therefore, pharmaceutical manufacturers strive to achieve a high level of automation in autoinjector technology, where the patient simply removes the safety cap, positions the injector and injects the drug by pressing a button – the subsequent injection process is completely automated. This means that all relevant injector functions must be checked before production batches are released to the market. This testing is performed according to ISO 11608-5.

KEY PARAMETERS IN AUTOINJECTOR TESTING

A modern autoinjector test sequence typically combines multiple measurements within a single automated workflow (Figure 1). These include:

- Cap removal force, measured either upwards or downwards, depending on the intended patient handling defined in the instructions for use
- Activation force and travel, ensuring reliable device triggering
- Injection depth, confirming that the needle penetrates only within the intended range

Figure 1: Example test setup according to ISO 11608-5. The test sequence combines multiple measurements within a single test.

"INTEGRATING THESE MEASUREMENTS INTO A SINGLE TEST RUN ON ONE SPECIMEN IMPROVES DATA INTEGRITY AND ENABLES DIRECT CORRELATION OF RESULTS."

- Injection time and flow behaviour, including the precise definition of "end of injection"
- Delivered volume, measured gravimetrically under controlled conditions
- Needle safety device activation and strength, where applicable.

Integrating these measurements into a single test run on one specimen improves data integrity and enables direct correlation of results. Automated systems further reduce operator influence – an important factor for comparability between R&D, quality control and external partners.

CAMERA-BASED MEASUREMENT AND TRACEABILITY

One notable development in autoinjector testing is the use of camera-based measurement systems. These allow non-contact detection of critical events, such as start and end of injection, needle exposure and liquid stream behaviour. High-speed, time-synchronised video capture improves accuracy, particularly for the very short injection times typical for emergency injectors.

Camera systems also support flexible definitions of "end of injection", accommodating different regulatory or internal interpretations, such as last continuous stream, last drop or time-based extensions. Importantly, the ability to calibrate such systems ensures long-term measurement confidence and regulatory acceptance.

Traceability is further enhanced by automatic documentation of environmental conditions (temperature and humidity), test configuration, sensor status and visual records of the injection process. This level of documentation is increasingly expected during audits and inspections.

PREVENTING MEASUREMENT ERRORS: STATIC AND SENSOR CONTROL

Gravimetric volume measurement is sensitive to electrostatic charging, particularly when working with glass containers and in low-humidity environments. Static effects can introduce significant weighing errors, especially during long injection times or when measuring small volumes. Optimised weighing accessories and controlled test environments are therefore critical to achieving reproducible results.

Equally important is sensor reliability. Daily sensor checks, guided by software workflows, can help to detect issues before test series begin. This preventive approach avoids costly re-testing and protects the integrity of large datasets generated during verification or release testing.

Figure 2: Testing autoinjectors without medication.

TESTING AUTOINJECTORS WITHOUT MEDICATION

Some of the medications used in autoinjectors are very expensive, which also makes functional testing with medication very costly. A cost-effective alternative is to test the mechanical function of the injector before filling it with medication (Figure 2). In order to perform such tests under realistic conditions, an electromechanical servo actuator can be used in the testing machine. This simulates the counterforce of the medication cartridge, which normally acts on the autoinjector mechanism.

For automated functional testing, the autoinjector is positioned in the testing machine and started using advanced, intuitive testing software, such as ZwickRoell's testXpert. The test then runs automatically within the testing machine. The result is a measurement of the force or torque required to remove the safety cap, as well as the spring rate of the built-in drive unit. Monitoring and calculation of results are also performed in the testXpert testing software, which also offers a fully integrated US FDA Part 11 option. To achieve higher throughput rates, this system can be equipped with a lightweight roboTest N handling system from ZwickRoell.

Figure 3: A fully automated testing system for autoinjectors.

FULLY AUTOMATED AUTOINJECTOR TESTING

When testing insulin pens or pen injectors, a time- and resource-efficient test process is often necessary. A materials testing machine (optionally available with integrated torsion drive), combined with an automated testing system, can help to ensure reliable and cost-effective test results (Figure 3). The testing assistant roboTest N supports the user with simple applications. With one magazine filling, a user can typically automatically test 40 insulin pens or autoinjectors. The roboTest N can be easily adapted to changing test requirements with a high level of flexibility without requiring special programming knowledge.

The robotic testing system roboTest R allows users to run fully automated tests on different functions of an insulin pen. It can, for example, measure the dosage setting, actuation force, glide force and specified dosage in one continuous process. It is possible to modify and combine the test methods of both test axes to suit specific testing needs.

Powered by ZwickRoell's autoEdition3 automation software, the robot removes insulin pens from the magazine, feeds them into the testing machine and starts the test automatically. This reduces the risk of operator influence and helps to ensure accurate, consistent results. It also significantly boosts efficiency by increasing specimen throughput. It is also possible to manually test specimens at any time. The testXpert testing software, with its expanded traceability option supporting FDA 21 CFR Part 11, makes it possible to generate complete, tamper-proof documentation for the entire testing process.

"THE TESTXPERT TESTING SOFTWARE, WITH ITS EXPANDED TRACEABILITY OPTION SUPPORTING FDA 21 CFR PART 11, MAKES IT POSSIBLE TO GENERATE COMPLETE, TAMPER-PROOF DOCUMENTATION FOR THE ENTIRE TESTING PROCESS."

EXTENDING TESTING TO ON-BODY DELIVERY SYSTEMS

Beyond classic spring-driven autoinjectors, the industry is seeing rapid growth in on-body delivery systems (OBDSs), also referred to as wearable, portable or variable injectors. These devices address the need to deliver larger volumes of high-viscosity biologics over extended periods, ranging from minutes to hours.

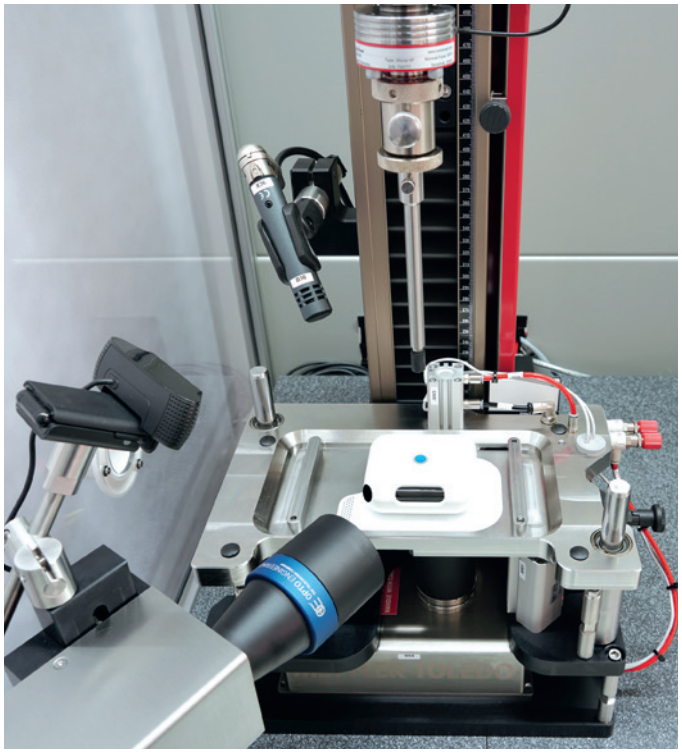

Figure 4: Testing system for OBDSs according to ISO 11608-6.

Testing OBDSs according to ISO 11608-6 introduces additional challenges, including long-duration volume measurement, evaporation control, prevention of crystallisation at the needle tip and interpretation of device feedback signals, such as LEDs or acoustic cues (Figure 4). Modular test platforms that combine peel testing, functional testing and camera-based monitoring enable comprehensive evaluation of these systems under realistic conditions.

Wolfgang Moersch

Wolfgang Moersch, International Marketing Manager at ZwickRoell, has nearly 20 years of experience in materials and component testing. He has held various roles at ZwickRoell throughout his career, and currently specialises in medical technology and the pharmaceutical industry, with a particular focus on drug delivery systems and device testing.

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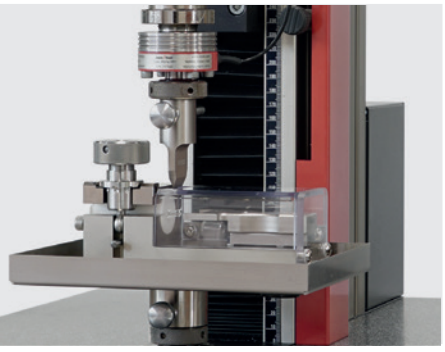
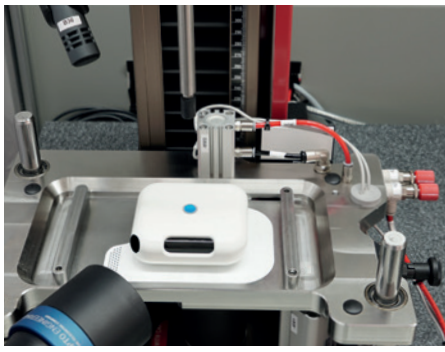
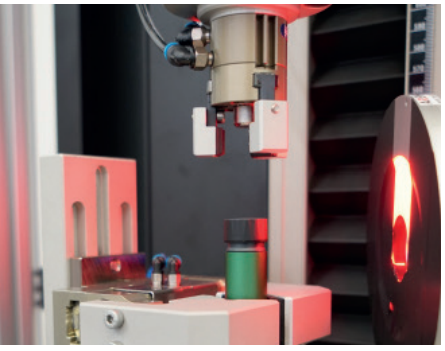
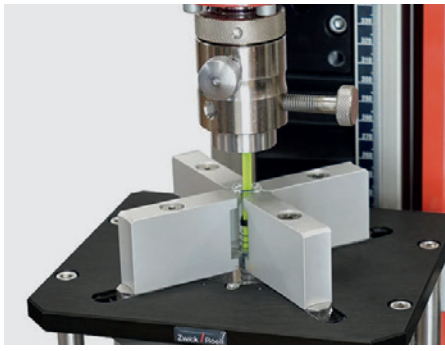


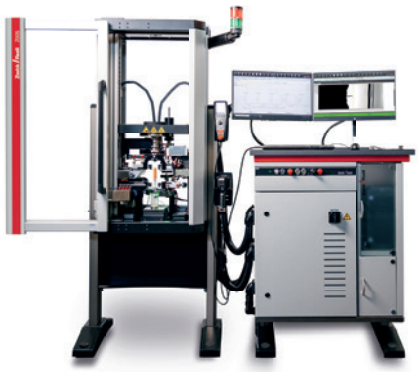






- Manual, semi-automatic and fully automated testing solutions for therapy systems (needles, (pre-filled) syringes, insulin pens, auto injectors)
- Traceable and tamper-proof test results in accordance with FDA 21 CFR Part 11
- ZwickRoell supports customers with DQ, IQ and OQ services

PHARMAPACK Europe 2026: Hall 4, booth no. 4F124



What is your testing challenge? info@zwickroell.com
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Interview: DARE IDDS – A Long-Term Subcutaneously Implanted Drug Delivery Device

In this exclusive interview, **Liz Proos** of **Daré Bioscience** and **Ashley Hawson** of **Cambridge Consultants** talk with ONdrugDelivery's Guy Furness about the DARE Intelligent Drug Delivery System – an advanced, connected implantable device that delivers programmable doses for up to a decade – its place in the market, the challenges faced during its design and its potential as novel drug delivery device.

Q What inspired the development of the DARE Intelligent Drug Delivery System (IDDS) and to what extent did patient needs shape the product vision?

LP The DARE IDDS is built on a legacy of innovation (Figure 1). The concept was originally developed out of Bob Langer and Michael Cima's lab at the Massachusetts Institute of Technology (Cambridge, MA, US) and was spun out into a company by one of their graduate students, John Santini. The core concept was to develop a technology that could address patient needs around medication adherence and reduce the treatment burden by offering a smart device that could deliver therapies automatically from months to years. Since then, Daré has pioneered the concept through a first-in-human clinical trial to deliver parathyroid hormone for treating osteoporosis, and we are now developing the platform for broader use, initially targeting contraception.

Q What were some of the biggest technical and regulatory challenges that your team faced in developing a ten-year implantable drug delivery system and how did you overcome them?

LP The major technical challenges were related to the overall design. How can we fit enough drug in a device small enough to be implanted safely? How can we make sure that we can communicate wirelessly and protect patients' privacy? How can we ensure that the device remains sealed to protect the electronics and the drug product throughout the ultra-long period that it's in the body? We addressed these challenges through creativity and collaboration, which is where our partnership with Cambridge Consultants really allowed us to take the concept to the next level.

AH One of the key things we had to figure out was how to ensure the hermetic sealing and biocompatibility for electronics that are going to be implanted for a full decade. There are also a lot of Class 3 regulatory requirements, software safety, cyber security issues and risk management concerns that need to be considered for this type of connected health product. Moreover, they typical cycles of iterative testing are quite challenging for an active implant that delivers a drug, as you are balancing parallel drug and device R&D activities while simultaneously navigating the preclinical and clinical trials with progressive levels of fidelity.

Figure 1:
The DARE IDDS.

"YOU WOULD THINK THAT WITH SUCH A NOVEL CONCEPT WE'D HAVE TO DEAL WITH A UNIQUE REGULATORY PATH, BUT IN PRACTICE IT WASN'T ALL THAT DIFFERENT FROM A STANDARD COMBINATION PRODUCT."

LP You would think that with such a novel concept we'd have to deal with a unique regulatory path, but in practice it wasn't all that different from a standard combination product. Even though the device and the delivery mechanism are novel, the drug remains the primary mode of action and that's what dictates the regulatory path. Because the IDDS's architecture operates on the same principles as technologies that already exist in the implantable space, such as cardiac devices, neurostimulators and other devices that have gone through an approval process, the groundwork for how we need to approach it from a device perspective has already been laid, which makes things much easier.

Q What makes contraception a particularly impactful lead indication for Daré's IDDS and how does it differ from existing long-acting contraceptive options?

LP While there are a lot of different options when it comes to contraception, years of user research has shown us that, in all cases, women feel that they have to compromise in some way with the current product offerings. Short-acting methods, such as taking a pill, might seem convenient and flexible, but there's a burden with taking regular medication, including anxiety about forgetting. Alternatively, with the longer-acting methods, such as implants or intrauterine devices, these concerns can be avoided, but those are multi-year commitments. Not all women are willing to commit to that because they don't know where life is taking them or what they might want to do over such a long term.

So we know that there's an appetite for a more flexible solution. That's where DARE-LARC1 comes in – a user-controlled, long-acting, reversible contraceptive. We can store up to 10 years of contraceptive, but with the ability for the woman to turn it on and off by herself. The aim is to empower women to make family planning choices when it's right for them, while continuously protecting them from pregnancy while the device is active. The device has the potential to be immensely impactful to women in rural areas and developing countries where access to reliable contraception can be challenging.

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Liz Proos is the Vice-President of Product Development at Daré Bioscience, a company focused on accelerating innovation in women's health. In this role Ms Proos is responsible for technical and strategic product development, leading a cross-functional R&D and product development team and key strategic external partners, including development of the proprietary DARE Intelligent Drug Delivery System (IDDS) platform technology, which is designed to provide programmable, precise, long-term drug delivery from a subcutaneously implanted device. A Wellesley College (Wellesley, MA, US) graduate, Ms Proos joined Daré as part of the acquisition of Microchips Biotech in November 2019 and has more than 26 years of experience in drug delivery science and product development of combination products and medical devices.

Ashley Hawson
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Ashley Hawson is Senior Vice-President of Innovation and Operations at Cambridge Consultants, where she co-leads the Healthcare business unit. She advises global clients on the strategy, development and delivery of technically novel Class II and III medical devices with transformative clinical potential. Known for operating at the intersection of strategy, experimentation and product development, Ms Hawson guides multidisciplinary teams to solve complex healthcare challenges across areas including active implantables, neural and physiological interfaces, sensing, data and intelligence. A Georgia Tech (Atlanta, GA, US) graduate, she has held leadership, operational and academic roles at GE, Tufts University and Cambridge Consultants, and is recognised for helping clients achieve breakthrough outcomes that meaningfully improve patient lives.

Q Can you elaborate on where the IDDS fits into Daré's broader product pipeline?

LP Daré is focused on closing the gap in women's health between promising science and real-world solutions. In addition to contraception, we have a broad pipeline of products that aim to address unmet needs in vaginal health, sexual health, menopause, infertility and a number other women's health applications that have historically been pushed to the side. It's exciting to be working on products that are going to be first-in-class in areas where there aren't many options right now. We're really looking to improve patient access and quality of life in these areas.

One of the unique aspects of the IDDS is that it can house multiple drugs in a single device because the drug compartments are all independent and can be individually and precisely delivered. This means that we're able to synchronise dosing, whether it's with other drugs or the patient. This is particularly exciting for infertility applications; it has the potential to significantly improve outcomes.

Another therapy area we're looking at is oncology. Breast cancer patients will often have to undergo a series of monthly injections for up to five years after they have completed their treatment, which is extremely burdensome for someone who has already gone through an immensely stressful and painful treatment process. We could potentially replace those injections with a single implantable device, which would free women from having to travel to a clinic or a hospital to get their therapy.

Then there are cases like Parkinson's disease where patients often will have "off episodes" in the morning, which are very debilitating. A device like ours could automatically deliver a dose overnight without the patient even having to be aware that it's happening, which can significantly improve their quality of life and also reduce the burden on caregivers.

The last one I'll mention specifically is metabolic diseases – there are a host of chronic conditions that require frequent injections that are a major burden for patients. A device like Daré's IDDS, which can administer the drug automatically, could massively increase compliance, which is a huge issue for chronic diseases.

"ONE OF THE UNIQUE ASPECTS OF THE IDDS IS THAT IT CAN HOUSE MULTIPLE DRUGS IN A SINGLE DEVICE BECAUSE THE DRUG COMPARTMENTS ARE ALL INDEPENDENT AND CAN BE INDIVIDUALLY AND PRECISELY DELIVERED."

Q Can you expand on how Daré's IDDS serves other stakeholders in the healthcare industry?

LP I attended several conferences last year, and the industry is still talking extensively about the need to transition care from the clinic to the home. A device such as the IDDS that can hold enough drug for months to years of therapy can facilitate that to a level most of the industry isn't even considering yet. It has the potential to improve the patient experience to a whole new level.

When you improve patient access and the patient experience, you inherently improve the factors that clinicians, caregivers and the rest of the healthcare system are concerned about. If patients are getting their medication, then their condition is being managed. If you're able to deliver drugs in a precise way that helps to reduce side effects, patients are less likely to seek extra care or be overly reliant on their caregivers. Conversely, if patients aren't adherent, their symptoms return and they require more intense care, including hospitalisations. So the easier you can make it for patients to be adherent, the better it is for the whole healthcare system.

AH If you step back and look at the big picture, by reducing the number of adverse events patients experience and making their treatments much less burdensome, we're addressing larger-scale socioeconomic needs with the potential to provide a widespread set of benefits. That includes sustainability benefits too – by virtue of moving care into patients' homes, there are additional gains just from reducing travel.

Q What role do you see the connected health applications of the IDDS, such as remote monitoring and dosing control, playing in the future of healthcare?

LP I think that the IDDS has significant potential within the connected health arena, in particular due to its wireless communication functionality

and its ability to seamlessly share and upload data. What's special about the IDDS is that because it's designed to operate either on-demand or on a pre-programmed schedule, the patient doesn't need to do anything extra to take advantage of the IDDS's connected features.

Also, connectivity gives patients the ability to query the device itself at any time, checking if it's dosing properly or just getting an update on their health. That's in contrast to traditional implants, where there's no active way for patients to get feedback. And patients need that feedback – they want confidence, they want to know that their medication is delivering, they want to know that their condition is being treated.

AH When I think about how the IDDS is positioned within the connected healthcare ecosystem, it's really easy to add in extra functionality and sensors because we've already cracked those problems – and we've already designed the device to live within the body for 10 years. What that means is that the IDDS could enable a closed-loop system. If you link an IDDS to a monitoring system, it can accurately and precisely respond to a patient's needs in real-time, before the patient even realises they need medication. It's another aspect of this technology that has the potential to fundamentally change how we care for patients.

Q What has the collaboration with Cambridge Consultants enabled that wouldn't have been possible otherwise?

LP The partnership has been absolutely critical to the development of the IDDS platform. Cambridge Consultants has such a deep expertise in creating these custom solutions, in solving the incredibly challenging engineering problems involved. If you think about what we originally presented to them, it was little more than a concept, a prototype and a list of things we wanted to achieve. They immediately embraced that and worked with us in a seamless collaboration. It feels like we are one team and we share the passion to bring innovation like this to patients.

"CONNECTIVITY ALSO GIVES PATIENTS THE ABILITY TO QUERY THE DEVICE ITSELF AT ANY TIME, CHECKING IF IT'S DOSING PROPERLY OR JUST GETTING AN UPDATE ON THEIR HEALTH. THAT'S IN CONTRAST TO TRADITIONAL IMPLANTS, WHERE THERE'S NO ACTIVE WAY FOR PATIENTS TO GET FEEDBACK."

AH It's been an incredibly easy and rewarding partnership – one of those ones that happens naturally without the need for hard work. That doesn't happen all the time and it's a precious thing when it does. I think we've both recognised that and have nurtured it along the way.

Q What excites you most about the future of the DARE IDDS and what kinds of partners or collaborators are you hoping to engage next?

LP We're very open to all types of organisations and all types of partnerships. We're excited to be able to offer this technology to the world essentially. We're keen to open our platform up and say we've spent many years working on this, we've solved the hard problems, we have a platform that is ready to now engage with. What we want to know is what are your drug delivery challenges? What are you trying to address for your patient populations? What is the potential value that IDDS can offer to the area you're focused in?

While Daré is focused on women's health, the IDDS platform could have extensive applications beyond our specific sector. That makes us really excited to engage with partners and stakeholders in areas beyond women's health because it allows us to explore the potential of the IDDS across healthcare. Precision dosing, improving patient access, remote monitoring, sustainable care pathways – we're addressing so many different aspects of real-world challenges that we want to see the technology adopted across diverse patient populations.

And, while our platform is novel and exciting, we recognise that it has some unique manufacturing requirements. So to facilitate future partnerships, we've invested in custom manufacturing capabilities – cleanrooms, manufacturing space – so that we're ready to start making products across multiple potential applications.

AH Daré has been prudent in how it's set itself up for enabling all future development that it'll need for this. And, as you can probably tell from reading the rest of the interview, Daré is a wonderful organisation to work with. The technology is mature and its state of readiness are very good. The company is in an excellent state and fantastic to work with.

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EARLY AUTOMATION CONSIDERATIONS FOR THE DEVELOPMENT OF DRUG DELIVERY COMBINATION PRODUCTS

SMC® Ltd.

Asmita Khanolkar and **Al Neumann**, both at **SMC**, uncover the manufacturing strategies that can be used to achieve design for automation, scale-up and sustainable solutions for clinical and commercial launch, describing the gains to be made in manufacturing efficiency when using small, automated work cells.

Today's novel drug delivery devices are complex, tailored, targeted and customised to meet the requirements of challenging applications. A robust manufacturing plan is needed from the first design input in order to successfully achieve automation for a scale-up strategy. In turn, this accomplishes integration of development through clinical and commercial manufacturing.

The CMC (Chemistry, Manufacturing, and Controls) side of the programme can have a huge impact on the timeline and costs of development. Iterations for both the drug and device are inevitable and ever faster turnaround is needed throughout development, manufacturing and testing cycles. Automated manufacturing plays a central role here.

Drug delivery devices cover a wide range of innovative solutions from autoinjectors and on-body devices to complex reconstitution devices, covering needs across parenteral injection, respiratory, transdermal and ophthalmic delivery solutions (Figure 1). The focus today is on providing patient-centric technology

"THE FOCUS TODAY IS ON PROVIDING PATIENT-CENTRIC TECHNOLOGY SOLUTIONS FOR PERSONALISED AND PRECISION MEDICINE, WHERE ONE SIZE DOES NOT FIT ALL."

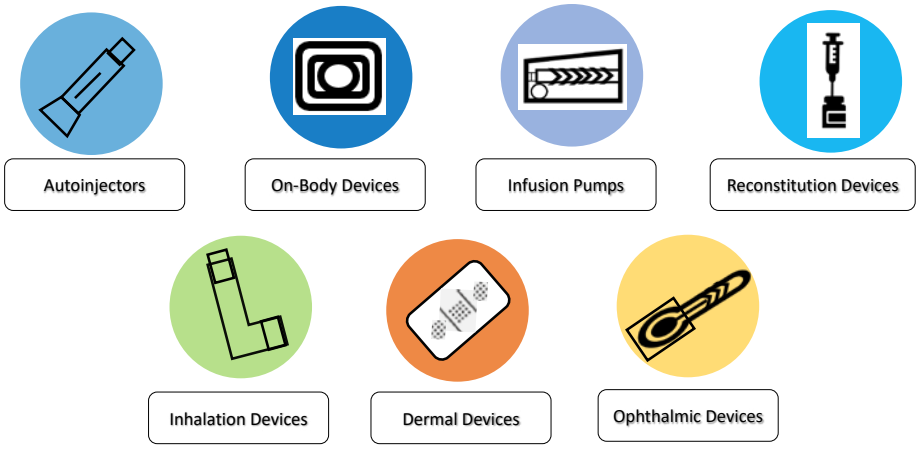

Figure 1: Innovative solutions make up today's complex drug-delivery devices.

"DEVICE MANUFACTURING INVOLVING COMPLEX ASSEMBLY PROCESS STEPS AND CUSTOM REQUIREMENTS CAN ALSO BENEFIT FROM DESIGN FOR AUTOMATION FROM AN EARLY STAGE."

solutions for personalised and precision medicine, where one size does not fit all.

For combination products, manufacturing strategies need to cover the device build as well as drug handling aspects, taking the CMC requirements into account. This can often be challenging as it requires broad expertise in various aspects of moulding, assembly, automation, fill-finish and packaging.

Especially when focusing on developing a novel therapy or drug chemistry, the delivery device and its manufacturing can become an afterthought. Automation and scalability can end up being considered further down the line too. The starting point of device manufacture is understanding all the steps from early development to commercialisation.

This can be missed, particularly when considering the interactions and touch points of the drug and device necessary to achieve overall project success. Maintaining consistent product performance throughout manufacturing scale-up in a product's lifecycle is crucial. Designing for automation can help developers to focus on this from the very beginning, by examining complex assembly steps and customer requirements. With the stringent requirements of speed to clinic, a timeline for development can be greatly streamlined by putting early efforts into design for automation, as well as a manufacturing strategy. Moreover, device manufacturing involving complex assembly process steps and custom requirements can also benefit from design for automation from an early stage.

MANUFACTURING STRATEGY

A manufacturing strategy starts with the scale requirements for the product. Depending on the application, the commercial product launch volumes can range from low to high. Low volume quantities are needed for development and clinical studies, and there is typically a steep jump to high commercial quantities. Suggestions that can be made early in the project include developing small work cells for repeatability of assembly process steps. Further proposals can cover product design and test recommendations to help with future, higher throughput equipment.

Small-batch work cells remain more flexible as product development evolves, while also supplying enough product for testing and market analysis at lower work cell costs. Additionally, they provide an opportunity to develop testing strategies and to explore techniques for assembly, work cell component handling and programming routines that can be adapted to higher throughput machines. In most cases, small work cells can help to expose any new product deficiencies and allow for early part modifications (Figure 2).

Design for Automation

Design for automation principles cover various areas of assembly, including standardisation, minimising component use, handling features, assembly orientations, self-alignment, tolerance stack-up and process optimisation. When it comes to assembly of complex devices, the focus is on de-risking the process and removing uncertainties, such that the product can be repeatedly manufactured in the same way for consistent device performance.

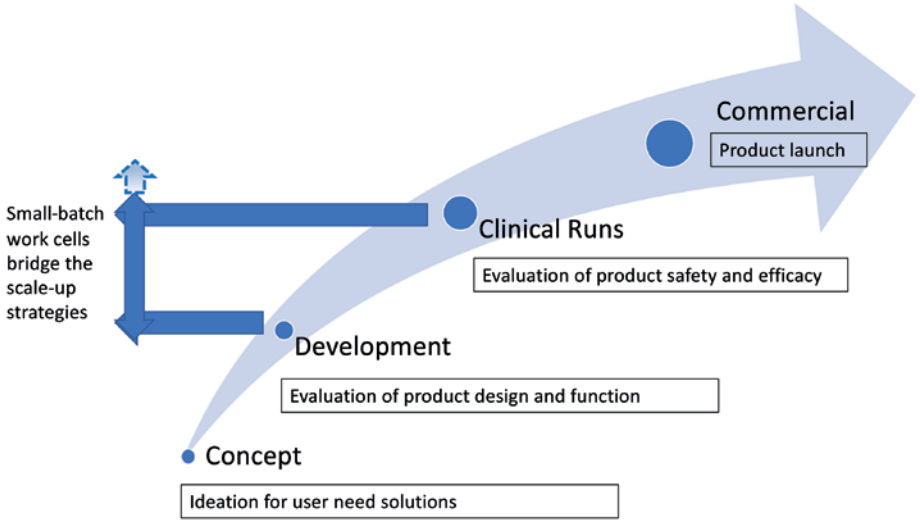

Figure 2: The need for small-batch, semi-automated work cells.

For drug delivery devices, successful clinical outcomes – in terms of pharmacokinetics and pharmacodynamics – depend on optimised and consistent delivery,[1] therefore constant high performance becomes the driving factor for success. Device design outputs for delivery performance are included in the US FDA's recommendations for establishing and assessing drug delivery performance via essential drug delivery outputs (EDDOs).[2] By incorporating design for automation, design outputs can cover the manufacturing and testing specifications in addition to the device design specifications, in order to meet the EDDO recommendations (Figure 3).

The design of small-batch, automated work cells focuses on optimised steps that can de-risk the process. There are many areas that can pose risks to the final product performance. A good first step is to look at the process, in order to evaluate steps that are critical and where early automation makes the most sense. These can include the handling of expensive components; challenging manual assembly steps that are not consistently carried out; custom assemblies, blind assemblies; multi-step assemblies; process steps that are difficult to test or must be quantified with certain parameters, time-intensive, time-sensitive or stringent requirements; and complicated joining, welding or gluing combinations.

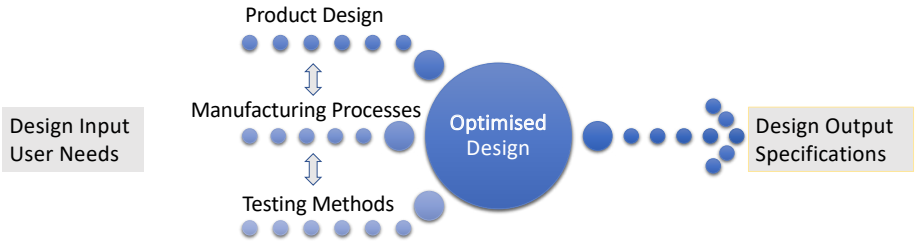

Figure 3: Design, manufacturing and testing outputs for optimised design.

Additionally, secondary operations, such as custom printing, packaging and labelling, can also pose manufacturing challenges and are better accomplished via automation in small work cells. Furthermore, when considering operator safety, steps that take an inordinate amount of dexterity can benefit from levels of automation.

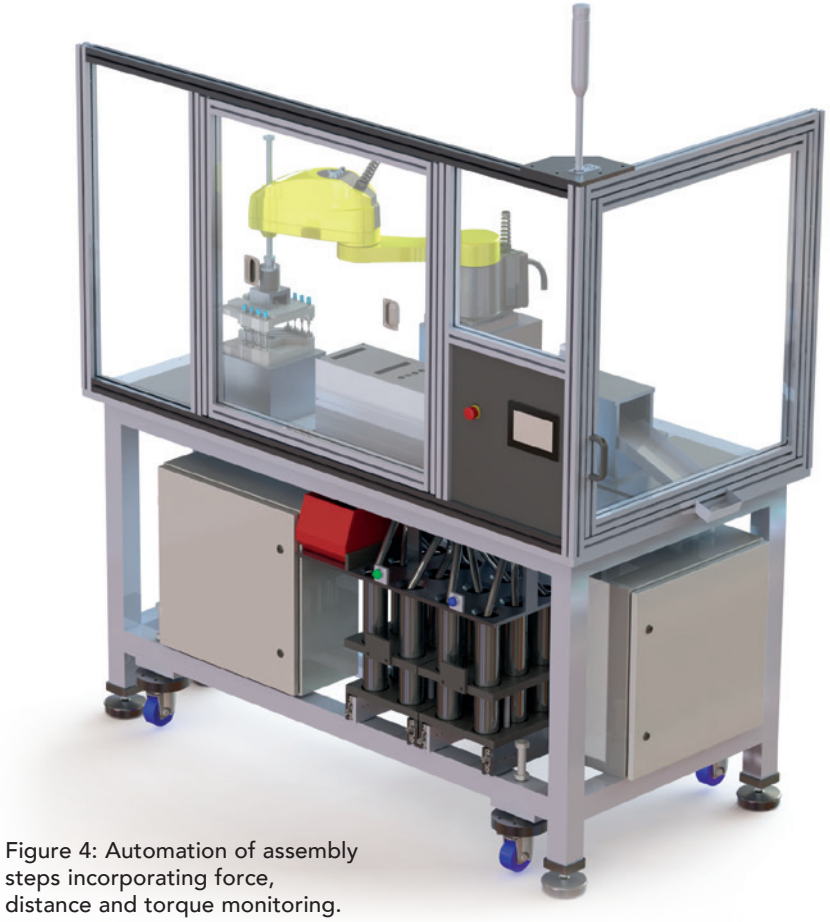

Figure 4: Automation of assembly steps incorporating force, distance and torque monitoring.

Component Handling

Component work cells can be used to orientate, print and handle challenging components. In the case of sharps and needles, these components may need to be presented one at a time in certain orientations. With the aid of vision systems, dimensional or visual inspection can be conducted prior to assembly. Advanced laser marking technologies can add value by pre-marking certain componentry while avoiding any loss at a later, more expensive assembly stage.

Device Assembly

Various assembly steps comprise of push, press, snap-fit or turning operations. Even though these operations may seem simple for manual assembly, process controls can be essential for performance, and data may need to be collected during critical assembly steps. In such cases, monitoring forces, displacement and torque can generate in-process data to assure repeatability in the assembly steps (Figure 4).

For operations requiring joining methods such as ultrasonic welding, laser welding or gluing, custom small-batch work

"FOR OPERATIONS REQUIRING JOINING METHODS SUCH AS ULTRASONIC WELDING, LASER WELDING OR GLUING, CUSTOM SMALL-BATCH WORK CELLS CAN HELP TO REMOVE UNCERTAINTIES IN THE PROCESS."

Figure 5: Operator-friendly semi-automated stations for assembly.

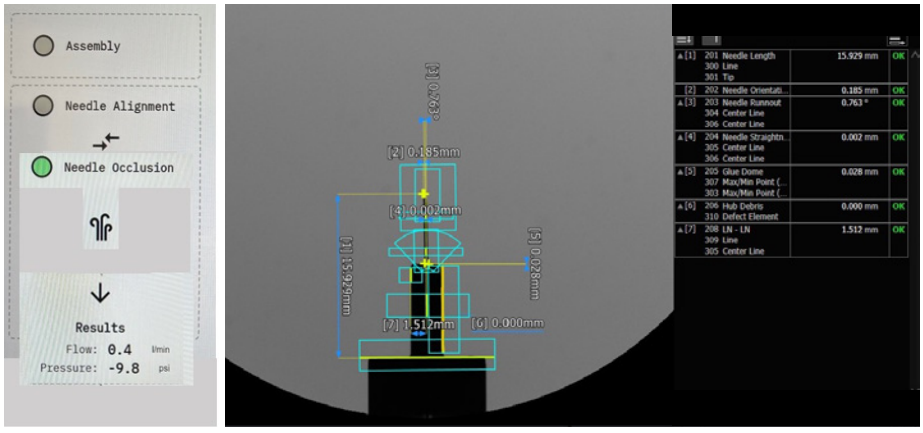

Figure 6: Testing concepts for needle alignment and occlusion.

cells can help to remove uncertainties in the process. Furthermore, part detection can identify any missing components. Glue dispensing and UV-curing is a common assembly operation; the quantity of glue and cure timing are important parameters to monitor. In this process, needle orientation, straightness and height post-gluing become critical parameters. Process data available from the work cells can help optimise the gluing process for consistent performance.

Ultrasonic welding, laser welding and other joining assembly methods rely on in-process controls since the final testing is often destructive. Due to this, it becomes imperative to collect data throughout the process. Some of the parameters that can be monitored include the cycle time, cycle completion verification and pass/fail statistics via machine vision testing. Operator ergonomics and safety regulations for a manufacturing environment can be incorporated into such small work cells (Figure 5).

Testing

Testing can be an integral part of a small work cell or a stand-alone station (Figure 6). It is important to identify the controls needed for each process and to set up relevant testing methodologies early on.

Custom leak, flow and pressure decay tests can help identify important failure modes, such as occlusion (Figure 7). Such methods can be validated to leak standards and can provide important insights into flow path occlusion as parts

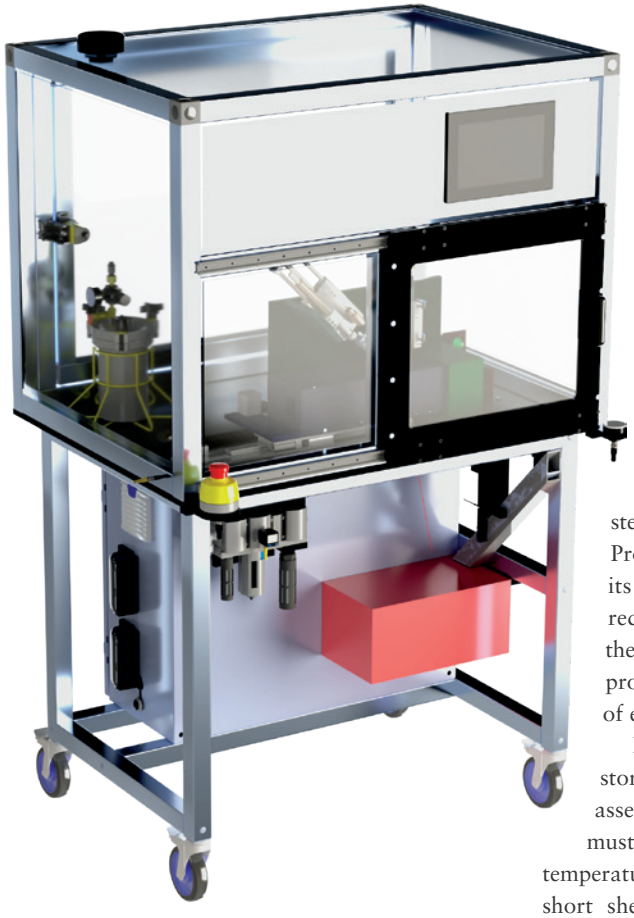

Figure 7: Testing station with reject sorting.

are assembled. Data collected during testing can help troubleshoot any issues with tolerance stack-ups or identify manufacturing defects early on. Machine vision provides additional insights into product quality and conformity. Figure 8 shows a summary of possible capabilities that can be automated.

Packaging & Labelling

Packaging and labelling work cells can significantly help to align the device development steps towards a finished product. Protecting a product and maintaining its sterility are key packaging requirements, and automation of the sealing, printing and labelling processes can help minimise the loss of expensive product.

For drug products that require cold storage, the process steps for device assembly and secondary packaging must incorporate careful handling of temperature-sensitive drugs or drugs with short shelf life. Real-time monitoring of process parameters in work cells can help de-risk handling of sensitive drug products. Semi-automated packaging work cells can also help to incorporate sustainable packaging solutions and handling of delicate packaging materials.

Pilot Line

The design for automation concepts in small work cells can be put together to run pilot-scale volumes (Figure 9). Depending on the quantity requirements, the line can be set up as modular stations or implemented in a rotary or linear line. Building guidelines for automation should be defined based on industry-approved standards.

HIGH-SPEED/HIGH-VOLUME LINES

The findings from small-batch work cells in pilot line concepts are used to map high-volume, high-speed automation lines. Without the working knowledge of small-scale automation steps and process parameters, large-scale production lines can become very expensive and risky to build. As artificial intelligence and machine learning tools become more sophisticated, data collected from process parameters through small stations and pilot lines can provide relevant information and insights for de-risking a high-volume line.

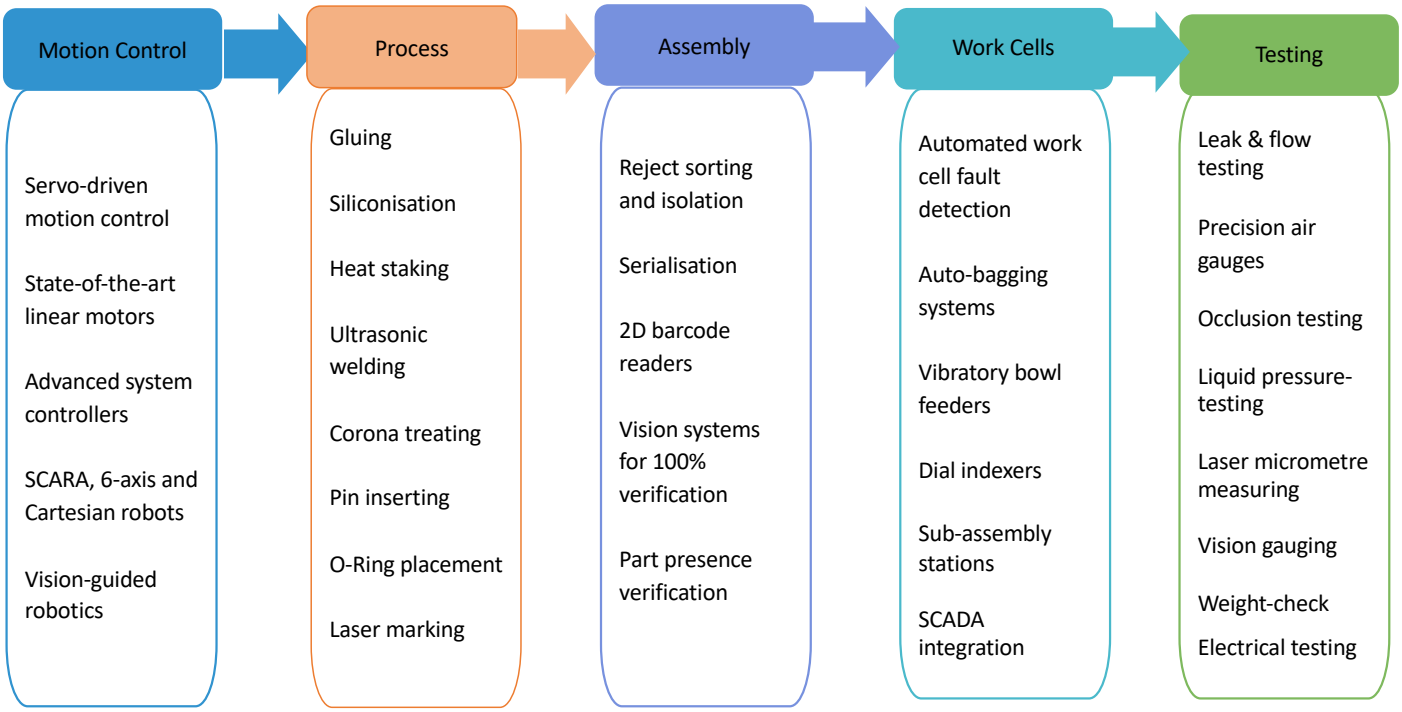

Figure 8: Some of the capabilities' matrix available for automation into work cells.

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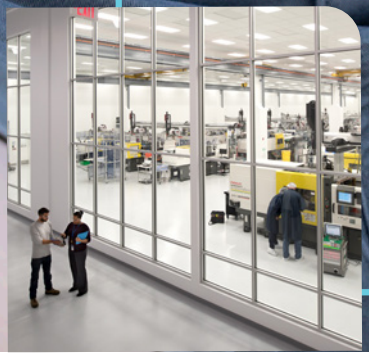
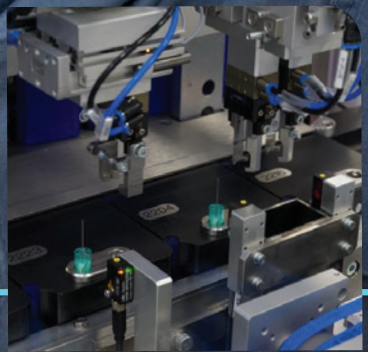

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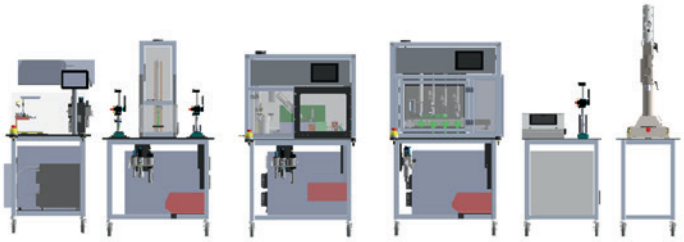
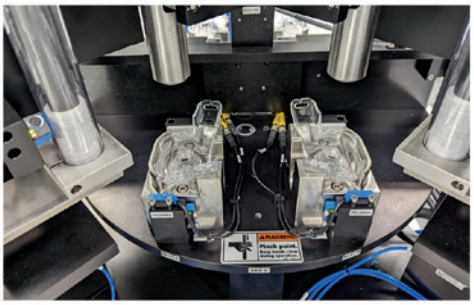
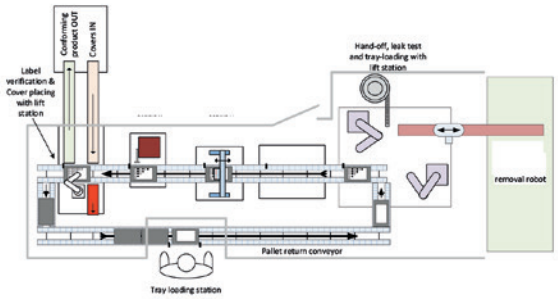


Semi-Automated Modular Stations



Rotary Dial Assembly



Tray Load and Test Packaging Station

Figure 9: From manual to semi-automated stations for a pilot line (up to 5 ppm).

CONCLUSION

In summary, automation in small work cells can help to increase speed to clinic and de-risk development. The data collected through small work cells can ensure consistent performance and help to avoid surprises during clinical testing due to manufacturing inconsistencies. Input from manufacturing, quality, regulatory and clinical teams involved with early manufacturing strategies can help to align a well-balanced CMC strategy for development of complex drug delivery devices and combination products. Designing for automation early on not only improves the manufacturing consistency of clinical supplies but also brings additional value to future high-speed and high-volume assembly systems.

REFERENCES

1. *Khanolkar A, White S, Margerison E, "A Novel Method to Optimize Drug Delivery for Parenteral Products Involving New Therapies and Unmet Needs". Pharm Res, 2023, Vol 40(10), pp 2303–2315.*
2. *"Draft Guidance for Industry: Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products". US FDA, Jun 2024.*

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Asmita Khanolkar, Senior Director at SMC Ltd, has a master's degree in Materials Science & Engineering from Worcester Polytechnic Institute (MA, US). With over two decades of manufacturing experience specialising in the medical device and pharmaceutical industry, she has managed various device projects from concept to commercial launch. Her product portfolio includes single use, wearable and implantable devices, as well as drug-device combination products for drug delivery, bio-therapeutics and pharmaceutical applications. Ms Khanolkar has held various engineering and management roles in new product development, manufacturing engineering, advanced quality planning, operations, supply chain and product lifecycle management. Her current responsibilities include a corporate leadership role supporting multiple sites in early technical engagement through commercialisation for medical devices, combination products and pharmaceutical services.

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TIME TO MARKET: INCREASED CUSTOMER VALUE THROUGH GLOBAL RAMP-UP EXCELLENCE

BAUMANN MEDICAL

David Pircher and **Leander Moser** of **BAUMANN Medical** discuss the advantages of having a global presence, which combines both local expertise and technical excellence with worldwide co-ordination of supply to deliver consistent and quality solutions.

The global demand for springs and stampings in medical devices is rising rapidly, driven by trends such as glucagon-like peptide-1 therapies, needlestick protection and self-treatment solutions. This growth coincides with complex supply chains and a fragmented global market. In this environment, scaling effectively from concept to global production is a key competitive advantage. Partners value not only technical capability, but also assurances that projects will move seamlessly from development to be implemented globally. They seek reliability, risk mitigation and co-ordinated expertise to navigate regulatory complexity and supply chain volatility.

Through strong collaboration, BAUMANN Medical has established a best-practice setup that maximises value for global projects. Combining technical excellence with local expertise and global unity, the company provides support at every stage of the lifecycle. Advanced engineering and material knowledge ensure compliance and performance, while regional teams provide on-the-ground support using standardised procedures. Co-ordinated manufacturing footprints deliver consistent quality and continuity, even in fragmented markets. Integrated supplier management reduces complexity and strengthens resilience, while proactive strategies – dual sourcing, capacity planning and contingency measures – safeguard against disruptions.

These aspects are all intended to support customers in the best way possible and allow for rapid adjustment of production

"GLOBAL PROJECTS IN THE MEDICAL DEVICE SECTOR NEED MORE THAN AN INTERNATIONAL PRESENCE – THEY REQUIRE A STRUCTURED APPROACH FROM INITIAL CONCEPT TO FULL-SCALE PRODUCTION."

levels. For pharmaceutical companies in particular, as well as contract and device manufacturers, having a partner with a global footprint is crucial to mitigate geopolitical risks and optimise costs.

TECHNICAL EXCELLENCE – THE FOUNDATION FOR GLOBAL OPERATIONS

Global projects in the medical device sector need more than an international presence – they require a structured approach from initial concept to full-scale production. Scaling begins with a robust design supported by simulation tools such as finite element method (FEM)/finite element analysis, ensuring predictable performance and compliance before physical prototypes are built. This technical foundation reduces risk and accelerates development.

Material expertise and process validation are critical for consistent quality across global sites. Biocompatibility, durability and regulatory approval drive material choices, while validated processes guarantee repeatability and reliability. Standardisation of equipment and workflows enables efficient technology transfer, training of local teams and rapid ramp-up in new markets without compromising quality.

Technical excellence means mastering processes, continuously improving them and adapting to evolving requirements. This systematic approach ensures sustainable quality and international competitiveness. To elaborate on the crucial role of technical excellence, the next section presents five key elements of global operations from a non-exhaustive, cross-sectional perspective (Figure 1).

Global Standardisation – The Common Language of Global Production

Standardisation underpins every successful ramp-up. Consistent processes, equipment and documentation enable the organisation to operate as one globally – speaking a common language across cultures and time zones. Applying standardised procedures and guidelines is more essential than ever. Global customers expect suppliers to guarantee identical quality standards worldwide, which builds trust in their reliability and efficiency.

BAUMANN Medical has advanced standardisation so that the same production process runs identically at every site. The result: a harmonised network that reduces complexity, ensures reliable planning and delivers consistent quality for original equipment manufacturers (OEMs) and contract manufacturers. Core processes and material flows are standardised, while certain steps are adapted to local circumstances – for example, fully automated packaging in one location and semi-automated packaging in another where labour costs are lower.

This balanced approach combines global consistency with local flexibility, ensuring efficiency without compromising quality. Standardisation drives operational excellence, mitigates geopolitical dependencies and strengthens supply chain resilience.

From Simulation to Validation – Turning Precision into Predictability

Simulation and virtual testing are essential parts of BAUMANN Medical's development process, helping the company to understand how materials behave even before the first prototype is built.

Using modern simulation technologies such as FEM can accurately predict material behaviour, stresses and deformations early in the development phase. This forward-looking approach reduces development cycles with repeated prototype builds, minimises waste and provides guidance for process steps and critical parameters. This is a crucial building block in making quality predictable – regardless of whether a component is manufactured in Europe, Asia or America.

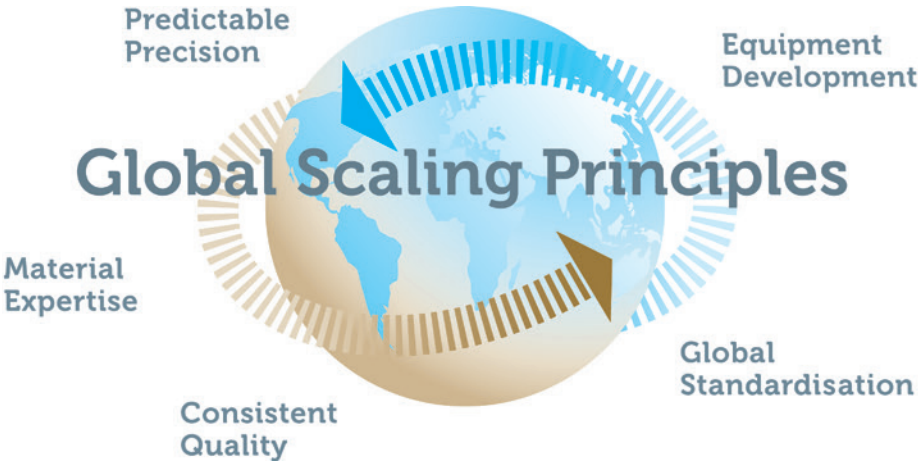

Figure 1: Five key principles for global scaling in drug delivery.

Material Expertise – Balancing Performance and Precision

Understanding various technical requirements – such as spring relaxation and its dependence on material properties, process parameters, stress state and storage time – is critical for reliable medical device design at an early stage.

However, selecting the right material is not only a technical decision but also a strategic one. The selection directly influences the performance, service life and efficiency of each product. Besides the technical aspects, supply chain management should consider commercial, logistical and supply chain risk aspects.

Consistent Quality Through Process Validation

Process validation ensures that processes are ready for series production – stable, predictable and under control. However, process validation is far more than a formal step to prepare for series production. In combination with the standardised setup, this ensures that the manufacturing process is reproducible, scalable and robust. This means applying the same standards and achieving the same results globally.

Validation not only achieves technical stability, but also builds trust. Above all, this applies internally to the co-operation between sites, but it also extends to customers. Comprehensive control over the processes delivers both quality and reliability. This reliability is one of the key reasons why the partnership is highly valued within global supply chains (Figure 2).

Figure 2: Quality in production – logbook entries.

In-House Expertise and Equipment Development

Another highly relevant factor of technical excellence is the development and building of machinery. BAUMANN Medical builds machines for its core processes in-house, which provides greater flexibility and full control over its production capabilities.

By designing and constructing its equipment internally – such as for wire cold forming or packing – technological agility and innovation are assured. Additionally, industrialising new processes quickly, implementing technological advancements seamlessly and maintaining consistent standards across all locations provide significant stakeholder benefits.

LOCAL EXPERTISE, GLOBAL UNITY – WHY FOOTPRINTS MATTER

In the medical component industry, having a local presence is more than a logistical advantage – it is a strategic necessity. Regulatory compliance, supply chain resilience and cultural understanding all depend on having teams embedded in key markets.

This principle extends to a globally connected approach – each site operates as part of one network, aligned by shared standards, synchronised processes and a collaborative culture. Documentation is created with a global mindset, ensuring applicability across locations. Every procedure, test and process step is locally compliant yet globally transferable – facilitating knowledge transfer and continuous improvement.

Global transfers go beyond moving machines – they translate customer expectations into timelines, validated processes and trained teams. Success demands clear understanding of volumes, deadlines and product maturity, with resources aligned across infrastructure, materials and people.

Embracing global diversity combines ideas and expertise, forming the cornerstone of every ramp-up and enabling the network to deliver optimal outcomes worldwide (Figure 3).

Scaling Global Projects: What Really Drives Success

Successfully scaling global projects requires early alignment and disciplined execution. It begins with a clear understanding of customer expectations – what needs to be delivered and by when, whether

Figure 3: Experts in BAUMANN Medical's factory.

"ACTING AS ONE GLOBAL TEAM AND INVOLVING THE RECEIVING SITE EARLY IN THE PROCESS SECURES SMOOTH KNOWLEDGE TRANSFER AND OWNERSHIP, REDUCING DELAYS."

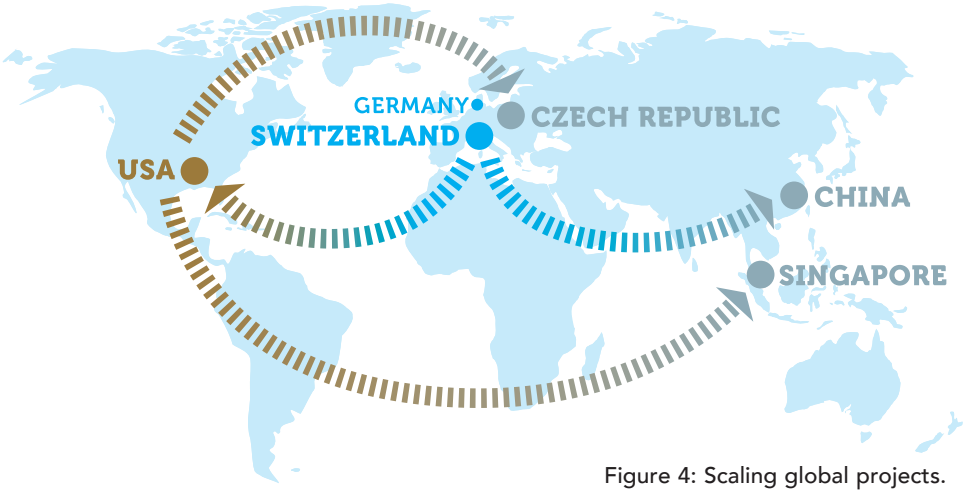

Figure 4: Scaling global projects.

considering prototypes, performance qualification batches or commercial products. This clarity drives the planning for transfer and ramp-up, ensuring infrastructure, raw materials, equipment, processes and trained personnel are ready on time.

Clear mapping of dependencies between internal work packages, as well as dependencies on external partners and milestones, ensures full transparency on schedule impact. Critically, identifying a path forwards, allows for proactive risk management and keeps the project on track.

Close alignment with all stakeholders guarantees flexibility to adapt to changing needs while maintaining timelines. Acting as one global team and involving the receiving site early in the process secures smooth knowledge transfer and ownership, reducing delays. To achieve this, three pillars are essential:

1. **Standardisation**: Implement standardised manufacturing lines and systems across all locations to ensure consistency, efficiency and quality.
2. **Competence Centre**: Establish a central competence centre (e.g. BAUMANN Medical Switzerland) as the hub for expertise, best practices and technical support.
3. **Global Knowledge Transfer**: Build a strong global team to drive effective knowledge transfer, ensuring processes and skills are replicated seamlessly worldwide.

Confirming process and site readiness before transfer, supported by globally applicable documentation, ensures consistency across locations. Multi-line validation delivers uniform quality globally. Robust, early preparation accelerates implementation, minimises risk and safeguards investments (Figure 4).

Selecting a partner with proven global experience adds resilience and efficiency. Ultimately, success relies on a shared understanding of scope, expectations and timelines, combined with flexibility to manage the unexpected and to shift smoothly during ramp-up.

SUPPLIER MANAGEMENT – THE BASIS FOR QUALITY AND RELIABILITY

Another key component of a strong global footprint is the careful selection

and management of suppliers. Supplier management plays a critical role, especially in an industry where individual components consist of a single material, such as stainless steel or carbon steel, that is purchased, precisely machined and then further processed into high-precision parts.

The ability to procure raw materials and other production materials competitively in the respective countries or regions where these materials are sourced is a key factor for success. Local purchasing of reliable raw materials not only ensures stable cost structures but also increases resilience to global price fluctuations and supply constraints.

For BAUMANN Medical, this means less dependence on international supply chains, greater planning security and even closer co-ordination with regional partners. The combination of global quality standards and regional procurement creates a robust foundation for reliable processes, stable supply and long-term customer trust (Figure 5).

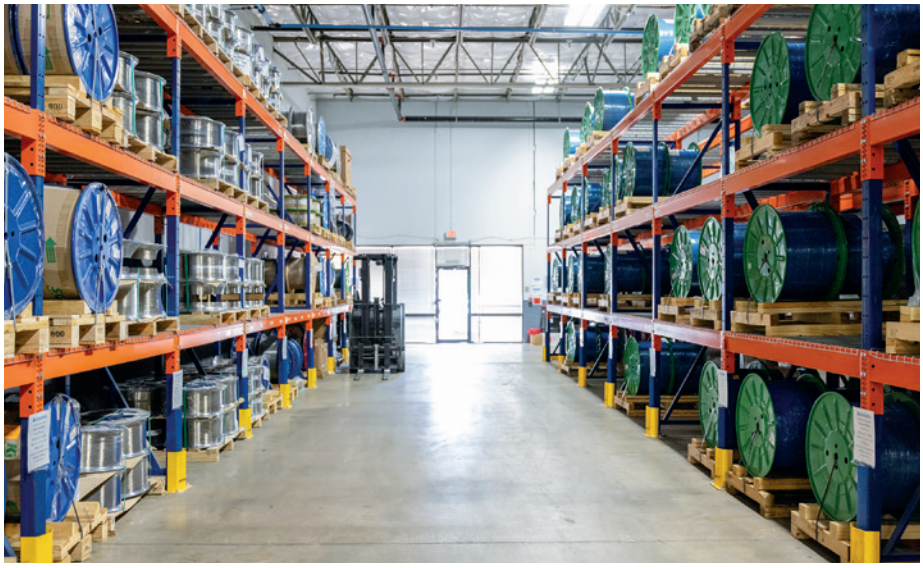

Figure 5: Warehouses in the US.

Supply reliability in healthcare is non-negotiable. Patients depend on uninterrupted availability and OEMs require assurance that their partners can deliver – even during periods of market volatility. Achieving this level of reliability necessitates building resilient supply chains, supported by contractual commitments and proactive risk management strategies.

ECONOMICAL PERSPECTIVE – KEY ELEMENTS FOR BEST PRACTICE

In today's highly regulated, competitive medical device industry, success requires more than technical expertise – it demands seamless collaboration across the supply chain. Managing relationships between global OEMs and contract and design managers is now a strategic priority for delivering quality, reliability and innovation at scale.

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OEMs often work with multiple contract manufacturers to meet global demand and compliance, but co-ordinating partners worldwide is complex. It requires clear communication, standardised processes and strong governance to ensure consistent quality and adherence to timelines.

Operational efficiency is critical; standardised systems reduce complexity, minimise waste and optimise resources – lowering the total cost of ownership. Markets face sudden shifts in demand due to regulatory changes, launches or global health events. Manufacturers must scale up or down without compromising quality or delivery.

Global competence centres and knowledge transfer accelerate time-to-market, enabling rapid ramp-up and consistent quality. Multiple locations solve logistical challenges, cutting freight costs and improving delivery times.

Preventative measures and local presences mitigate geopolitical risks, shorten lead times and reduce the carbon footprint – combining risk management with sustainability. BAUMANN Medical's global governance and proven frameworks strengthen reliability, ensure compliance and deliver predictable outcomes that protect investments and improve profitability.

"IN A FRAGMENTED MEDICAL DEVICE MARKET, SUCCESS DEPENDS ON COMBINING GLOBAL CONSISTENCY WITH LOCAL FLEXIBILITY, ENSURING COMPLIANCE, RELIABILITY AND SPEED."

CONCLUSION

Global ramp-up excellence is more than scaling production – it is about creating customer value through technical mastery, standardised processes and seamless knowledge transfer. In a fragmented medical device market, success depends on combining global consistency with local flexibility, ensuring compliance, reliability and speed. BAUMANN Medical's approach integrates advanced engineering, material expertise and in-house equipment development with a harmonised global footprint and strong supplier management. This enables rapid time-to-market, risk mitigation and cost optimisation, which is critical for OEMs and contract manufacturers facing regulatory complexity and volatile demand. By acting as one global team, supported by competence centres and proven governance, BAUMANN Medical transforms complexity into clarity, delivering predictable outcomes and sustainable growth. It is not just about components – it is about enabling global success through partnership and shared expertise.

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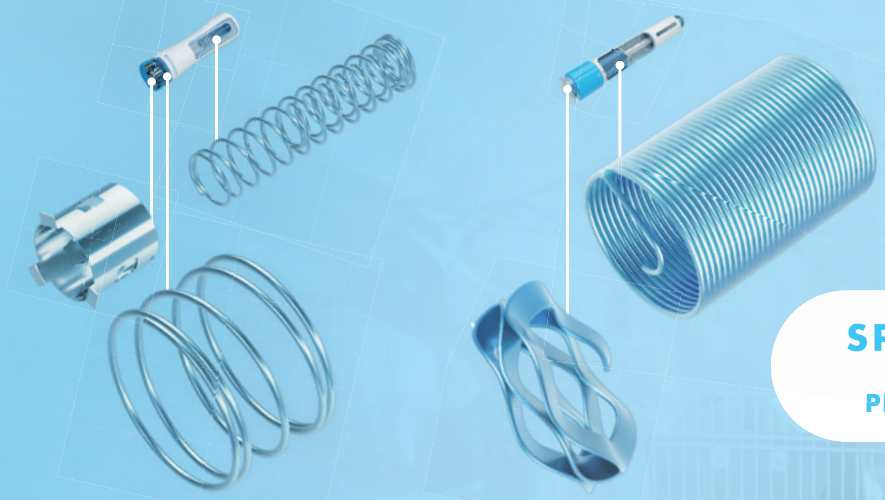

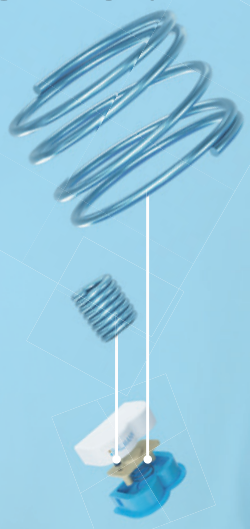

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Interview: Developing Wearable Injectors

Liat Shochat discusses her extensive experience in wearable drug delivery device development, covering the various challenges that arise from the inherent complexity of these devices, even with multiple successful wearable devices on the market, as well as the best way to engage with contract development organisations such as **EdgeOne Medical**.

Q How does EdgeOne Medical's experience with combination products allow you to bridge the gap in complexity when moving from a standard prefilled syringe (PFS) to a wearable device?

A When EdgeOne Medical was founded in 2012, our goal was to become a truly independent combination product development partner to biopharma, supporting the full product lifecycle from early feasibility studies through to commercial readiness, with all its different complexities. Emerging just as the combination product landscape was accelerating, EdgeOne played a contributing role in some of the industry's earliest advances in subcutaneous delivery, spanning PFSs, pen injectors, autoinjectors and, ultimately, the first commercially successful on-body injectors (OBIs).

Most importantly, our foundations were built on the deep expertise of our team, who had held leadership roles in pharma and medical devices and understood the ecosystem in practical terms. We know and understand the regulatory expectations, development pitfalls, manufacturing requirements and the commercial realities that define successful combination product development programmes.

"MOST IMPORTANTLY, OUR FOUNDATIONS WERE BUILT ON THE DEEP EXPERTISE OF OUR TEAM, WHO HAD HELD LEADERSHIP ROLES IN PHARMA AND UNDERSTOOD THE ECOSYSTEM IN PRACTICAL TERMS."

In short, EdgeOne Medical's success comes from planning and executing a viable, de-risked path to commercialisation from an early stage. That's where our experience makes the difference – knowing which questions to ask, how to connect the right disciplines and expertise and how to carry that same consistency from the lab to the patient.

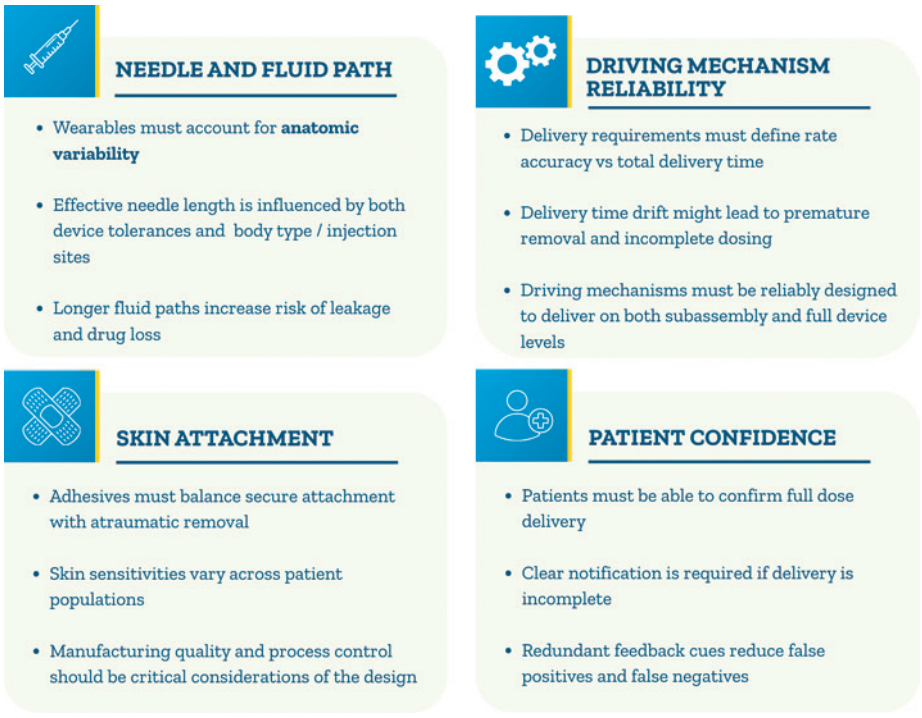
Q As drug developers consider the shift into wearables, how should they think about selecting the right delivery platform?

A Across every platform, the same fundamental goal prevails – to reliably deliver the correct dose to the intended tissue depth, and to do so in a way that gives the patient confidence that they have received their complete dose. Achieving this is not a trivial task for PFSs or pen injectors, and delivering that same level of consistency with a wearable device is even more challenging, requiring the right mix of expertise and partnership to create a viable, de-risked path to commercialisation.

Reviewing the drug delivery device landscape, there is no single volume threshold or "magic volume number" that dictates when the therapy should shift into a wearable format. However, one can see industry trends that fall within a few practical ranges, where less than 1.5 mL is typically in a syringe or pen injector, 1–5 mL often moves into an autoinjector, 3.5–20 mL is where OBIs prove most viable and over 20 mL doses often take the form of near-body or off-body infusion pumps (Figure 1).

In addition, when choosing the right wearable platform, developers should compare and consider how the device attaches to the body, the user interface and notifications, the delivery duration and the accuracy in advance. It's also important to check if the correct risk controls were

Figure 1: The volume ranges most suited to each injectable device format.



"WITH HANDHELD DEVICES, THE PATIENT CONTROLS PLACEMENT AND HOW WELL THE DEVICE IS STABILISED ON THE INJECTION SITE. HOWEVER, WITH WEARABLES, THE DEVICE DESIGN MUST ACCOUNT FOR THE ANATOMIC VARIABILITY THAT INFLUENCES THE EFFECTIVE NEEDLE LENGTH AND DELIVERY PERFORMANCE."

Figure 2: Key principles for wearable device development.

implemented by design, such as sensors and feedback for skin-proximity detection, flow monitoring and occlusion detection, as well as factors relating to reliability, supply chain and manufacturability.

Q Drawing on your background, what are the non-negotiable technical principles that you insist on to ensure that a device is not only innovative but robust enough for commercial launch?

A When I consider my own work and that of my colleagues who have spent years designing wearable devices, a few non-negotiable technical principles consistently stand out. Not everyone may agree with my perspective, but it was shaped by lived experience and scars earned while bringing multiple wearables from concept to commercial launch (Figure 2).

Firstly, needle and fluid path factors, such as needle length, dimensional tolerances and injection-site variability with different body types, are critical design considerations. Some may argue that these are the same parameters we evaluate when selecting a pen injector, which is correct. With handheld devices, the patient controls placement and how well the device is stabilised on the injection site. However, with wearables, the device design must account for the anatomic variability that influences the effective needle length and delivery performance. In addition, a longer fluid path means that the design must consider potential drug loss due to its length and the risk of leakage, especially when delivering larger volumes or operating at higher pressure.

There are also many details to consider when selecting adhesives. I tend to group them into six areas – attachment strength, ease of removal, post-use residuals, skin sensitivities, liner removal behaviour and manufacturing quality. The adhesive must attach quickly and securely, holding the device in place for the full duration of delivery. At the same time, it must be easy to remove when needed, without causing trauma to the skin or leaving residual adhesives.

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Liat Shochat is Vice-President of Combination Product Development at EdgeOne Medical and has over 21 years of experience in managing the design and development of combination products and medical devices. Her expertise includes strategic and technical development, lifecycle management and the global launch of single-use disposable electromechanical drug delivery platforms, drug-device combination products and medical devices, including for West Pharmaceutical Service's SmartDose® wearable delivery system for home use. Throughout her career, Ms Shochat has held management roles in R&D, engineering, project management, regulatory, human factors and clinical trials.

In my experience, both as a patient and as someone who has evaluated many marketed devices – on more than a few devices, the adhesive can cause more trauma than the injection itself. When selecting materials, particularly for patients with sensitive skin, might be necessary to evaluate alternatives, such as silicone-based adhesives, in place of standard acrylics or non-woven constructions. Beyond the adhesive itself, the liner must peel away cleanly, without tearing or leaving fragments behind, or this may result in a user error. In some markets, including Japan, regulators and quality requirements specifically assess fibre debris generated by the adhesive, making manufacturing quality and process control considerations a critical part of the design.

Many wearable therapies have clinical requirements that require longer delivery durations, which poses the question of which is important for a given therapy – the moment-to-moment precision of the delivery rate or the overall delivery time? When answering this question, one should primarily consider usability on top of clinical considerations, such as the pharmacokinetics. For example, if the expected delivery time was stated to be five minutes, and the delivery time drifts beyond that, the user might prematurely remove the device without waiting for the completion cue, resulting in an incomplete delivery. With that in mind, it is important to define these and translate these considerations into the design requirements. Also, with the understanding that the driving force is mechanical or electromechanical in nature, it is important that the components of the drive mechanism are designed to reliably deliver effective doses and reflect it correctly in the design outputs.

Lastly, in drug delivery, a patient's confidence is more critical than their comfort and convenience. Patients must be able to reliably confirm that they received the full dose and, if they don't, that fact will be clearly communicated. In both scenarios, clear and reliable notification methods are needed. These can be visual, audible or haptic. My recommendation is to design in redundancy, with at least two independent and aligned cues, to ensure that the patient doesn't receive a false positive or negative.

"THE MAJOR HURDLE, AND ONE THAT WAS A REAL CHALLENGE UNTIL FAIRLY RECENTLY, IS THE REGULATORY AND STANDARDS LANDSCAPE."

Q From your vantage point, what were the unresolved hurdles or blind spots with wearable devices that the industry is yet to address?

A Here, let's focus on the lenses that most directly affect wearable device development today – regulatory clarity, reimbursement and supply chain resilience. The major hurdle, and one that was a real challenge until fairly recently, is the regulatory and standards landscape. For a long time, wearable device developers had to navigate different guidance documents, including two separate US FDA guidance documents, one for infusion pumps and one for pen injectors; and two main technical standards, those being an earlier version of ISO 11608 that focused primarily on pens and ISO/IEC 60601-2-24, which was an older standard meant for infusion pumps mainly used in clinical settings. None of these reflected the needs for OBIs intended for self-administration at home. Therefore, device developers and manufacturers were operating with significant gaps in the regulatory pathway and gaps in the supporting technical standards. Today, due to good collaboration between regulatory agencies and industry, we are in a much better place.

"IN DRUG DELIVERY, A PATIENT'S CONFIDENCE IS MORE CRITICAL THAN THEIR COMFORT AND CONVENIENCE. PATIENTS MUST BE ABLE TO RELIABLY CONFIRM THAT THEY RECEIVED THE FULL DOSE AND, IF THEY DON'T, THAT FACT WILL BE CLEARLY COMMUNICATED."

The second challenge is reimbursement pathways. For syringes, pens and autoinjectors, these are well-established. Wearables don't yet have the same clarity, largely because these devices are newer and less common than the others, involving more complex cost structures and device classifications. This creates uncertainty for pharma teams planning go-to-market strategies.

The third challenge, felt particularly keenly in the last several years, is supply chain resilience. We've seen significant disruptions both during and after the covid-19 pandemic. Ensuring consistent and reliable material availability in accordance with global regulatory requirements has become increasingly challenging. And, as some wearable systems are electromechanical, there's additional complexity to deal with when outsourcing components – especially electrical ones. Many OBIs require batteries or an alternative energy source, causing further complexity, including safety requirements, disposal regulations and broader environmental considerations. It's an area where I think the industry could benefit from more consistent frameworks and shared infrastructure.

Q What additional tests would you recommend wearable device developers integrate into their "planned testing"?

A On top of the essential drug delivery outputs and primary functions in different challenging preconditions, one of the first that comes to mind is from ISO 11608-6 – attachment to the body. Beyond the functional considerations mentioned earlier, development teams should evaluate initial tack, peel and shear performance, then supplement that with human-factors assessments, such as liner-removal behaviour and on-body simulations across diverse skin types and anatomical contours.

Another key area is needle and fluid path testing, including hold-up volume, leakage at vulnerable points, internal pressure build-up

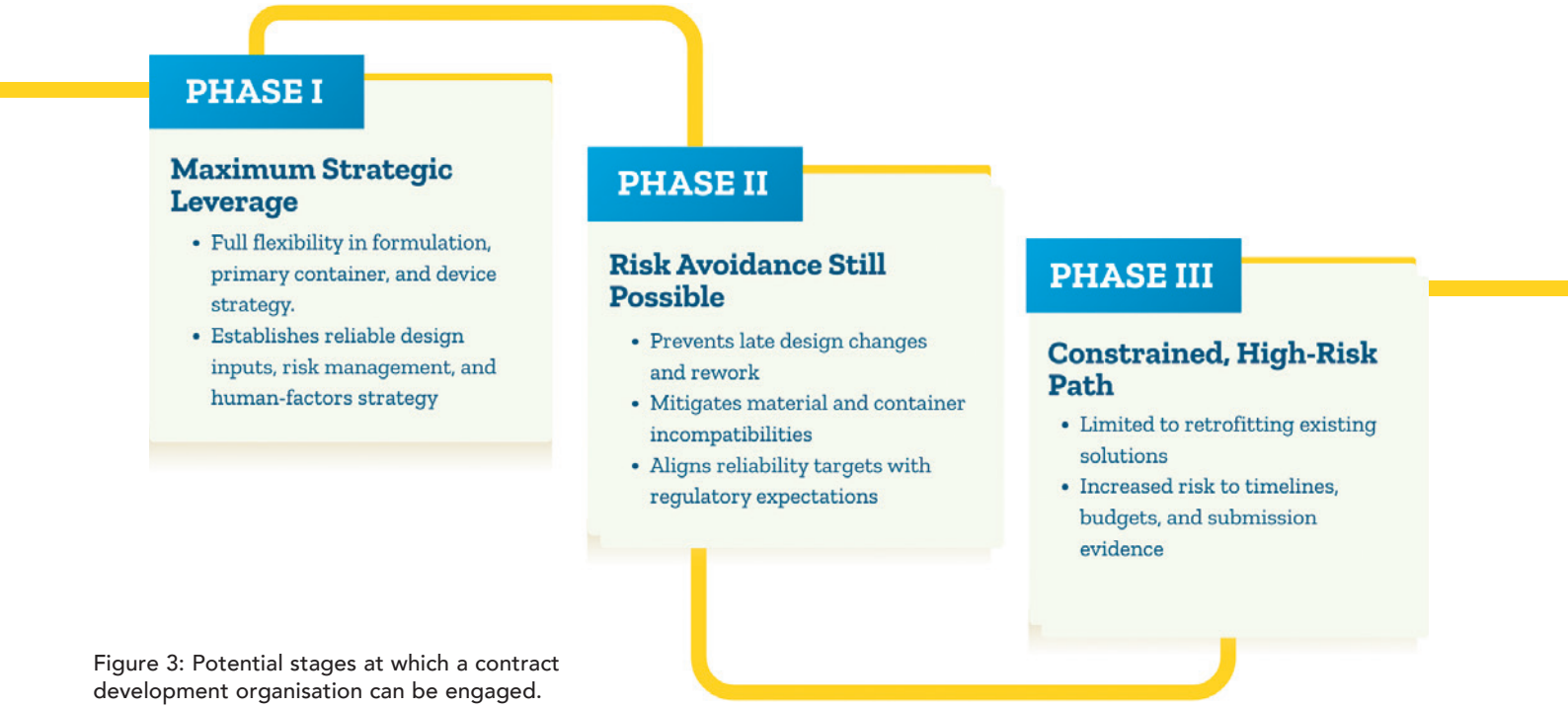

Figure 3: Potential stages at which a contract development organisation can be engaged.

and tolerance stack-ups that impact effective needle penetration and dose accuracy. Because OBIs are larger and interact differently with the body than handheld devices, early drop testing is essential for confirming enclosure integrity, adhesive retention, sharp-injury protection and drive-mechanism robustness after free fall.

Third, for electromechanical OBIs, thermal-effect evaluations are needed to ensure that the heat generated by the batteries and actuators does not compromise drug stability or raise skin-contact temperatures beyond safe levels. Here, the IEC 60601 and HE75 standards are good references. In addition, if software is included, hardware, cybersecurity and software validation activities will be required. Integrating these activities early can help to identify true system vulnerabilities and prevent the late-stage redesigns that can derail wearable development programmes.

Q What is the "golden window" for engaging an organisation like EdegOne Medical?

A From EdgeOne Medical's perspective, the golden window is as early as possible – ideally through Phase I, when there is still meaningful flexibility in the formulation, primary container and device strategy. This is also consistent with broader industry and regulatory thinking (Figure 3). Engaging us early creates the greatest opportunity to shape a wearable-ready drug-device strategy by confirming technical feasibility, guiding primary container choices and then selecting the most suitable delivery platform for programme needs. In addition, it helps us to establish robust design inputs and risk management strategies, as well as to build a human factors test plan.

Phase II engagement still offers significant strategic value by helping teams avoid late design changes, material or container incompatibilities and unrealistic reliability targets. By contrast, waiting until Phase III leaves limited, high-risk "retrofitting" options and constrains our ability to optimise the development programme without major timeline, budget or submission evidence impacts.

In our experience, we have had clients come to us from both sides of the spectrum – well-experienced clients engage us two to three years before their Phase II or III clinical study, ensuring good platform and component selection and sufficient time for all development activities, as well as some slack for any potential surprises or necessary changes. Other clients, who might be newer to combination product development, come to us with less than six months to go until their clinical or commercial submissions are due, which is inherently risky. In these cases, we needed to align timeline expectations and generate the required documentation and objective evidence needed to support their submission.

Q Do you have any final thoughts?

A I'll be speaking at Pharmapack in January 2026 on two topics that are close to my heart – "Beyond the Basics: Smart Approaches to Drug Delivery System Selection" and "Piecing It Together: Overcoming Real World Challenges in Wearable Drug Delivery Systems". I genuinely encourage our readers to reach out as this industry moves forward through open conversations and collaborations. I'm always excited to exchange ideas, compare lessons learned and support and bring to market new combination products.

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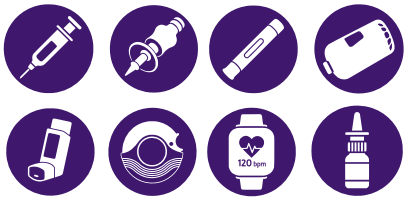

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Expert View

DEVELOPMENTAL ADVANTAGES IN INJECTABLE COMBINATION DRUG PRODUCTS

Oliver Eden of Jabil Healthcare and **Travis Webb** of Pii, a Jabil company, consider how regulatory considerations and patient-centric device designs are transforming the landscape of self-administered injectable drugs.

One of the biggest changes in pharmaceuticals over the past 10 years has been the increase in self-administered injectable drugs such as breakthrough medicines for chronic conditions. This transformation goes beyond process change and represents a strategic advantage for developers that embrace early collaboration between drug formulation scientists and device engineers.

The intersection of formulation science, device design, regulatory considerations and patient-centric clinical trials is now the crucible in which successful therapies are forged. The days of developing drugs and devices in silos are over. Instead, pharma brands must foster ongoing dialogue between formulation scientists, device engineers and regulatory experts from the outset.

THE RISE OF SELF-ADMINISTRATION

An increasing prevalence of chronic diseases, patient preference for convenience and advances in delivery technologies, such as autoinjectors, are transforming how therapies are administered. As biologics and other novel formulations become more common, treatment is shifting beyond traditional healthcare settings to the hands of patients themselves. Every pharma company would likely offer medicines in a simple pill if they could; however, many biologics cannot be formulated as oral tablets because they break down or lose potency in the gastrointestinal tract.

As a result, developers are advancing injectable and device-based delivery options that ensure therapeutic effectiveness. In a real sense, the drug determines the device. As patients seek therapies that align with their daily routines, pharmaceutical companies are responding with prefilled syringes (PFSs), autoinjectors and wearable devices that simplify administration while supporting patient retention, adherence, compliance and persistence.

Self-administration is now a key focus, with autoinjectors and on-body devices designed to make dosing intuitive and convenient. Devices must accommodate patients with needle-phobia or limited dexterity, along with maintaining a consistent dosing regimen. Pharma companies are increasingly aware that device usability directly impacts adherence. If a patient struggles with a device or fails to complete an injection, therapeutic outcomes worsen.

The mission with self-administration is not just to persuade patients to inject themselves but also to ensure that, when they do, they follow the provider's instructions. You can provide a patient with an injection device that they are happy to use, only to find that they lift the device from the skin halfway through the injection sequence and only deliver half the dose. The goal is to produce products that empower patients to take control of their own dosing with devices that are not just easy to use, but are easy to use correctly.

The rise in self-injections has also affected regulatory agencies such as the US FDA and EMA, which have responded by intensifying their focus on the patient experience and usability. Recent FDA guidance has emphasised the need to consider human factors early in development to ensure that combination drug products are intuitive, safe and effective for patients. Common themes across regulatory bodies for combination products include early classification, integrated risk management for both drug and device, human factors and usability studies, and labelling and instructions.

"THE DAYS OF DEVELOPING DRUGS AND DEVICES IN SILOS ARE OVER. INSTEAD, PHARMA BRANDS MUST FOSTER ONGOING DIALOGUE BETWEEN FORMULATION SCIENTISTS, DEVICE ENGINEERS AND REGULATORY EXPERTS FROM THE OUTSET."

FORMULATION AND REAL-WORLD FUNCTION

Early integration of formulation and device development creates products that are stable, user-friendly and compatible with delivery systems optimised for real-world use. There are also formulation aspects that help with patient convenience. For example, long-acting injectables allow patients to reduce the required number of doses. This cross-disciplinary approach is essential for pharma companies to meet regulatory expectations, enhance patient satisfaction, and ensure speed and success in a competitive landscape.

A combination product, as the name suggests, combines three different elements – the drug product itself; the primary pack, such as a PFS with a staked needle or a 3 mL cartridge; and a delivery system such as an autoinjector. The shift in collaboration is driven by the complex interdependencies between the drug, its primary packaging (such as a PFS or cartridge) and the delivery device. It demands a nuanced approach.

The form and function of the delivery device can affect the way that the drug itself is formulated and vice versa. Consideration should be given to how the drug will interact with the device to ensure consistent injections. Each device component must be examined and tested for efficacy in combination with other parts.

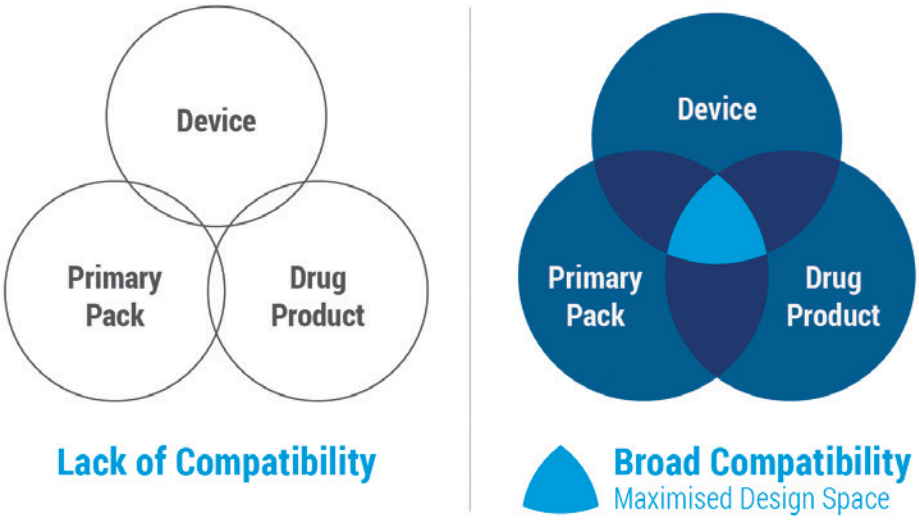

Figure 1: Compatibility among components.

Chemical and physical stability, device compatibility and patient usability must be balanced. PFSs, for example, expose drug products to prolonged contact with elastomeric components and lubricants, complicating the delivery of uncompromised quality in the drug formulation.

In the past, this interaction between the drug and the delivery system received insufficient early attention. As shown in Figure 1, working in silos only to bring the device and drug together at a later stage can result in unexpected incompatibilities that send a team back to the drawing board with significant delays, added costs and rework.

Critical Quality Attributes	Formulation	Prefilled Syringe	Autoinjector	Manufacturing
Identity	High	None	None	None
Assay/Impurity	High	Weak	None	Weak
Sterility	Weak	Weak	Weak	High
Particulate Matter	High	High	None	High
pH/Osmolality	High	Weak	None	Weak
Viscosity	High	High	High	High
Dose Delivery Accuracy	High	High	High	High
Injection Time	High	High	High	High
Activation Force	None	None	High	Weak

Table 1: Interdependence of key components.

Formulation science is broad, and there is not necessarily one formulation that will work for a drug. However, once clinical trials have begun and formulation efficacy data are gathered, it becomes increasingly difficult for the drug maker to change it without added time, costs and complications.

Considerations for drug-device compatibility include the following:

- **Lubricants** used in primary packs (such as PFSs) can impact drug stability
- **Excipients** may cause an unexpected reaction
- **Stabilisers**, such as sucrose and trehalose, can increase viscosity and impact injection force
- **Buffers** must be compatible with syringe materials to minimise risks such as aggregation
- **Surfactants** prevent surface adsorption but may degrade into particulates, potentially clogging needles and disrupting reliable dose delivery.

Device engineers must accommodate formulation challenges to account for the delivery system. Table 1 shows the sensitive interdependencies that exist between each of the components. In almost all cases, the critical quality attributes rely on two or more elements working together synergistically. Dose delivery and injection time rely on all elements – formulation, primary pack and injector – working together.

There has been a significant shift in how drug and device development intersect over the past few years. It is notable that in recent years, clients with drugs in preclinical stages, not yet undergoing IND-enabling studies, are enquiring about autoinjectors types, options available and multidose flexible patterns.

When drug and device developers assess interactions and key factors together, they will have more flexibility to make modifications and solve adverse interactions. Executing this during early phases before generating clinical data can prevent design rework on the back end.

HUMAN FACTORS AND USABILITY

The patient is at the heart of modern injectable drug development. Usability testing, human factors studies and real-world data collection are now integral to the process. Regulatory agencies expect manufacturers to demonstrate ease of use, accessibility and minimal burden on the patient – in addition to clinical efficiency – during submissions.

Formative human factors studies are valuable early on and throughout the development programme. This includes both the drug delivery system and the proposed instructions for use. Comprehensive training programmes, such as those implemented for prefilled pen devices in clinical trials, help to ensure that patients use correct injection techniques, reducing variability in trial data and accelerating time-to-market.

Fewer than 14% of drugs progress from Phase I trials to the commercial market.[1] Recent FDA transparency initiatives show that usability gaps, such as missing human factors validation, are increasingly cited in Complete Response Letters (CRLs) for combination products. These deficiencies often trigger requests for additional studies, delaying approval.[2] CRL issuance and resubmission cycles can add median delays of ~435 days or a range from 47 up to 2,374 days before eventual approval.[3]

It is important that, if a particular route of administration with a drug is not performing as expected, it is identified as early as possible to minimise wasted investment. It is equally important that drug assets with demonstrated value are made available to patients as early as possible.

CLINICAL TRIAL DESIGN

Designing clinical trials is crucial for the commercial success of a new drug. Integrating formulation properties with delivery device design early in the drug development process provides significant long-term advantages. Matching device capability with formulation properties is key to developing robust, differentiated combination drug products.

As pharma companies consider the interplay between the regulators, contract research organisations, study sponsors and themselves, it is important that each new drug has the best opportunity to succeed through collaborative processes. This seems to be industry's direction of travel, with smart technologies and artificial intelligence increasingly being introduced into clinical trials to collect data and achieve results as quickly as possible.

Connected devices can enhance clinical trial speed and assessments of drug performance by automatically monitoring and reporting data on self-administration practices, compliance and device performance. Connected autoinjectors, if designed well, remove reliance on patient self-reporting and provide ongoing feedback that informs future device improvements. However, human factors must also be tested with any added technology. Imposing added technological burdens – such as requiring less digitally savvy populations to input data into a smartphone app – may not be the best route when more passive connectivity methods are possible.

Passive data transmission, such as autoinjectors that use a charging station for data capture and automatically send usage data via a cellular network without any patient action, supports decentralised trials in more remote, less populated regions.

REGULATORY STRATEGY: DATA IS KEY

Navigating the regulatory landscape for combination products is complex. Agencies expect manufacturers to demonstrate not only clinical efficacy but also usability, safety and accessibility. While the FDA is centralised and the EMA is decentralised with additional steps for device conformity, they both emphasise usability, risk management and integrated lifecycle controls. Early engagement with regulatory bodies and comprehensive data generation on device compatibility, stability and human factors are essential.

Processing data becomes much easier when healthcare providers can see the frequency of dosing and how patients are navigating their treatment protocols. Clinical endpoints can be affected by patient deviation from protocol-defined adherence, compliance and persistence targets. Connected devices that automatically upload data in real time provide faster and more reliable data, which can help to address issues with a drug product that may have suffered a setback or even a failure because of patient adherence problems. Earlier and more frequent data collection enables issues to be addressed sooner, leaving teams better equipped to resolve problems without having to repeat studies or extend trials because the data are late or do not make sense.

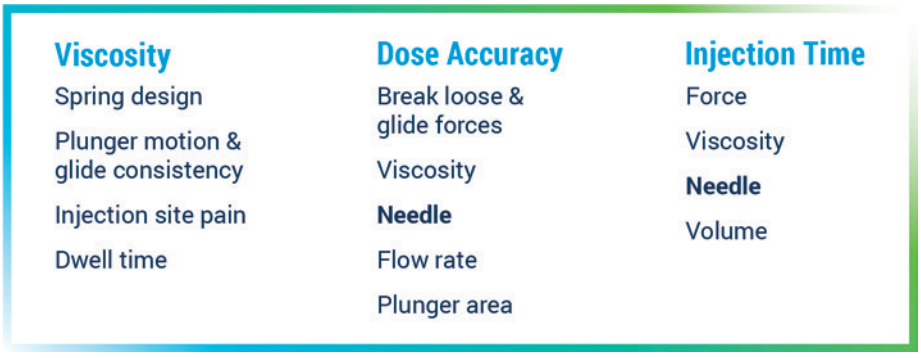

Figure 2: Success depends on viscosity, dose accuracy and injection time.

Addressing the success factors listed in Figure 2 requires co-operation between formulation scientists and device engineers. Delivering high-viscosity formulations demands precise co-ordination of needle design, drive-force mechanics and fluid resistance dynamics to balance injection time and patient comfort. Usability studies and patient feedback then help to refine these systems to improve ease of use and overall device performance.

CONCLUSION

The shift towards patient self-administration of injectable drugs is reshaping the pharmaceutical industry. Collaboration between drug and device developers has become a strategic advantage, allowing the device to be customised for the specific requirements of the drug product while ensuring desired performance and reliability. The benefits include minimising design cycles, shortening development timelines and reducing associated costs.

By embracing cross-disciplinary co-operation, integrating human factors and usability studies, and engaging regulatory bodies early, pharma companies are better able to deliver therapies that are safe, effective and accessible. This integrated approach offers a smarter, faster and more patient-aligned path to both clinical and commercial development. In an increasingly competitive landscape, it is the key to improving patient outcomes and achieving market success.

ABOUT THE COMPANIES

Jabil is one of the world's largest healthcare manufacturers and a trusted partner to top pharmaceutical brands for comprehensive engineering, supply chain and manufacturing solutions. With 60 years of experience and a network of over 100 sites worldwide, Jabil delivers scalable, customised solutions from concept to commercialisation.

Pharmaceutics International, Inc (Pii), a Jabil company, is a CDMO that provides comprehensive solutions for aseptic and oral dosage forms. Founded in 1994 by Dr Syed Abidi, a pioneering formulation scientist, Pii has over 30 years of experience handling complex formulations, potent compound, and controlled substances. Based in Maryland, US, Pii's capabilities include lyophilisation, high potency isolation and robotic filling.

Oliver Eden

Oliver Eden, Senior Director, Global Business Units Business Unit Director at Jabil Healthcare, is focused on the development and commercialisation of drug delivery devices for the division's pharmaceutical delivery systems business. Operating from the UK, Dr Eden earned his Master's in Mechanical Engineering and PhD in Biomaterials Engineering from the University of Exeter (UK).

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Travis Webb

Travis Webb, Chief Scientific Officer, Pii, a Jabil company, has over 17 years of experience in both analytical and formulation contract development across multiple dosage forms including injectables, liquid pulmonary, oral solids and liquids, and topical drug products. During his career he has developed over 20 approved drug generic and NDA drug products and helped bring numerous INDs to various clinical stages. Mr Webb also has extensive experience with quality by design and paediatric drug product development for both the US and Europe, supporting IND/NDA filings and communicating with regulatory agencies. He holds an MS in Pharmaceutical Chemistry from the University of Florida (US) and a BS in Biochemistry from Troy University (AL, US).

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REFERENCES

1. *Cross R, "Drug development success rates are higher than previously reported". Chemical & Engineering News, Feb 2018.*
2. *Waldron J, Kansteiner F, "'Weak' evidence and an 'unpleasant' odor: FDA sheds light on drug refusal process". Fierce Biotech, Jul 2025.*
3. *"Top Reasons FDA Rejects Drug Applications: Lessons from Safety and Adverse Event Data". Velsafe, Aug 2025.*

ACCELERATING PATIENT-CENTRIC THERAPIES FROM DEVELOPMENT TO DELIVERY

Justin Schroeder of **PCI Pharma Services** outlines its product service offering to the drug delivery industry, including sterile fill-finish services, drug-device combination product development and testing, clinical and commercial device assembly, packaging, storage and distribution, among other services.

PCI is a CDMO that provides expertise and solutions in sterile fill-finish and specialist final assembly, testing and packaging of advanced drug delivery and drug device combination products. With its seamless, integrated injectable solutions, comprehensive approach and dedication to excellence, PCI provides convenient, easy-to-use and patient-centric therapies throughout clinical trials, product launch and commercial market supply (Figure 1).

One of its key strengths is the flexibility it provides in offering solutions that cater to a diverse, global client base. Whether manufacturing and packaging niche personalised medicines or large, annual-volume treatments, PCI has the global capability and capacity to scale its services to meet specific needs, delivering a streamlined drug-device combination product pathway.

STERILE FILL-FINISH AND LYOPHILISATION

From early clinical batches to global commercial supply, PCI's aseptic manufacturing and lyophilisation capabilities are trusted across formats and formulations. With nearly three decades of sterile excellence, its scientific expertise and scalable technologies deliver a broad range of small and large molecules, including high-value APIs, such as monoclonal antibodies, oligonucleotides and peptide drug products. Bringing agility and deep technical collaboration to the forefront

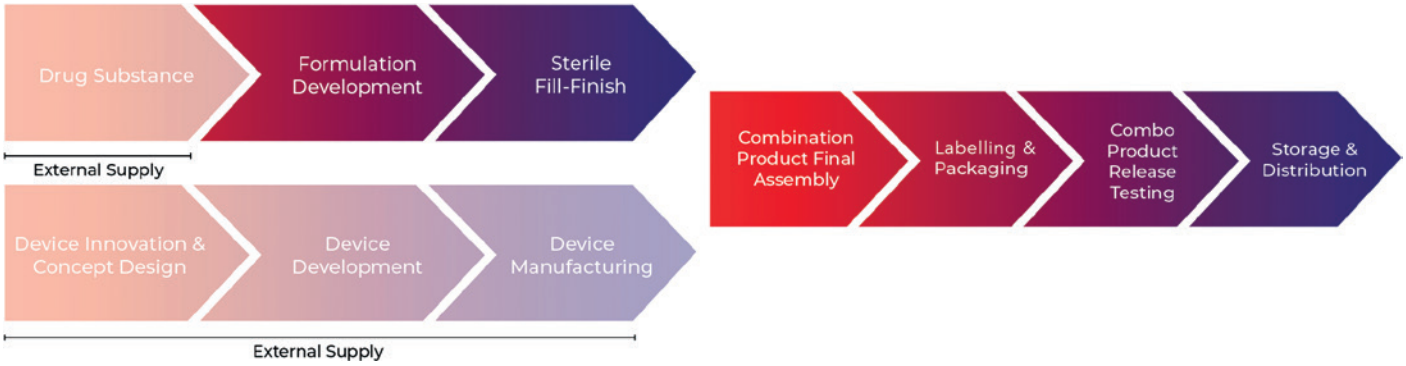

Figure 1: Combination product value chain.

of sterile product development, PCI's Pharmaceutical Development Centres of Excellence support phase-appropriate formulation, analytical and process development services offering clients a modality-agnostic, science-driven approach, supporting the strategic transition from vials to syringes or cartridges.

PCI's scalable vial, syringe and cartridge filling capabilities across Europe and North America are setting new industry standards, while its GMP Annex 1-compliant technologies deliver quality at every stage. Flexible infrastructure supports both small- and large-scale supply, with maximum batch sizes for prefilled syringes (PFSs) ranging from 2,000 to 300,000, providing a strategic pathway from development to commercialisation for a streamlined sterile supply chain.

ADVANCED DRUG DELIVERY AND DRUG-DEVICE COMBINATION PRODUCTS

Driven by innovation and patient-centricity, PCI's design and development expertise, combined with its device-agnostic assembly and advanced clinical and commercial packaging capabilities, offers flexible solutions for a diverse portfolio of conventional and specialty injectable drug delivery devices. Tailored to unique design, development and manufacturing needs, PCI offers a complete range of capabilities, services and expertise, including:

- Expert design process focused on human factors engineering and technical functionality
- Packaging designs optimised for manufacturability, scalability, automation and sustainability
- End-to-end drug-device combination services including:
  - PFS assembly
  - Needle safety-system assembly and precision labelling
  - Pen, autoinjector and on-body injector final assembly
  - Integrated side- or top-open cartons
  - In-process functional testing and final release
  - Serialisation
  - Cold-chain storage and distribution.

> "TAILORED TO UNIQUE DESIGN, DEVELOPMENT AND MANUFACTURING NEEDS, PCI OFFERS A COMPLETE RANGE OF CAPABILITIES, SERVICES AND EXPERTISE."

EXPERT ADVICE FROM DEVICE STRATEGY TO PACKAGING DESIGN AND SUSTAINABILITY

With a global network of experts, PCI provides guidance at critical time points to assist its customers in developing an optimised, patient-centric drug-device combination product. Its rich experience can help determine the best device container and strategy for a drug product and patient population. From the use of established well-accepted platforms with regulatory approval as part of a drug-device combination product, which may be deemed a lower risk approach for a new development programme, to a more innovative approach that may be deemed more attractive for specific patient populations compared with more traditional and readily available platforms.

> "ITS DEDICATED TEAM OF IN-HOUSE DESIGN SPECIALISTS DELIVERS INSIGHTFUL PACKAGING DESIGN AND PRACTICAL KNOWLEDGE TO DELIVER DIFFERENTIATED, SUSTAINABLE AND COST-EFFECTIVE PACKAGING SOLUTIONS."

PCI's pharmaceutical packaging design department provides an innovative and value-added service. Its dedicated team of in-house design specialists provide insightful packaging design and practical knowledge to deliver differentiated, sustainable and cost-effective packaging solutions. Working with its client partners as early as possible during the clinical trial stage, PCI's design department, together with a cross-functional network of experts in sterile drug product manufacturing, engineering, operations and approved vendors, develops expert design processes focused on human factors engineering and technical

functionality, delivering optimised designs for manufacturability, scalability and automation. This seamless solution ensures that key considerations are addressed at the right time, leading to both cost and time efficiencies and ultimately ensuring a swift speed to market.

SCALING FROM CLINICAL TO COMMERCIAL SUPPLY

With true customer focus and flexibility at the core of its drug-device assembly and packaging capabilities, PCI's device-agnostic technologies can adapt to the unique requirements of varying platforms and bespoke device requirements from concept to commercialisation. For example, its specialised clinical and low-volume commercial autoinjector assembly lines provide a multi-platform autoinjector solution with the added capability to assemble and label needle safety-system platforms, making it the ideal technology for development studies, clinical trials and niche orphan drugs.

Providing an integrated, scalable solution, PCI's mid-to-high volume commercial assembly technologies are also able to accommodate multiple drug-device combination product types at a larger scale for later-stage clinical programmes, product launch and ongoing commercial market supply. Supporting true customisation, its technologies can easily and cost-effectively be tooled for new autoinjector change parts, allowing PCI to respond quickly and efficiently to technological changes and future innovation.

"WITH TRUE CUSTOMER FOCUS AND FLEXIBILITY AT THE CORE OF ITS DRUG-DEVICE ASSEMBLY AND PACKAGING CAPABILITIES, PCI'S DEVICE-AGNOSTIC TECHNOLOGIES CAN ADAPT TO THE UNIQUE REQUIREMENTS OF VARYING PLATFORMS AND BESPOKE DEVICE REQUIREMENTS FROM CONCEPT TO COMMERCIALISATION."

	Phase I	Phase II	Phase III	Launch	Commercial
Pharmaceutical & Analytical Development	● ●	● ●	● ●	● ●	● ●
Sterile Fill-Finish Vials	● ●	● ●	● ●	● ●	● ●
Sterile Fill-Finish PFSs	● ●	● ●	● ●	● ●	● ●
Sterile Fill-Finish Cartridges	● ●	● ●	● ●	● ●	● ●
Drug-Device Combination Product Final Assembly & Testing	● ●	● ●	● ●	● ●	● ●
Clinical Labelling & Packaging	● ●	● ●	● ●		
Commercial Labelling & Packaging				● ●	● ●
Storage & Distribution	● ●	● ●	● ●	● ●	● ●

Table 1: Availability of PCI's services (● US, ● EU).

STRATEGIC INVESTMENTS TO MEET GLOBAL DEMAND

Guided by delivering flexible, future-ready solutions that empower its clients to meet patient needs, PCI continues to make strategic investments to expand its global sterile fill-finish, device assembly, testing and packaging network (Table 1).

San Diego, CA, US

PCI has acquired of Ajinomoto Althea, a CDMO with proven expertise in clinical and commercial sterile vial, PFS and cartridge filling. This strategic acquisition has expanded PCI's capabilities, capacities and technologies, including isolator-based syringe filling lines for the aseptic manufacturing of biologics, including messenger RNA, monoclonal antibodies, lipid nanoparticles, oligonucleotides, peptides and other complex modalities. This increased capacity can fulfil the needs for traditional PFSs and PFSs with advanced needle safety-system technologies, as well as PFSs for autoinjectors.

León, Spain

Strengthening PCI's clinical-to-commercial-scale PFS filling solutions in Europe is another important step and, as part of a US$25 million (£19 million) investment plan, it is investing in new high-speed isolator-based PFS and cartridge technology at its European sterile fill-finish facility in León. The new fully automated PFS filling technology can deliver up to 12,000 units per hour, with a maximum batch size of 300,000 syringes.

Ireland

In 2024, PCI acquired a 90,000 sqft pharmaceutical packaging facility in Dundalk providing commercial-scale injectable drug-device assembly and packaging together with ambient and

refrigerated storage. Continuing the expansion, a new 80,000 sqft facility at its CityNorth campus in Stamullen is nearing completion. This facility will add further final assembly, labelling and packaging capacity for vials, PFSs and drug-device combination products, including autoinjectors and pens.

Rockford, IL, US

In the US, PCI's infrastructure investment includes two new large-scale facilities at its Rockford campus. These state-of-the-art facilities will house over 25 dedicated suites with multi-format lines for clinical- and commercial-scale assembly and packaging of PFSs, autoinjectors, vials and pen-cartridge combinations. They incorporate extensive ISO-standard product-testing capabilities and premium top-load carton technology.

With the aim of accelerating advanced drug delivery and drug-device combination products through clinical trials to commercialisation as efficiently and cost-effectively as possible, one facility will support the whole development lifecycle, from clinical to commercial final assembly and packaging, of an injectable drug product under one roof. This approach combines efficiencies and streamlines drug product journeys from their clinical stages through launch and commercialisation. Both facilities will be GMP ready early 2026.

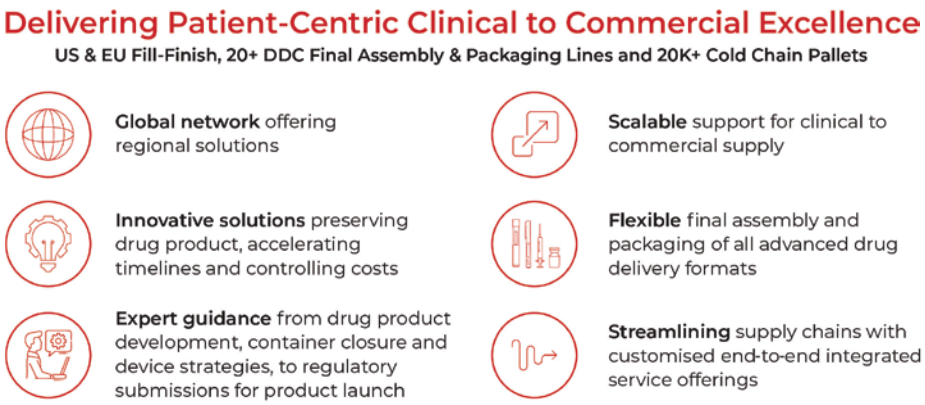

Figure 2: PCI's value-added service offering.

SEAMLESS, ACCELERATED SUPPLY CHAIN SOLUTIONS

PCI's highest priority is ensuring that life-changing medicines reach those who need it most. As an integrated global CDMO, it is an expert in manufacturing, packaging and supply chain considerations, harnessing its experience and expertise to deliver seamless solutions (Figure 2). PCI provides sterile fill-finish and lyophilisation solutions from development to commercialisation, together with custom assembly, testing and packaging solutions for sterile injectables in unified, integrated environments. This approach allows for streamlined knowledge sharing and communication between teams, ensuring that the drug-device combination product packaging is optimised for product, patient and production.

Supporting a quick-to-patient supply chain, PCI's scalable, device-agnostic technologies, coupled with its extensive, readily available assembly and test tooling for the most common device platforms, removes the need for a lengthy project lead time of up to six months for new tool sets and provides significant time and asset cost savings. With in-house laboratories, it provides a range of packaging and analytical services to support development projects, as well as the clinical and commercial supply of medicines globally.

From product ID testing, method transfer, release and stability testing, through functional autoinjector system testing, to ISO standard testing to assess key performance metrics such as cap removal force, activation force, dose accuracy and injection time, PCI ensures that its clients' therapies meet regulatory guidelines and are ultimately safe for patient use. PCI offers expertise and solutions tailored to the unique demands of its customers' development programmes and the patients they serve. Its integrated solutions for drug delivery, comprehensive approach and dedication to excellence positions it as a leader in this rapidly evolving industry.

Justin Schroeder

Justin Schroeder is the Global Vice-President of Technical Services at PCI. Mr Schroeder is responsible for ensuring PCI's global clients realise seamless lifecycle management and successful commercialisation of their therapies. Across over 25 years of experience in outsourced pharmaceutical services, he has held leadership roles in various functional disciplines in global roles including package engineering and design development, project and programme management, marketing, business development and progressive roles in senior executive leadership. In his current role, Mr Schroeder leads various functional disciplines in the creation and application of innovation solutions for clients with a focus on optimised drug delivery systems for patients, adaptive supply chain architecture and strategies for short- and long-term lifecycle management.

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Gerresheimer is an innovative system and solution provider and global partner for the pharma, biotech and cosmetics industries. The company offers a comprehensive portfolio of pharmaceutical packaging, drug delivery systems, medical devices and digital solutions. Gerresheimer ensures the safe delivery and reliable administration of drugs to the patient. With around 13,600 employees and over 40 production sites in 16 countries, Gerresheimer has a global presence and produces locally for regional markets.

To learn more, see **Page 78**

GORE

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W. L. Gore & Associates is a global materials science company that solves complex technical challenges in demanding environments – from space to the human body. Founded in 1958, Gore fosters a team-oriented culture with about 13,000 Associates and generates US$5.3 billion (£4 billion) in annual revenue.

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GRAND RIVER
ASEPTIC MANUFACTURING

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Grand River Aseptic Manufacturing (GRAM) is a pharmaceutical contract development and manufacturing organisation providing fill-finish services for liquid and lyophilised vials, syringes and cartridges. GRAM's syringe and cartridge technology and drug delivery partnerships place it at the forefront of client value delivery and pharmaceutical manufacturing services.

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INSTRON

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Instron manufactures and services a wide range of mechanical testing equipment used in the design and production of drug delivery devices. A strategic partner to global companies of all sizes, Instron helps its partners investigate new technologies and ensure product quality while maintaining the highest levels of data integrity and security.

To learn more, see **Page 48**

KERN LIEBERS
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KERN LIEBERS is a medium-sized family business headquartered in southwestern Germany. Its Smart Springs and Smart Parts are intelligent functional components developed to meet the highest technical requirements and deliver maximum functionality. Each spring and each part not only fulfills a specific task – it also assumes responsibility for the functionality and reliability of the entire system at over 40 locations worldwide.

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Nipro Pharma Packaging specialises in developing and manufacturing advanced pharma packaging products and complete packaging solutions for early development drugs or the enhancement of packaging solutions for existing drugs.

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OWEN MUMFORD
Pharmaceutical Services

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Owen Mumford is a medical device manufacturer that develops products for its own brand and custom device solutions for pharmaceutical and diagnostic companies. Owen Mumford provides research, design and manufacturing capabilities for device production.

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pci
PHARMA SERVICES

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PCI Pharma Services is a global contract development and manufacturing organisation that provides integrated end-to-end drug development, manufacturing and packaging solutions to increase product speed to market and opportunities for commercial success. PCI's experience includes more than 90 successful product launches each year and over five decades in the delivery of supply chain healthcare services.

To learn more, see **Page 118**

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Probotec engineers and builds industrial automation systems; designing, integrating and installing robotics, PLC programming, offline simulation and traceability data systems to automate manufacturing processes. This includes robot-controlled assembly, handling and quality tracing on production lines, improving precision, repeatability and data capture in regulated environments.

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Sebastian Block
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SCHERDEL is a global, family-owned and ISO 13485 certified manufacturer of customised spring and stamping solutions, supported by advanced numerical simulation, ISO 7 cleanroom processing and patented detangling systems. With a long history of innovation and continuous expansion, SCHERDEL provides reliable, local-to-local support for drug delivery device markets worldwide.

To learn more, see **Page 72**

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Shaily specialises in the design and manufacturing of high-quality pen injectors, autoinjectors and drug delivery devices for the pharmaceutical and medical device sectors. With a commitment to innovation and precision, Shaily provides advanced drug delivery solutions that enhance patient care and meet the stringent requirements of the global healthcare industry.

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SMC Ltd is a global contract manufacturer for the pharmaceutical, medical device and diagnostics industries. With over 35 years of experience, SMC specialises in "end-to-end" integrated solutions for clinical and commercial manufacturing of drug delivery combination products. SMC's services include device development, manufacturing, automation, fill-finish and more.

To learn more, see **Page 94**

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As Part of **Terumo Medical Care Solutions**, the Pharmaceutical Solutions Division develops patient-oriented parenteral delivery solutions for therapeutic performance and safety. Terumo's expert teams lead the industry in developing and manufacturing advanced, high-performing infusion and injection technologies, including contract development and manufacturing organisation services for all parenteral applications.

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tip-top specialise in the design and development of Proprietary sharps protection technology for out-licensing to the medical and pharmaceutical sectors and has amassed a large portfolio of patents relating to standalone safety needles and integrated needlestick protection systems for prefillable syringes.

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ZwickRoell is a materials testing system developer and manufacturer. The company develops and manufactures both the load frames and all main components itself. With 15 product groups and testing solutions for more than 20 industries, as well as support from the company's approximately 1,900 employees representing over 50 countries, ZwickRoell is an expert partner in the field of materials testing.

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OUTSTANDING SPONSOR

West Pharmaceutical Services is a provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps ensure the safe, effective containment and delivery of life-saving and life-enhancing medicines. With over 10,000 team members across 50 sites worldwide, West helps support its customers by delivering approximately 43 billion components and devices each year.

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KEY SPONSOR

Ypsomed is a leading developer and manufacturer of self-injection systems for liquid medications, offering the most comprehensive and innovative platform portfolio for pens, autoinjectors, and on-body devices. Backed by a proven track record of over 40 years, Ypsomed's tailored solutions are delivered with best-in-class execution and ready to integrate with digital health services. Ypsomed is headquartered in Burgdorf, Switzerland, employing more than 2,000 people worldwide.

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KEY SPONSOR

SHL Medical designs, develops and manufactures self-injection solutions, such as autoinjectors, pen injectors and specialty delivery systems for large-volume and high-viscosity formulations. By partnering with leading pharma and biotech companies, SHL Medical will continue to develop and supply products and services to support, engage and oversee patients whose quality of life relies on innovative self-treatment therapies.

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BAUMANN Group, headquartered in Switzerland and employing around 1,400 people across nine countries, manufactures over 4.8 billion springs, stampings and bendings annually – approximately 152 per second. Baumann Medical, an independent division within the group, provides tailor-made solutions and services in medical devices at ISO 13485 certified sites, addressing the specific needs of the medical and pharmaceutical industries.

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To learn more, see **Page 101**

BBS Automation is an automation provider with 2,500 employees in 20 sites worldwide, offering a broad range of solutions, including assembly, testing, winding, insertion and take-out technology, feeder and palletising systems. Serving the mobility, medtech, consumer goods, new energy and electronics industries, BBS delivers solutions from a single source, at sites across Europe, North America and Asia. BBS is part of the Dürr Group.

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As a partner of choice for pharmaceutical and biotech companies across the globe, **BD Medical – Pharmaceutical Systems** provides a broad range of parenteral drug delivery systems including prefillable syringes, safety and shielding systems as well as advanced drug delivery solutions that help ensure pharma meets its drug delivery goals while considering drug complexity, viscosity and dosing volume.

To learn more, see **Page 58**

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Cambridge Consultants develops breakthrough products and services, creates intellectual property and provides business consultancy in technology-critical issues. With over 800 staff, including engineers, scientists, mathematicians and designers, and offices in Cambridge (UK), Boston, Tokyo and Singapore, Cambridge Consultants offers solutions in healthcare, digital health, medical technology, biotech and multiple other industries.

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Contexo is a family-run mechanical engineering company based in Germany that specialises in building high-performance assembly machines. Most of Contexo´s machines process plastic parts with sizes of up to 500 cm^3 and can handle over 80 production processes. In the medical device sector, Contexo focuses on primary packaging and diagnostic products, as well as contract manufacturing services.

To learn more, see **Page 64**

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Credence MedSystems solves challenges in parenteral drug delivery. Its philosophy of Innovation Without Change preserves existing processes and primary package components. Companion includes needle-retraction, reuse prevention and usability features. The Dual Chamber platform simplifies delivery requiring reconstitution or sequential delivery. The Metered Dosing lineup enables precise microdosing in ophthalmics and aesthetics.

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Roelant Storms
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Datwyler engineers high-quality, system-critical elastomer components. From initiating development to scaling production to second sourcing, Datwyler delivers hands-on consultation and a wide range of solutions for vials, pre-filled syringes, cartridges, autoinjectors and on-body devices.

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Daré Bioscience is a purpose-driven health biotech company focused solely on closing the gap in women's health between promising science and real-world solutions. Across contraception to menopause, pelvic pain to fertility, vaginal health to infectious disease, it swaps silence for serious science, turning what has been invisible, solvable.

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DCA is a product design consultancy with a wealth of experience developing leading drug delivery devices for global markets, including all types of injection, infusion, inhalation, intranasal, oral and topical devices. DCA provides comprehensive, expert support for device design and development, including strategy, usability, connectivity, engineering, electronics, medical device software and industrialisation.

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EdgeOne Medical is a global contract device development organisation (CDDO) that supports the compliant device development and testing of combination products. EdgeOne Medical has a combination of multidisciplinary product development experts combined with in-house ISO 13485 certified testing labs. These capabilities provide clients with a partner that has a successful track record of derisking, navigating and accelerating device development programmes.

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