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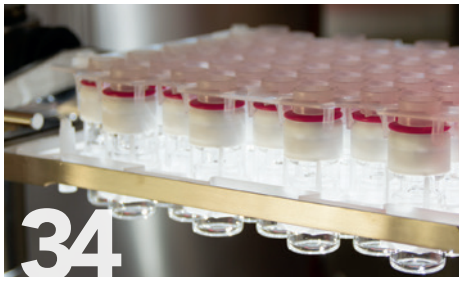

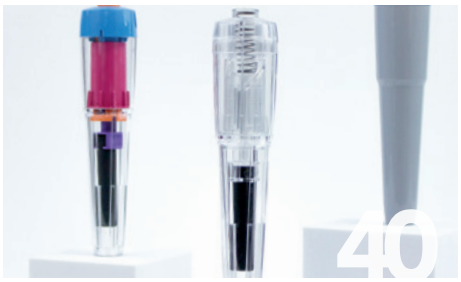

SUSTAINABILITY IN DRUG DELIVERY

ONdrugDelivery Issue N° 185, April 27th, 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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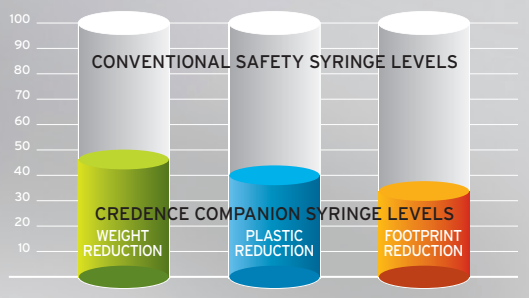

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Making Sustainability Work:

The Practicalities and Potential of the Green Revolution

Sustainability is a key topic for any company considering its strategic goals for the next decade and beyond. With increasing pressure coming from regulators, consumers and industry peers, the pharmaceutical sector is no exception to this trend. In this issue of ONdrugDelivery, we dig into the progress and potential of sustainability within the drug delivery world and consider how sustainability need not be seen as an obstacle to be overcome, but instead as an opportunity that goes hand-in-hand with, and often prompts, better solutions.

Leading the issue, we look to one of the key sustainability topics in drug delivery today – pressurised metered dose inhaler (pMDI) propellants. Providing insight into the practicalities and realities of the pMDI propellant switch, and why pMDIs are worth the effort, we hear from **Orbia Fluor & Energy Materials**, the developer and manufacturer of one of the leading low-global-warming-potential propellants (Page 8), and **Aptar Pharma**, a key player in adapting these devices to work with these new propellants (Page 14).

Moving to a broader perspective, the discussion then turns to the principles of sustainable design across the industry. Opening this run of articles, **Pharmacentric Solutions** provides an overview of the challenges and opportunities inherent in a more unified Design for Sustainability initiative (Page 20) and, in an exclusive interview with Guy Furness, Prof Hanns-Christian Mahler of **ten23 health** talks about the role of CDMOs and why forward-looking companies should take sustainability beyond the bare minimum mandated by current regulations (Page 26). Following on, **Jabil** makes the case for integrating sustainability metrics as a core input parameter of device designs (Page 29) and **ARaymond** goes into detail about the development of its eco-designed packaging nest – RayDyLyo® (Page 34).

In the next part of this issue, the focus shifts towards sustainable materials, with **Covestro** kicking off this section with an analysis of the role of single-use devices and how different materials can unlock the potential for recycling in the industry (Page 40). **Ypsomed** then dives into bio-based plastics, and how they have been incorporated into the company's new product developments (Page 46). Lastly, turning our attention to the later stages of development, **Sanner** then considers the challenges and possible best practices for pivoting material choice towards more sustainable alternatives late in the development cycle (Page 52).

Our closing articles then consider sustainability strategies. First, **Vetter** considers how a holistic approach at the operational level is key for CDMOs looking to make productive investments into improving their sustainability – something that partners are increasingly demanding (Page 56). **Owen Mumford** then rounds out the issue with a deep dive into lifecycle assessments, putting forward that their potential can be enhanced by transforming them from one-off analyses to a living, real-time tool for product development and a foundation for standardisation across the industry (Page 60).

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GWP, global warming potential; **HFA**, hydrofluoroalkane; **HFO**, hydrofluoroolefin; **pMDI**, pressurized metered dose inhaler.

Expert View

ENABLING A SUSTAINABLE FUTURE FOR pMDIs WITH LOW-GWP MEDICAL PROPELLANTS

Markus Laubscher of Orbia Fluor & Energy Materials discusses the role of pressurised metered dose inhalers in the context of healthcare's drive towards sustainability, considering the need for lower-global-warming-potential propellants and why it is important to preserve these inhalers as a key aspect of respiratory care.

"AS HEALTHCARE SYSTEMS WORK TOWARDS AMBITIOUS DECARBONISATION TARGETS, pMDI PROPELLANTS HAVE BECOME A FOCUS FOR SUSTAINABILITY EFFORTS ACROSS THE RESPIRATORY ECOSYSTEM."

Sustainability is rapidly becoming one of the defining challenges for the pharmaceutical industry. Healthcare systems around the world are working to reduce their environmental impact while maintaining – and ideally improving – patient outcomes. Globally, healthcare is responsible for an estimated 4.4% of greenhouse gas emissions,[1] highlighting the scale of the challenge facing the sector.

Pressurised metered dose inhalers (pMDIs) remain one of the most widely used and clinically important drug delivery systems for asthma and chronic obstructive pulmonary disease (COPD). They are portable, reliable, relatively inexpensive and familiar to both patients and healthcare professionals. For many patient groups, including children, older adults and those experiencing acute exacerbations, they remain the most appropriate delivery platform.

However, pMDIs are also facing increasing scrutiny because of the propellants that enable their function. Historically, these devices have relied on hydrofluorocarbons (HFCs), such as HFC-134a and HFC-227ea, which have high global warming potentials (GWPs). As healthcare systems work towards ambitious decarbonisation targets, pMDI propellants have become a focus for sustainability efforts across the respiratory ecosystem.

The industry is now moving beyond the question of whether change is needed to how it can be delivered without compromising patient care. Low-GWP propellants, which have now been accepted and are being implemented, provide a clear path to achieving this, enabling more sustainable pMDIs while preserving clinical performance and patient access.

THE GROWING URGENCY OF SUSTAINABLE RESPIRATORY CARE

The intersection of climate change and respiratory health is undeniable. Rising global temperatures, more frequent wildfires and worsening air pollution are all contributing to increasing rates of respiratory disease. Air pollution alone is responsible for an estimated 8.1 million premature deaths globally each year,[2] with respiratory disease among the leading causes. Climate change is also altering pollen seasons, thereby increasing allergen exposure, and contributing to more frequent wildfire smoke events, all of which can exacerbate asthma and other respiratory conditions.

Chronic respiratory diseases already affect hundreds of millions of people worldwide. Asthma impacts more than 260 million people globally,[3] while COPD affects an estimated 400 million people and remains one of the leading causes of death worldwide.[4] At the same time, healthcare systems are under increasing pressure to reduce their own environmental footprints.

Amidst this, pMDIs have emerged as a focal point in sustainability discussions because of their widespread use and measurable carbon footprint – in the UK, they account for around 3% of the UK NHS' carbon footprint.[5] Lifecycle assessments consistently show that the propellant released during pMDI use accounts for over 90% of a pMDI's greenhouse gas emissions.[6] This has prompted the industry to explore alternative approaches that can preserve the clinical advantages of pMDIs while reducing their environmental impact.

DPIs: AN IMPORTANT OPTION, BUT NOT A UNIVERSAL SOLUTION

Dry powder inhalers (DPIs) are often highlighted as a lower carbon alternative because they do not require propellants. From an emissions perspective, lifecycle assessments show that low-GWP pMDIs can dramatically reduce their carbon footprint, bringing them into a similar range to DPIs. One study reported emissions of approximately 2.06 kg CO_2-equivalent (CO_2e) for a low-GWP pMDI compared with 0.69 kg CO_2e for a DPI.[7]

However, respiratory care is rarely a one-size-fits-all scenario. DPIs rely on the patient generating sufficient inspiratory flow to effectively disperse the powder formulation, which can present challenges for certain patient groups, including young children, older adults and those experiencing severe respiratory distress.

Importantly, incorrect use and the resulting poor disease control can lead to exacerbations requiring medical intervention. These events carry a significant environmental burden, driven by hospital visits, emergency care and additional treatments. Studies have also shown that errors in DPI use remain common, with reports of incorrect technique in up to 76% of patients, potentially reducing treatment effectiveness.[8]

"CLINICAL GUIDELINES EMPHASISE THE IMPORTANCE OF SELECTING INHALER DEVICES BASED PRIMARILY ON PATIENT CAPABILITY AND CLINICAL NEED."

Figure 1: pMDIs containing low-GWP propellants will soon be available on the market.

For this reason, clinical guidelines emphasise the importance of selecting inhaler devices based primarily on patient capability and clinical need. While DPIs play a vital role in respiratory therapy, they cannot replace pMDIs across all patient populations and treatment scenarios. As a result, the long-term viability of respiratory care will depend on maintaining a diverse range of inhaler options.

THE REALITY OF LOW-GWP PROPELLANTS

The strategy for reducing the environmental impact of pMDIs is the development of low-GWP propellants. These propellants are no longer theoretical or under investigation – products are being manufactured today and are expected to be introduced to the market imminently (Figure 1).

Among the available options, HFC-152a has emerged as a particularly compelling solution, alongside other medical propellants, such as HFO-1234ze(E). Compared with traditional propellants like HFC-134a, both HFC-152a and HFO-1234ze(E) offer a dramatically lower GWP while maintaining the physical and performance characteristics required for effective aerosol delivery.

Lifecycle analyses suggest that pMDIs formulated with HFC-152a can achieve reductions in the carbon footprint of the medical propellant of 90% compared with conventional devices containing HFC-134a.[9] Crucially, this reduction can be achieved while preserving the familiar device format that patients and clinicians already understand.

From a healthcare perspective, this continuity matters. Device switching can introduce challenges related to patient education, adherence, and pMDI use and technique. By retaining the fundamental operating principles of pMDIs, low-GWP propellants offer the possibility of significant environmental improvement without fundamentally altering the patient experience.

TECHNICAL AND REGULATORY CONSIDERATIONS

Despite their promise, introducing new propellants into pMDIs is far from straightforward. pMDIs are combination products in which the device, formulation and propellant must function together in a carefully balanced system. Extensive development, safety, toxicology, stability testing and regulatory engagement have been successfully carried out, enabling the first low-GWP propellants to reach the point of commercial introduction (Figure 2).

Manufacturing infrastructure considerations, including adjustments to filling lines, storage systems and safety protocols, have also been addressed by early adopters (Figure 3). Additionally, regulatory frameworks have been navigated with robust clinical and analytical data demonstrating equivalence in safety, quality and therapeutic performance. As a result, several pharmaceutical companies are now on the verge of introducing low-GWP pMDIs to the market, while others will need to accelerate their efforts to keep pace with this transition.

Figure 2: 5 L bulk suspension/solution manufacture with HFA-152a in ATEX-rated equipment.

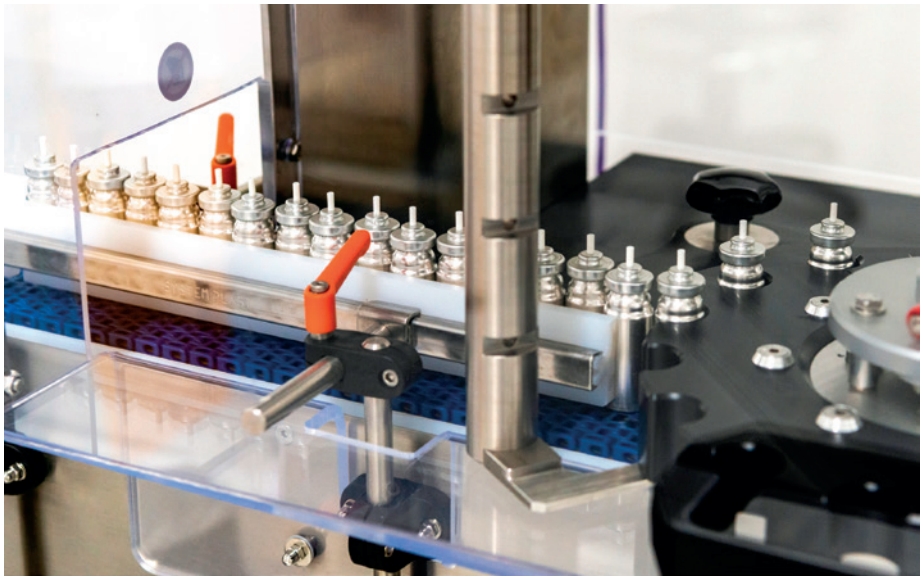

Figure 3: A semi-automated check-weigher, which enables a 100% check that all pMDI units are filled to the correct specification. Any out-of-specification pMDI units are automatically rejected.

DELIVERING SUSTAINABILITY WITHOUT COMPROMISE

Respiratory disease is already a major challenge for global healthcare, and demand for effective treatments will continue to grow. Ensuring that patients can retain access to reliable and clinically appropriate pMDI options must remain the industry's priority.

Simultaneously, the healthcare sector has a responsibility to contribute to global climate goals. The development of low-GWP propellants demonstrates that meaningful environmental progress can be achieved without sacrificing the clinical strengths that have made pMDIs indispensable for millions of patients.

By investing in innovation, supporting collaboration across the respiratory care ecosystem and maintaining a patient-centric approach, the pharmaceutical community has an opportunity to reshape the future of inhaled drug delivery. The transition to lower-GWP propellants is not simply an environmental initiative – it represents a crucial step towards ensuring that respiratory care remains both clinically effective and environmentally sustainable for generations to come.

"THE DEVELOPMENT OF LOW-GWP PROPELLANTS DEMONSTRATES THAT MEANINGFUL ENVIRONMENTAL PROGRESS CAN BE ACHIEVED WITHOUT SACRIFICING THE CLINICAL STRENGTHS THAT HAVE MADE pMDIs INDISPENSABLE FOR MILLIONS OF PATIENTS."

ABOUT THE COMPANY

Orbia's Fluor & Energy Materials (F&EM) business is a global developer, manufacturer and supplier of the fluoroproducts that play a fundamental role in enhancing everyday lives and shortening the path to a sustainable, circular economy. Backed by over 35 years of experience, Orbia F&EM products are used in a vast range of applications, including electric vehicles and energy storage, urban and rural infrastructure, indoor climate management, food and medicine refrigeration, and in treating respiratory conditions through the development of healthy and innovative low-GWP propellants for pMDIs. Orbia F&EM has 1,700 employees and eight manufacturing facilities worldwide, serving 60 countries through a global sales and distribution network.

Markus Laubscher

Markus Laubscher is Head of the Pharma Business Unit within Orbia F&EM, driving the innovation, delivery and low-GWP transition within the area of medical propellants for respiratory therapies. Driven by Orbia's purpose to improve outcomes for patients and the planet, he helps shape the future of propellants and their responsible use across the respiratory pharmaceutical industry. With Orbia's long-standing legacy in respiratory innovation, Mr Laubscher is at the forefront of the transition to next-generation, low-GWP propellants, set to redefine respiratory treatment and reduce environmental impact across the sector.

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REINVENTING THE pMDI: EVOLVING A PROVEN PLATFORM FOR A LOW-GWP FUTURE

Aptar pharma

Chris Baron of **Aptar Pharma** discusses how lower-global warming potential pressurised metered dose inhalers are moving from development to commercialisation and explains why manufacturing readiness and supply resilience are critical, going on to introduce Aptar Pharma's ZEN30 Futurity®, designed to anticipate current and emerging regulatory expectations.

For more than half a century, pressurised metered dose inhalers (pMDIs) have been a cornerstone of respiratory care, delivering life-saving therapies to hundreds of millions of patients worldwide.[1] Their proven performance, affordability and ease of use have made pMDIs a trusted mainstay for patients and healthcare systems alike, particularly in acute and rescue settings, where reliability and familiarity are essential.[2]

Over time, the platform has demonstrated an exceptional ability to evolve, adapting to regulatory changes and advancing scientific understanding. Today, healthcare systems are facing growing pressures to meet sustainability commitments, and turning their attention towards the environmental impact of drug delivery systems. For pMDIs, this focus is driving a transition towards lower-global warming potential (GWP) propellants, offering a meaningful opportunity to reduce their carbon footprint.[2]

> "HEALTHCARE SYSTEMS ARE FACING GROWING PRESSURES TO MEET SUSTAINABILITY COMMITMENTS, AND TURNING THEIR ATTENTION TOWARDS THE ENVIRONMENTAL IMPACT OF DRUG DELIVERY SYSTEMS."

Figure 1: Low-GWP pMDIs support environmental progress while meeting patient needs.

While its implications are far-reaching, this shift is not about replacing a trusted platform but deliberately evolving it. Successfully navigating this transition requires innovation across formulation, device design and manufacturing, alongside a focus on de-risking development and preserving continuity of care. With the right expertise and integrated support, low-GWP pMDIs can deliver meaningful environmental progress while maintaining the standards that patients and healthcare systems depend on (Figure 1).

THE NEXT CHAPTER IN THE EVOLUTION OF pMDIs

While incremental regulatory milestones have guided pMDI innovation, the most significant shift came with the introduction of the Montreal Protocol. This landmark treaty aimed to phase out harmful greenhouse gases, including chlorofluorocarbons (CFCs), which were widely used in pMDIs at the time. This change catalysed the development of alternative propellants based on hydrofluoroalkanes (HFAs), demonstrating that the platform could evolve while maintaining continuity of care for patients worldwide.[1]

In 2016, the Montreal Protocol was amended to recognise that HFAs are themselves greenhouse gases, prompting the need for new low-GWP solutions.[2] At the same time, regulatory frameworks continue to advance, including a global movement towards restricting per- and polyfluoroalkyl substances on the horizon, shaping expectations around material selection.[3] These pressures are compressing development timelines and adding complexity to innovations, setting the stage for the next generation of pMDIs.

WHY pMDIs STILL MATTER IN GLOBAL RESPIRATORY CARE

Despite the growth of alternative inhalation technologies, pMDIs remain indispensable in global respiratory care. Their continued relevance is rooted in a combination of patient reliance, global accessibility enabled by large-scale manufacturing capacity, cost effectiveness and practical advantages that alternative technologies have yet to match at scale.[2]

For patients, familiarity and preference matter. pMDIs are deeply embedded in real-world disease management, particularly for rescue medications where confidence and ease of use are critical. This is especially true for paediatric and elderly populations, as well as for patients managing acute exacerbations.[2,4]

From a healthcare system perspective, pMDIs remain among the most cost-effective and scalable inhalation solutions available. They have global access, including in regions where alternative devices may be less practical due to cost, infrastructure or supply constraints.[2,4]

While innovation in inhalation therapy continues, replacement of a specific drug delivery technology is not always the optimal solution. For many therapies and patient populations, evolving the pMDI platform offers the most realistic and effective pathway to reducing the healthcare sector's CO_2 footprint, while ensuring both clinical continuity and patient access.[2]

LOW-GWP PROPELLANTS AS A CATALYST FOR INNOVATION

To advance the evolution of the pMDI platform, two next-generation low-GWP propellants, HFA152a and HFO1234ze, have emerged as viable solutions. These propellants offer a reduction in GWP of more than 90% compared with current propellants, supporting industry-wide emission reduction commitments.[2]

While low-GWP propellants enable meaningful reductions in environmental impact, they also introduce technical considerations that ripple across the pMDI system. Differences in vapour pressure, density and solvency between legacy propellants and low-GWP propellants influence multiple aspects of inhaler performance,[2,5,6] including:

- Formulation stability and excipient interactions, which can affect dose uniformity and shelf life
- Aerosol generation and spray characteristics, with potential implications for lung deposition and patient experience
- Extractables and leachables risk linked to device–material interactions, particularly at the level of the metering valve, elastomers and seals
- Manufacturing and filling requirements, including safe handling of flammable materials and ATEX considerations.

These changes make it clear that low-GWP reformulation is not as simple as substitution. Instead, it acts as a catalyst

"FOR MANY THERAPIES AND PATIENT POPULATIONS, EVOLVING THE pMDI PLATFORM OFFERS THE MOST REALISTIC AND EFFECTIVE PATHWAY TO REDUCING THE HEALTHCARE SECTOR'S CO_2 FOOTPRINT."

for innovation, prompting a reassessment of components that were originally designed around different propellant chemistries.

EVOLVING THE VALVE TO ENABLE THE NEXT GENERATION: ZEN30 FUTURITY®

At the centre of the pMDI system is the metering valve – the interface and engine between device, formulation and patient. Legacy valves were developed for the physicochemical properties of traditional HFAs, and relying on these designs for low-GWP propellants can increase development risk.

ZEN30 Futurity® represents a deliberate redesign of the metering valve, purpose-built to perform reliably with the new low-GWP propellants (Figure 2). Rather than adapting existing designs post hoc, the valve was engineered from the outset to address the challenges introduced by new propellant chemistries.

Figure 2: The ZEN30 Futurity® is Aptar Pharma's pMDI valve, designed and optimised for low-GWP formulations.

"DESIGNED WITH PATIENTS IN MIND, ZEN30 FUTURITY® PRESERVES FAMILIAR INHALER ARCHITECTURE AND DELIVERY CHARACTERISTICS."

Designed with patients in mind, ZEN30 Futurity® preserves the familiar architecture and delivery characteristics of pMDIs. This supports continuity of use by minimising changes in patient technique, reducing retraining needs and maintaining confidence in dose delivery. Additionally, carefully selected polymers and elastomers reduce the extractables and leachables risk, while robust moisture-barrier performance protects formulation stability, helping to safeguard not only formulation integrity but also patient safety in real-world environments.

DE-RISKING THE TRANSITION WITH CONFIDENCE AT EVERY STEP

For pharmaceutical companies, transitioning to low-GWP pMDIs introduces interconnected challenges across formulation, device design, manufacturing and regulation. Addressing these challenges in isolation can increase uncertainty and prolong development timelines. Instead, successful transitions rely on an integrated approach that manages risk across the entire pMDI system – not only for today's requirements but with an eye towards what comes next.

Aptar Pharma brings decades of pMDI expertise to support this transition, combining valve design leadership with deep formulation, analytical and regulatory capabilities. From the outset, ZEN30 Futurity® was developed to anticipate both current and emerging regulatory expectations, including from the European Chemical Agency, helping pharmaceutical partners to avoid short-term solutions that could require redesign or revalidation later on. This future-focused, de-risking approach provides greater design certainty as sustainability programmes move forwards.

By enabling formulation and device development to progress in parallel, Aptar Pharma helps reduce trial-and-error and provides earlier insight into how changes in propellant chemistry may affect performance. Advanced development tools, such as Nanopharm's (Cwmbran, Wales) SmartTrack™ platform, integrate *in vitro* testing, *in silico* and computational fluid dynamics modelling, and physiologically based pharmacokinetic simulations. These capabilities allow potential performance changes to be anticipated earlier in development, supporting more informed decision-making and helping to avoid late-stage surprises that could impact development timelines or the patient experience.

This integrated approach extends beyond development into regulatory readiness and supply continuity. Aptar Pharma provides robust documentation packages, including combination product support, Article 117 dossiers and EU Medical Device Regulation-aligned materials, helping pharmaceutical partners to navigate evolving regulatory expectations with greater confidence.

Additionally, in-house elastomer manufacturing and end-to-end supply chain control help to protect quality, timelines and patient access as products scale towards commercialisation.

Together, these capabilities enable pharmaceutical partners to move forwards with greater certainty, accelerating the path to market for low-GWP pMDIs while maintaining product performance and reliability, long-term compliance and patient confidence.

"APTAR PHARMA BRINGS DECADES OF pMDI EXPERTISE TO SUPPORT THIS TRANSITION, COMBINING VALVE DESIGN LEADERSHIP WITH DEEP FORMULATION, ANALYTICAL AND REGULATORY CAPABILITIES."

Figure 3: ZEN30 Futurity®, a proven pMDI platform, evolving for the next generation.

SCALING THE NEXT GENERATION RESPONSIBLY

As low-GWP pMDIs move from development to commercialisation, manufacturing readiness and supply chain resilience become critical. Aptar Pharma addresses these considerations early. ATEX-rated R&D facilities enable safe mixing and filling of formulations that use flammable low-GWP propellants, supporting an accelerated and smooth progression from development to scale-up.

Supply chain resilience is reinforced through end-to-end control, from component manufacturing to global supply. This approach helps to ensure that the evolution of pMDIs remains practical, allowing global availability of essential respiratory therapies while minimising the risk of disruption (Figure 3).

A PROVEN PLATFORM, READY FOR ITS NEXT GENERATION

Each major shift in pMDI history has shown continuity through innovation, responding to new regulatory and sustainability realities without compromising performance or patient confidence. Rather than disrupting a trusted delivery platform, the transition to low-GWP propellants requires careful redesign and forward-looking materials.

Through the purpose-built design of the ZEN30 Futurity®, combined with development, regulatory and manufacturing expertise, Aptar Pharma enables pharmaceutical partners to move forwards with clarity and confidence. By preserving familiar pMDI architecture and consistent performance, the next generation of low-GWP inhalers is positioned to support patient confidence and healthcare system resilience, while contributing meaningfully to reduced environmental impact.

The pMDI platform has evolved before – and with the right expertise and foresight, it is ready to do so again.

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Expert View

CHALLENGES & OPPORTUNITIES TO OPTIMISE SUSTAINABILITY IN PHARMACEUTICAL PACKAGING & COMBINATION DEVICES

Greg Anderson of Pharmacentric Solutions discusses the need to improve the sustainability and circularity of pharmaceutical packaging and drug delivery devices, looking at the challenges and providing a clear outline of the potential opportunities for improvement.

"THE URGENT NEED TO IMPROVE SUSTAINABILITY IN MEDICINE PACKAGING IS DRIVEN BY THE CONVERGING PRESSURES OF CLIMATE CHANGE, GOVERNMENT POLICY AND INTERNATIONAL LEGISLATION."

Sustainability has increased in priority in the pharmaceutical and life science sectors as global health systems confront the environmental consequences of medical products across their entire lifecycle. Healthcare accounts for an estimated 4.4% of net global emissions, with pharmaceutical packaging and combination devices being significant contributors to this footprint, both in terms of material use and associated emissions.[1] Packaging is essential for ensuring product stability, sterility and patient safety, yet it also generates substantial waste and carbon output across global supply chains.[2] Combination devices, meanwhile, occupy a unique position as they are both a packaging and drug delivery system.

One platform, metered dose inhalers (MDIs), which rely on hydrofluorocarbon propellants, contribute disproportionately to healthcare-related greenhouse gas emissions and are recognised as a major sustainability concern. The industry is trying to tackle this by pivoting to low global warming potential (GWP) propellants, but there are many other opportunities in medicine packaging and devices to enhance sustainable solutions and begin to meet the sustainability targets set by global customers.

The urgent need to improve sustainability in medicine packaging is driven by the converging pressures of climate change, government policy and international legislation. Pharmaceutical manufacturers – and their suppliers – are facing growing scrutiny over their environmental performance,[3] as is the wider packaging industry. Retail is driving ongoing packaging material innovation that can advance pharma's sustainability ambitions.[4] Regarding sustainable packaging, pharma must work together to set global guidelines and support initiatives with its suppliers and stakeholders, including regulators, healthcare systems and patients. Solutions need to be piloted, refined and constantly updated as innovation opportunities are developed.

It is key to note that sustainability efforts must not compromise clinical performance. Any innovation or redesign of pharmaceutical packaging or combination products should preserve – and ideally enhance – drug stability, dose accuracy, usability and patient adherence. Achieving this balance requires integrating environmental science, materials engineering, human-centric design and pharmaceutical regulation. Understanding the importance of sustainability in this context is therefore essential for guiding innovation that is both environmentally responsible and clinically robust.

BACKGROUND

International sustainability frameworks, including the EU Green Deal, emerging US FDA guidance and the UK's exemplary NHS Delivering Net Zero initiative,[5] are accelerating the shift toward low-impact materials, circular-economy principles and transparent lifecycle reporting. The Ellen MacArthur Foundation Global Commitment is a "must read" for any packaging or device specifier and is a great opportunity to engage with sustainability as a subject.[6]

"IF FMCG MOVE AWAY FROM AN ESTABLISHED MATERIAL, SUCH AS PVC, THEN VOLUME WILL DROP CONSIDERABLY AND THIS WILL ULTIMATELY LEAD TO A HIGHER COST OF GOODS. THIS IS A REAL RISK FOR PHARMA IF IT FAILS TO KEEP UP."

The bottom line is that these policy drivers create both challenges and opportunities for pharmaceutical companies to innovate in packaging and combination device design (essentially all drug delivery platforms). Understanding this context is essential for evaluating the technical, regulatory and environmental constraints that shape sustainable product development. Considering these sustainability challenges, new ways of introducing sustainable design are needed, whilst still meeting established industry expectations, which include:

- All materials must have a known and tested provenance
- Delivery platforms must have consistent, proven and reliable performance
- Quality and safety standards must be met
- Patient use of packaging and devices must be validated and verified.

Those within the industry will be well aware of the regulations and standards that have to be adhered to during packaging and device development. These initiatives have evolved over time and are in place to improve patient safety and manufacturing efficiency, and include:

- Design For Manufacturing and Assembly
- Failure Modes and Effects Analysis
- Application of usability engineering to medical devices
- Quality by Design.

THE OPPORTUNITY

Building on these well-established initiatives, there is the opportunity now to add another: Design for Sustainability (DfS). This initiative would include pharma, component suppliers and manufacturers, healthcare providers and recyclers. DfS would be instructed by design guidelines that could be widened to become standard for the pharma industry.

DfS would go beyond competitive advantage – doctors do not choose a medicine because of the packaging. That said, MDIs are an example where device choice is being guided by sustainability concerns due to their high GWP.[7] This highlights the impact (and business cost) of ignoring sustainability. The switch away from MDIs may change with the introduction of lower GWP propellants.

With respect to pharma packaging materials, these have essentially always been an extension of materials used in the fast-moving consumer goods (FMCG) industry. Pharma typically diverts materials used by FMCG but specifies additional expectations around quality, performance and manufacturability – and pays extra for these enhanced specifications. For context, FMCG produced 427 million tonnes of packaging in 2025.[8] Pharma has an estimated annual production of 40 million tonnes for blisters and bottles. FMCG is not only driving sustainable solutions for material innovations but also introducing guidelines for pack "cradle-to-grave" use. If FMCG move away from an established material, such as polyvinyl chloride (PVC), then volume will drop considerably and this will ultimately lead to a higher cost of goods. This is a real risk for pharma if it fails to keep up.

With the high material volumes used, FMCG is under even more pressure to improve their sustainability targets and meet customer expectations, often driven by supermarkets and customers who have a choice of what they buy. It would be logical to follow where FMCG packaging has gone when setting industry standards and guidelines. Pharma can continue to learn from FMCG not only with sustainability specifications, but also with recycling. The one subtle difference here is that used FMCG packaging has well-established (and efficient) kerbside collection. Medicines packaging waste cannot have this, due to risks around safety, security and contamination. Traditionally, this has meant that pharma has not specifically designed or specified packaging (or devices) for recycling. It has now begun the journey to improve sustainability, but it will be crucial to take this to the next level and design for sustainability and recycling.

There is a huge opportunity for pharma to create its own platform guidelines by learning from FMCG's newly established guidelines. In the UK for example, RECOUP (Peterborough, UK) has partnered with material suppliers, recyclers and customers to create the Recyclability by Design guide,[9] which has many transferable recommendations that pharma can build recyclability strategies from, including:

- Use lifecycle analysis to create a measurable benchmark for design optimisation
- Use polymers that are easier to separate when recycling and understand sorting methods
- Use polymers that have a lower CO_2-equivalent burden (some are better than others)
- If additives are blended into a polymer to enhance performance, minimise them
- Avoid the use of pigments – use natural/clear material and use labels to differentiate branding/information (note that every medicine must be labelled)
- Labels should be polypropylene (PP)/oriented PP/high-density polyethylene (HDPE) – do not use metallised polymers
- Minimise label coverage (≤ 60%)
- Use water-releasable adhesives (needs temperatures of 60–80°C)
- Tamper-evident features – optimise materials and specify for recycling
- Use monomer components where possible, such as PP/HDPE/low-density polyethylene (LDPE)
- Replace PVC with better materials, such as ethylene vinyl alcohol (EVOH) for barrier properties or PP/polyethylene terephthalate (PET) for blister packs – the latter is gaining traction and is a game-changer
- If aluminium laminates must be used (for high barrier requirements), then make them lightweight and plan a recycling strategy (e.g. pyrolysis)

- Do not use biodegradable materials unless you can guarantee end-of-life recycling – landfilled biodegradable materials can create methane if uncontrolled, which is 23 times more harmful than CO_2 as a greenhouse gas.[10]

The above guidelines can be applied to combination devices, but also factor in other sustainable opportunities, such as:

- **Optimise Plastic Use:** Lightweighting not only minimises the material used – thin-wall moulding enables faster moulding cycle times. Use software tools to verify.
- **Use Design for Disassembly (DfD) Principles:** This is a newer concept but, as combination devices are developed for high-speed assembly (typically these are high-volume products), automation is common. Equipment manufacturers are now also being asked to provide disassembly machines during device development.
- **Minimise Device Size:** Designing compact devices not only makes them "pocket friendly" for the patient but also optimises packaging throughout the whole end-to-end supply chain.
- **Add Simple Features to Benefit Patient Use:** It is imperative that designers fully understand patient needs and incorporate these into any device design. Innovative ideas should also be sustainable. An example of this is taking the simple plastic MDI actuator and redesigning it to be more sustainable and also to offer patient benefits (Figure 1).

These are just a few of the opportunities that pharma – and, just as importantly, its suppliers – could incorporate into shared industry guidelines. If these guidelines are followed, recycling would become more efficient and effective. There is a certain amount of alignment between some pharma companies via the Pharma Manufacturing Forum Emission Reduction Memorandum.[11] This 2023 memorandum captures top-level acknowledgement that the industry has to work together and proposes initiatives for suppliers to report their emissions (primarily Scopes 1 and 2), but there is also the opportunity to detail Scope 3 Category 1 emissions (purchased goods and services). This is where DfS really counts and, if these are to be implemented, pharma must drive these opportunities together.

Figure 1: Redesigned sustainable MDI Actuator.

"THE SAD TRUTH IS THAT, CURRENTLY, MOST USED MEDICINE PACKAGING AND DEVICES END UP IN LANDFILL, CRUDELY CALCULATED TO BE BETWEEN 85–95%."

COMPLETING THE CIRCLE

Pharma packaging and device circularity is the ultimate goal for the industry. Making these components more recyclable is a major part of the challenge, and the opportunities highlighted above begin to make this more achievable. The major task is making disposal less linear and more circular. So, what currently happens to used medicine packaging and devices?

The sad truth is that, currently, most used medicine packaging and devices end up in landfill, crudely calculated to be between 85–95%. Note that early inhaler recycling pilots had a return rate of less than 1%.[12] The current choices for packaging and device disposal in the UK (and many other countries) are:

- **Landfill:** Unfortunately, this is where the vast majority of used packaging goes.
- **Incineration:** An option used in controlled healthcare systems.
- **Recycling:** To date, there is no national capability – this needs to change.

Landfill is the worst scenario. There is the key risk of contamination, as well as it offering no circularity. Incineration of medicinal waste is typically undertaken at defined high temperatures with very limited waste-to-energy usefully recovered, but it is better than landfill. The last option is recycling. This can offer circularity if managed well, and this route could ultimately be implemented by following the guidelines detailed above.

A major challenge with medical recycling is collecting used packaging efficiently. The inherent value of any medicine pack

is the medicine itself. As mentioned prior, used medicine packaging cannot make use of kerbside collection. Schemes proposing the use of postal services have come up against issues such as pack size (in that they may not fit through some letterboxes), security, cold chain requirements and cost. In the UK, a Ventolin (salbutamol, GSK) MDI costs £1.50, the alternative Ventolin dry powder inhaler (DPI) variant costs £1.99.[13] A second-class stamp to return these is £3.50. Any return strategy must be viable, robust, affordable and scalable.

With this in mind, many common chronic diseases typically require the patient or carer to return to the pharmacy for repeat prescriptions. This could be the ideal reverse-logistics opportunity to return used packaging and also for the pharmacist to ensure compliance – it is well known that 30–50% of medicines are not taken properly,[14] and poor adherence is never sustainable. Currently some injectors are returned in sharps bins for incineration, but this is not widely mandated. Historically, there have been take-back schemes for inhalers that have come and gone, with the reasons for poor uptake including lack of alignment, lack of ongoing communication strategies for all stakeholders and lack of viability due to low return rates.

A new national take-back scheme has recently started in the UK,[15] although, unfortunately, it currently only collects MDIs. The aluminium MDI aerosol cans have a high recycling rate and the plastic actuators can also be recycled (although plastics can only be reprocessed a limited number of times). Importantly, any residual propellant can be recovered and reused. With the new low-GWP propellants, this will still be a valuable capability. The scheme has the capacity to recycle 200,000 MDIs per day and the higher the volume returned, the more viable the scheme will be. The commercial success of this scheme will be worth following as such schemes do not come without running costs. Ideally, there should be the additional opportunity to extend it to other inhaler platforms – a key factor, as some patients have already switched to DPI devices for sustainability reasons. Furthermore, why not include injectors and other combination platforms? Expired EpiPens seem an ideal device to target.

> "PUT SIMPLY, RECYCLING ENABLES PACKAGING AND DEVICES TO USE MANDATED QUALITY MATERIALS THAT PERFORM TO EXACTING STANDARDS AND MEET CUSTOMER EXPECTATIONS ON SUSTAINABLY."

This obviously involves specialist recycling but, if the industry is to meet sustainability expectations, it has to think differently and turn words into actions. Put simply, recycling enables packaging and devices to use mandated, quality materials that perform to exacting standards and meet customer expectations on sustainably. It is achievable, proven and takes the industry towards device circularity.

FURTHER OPPORTUNITIES FOR ENHANCED SUSTAINABILITY

Device Training

As mentioned, adherence is a known ongoing issue, especially with combination device platforms.[16] Human factors testing and effective ergonomic design, coupled with clear instructions, can help to mitigate this risk. Effective training and training aids can help to optimise patient use,[17] especially with combination products. An associated training programme should be implemented with any new platform device development.

Patient Instruction Leaflets

It is mandatory to supply instructions for use (IFU) with every medicine pack. These should include clear recycling instructions for all packaging and device components. There is an opportunity to remove leaflets and use QR or serialisation codes. This could provide more in-depth information, which would in turn reduce pack size and manufacturing complexity. Patients without phone or internet availability could have the IFU printed in the pharmacy. Any updated leaflets would be rapidly available with this digitisation, a latent additional safety benefit. Trials with digital leaflets are already underway.[18]

Cartons

Typically, every medicine is supplied in a carton. These cartons are recycled via kerbside collection, and there is again the opportunity to add recycling information for all of the packaging and the device on the carton (following sustainable printing guidelines). There is also potential for innovation with cartons, such as the MDI Plus (MDI PLUS, Kildare, Ireland), which repurposes the MDI carton as a spacer (Figure 2). This has been shown to be clinically (and cost) effective and it is not only sustainable but also offers genuine patient access to optimised medicine delivery.

Cold Chain Packaging

With increasing global use of glucagon-like peptide-1 (GLP-1) injectors and vaccines, the demand for cold-chain storage is ramping up. This is inherently carbon-intensive because it relies on heavy insulation, refrigerants and single-use materials. Strict controls and standards have to be adhered to with the use of cold-chain materials, and there is again an opportunity to innovate. One such innovative

Figure 2: MDI Plus.

material is PluumoPlus (AEROPOWDER, Northampton, UK). This innovation uses bird feathers, which are repurposed into a proven, cost-effective and highly efficient thermal packaging solution suitable for life science applications.

Refillable Devices

Refillable devices are typically a more sustainable option. For example, capsule-based inhalers are both well established and clinically proven. However, capsules do need to be protected, so existing laminate materials are being replaced with more sustainable alternative packaging. Complex devices, such as Respimat by Boehringer Ingelheim, have transferred to a refill-based approach. Any refillable device should be simple to refill (proven through human factors testing), have a defined useable life, use minimal materials for the refill pack and be fully recyclable at end of life.

Electronics

Electronics are not easy to recycle. If they are to be used (and can be proven to enhance compliance), they should be reuseable and detachable. History has highlighted the challenges of using captive electronics in a combination device (e.g. DigiHaler by Teva) and consideration should be given to cost, regulations (e.g. the EU's Waste from Electrical and Electronic Equipment Directive), supply chain component complexity, software, robustness and potential battery risks.

Shelf Life

Medical products must offer a minimum shelf life. With complex and extended supply chains, medicines run the risk of having to be written off and destroyed as they near the end of their shelf life. This is a hidden – and often unmeasured – cost that also bears an environmental impact. There is an opportunity with certain medicines to optimise packaging to extend shelf life. However, desiccants are not easy to recycle, so care must be taken when considering their use.

"INNOVATIVE DESIGN AND 'SPECIFICATION FOR SUSTAINABILITY', COUPLED WITH INDUSTRY-WIDE COMPLIANCE TO SUSTAINABILITY GUIDELINES WILL NOT ONLY HELP MEET SUSTAINABILITY TARGETS BUT ALSO ENABLE MORE EFFICIENT AND EFFECTIVE RECYCLING, DRIVING UP CIRCULARITY."

CONCLUSION

Designing sustainable pharmaceutical packaging and combination devices requires a multidisciplinary approach that integrates environmental science, engineering, user behaviour and policy. Innovative design and "specification for sustainability", coupled with industry-wide compliance to sustainability guidelines will not only help to meet sustainability targets but also enable more efficient and effective recycling, driving up circularity. To achieve this end goal, pharma will require suppliers, healthcare systems, patients and recyclers to be key partners in this future vision. Regulatory momentum and patient awareness are accelerating this transition, but success will rely on continued innovation, cross-sector collaboration and a commitment to clinical excellence alongside environmental responsibility.

ABOUT THE COMPANY

Pharmacentric Solutions advises on device and packaging strategies for the life sciences Industry. It connects innovators with industry and has "design for sustainability" as one of its core specialities.

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Greg Anderson

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Interview: Taking Sustainability Beyond Compliance

In this exclusive interview, **Prof Hanns-Christian Mahler** of **ten23 health** engages in a wide-ranging discussion with ONdrugDelivery's Guy Furness about current challenges and trends in the drug delivery industry, particularly on the topic of sustainability – its advantages, difficulties and why companies should aim to do more than the bare minimum required by the regulation.

Q What do you think is the biggest misconception that biotech founders have about outsourcing development and manufacturing?

A When I specifically think about biotech startups, I think that there may not be a full appreciation of what is required to take a clinical R&D prototype to a full-scale commercial product. To take an example from my own experience, I once had a customer tell me that they didn't need a formulation for a sterile injectable, which put a smile on my face because every sterile medicine requires a formulation – you need to put it into some kind of formulation to be able to administer it to a patient.

"WHILE A MOLECULE IS THE ESSENCE OF A MEDICINE, THERE IS A LOT MORE TO GETTING THAT MOLECULE TO A PATIENT IN USABLE FORMAT – THAT'S WHERE PHARMACEUTICAL R&D REALLY KICKS IN AND WHERE THE EXPERTISE OF CDMOs LIKE ten23 BECOMES REALLY VALUABLE."

The question is only how much time and effort you want to put into your formulation development, depending on the stage of the development programme. Sometimes biotech founders don't intuitively appreciate how complex the whole process is, from defining a formulation to choosing primary packaging, and how those choices impact how the final product will be used – and whether you'll even be able to manufacture it in the first place.

Beyond the formulation, there are many other aspects that newer entrants to the pharma world might not have thought about. How do you make the product stable for storage? How do you actually administer it to patients? How do you manufacture and fill it at scale? Do you choose a cartridge, prefilled syringe or on-body injector (OBI)? Which needle size do you intend to use for the injection? I think that a lot of biotechs focus on the molecule first and foremost, and, while a molecule is the essence of a medicine, there is a lot more to getting that molecule to a patient in usable format – that's where pharmaceutical R&D really kicks in and where the expertise of CDMOs like ten23 becomes really valuable.

Q What do you think will be the key trends in pharmaceutical manufacturing in 2030 and beyond?

A If I look back at pharmaceutical manufacturing in the last decade or so, it was mostly about large-volume production – making the same product for everyone. It was a case of "Don't make it too complicated". Nowadays, however,

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Professor Hanns-Christian Mahler, PhD, is Chief Enablement Officer and Board Member of ten23 health. He previously built and led the Drug Product Services Business Unit at Lonza AG (2015 to 2021), led different organisations involved in sterile product development and sterile manufacturing at F Hoffmann-La Roche (2005–2015) and worked as Principal Scientist and Chemistry, Manufacturing and Controls Leader at Merck KGaA (2000–2005). Prof Mahler is additionally Lecturer and Adjunct Professor at the University of Basel and University of Frankfurt/Main (Germany), Editor for various scientific journals, and serves as an Expert at the European Pharmacopoeia Commission. He studied pharmacy and holds a PhD in Pharmacology & Toxicology from the University of Mainz (Germany) and obtained his *venia legendi* and title as Extraordinary Professor from the University of Frankfurt/Main.

we're seeing more segmented patient populations that require smaller batch sizes, especially in personalised medicines. In a nutshell, I expect that the market will move further towards differentiated solutions for patients, which is great from a patient perspective.

From a manufacturing perspective, this means that you will need smaller batches; you will need to have solutions that aren't one-size-fits-all. Achieving this may require capabilities that may or may not yet exist, even within larger corporations. I think we're going to see an increase in the number of specialist providers developing expertise in specific niches that are in demand in the wider market and seeing success with that approach.

Take OBIs as an example, which are a currently growing sector. OBIs are very effective for high-volume subcutaneous delivery, but we haven't built up the institutional knowledge for manufacturing and filling and assembling them yet – it requires speciality knowledge and assets. Currently, OBIs are manufactured in batch sizes on the order of 10,000 units, not the millions we are used to with traditional products.

Q Do you think that smaller batch sizes open the door to more innovative device solutions being given more of a chance?

A Yes, I think I'd agree with that – particularly in tandem with the greater prominence of CDMOs that can help pharma companies manage the risk where they might not have device-side expertise in-house. Let's consider subcutaneous delivery as an example; I remember being part of discussions in around 2007 or 2008 where I asked clinical colleagues what's the biggest volume we can deliver subcutaneously. Back then, I was told it was 0.5 mL by most, 1 mL by some and 2 mL by the really brave ones. Now, of course, we're delivering 10 mL. I recently read a paper where some colleagues at Eli Lilly performed a clinical study where they delivered up to 25 mL subcutaneously, also without permeation enhancers.

I've always been confronted with a lot of conservatism working in pharma, mostly driven by a fear of risk. It's understandable – we don't want to put the molecule or the patient at risk. Taking an exciting or innovative new approach is seen as inviting failure for the whole project because you're multiplying the uncertainties involved. Having said that, I think the industry struggles when it doesn't question its assumptions, such as how much we can deliver subcutaneously.

It's good to see the field evolving, although I think it could evolve much quicker. It's somewhere that CDMOs can really assist with speciality knowledge and capabilities. Let's say a pharma company needs to fill some cartridges for an in-development OBI – does it make sense for them to build their own specialist facility for only a few batches? Of course not. A CDMO, on the other hand, can have that specialist facility and use it for multiple projects with multiple partners. I think that's a healthy evolution.

Q Do you think sustainability is a competitive differentiator for pharma when selecting a CDMO?

A To start with, I believe pursuing sustainability is the right thing to do, regardless of any competitive advantages it might bring. That said, I do think that some have embarked on sustainability for that reason. Although, in the last few years, sustainability has become less of a priority for some companies, given the broader geopolitical perspective.

"SUSTAINABILITY IS NOT ABOUT PUTTING UP BARRIERS – I'M ALWAYS MORE FOND OF PARTNERSHIP RATHER THAN BEING COMPETITIVE ABOUT THINGS."

"SUSTAINABILITY SHOULD BE A MOST IMPORTANT TOPIC FOR EVERYONE IN THE HEALTHCARE BUSINESS, PHARMACEUTICAL MANUFACTURERS AND CDMOs ALIKE, BECAUSE THE HEALTH OF THE ENVIRONMENT AND HUMAN HEALTH ARE INTRINSICALLY LINKED."

For ten23 health, it's an important topic. In my opinion, sustainability should be a most important topic for everyone in the healthcare business, pharmaceutical manufacturers and CDMOS alike, because the health of the environment and human health are intrinsically linked; the more we adversely impact the environment, the more we adversely impact the health of patients. Asthma is a clear example of this, but it's far from the only one.

I have heard some argue that the industry is already doing enough good for the world by developing medicines, so why do we need to worry about greenhouse gas emissions or waste? To which I say, again, if you destroy the environment, you're damaging health as a secondary impact. There is absolutely no excuse for the pharma industry not to tackle sustainability. I always bring up the reference point that healthcare is responsible for 5% of global greenhouse gas emissions, which is comparable with the automotive industry.

There's a wonderful PhD thesis from the University of Oxford (UK) by Amy Booth. She analysed the approaches of multinational pharmaceutical companies with regards to climate action, and the interviewees said that it's secondary to patient wellbeing. They also said that sustainability depends on if it's affordable – it shouldn't impact profitability. As far as they were concerned, it's a question for the supply chain, regulators and policymakers. There's a lot of blame-shifting going on and, while a lot of companies are signed up to the Science Based Targets initiative (SBTi), only 16% are on track to meet the SBTi targets.

At ten23, we have an very open-book policy and are happy to share what

we're doing and how we evaluate our suppliers. Sustainability is not about putting up barriers – I'm always more fond of partnership rather than being competitive about things. We've been increasingly performing sustainability audits, though I'd still like to do more of them.

We've also achieved B Corp certification, which is a certification for sustainability, diversity and other considerations beyond being solely profit-focused. What I've found interesting is that I'm still frequently being asked what B Corp means. In practice, people outside of sustainability-focused roles don't really know a lot about the topic.

Q While sustainability as a topic tends to be dominated by CO_2, do you think that companies need to balance thinking about greenhouse gases with other concerns, such as water pollution and air quality?

A I cannot agree more; when I'm giving presentations about sustainability, one of my key slides is there to emphasise that "sustainability is more than decarbonisation". Pharma has a big impact on greenhouse gas emissions (CO_2 equivalents), but other considerations, such as waste or impact on biodiversity, are equally as important. Look at the number of disposables we produce from primary packaging alone, which all basically goes to waste. It's a question of resource use.

Then there's water, both from a withdrawal and wastewater perspective. On the wastewater front, we need to consider both contaminants that are produced during pharmaceutical manufacturing and disposal of the end products. For example, some people flush their medication down the toilet, and we need to take account of that.

Sustainable development goals can be really useful in situations where you have both a positive and a negative impact. They can help focus sustainability programmes on what we can do and how we can minimise our negative impact, such as waste. In practice, there will be unavoidable waste, unavoidable CO_2, so you have to think about how to do good beyond that, such as protecting forests that also add to biodiversity – which is something ten23 is working on in Pakistan with a fellow B Corp company. We also support an organisation called Seven Clean Seas, which removes plastic and other trash from the ocean.

I think that becoming too focused on decarbonisation is an overall negative for the industry. Instead, I think pharma needs to really expose itself to the topic, face up to the bad it's doing and think about the good it can do. It's about reducing and avoiding negative impacts – not only offsetting them – and taking overall responsibility as a business.

In truth, once you start paying attention to sustainability, it usually becomes a case of simply being more efficient and making better products – if you do things well, then they often become more sustainable. To go back to your earlier question, in practice, the real competitive advantage from embracing sustainability is that it is actually financially beneficial from an operational perspective. At the end of the day, there is nearly always a positive business case to be made for sustainable investments.

As an example, if you're buying photovoltaics for a facility, there's a big up-front investment to make, but it will offset operational costs in the long term. It can even offset operational risk because energy costs will probably go through the roof in the coming years. If you factor in your expected energy costs in 10 years from now, they will not be the same as today. You can go beyond that and think about batteries and energy storage, but even at the basic level it's a positive business case.

Q For sustainability, do you think that minimum compliance with regulations is enough or does pharma need to go beyond?

A In short, no, it's not enough. To use an analogy, think about it in terms of quality by design. If you don't follow good principles when you design a device and you manufacture it with tolerances that just scrape over the bare minimum, it will always be on the edge of failure – it won't take very much for it to break or just stop working. That's not a robust commercial product and the industry wouldn't accept it.

That said, in my view, I don't see a lot of people going beyond pure compliance with sustainability. For example, we're already seeing a lot of companies struggling to meet the EU's Corporate Sustainability Reporting Directive. At, ten23 we've opted into voluntary transparent reporting, but I'm not seeing that as a common approach. In fact, people ask me "Why are you doing this?" The simple answer is that we want to be transparent and that it's the right thing to do. I don't think that sustainability regulations are going to be enough to protect the planet, so we're going to have to do more than minimum compliance if we want to achieve meaningful results. But, ultimately, it's going to be a question for leadership to determine how far they want their companies to go.

"I DON'T THINK THAT SUSTAINABILITY REGULATIONS ARE GOING TO BE ENOUGH TO PROTECT THE PLANET, SO WE'RE GOING TO HAVE TO DO MORE THAN MINIMUM COMPLIANCE IF WE WANT TO ACHIEVE MEANINGFUL RESULTS."

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Expert View

SUSTAINABILITY IN DRUG DELIVERY

Adam Tilley and **David Cook**, both of Jabil, explore how carbon footprint considerations can be integrated into the drug delivery device design lifecycle, highlighting key sustainability decisions faced by design engineers and emerging tools that support those evaluations.

"OVER 70% OF A DEVICE'S CARBON FOOTPRINT IS DETERMINED DURING THE EARLY CONCEPT DEVELOPMENT PHASE."

The healthcare sector accounts for approximately 4–5% of global CO_2 emissions, with manufacturing, packaging and transportation representing the largest contributors.[1] As of 2025, this share of medical devices and associated packaging represented US$25.1 billion (£18.7 billion) and is projected to rise to $47.1 billion by 2033.[2,3]

Sustainability regulations, including the UN Sustainable Development Goals and the EU Corporate Sustainability Reporting Directive, are increasing accountability for CO_2 emissions. As a result, the medical device and pharmaceutical sectors – especially single-use drug delivery systems such as autoinjectors – are under increasing pressure to adopt more sustainable practices.[4]

Single-use disposable devices represent the third-largest contributor to device-related emissions, after facility energy use and pharmaceutical production. Approximately 70% of injectors are single-use devices. The expanding glucagon-like peptide-1 (GLP-1) drug market, which currently relies heavily on single-use injectors, could triple in value by 2033, resulting in hundreds of millions of additional devices being manufactured.[5]

With the healthcare market trending towards an increase in single-use medical devices, businesses must consider how to keep up with the changing regulatory landscape to avoid fines or greater legal ramifications. For example, the EU Corporate Sustainability Reporting Directive came into effect in 2023, calling for hospitals, care homes, device manufacturers and all others involved in the supply of drug delivery devices to report their environmental impact, from initial supply of materials to final disposal.[6] Additionally, France has introduced the Anti-Waste and Circular Economy (AGEC) legislation, which puts the responsibility on the manufacturers to reduce waste,[7] while Germany has introduced the Corporate Due Diligence in Supply Chains Act of 2021, which mandates that large companies must account for the environmental risks associated with their supply chains.[8]

These legislative measures indicate a growing focus on the mitigation of manufacturers' environmental impact, which leads to more decisions for design teams. When a product is designed, the end-of-life must be considered – will it be reused, recycled or repaired? It is no longer enough to just dispose of a product; accountability at all stages of the product's lifecycle is being increasingly placed on the manufacturer.

SUSTAINABILITY AS AN INPUT REQUIREMENT

Over 70% of a device's carbon footprint is determined during the early concept development phase. Early integration of design for sustainability into device development is critical to reducing environmental impact while balancing functionality, usability, cost and quality. Establishing specific, measurable and attainable sustainability goals within initial device requirements is key to success. A weighted scoring and selection process can then be used for a holistic approach to assess sustainability in the context of other requirements.

If sustainability factors are only considered in the later stages of the development process, the level of difficulty in making beneficial changes increases significantly, while the impact decreases, as shown in Figure 1. Later alterations also add significant cost and time to the development lifecycle.

Some of the greatest benefits to environmental impact can be achieved through reducing transportation and

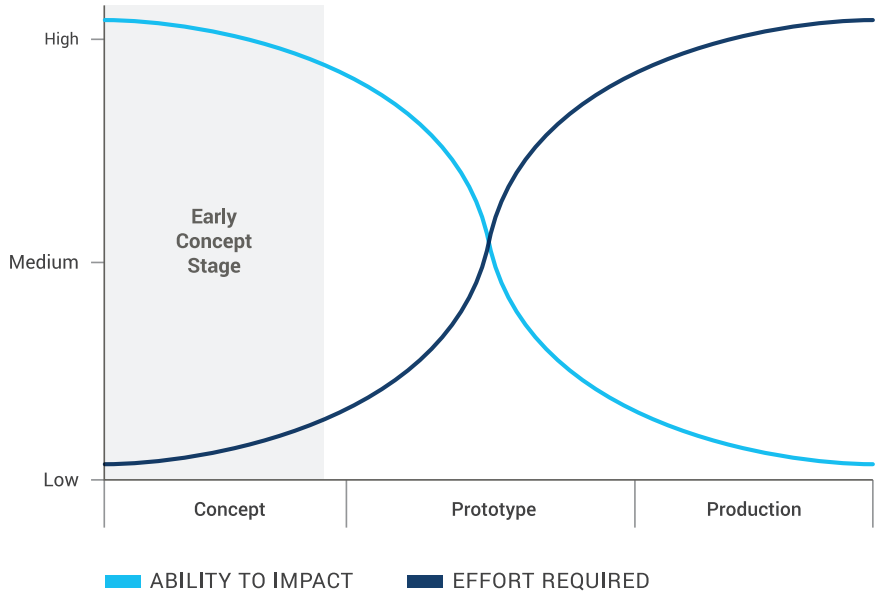

Figure 1: Device sustainability – ability to impact versus effort required.

energy-related costs and by considering early on where and how a device will be manufactured. For example, an injection-moulding facility with energy-efficient machine co-ordination, on-site renewable energy generation and battery storage can reduce CO_2 emissions by hundreds of metric tonnes compared with conventional facilities. Including these efficiencies when estimating the carbon footprint at the design stage may allow for compromises elsewhere in the design to achieve the same sustainability targets.

DESIGN FOR SUSTAINABILITY

A critical aspect of design for sustainability is identifying effective opportunities for reducing the carbon footprint of a product across three stages – concept selection, detailed optimisation and detailed simulation (Figure 2).

Stage 1: Concept Selection

Modular Design

Specific logistical and disposal requirements for integral parts can make an entire device single use. By shifting to a modular design approach, a device can be made reusable with individual single-use components. Designing common modules for use across multiple configurations and allowing for separation of differently disposable elements can significantly reduce a device's waste footprint and recycling complexity. Using autoinjectors as an example, prefilled syringes, cartridges and needles all contain opportunities for modular compatibility to help mitigate the device carbon footprint.

Component Reduction

Simplifying a device is often the most straightforward way to reduce its carbon footprint, even when it requires some novel engineering. A reduction in the types and volume of material used can make a device's introduction into a circular economy more direct, which results in positive outcomes for transport, manufacture and assembly.

Stage 2: Detailed Optimisation

Design for Manufacturing

In mass-produced autoinjectors, injection-moulding of the plastic components is a key opportunity improving sustainability. The total material and energy used per shot can be reduced by coring out features, optimising runner systems and selecting resins that have lower processing temperatures.

Design for Assembly

The assembly process of a device is an essential consideration when maturing a prototype towards production to ensure that desired production rates can be met while maintaining device functionality. However, disassembly for potential recycling – or recovery of partially assembled devices, unused devices and post-use devices – is often overlooked. New legislation, such as the AGEC law, is putting increasing focus on end-of-life optimisation. To this end, structured device disassembly is just as vital as reliable assembly. The ability to recycle manufacturing rejects, post-use and post-expiry devices to reprocess their materials should be engrained into the design. Methods of optimising this include:

- Avoiding lubricants and solvents that can contaminate waste streams and eliminate the circular economy of a device.

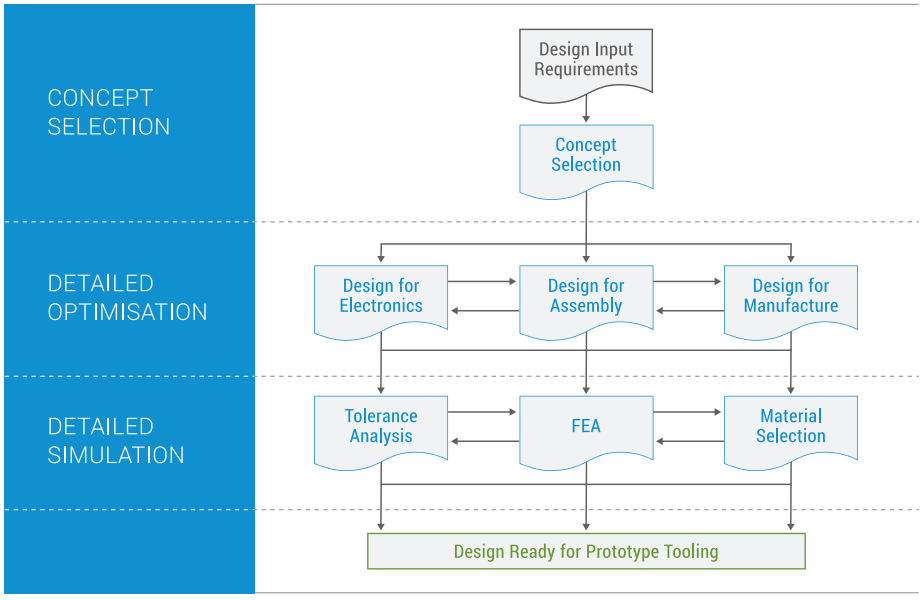

Figure 2: Early-stage design process elements.

- Minimising the use of fasteners such as screws or bolts that make disassembly less viable. If these are required, ferrous materials are preferred to allow for magnetic separation.
- Limiting high-energy joining methods such as ultrasonic and laser welding.
- Avoiding inks or paints that can contaminate plastic batches; use embossing, debossing or laser marking instead.
- Reducing the number of different materials used to make disassembly and recycling easier and more straightforward.

While some components are inherently single-use and must be disposed of, reducing the embedded energy wherever possible is essential in the design for assembly process.

Stage 3: Detailed Simulation

Material Selection

As discussed, optimising component material selection is highly valuable in a sustainable design. However, understanding the most sustainable material to progress at the early design stage can be difficult. Considerations include:

- Environmental impact of the material production
- Carbon footprint of the supply chain for a given material
- Viability of the use of recycled materials or renewable feedstock
- The sustainability credentials of a material supplier
- The expected end-of-life of the material
- Viability of recycling.

For resins in particular, the feedstock used is critical. Sustainably produced medical-grade materials are available, made up of 95–100% biocontent (biogas) and functionally almost identical to their existing non-sustainable counterparts. These materials may reduce carbon footprint by more than 50% compared with fossil-based alternatives. The race to get a drug delivery device to market, alongside the associated drug development timeline, can be intense, so sustainable materials should be considered as early as possible, based on information sharing throughout the supply chain and the use of lifecycle analysis (LCA) tools.

> "MITIGATING THE CARBON FOOTPRINT OF A DEVICE IN THE EARLY DESIGN STAGE IS A DIFFICULT TASK THAT INVOLVES ESTIMATING THE IMPACT OF ALL AVAILABLE DESIGN CHOICES."

ENGINEERING TOOLS

Mitigating the carbon footprint of a device in the early design stage is a difficult task that involves estimating the impact of all available design choices. LCA tools evaluate environmental impacts across a product's lifecycle – from raw material extraction to end-of-life disposal – supporting more sustainable design decisions. Considerations include raw material extraction, component manufacturing and transportation, and up-to-usage and end-of-life disposal or recycling. This relies on standardised procedures defined in ISO 14040 and 14044, as well as thorough databases with environmental and sustainability information that quantify environmental impacts such as energy usage, carbon footprint, water consumption and pollution. These tools allow for the simulation of different configurations to equip design engineers with the information needed to make more sustainable decisions.[9]

Different LCA tools exist and have varied use cases. Some are designed for quick assessments at an early stage to gauge feasibility and integrate with workflows, while others offer the ability to give feedback into a computer-aided design environment of real-time environmental considerations, or even develop a supply-chain digital twin for real-time impact analysis.[10]

LCA tools are useful under the right circumstances but can be limited by the quality of the databases that they pull from, as well as the experience of the user. Detailed analyses require high-quality granular data, which can be difficult to obtain from suppliers, especially in complex supply chains. As such, simulations must sometimes be performed using generic data relating to materials, energy and logistics for comparative assessments only. This can be mitigated by engaging with large manufacturers that have experience in the drug delivery industry and access to global suppliers.

Case studies have shown that the assessment can also produce varied results depending on user experience and the tool being used. While the same rough conclusions can be reached, some parameters can strongly influence the result, meaning that, depending on how knowledgeable the user is, the tool can influence them to an incorrect conclusion.[11]

LCA tools are best used when implemented at early-stage design development and developed with a level of flexibility in the models to account for risk of later change in the design.

CASE STUDY

The sustainability benefits of early-stage design decisions can be demonstrated using the example of an autoinjector platform, with the key design objectives of:

- Enhancing sustainability and reducing environmental impact
- Minimising cost while supporting a broad product portfolio
- Providing a configuration for connectivity.

These objectives led to a design based on a novel modularisation approach, featuring a reusable spring-loaded drive unit coupled with single-use cassettes. As previously stated, the use of modularisation provides a significant reduction in single-use materials and embedded energy due to the disposal of the cassettes rather than an entire autoinjector device. This modularity could be extended to integrate electronics, sensors and wireless connectivity by pairing with a home hub for automatic data transfer and device charging.

Compared with traditional 2.25 mL single-use autoinjectors, the design

demonstrated an approximately 80% reduction in lifecycle carbon footprint. This was achieved through modular design, sustainable material choices and advanced assembly methods, which were considered throughout development.

Connectivity in autoinjectors enables automated data transfer to healthcare providers, reducing the need for in-person visits and contributing to further lifecycle emissions savings.

AUTOINJECTORS AND WHAT LIES AHEAD

The GLP-1 market is expected to grow at a compound annual growth rate of 12.4%, while the insulin delivery device market is projected to grow by 7.9% annually.[5,12] There is some uncertainty of the direction of the GLP-1 form factors market, as recent clinical trials have shown efficacy of oral therapies, which could lead to a shift away from autoinjector use.[13] Conversely, other studies have shown that, while oral solutions are appropriate for targeting diabetes and weight loss, injected therapies remain the more effective option for weight loss.[14] This suggests that autoinjector demand will continue to grow, even if not at the forecasted 12.4% rate.

Cold chain requirements for temperature-sensitive therapies are a significant contributor to the carbon footprint of drug delivery systems, driven by high energy consumption during storage and transport.[15] There is an industry focus on the development of drug reconstitution models to remove the need for cold chain storage for some drug therapies. Where possible, this carbon reduction may offset the impact of the delivery device, although this will also drive more complex device development with solutions for controlled mixed- and multi-chambered devices.

Adam Tilley

Originally an intern at Jabil during his master's degree, Adam Tilley, Mechanical Design Engineer, joined Jabil full-time in 2025 and has worked across a wide range of medical device projects. He specialises in design of test fixtures and test methods, management of testing campaigns and implementation of design for sustainability. Mr Tilley has a bachelor's degree in mechanical engineering from Technological University Dublin (Ireland), and a master's degree in biomedical engineering from University College Dublin (Ireland).

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David Cook

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CONCLUSION

Designing sustainable drug delivery devices remains complex. However, integrating sustainability considerations early in the design process enables greater flexibility and impact in reducing lifecycle carbon emissions, with minimal effect on cost and development timelines. Defining sustainability goals as an input requirement is necessary to better realise opportunities for carbon reduction during design development for manufacturing and assembly, and as a critical factor in other business strategy decisions.

ABOUT THE COMPANY

Jabil (formerly Nypro) is one of the industry's largest, most comprehensive healthcare manufacturing solutions and capabilities providers. Its customers have access to an array of engineering, design and manufacturing solutions acrossmultiple sectors in both the healthcare industry and many more. The Pharmaceutical Delivery Systems business within Jabil continues to accelerate

> "COLD CHAIN REQUIREMENTS FOR TEMPERATURE-SENSITIVE THERAPIES ARE A SIGNIFICANT CONTRIBUTOR TO THE CARBON FOOTPRINT OF DRUG DELIVERY SYSTEMS, DRIVEN BY HIGH ENERGY CONSUMPTION DURING STORAGE AND TRANSPORT."

leadership within the industry, with disciplined and innovative execution on design, engineering, product development and manufacture across multiple platforms including autoinjectors, inhalers and dosing.

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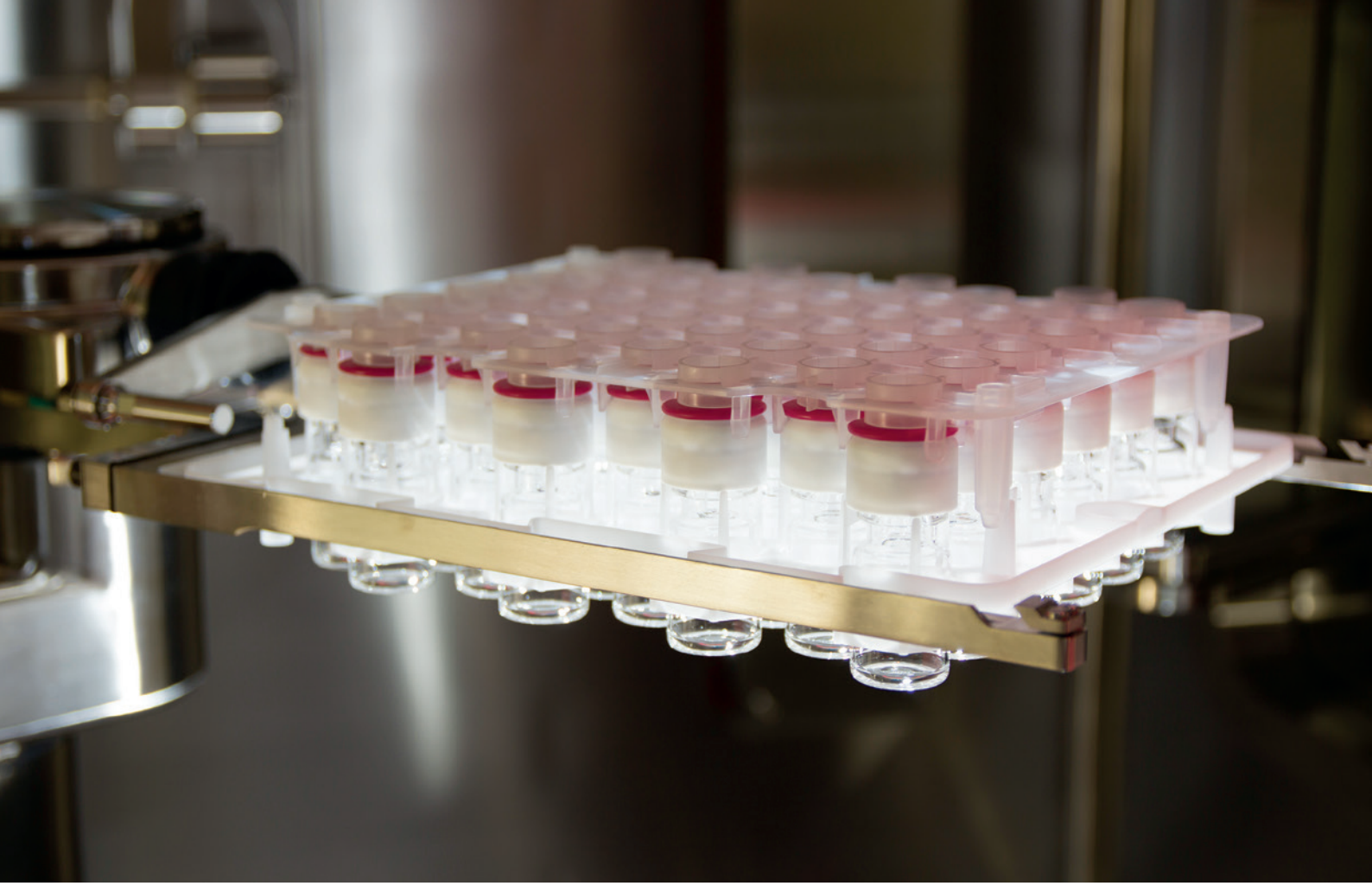

ECO-DESIGN DRIVING NEST AND READY-TO-USE PACKAGING INNOVATION

Lionel Maritan and **François Ciavatti** of **ARaymond** discuss RayDyLyo®, an eco-designed nest developed to reduce the overall impact of ready-to-use components, reflecting on insights gained from lifecycle assessments, outlining the progress still to be made and illustrating how a pragmatic, inventive, eco-centric design approach can drive the development of packaging solutions with a measurably lower environmental footprint.

ENSURING PATIENT SAFETY WHILE DELIVERING SUSTAINABLE EVOLUTION

The pharmaceutical industry is undergoing one of the most significant transformations in its history. Scientific evidence makes the scale of the climate challenge unmistakable – at current emission rates, the world could exceed its remaining carbon budget for limiting global warming to 1.5°C within the next decade.[1] Against this backdrop, the fill-finish industry faces a dual mandate: maintain patient safety and line performance while reducing its environmental impact.

In a sector where single-use components and protective formats ensure quality, reliability and sterility, progress now relies on voluntary, industry-driven actions.

Within this context, ready-to-use (RTU) containers have become a cornerstone of modern aseptic processing. They reduce human interventions and enable automation

"IN A SECTOR WHERE SINGLE-USE COMPONENTS AND PROTECTIVE FORMATS ENSURE QUALITY, RELIABILITY AND STERILITY, PROGRESS NOW RELIES ON VOLUNTARY, INDUSTRY-DRIVEN ACTIONS."

in ISO 5/Grade A environments aligned with EU GMP Annex 1 expectations.[2] At the same time, industry-wide assessments consistently identify primary packaging – and in some cases secondary packaging – as major contributors to the manufacturing-stage carbon footprint of parenteral products,[3] making material and format decisions inseparable from environmental impact. As RTU formats expand beyond prefilled syringes to include vials and cartridges, attention is increasingly turning to how eco-design can guide next-generation components.

ECO-DESIGN AS A STRATEGIC LEVER FOR SCOPE 3 REDUCTION

For pharmaceuticals, products take years to develop and then remain on the market for decades, during which time any modification is tightly constrained.[4] This makes upstream eco-design critical – the environmental performance of a component is largely determined long before it reaches commercial use.

At ARaymond, eco-design is a core driver of its innovation strategy and is fundamental to achieving the validated objectives of the Science Based Targets initiative. To deliver on these ambitions, ARaymond has introduced company-wide eco-design training programmes. Some are offered to over 5,000 employees, highlighting the contribution each person can make to this approach. Others focus specifically on product development teams (over 1,000 employees) and include, for example, advanced modules on lifecycle assessments (LCAs).

All training programmes are grounded in four "golden rules", which now guide the company's product development practices:

- Material choice
- Weight reduction
- Ease of disassembly
- End-of-life principles.

RayDyLyo is one of the first products to benefit from this approach, and its development has helped mature ARaymond's eco-design methodology. It is a gamechanger for RTU vial closure systems (Figure 1).

RAYDYLYO: AN RTU VIAL CLOSURE SYSTEM FOR INJECTABLES

Developed by the healthcare division of ARaymond, RayDyLyo has already demonstrated robust performance across clinical and commercial fill-finish operations as an RTU, press-fit alternative to aluminium crimped seals, meeting the mechanical, aseptic and operational requirements of modern fill-finish environments:

"RayDyLyo HAS ALREADY DEMONSTRATED ROBUST PERFORMANCE ACROSS CLINICAL AND COMMERCIAL FILL-FINISH OPERATIONS AS AN RTU, PRESS-FIT ALTERNATIVE TO ALUMINIUM CRIMPED SEALS."

- **One-Step Press-Fit Application:** Delivers consistent, design-driven container-closure integrity and eliminates crimping-related variability, particle generation and stopper deformation.
- **Enhanced Contamination Control Performance:** Components are supplied sterile and RTU, qualified for use in ISO 5/Grade A environments and aligned with Annex 1 expectations for reduced mechanical complexity and minimised interventions.
- **High-Throughput Compatibility:** Supports manual clinical operations as well as fully automated lines operating above 300 units/min, without the need for crimping heads or secondary closing stations.
- **Broad Dimensional Compliance with ISO 83621/ISO 83622 Vials and Stoppers:** Facilitates seamless integration with existing customer references and reduces onboarding and requalification efforts.
- **Reduced Operational Risk and Mechanical Failure Modes:** Simplified handling, fewer moving components and the elimination of tool-dependent process steps.
- **Lower Total Cost of Ownership:** Reduced equipment architecture, a smaller classified area footprint (Grade A/B), fewer maintenance operations and improved process capability across campaigns.
- **Full RTU Workflow Compatibility:** Supported by a complete portfolio of secondary packaging solutions – including tubs and nests, rapid transfer port bags and standard bag configurations – ensuring alignment with established transfer, loading and aseptic handling processes used in isolator and restricted access barrier systems environments.

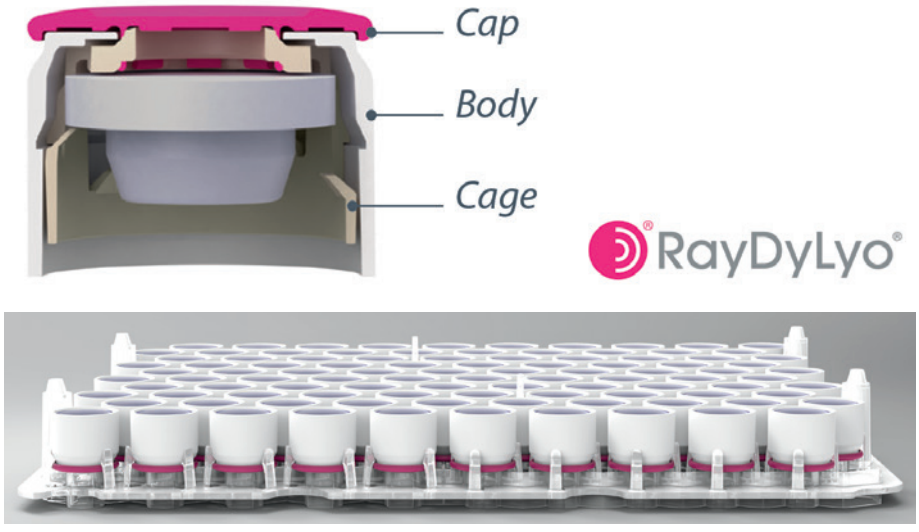

Figure 1: Cross-section of the RayDyLyo cap showing its three assembled components with the embedded standard stopper and the standard RayDyLyo nest 13 mm (100 positions).

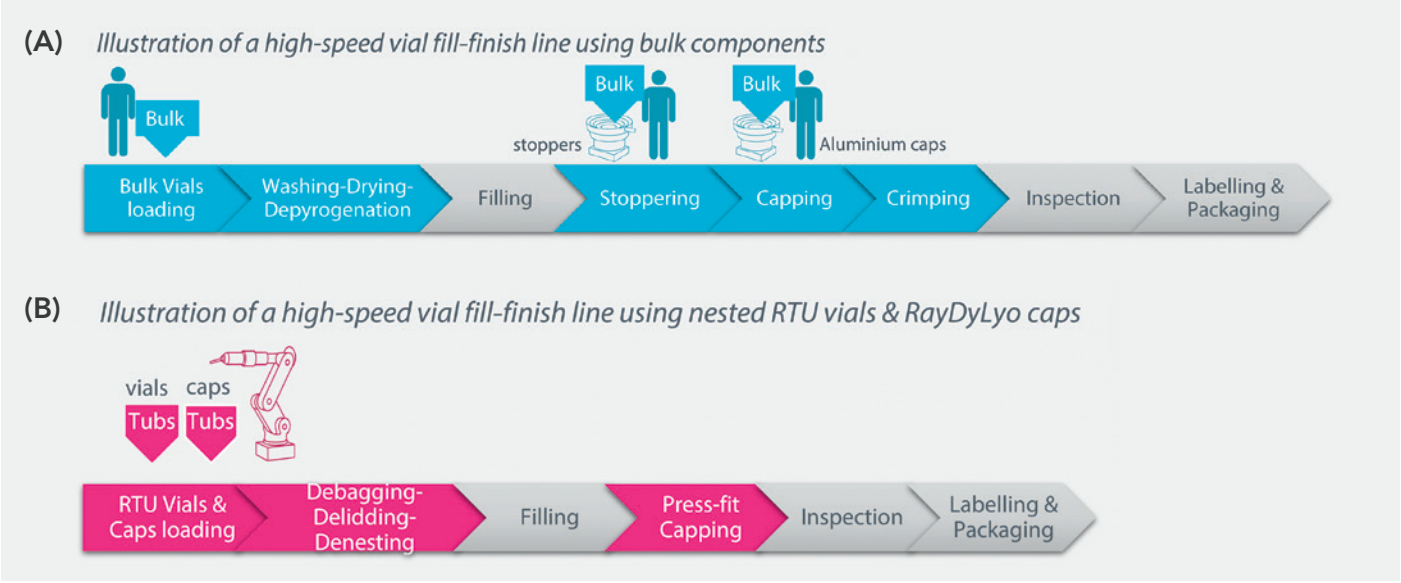

Figure 2: (A) Comparison of a conventional bulk vial fill-finish process (B) an RTU workflow using RTU vials and RayDyLyo pressfit caps.

The RTU approach removes the washing, drying and depyrogenation steps, and eliminates the crimping operation. This reduction in mechanical complexity and aseptic interventions enables a more streamlined, automation-ready process (Figure 2).

Why Did the Nest Come First?

ARaymond completed an internal cradle-to-gate LCA of the RayDyLyo RTU system, covering the closure, nest, tub and bags, but excluding the stopper. While not third-party reviewed, the study follows ISO 14040/14044 principles to ensure transparency, reproducibility and a consistent basis for comparing packaging configurations.[5]

The analysis showed that the RayDyLyo closure and its associated nest were the main contributors to the system's environmental footprint:

- **Nest as Main Contributor:** The polybutylene terephthalate (PBT)-based nest represented one-third of the overall impact, making it the single largest contributor (Figure 3A). This reflects the relatively high footprint of PBT resin compared with commodity polymers, driven by its more complex synthesis route and higher embodied energy.
- **Minor Contributors:** Combined, the other packaging elements (tub, bags and Tyvek®) accounted for 16% of the total footprint within the study boundaries.

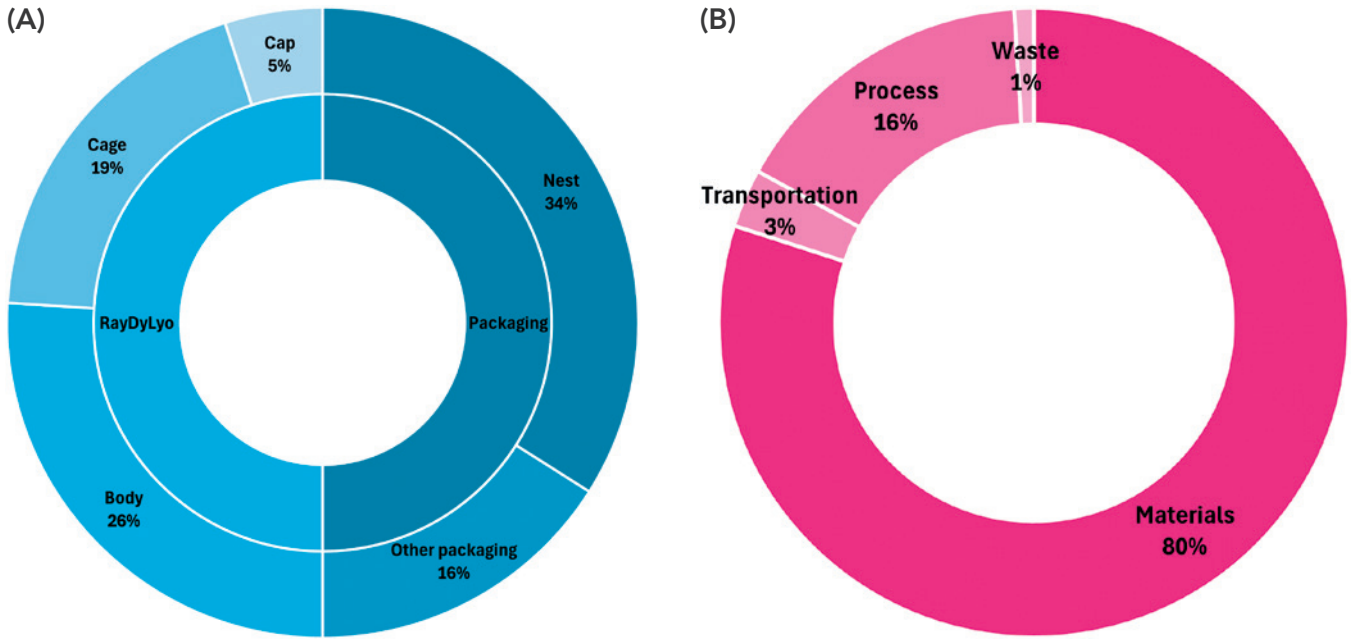

Figure 3: (A) LCA contributions of each component in the system. (B) Share of the four main LCA stages.

- **Raw Materials Dominance:** Materials accounted for 80% of the total footprint across most environmental indicators (Figure 3B). The extraction and production of virgin plastics typically have the most impact due to energy-intensive polymerisation processes and upstream petrochemical feedstocks.

Together, these insights clearly positioned the nest as the most impactful and technically feasible target for redesign – a component where significant environmental gains can be achieved without altering the fill-finish fundamentals.

RETHINKING THE NEST: AN ECO-DESIGN ENGINEERING JOURNEY

Unveiled at the latest Pharmapack Europe, the redesigned nest for 13 mm RayDyLyo caps showcases a proof of concept born from a blend of creative engineering and agile, iterative exploration.

A full reassessment of the nest architecture identified non-critical material zones and enabled geometry optimisation, while preserving functional performance and reinforcing Design for Manufacturing principles. Structural elements were minimised without compromising the rigidity required for handling, transport and high-speed aseptic filling.

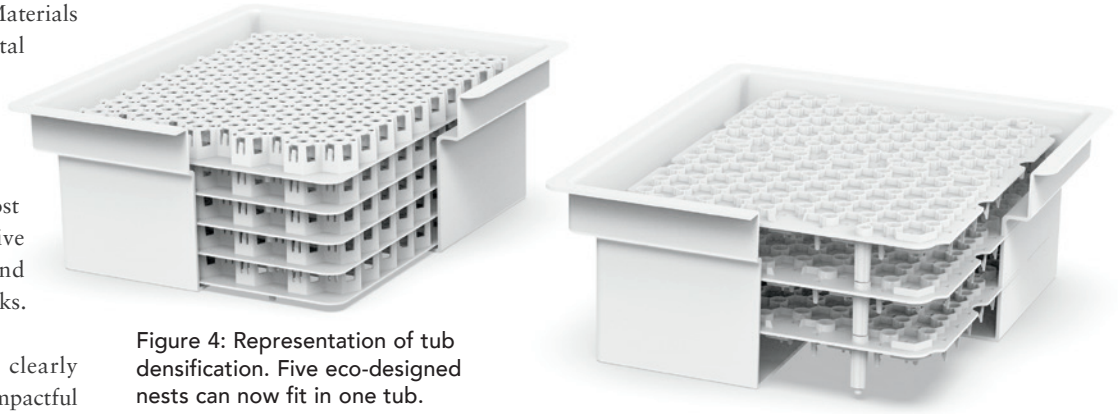

Figure 4: Representation of tub densification. Five eco-designed nests can now fit in one tub.

Key outcomes included:

- **Weight Reduction (~44%):** The drop from 133 to 74 g is the single most powerful driver of environmental improvement. Reducing mass directly lowers impacts across multiple LCA indicators, from fossil resource use to climate change and cumulative energy demand.

- **Material Transition:** Switching from PBT to polypropylene (PP) reduces embodied energy and improves the environmental profile of the nest. PP also offers lower density and better recyclability potential.

- **Densification (~66%):** The redesigned geometry increases packout efficiency from three to five nests per tub (Figure 4). This reduces the number of pallets shipped and stored, decreases the frequency of line replenishments in Grade A/ISO 5 zones and allows for potential warehouse and intralogistics improvements. By moving more product with fewer shipments and materials, the new configuration also reduces downstream waste generation and improves value chain efficiency for customers.

- **Robust by Design:** Design for Manufacturing was integrated from early concept generation stages. Moldflow® polymer flow simulations were used to validate the redesigned structure under real processing conditions.

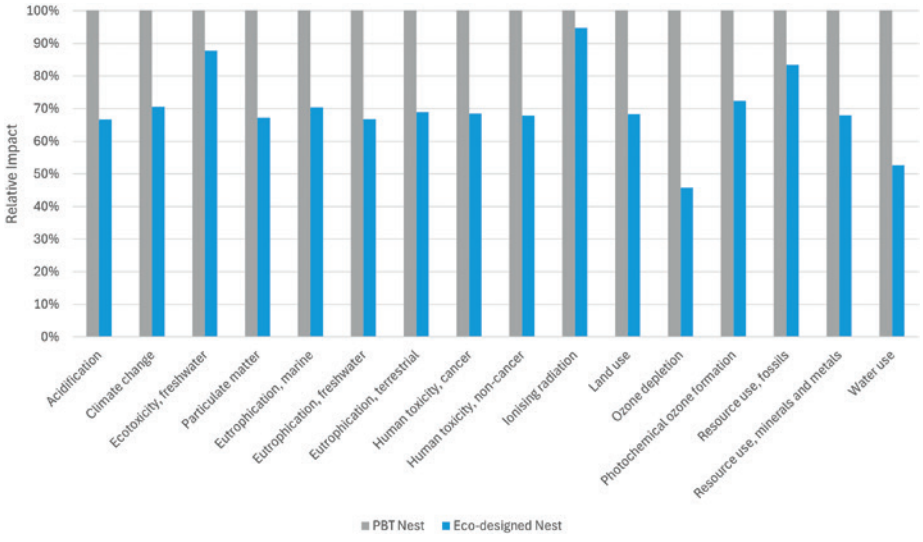

Figure 5: Relative reduction of environmental impacts across the 16 indicators between a current and eco-designed nest.

ENVIRONMENTAL GAINS DOWN BY 25%

The cradle-to-gate LCA quantifies how the redesign affects upstream environmental burdens:

- **Nest Level (Component):** Compared with its former design, the new nest delivers an average of 63% overall impact reduction, including a 63% decrease in climate impact, a 50% cut in resource use and an 89% reduction in water consumption. It reflects the combined effect of weight and material changes.

- **System Level (Nest + Tub + RayDyLyo Cap):** The footprint of the whole RayDyLyo system decreases by 25% on average across all 16 environmental indicators – evidence that a targeted modification of the secondary packaging (nest) can meaningfully lower the footprint of the overall RTU closure system (Figure 5).

As the redesign remains within a fossil-derived material family, the improvement is consistently visible across all 16 markers. Alternative solutions – whether focused on resource efficiency or on fossil-free materials – will require systematic LCA-based trade-off assessments to ensure that transitions are controlled and genuinely beneficial.

While densification effects are less visible within these boundaries, the analysis highlights a point of methodological importance: increasing the number of usable units per transported and stored volume directly influences several downstream mechanisms typically captured within Scope 3 categories.

From a broader lifecycle perspective, the results illustrate how early design decisions can support downstream objectives related to circularity, responsible material stewardship and more efficient use of existing infrastructure. The redesigned nest therefore demonstrates not only the improved upstream performance but also a structural capacity to enable lower-impact operations further along the value chain, even if these effects are not quantified within the present study.

A MEASURED START TOWARDS MORE SUSTAINABLE RTU PACKAGING

The eco-designed nest marks a meaningful first step, even though it remains a fossil-based, single-use medical-grade component aligned with today's sterilisation and regulatory constraints. Achieving genuinely sustainable RTU packaging will require co-ordinated progress on several fronts:

- The development of next-generation polymers (recycled, bio-sourced or mass-balanced)
- Broader use of monomaterial or disassemblable architectures
- Stronger cross-industry collaboration to improve end-of-life pathways.

With this redesign, ARaymond has established a repeatable, LCA-guided eco-design methodology that will steer future developments across the RTU platform. Applying the same structured, data-driven approach when designing upcoming components will help to ensure that new solutions balance performance with measurable environmental gains. As ARaymond's environmental product declarations undergo third-party verification, this methodology will reinforce the company's role as a strategic sustainability partner in the fill-finish ecosystem – helping to shape more resource-efficient, resilient and climate-aligned pharmaceutical operations.

"EARLY DESIGN DECISIONS CAN SUPPORT DOWNSTREAM OBJECTIVES RELATED TO CIRCULARITY, RESPONSIBLE MATERIAL STEWARDSHIP AND MORE EFFICIENT USE OF EXISTING INFRASTRUCTURE."

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RETHINKING DRUG DELIVERY: ENABLING RECYCLING AND MATERIAL EFFICIENCY IN HEALTHCARE

Dr Bernd Garska and **Sven Schlecht**, both of **Covestro**, highlight how single-use drug delivery devices can be re-thought to help solve the climate and environmental challenges in the healthcare sector.

The healthcare industry is crucial for global wellbeing; however, it comes at a significant environmental cost. If the global healthcare industry were a country, it would rank as the fifth-largest emitter of greenhouse gases (GHGs), contributing nearly 4.4% of global net emissions and emitting over 2 gigatons of CO_2 equivalents annually.[1]

The covid-19 pandemic further highlighted this issue, generating millions of tonnes of medical plastic waste, much of which was either incinerated or sent to landfill due to infection risks or material complexity. Studies also found that a significant percentage of medical plastics during the pandemic were single-use, emphasising the scale of the challenge.[2] This reality underscores the urgency of redesigning how plastics are used in healthcare, with sustainability as a core principle. With an urgent need for a circular economy in healthcare, achieving this goal requires innovation across

"DRUG DELIVERY DEVICES PRESENT A PARTICULAR CHALLENGE FOR A CIRCULAR ECONOMY DUE TO THEIR OFTEN-COMPLEX MATERIAL COMPOSITION, SMALL SIZE AND POTENTIALLY CONTAMINATED PARTS."

"AFTER POLYMERISATION, THE MATERIAL IS INDISTINGUISHABLE IN MOLECULAR STRUCTURE AND RETAINS THE PERFORMANCE CHARACTERISTICS OF CONVENTIONAL PC, ENSURING SEAMLESS INTEGRATION INTO EXISTING MANUFACTURING PROCESSES."

materials, designs and recycling pathways; healthcare organisations must become thought leaders in sustainability.

Drug delivery devices present a particular challenge for a circular economy due to their often-complex material composition, small size and potentially contaminated parts. These factors make them difficult to handle in conventional plastics waste management systems.

Three fundamental approaches to re-imagining single-use drug delivery devices to help solve environmental challenges in the healthcare sector include:

- Bio-circular-attributed feedstocks[3] for immediate footprint reduction
- Smart design and material selection to reduce wall thickness and reduce material complexity
- Make use of attractive (new) recycling pathways (technically and commercially).

BIO-CIRCULAR FEEDSTOCKS FOR CARBON REDUCTION

An impactful choice for more sustainable designs lies upstream at the material selection stage. Selecting a plastic material produced with alternative, bio-circular raw materials, as defined by International Sustainability and Carbon Certification (ISCC) Plus,[3] can offer a scalable solution for reducing the carbon footprint of a medical device from the outset. By changing from purely fossil-based plastics to equivalent grades with certified attributed share, manufacturers of drug delivery devices can reduce their of Scope 3 emissions, while still maintaining the high-performance characteristics required in medical devices.[4]

Bio-circular-attributed polycarbonates (PCs), for example, are produced with raw materials that are chemically identical to those used in standard PCs. However, a defined share of these raw materials is related to biological waste and residual streams, such as used cooking oils or biomass residues, instead of crude oil. Through the mass-balance approach, these alternative raw materials are fed into production and yield PCs that are identical in performance, processability and regulatory compliance to their conventional counterparts, yet offer a significantly reduced carbon footprint.[4]

Substitution of carbon from fossil-based feedstocks with carbon from bio-circular feedstocks begins with the extraction of carbon from sources such as used cooking oil. These materials undergo processing to make them amenable to the conventional processes that are typically used to extract hydrocarbons (e.g. phenol and acetone) from crude oil, which are then refined into the same chemical raw materials required for the synthesis of PCs. After polymerisation, the material is indistinguishable in molecular structure and retains the performance characteristics of conventional PC, ensuring seamless integration into existing manufacturing processes. Equivalence studies have been conducted to support and simplify regulatory assessments.

Solutions such as Covestro's Makrolon® RE PC provide ISCC PLUS-certified[3] bio-circular-attributed drop-in alternatives to existing healthcare applications already using PC. These grades can claim up to 89% bio-circular-attributed content, offering a reduction in carbon footprint compared with fossil-based PC.[5,6]

Mass-balance accounting, following guidelines laid out by the ISCC, ensures transparent tracking of renewable content, third-party verification and regulatory-aligned carbon reporting. With ISCC certification, Scope 3 carbon reductions can be transferred, or claimed, aligning with the goals of the EU Green Deal, Corporate Sustainability Reporting Directive and GHG Protocol frameworks.[2,7,8] Importantly, this approach emphasises that sustainability starts at the molecular level; choosing renewable attributed feedstocks for the production of plastics reduces the amount of carbon derived from fossil sources, which has a direct impact on the carbon footprint of devices produced with this bio-feedstock-attributed plastic.[4]

Case Study: Over 90% CO_2 Reduction

In a recent case study, Covestro demonstrated that a multi-component drug delivery device, produced using Makrolon® RE and manufactured with electricity from renewable sources (e.g. wind power), could reduce the product-level carbon footprint by over 90% relative to the same device made with conventional fossil-based PC.[6] The resulting carbon footprint reduction demonstrates that significant environmental improvements are achievable without compromising on device performance or patient safety.

It is also worth noting that the adoption of materials derived from bio-circular feedstocks not only helps to reduce the global consumption of fossil-based materials but also reduces risks from exposure to either emerging corporate environmental, social and governance mandates that emphasise carbon footprint reduction or international policy frameworks. The benefits of either revising existing devices that use conventional PC or developing new designs with renewably sourced materials, such as Makrolon® RE PC, represent a huge contribution that device manufacturers can make towards more sustainable healthcare.

"SIGNIFICANT ENVIRONMENTAL IMPROVEMENTS ARE ACHIEVABLE WITHOUT COMPROMISING ON DEVICE PERFORMANCE OR PATIENT SAFETY."

REDUCING MATERIAL USE THROUGH MORE SUSTAINABLE DESIGNS

Material efficiency is both an economic and environmental imperative in modern product design. Minimising material usage complements strategies that use sustainable materials, further reducing the overall environmental impact of medical devices. Beyond lowering the fossil-based carbon usage of the materials of construction, efficient design minimises transport weight, energy use during moulding and waste generation.[6,9]

The physical properties of PC – in particular the combination of rigidity and ductility – enables designers to implement thin-wall designs without sacrificing mechanical integrity. Transitioning from conventional wall thicknesses to thin-wall geometries can result in a weight reduction of ~42%, while maintaining superior strength and rigidity compared with polypropylene or polyamide alternatives.[6]

This capability is particularly critical for autoinjectors and inhalers, where precision and mechanical reliability are critical. Advanced simulation techniques, including computational fluid dynamics and structural analysis, can enable designers to optimise part geometries for functional performance. This targeted approach ensures that material is used efficiently, with thicker sections only implemented where required. Simulations can also assist with the injection-moulding process design to ensure efficient manufacturing. It should also be noted that, within medical-grade PC ranges, multiple molecular weights are available to help balance the needs of performance and manufacturability.

The consistent mechanical properties and dimensional stability of PC across humidity conditions reduces design uncertainty compared with polyamide, whose properties vary significantly.[9] The design of autoinjector components, such as bodies, plungers and strikers, illustrates this principle. Traditionally, high-stress components such as strikers require glass-fibre reinforced polyamide or polybutylene terephthalate, whereas advanced PC grades, such as Makrolon® M424LF, provide sufficient stiffness and low friction inherently, enabling drop-in replacements while simplifying material complexity and lowering the carbon footprint.[6] Finite element method simulations confirm that PC strikers meet creep and durability requirements without resorting to excessive material usage, demonstrating how sustainable designs are intricately linked to material selection.

It should also be noted that reducing material complexity also enhances recyclability through easier sorting and streamlines the moulding steps. The physical properties of PCs can also help to enable new approaches to eliminate clips or fasteners that can complicate disassembly and sorting for recycling. Snap-fit designs, living hinges and integrated features can replace these elements while maintaining functionality.

HOW PC PAVES THE WAY FOR OPEN- AND CLOSED-LOOP RECYCLING IN HEALTHCARE

Beyond in-use performance, PC still retains much of its functionality after recycling, enabling its use in materials formulated with mechanically recycled PC. PC has been part of polymerase chain-reaction-containing materials for several decades, and the material is well-positioned to meet emerging demands for recyclate content in electronics and automotive applications.

Previous studies have shown that the stability of PC translates to consistent performance in recycled applications, with minimal degradation of mechanical properties through multiple recycling cycles.[3] Studies have also shown that properly processed recycled PC can maintain its original impact strength and tensile properties, making it suitable for demanding applications even after recycling.

> "IT SHOULD ALSO BE NOTED THAT REDUCTION OF MATERIAL COMPLEXITY ALSO ENHANCES RECYCLABILITY THROUGH EASIER SORTING AND STREAMLINES THE MOULDING STEPS."

PC Simplifies Recycling for Healthcare

Covestro developed drug delivery device demonstrators composed entirely of PC-based plastic materials to illustrate how simplified materials can function together and simplify recycling. In this concept, medical-grade PC materials with desired functionalities (e.g. low friction or high creep resistance) simulated the functioning of a single-use autoinjector. Due to the inherent compatibility of the plastic components, separation for recycling was simplified by focusing solely on separation of glass and metal from plastics. Even with fully mixed plastic components, the resulting recyclate retained good properties, even after several re-processing steps. Lifecycle assessment calculations suggest that 100% recycled PC could

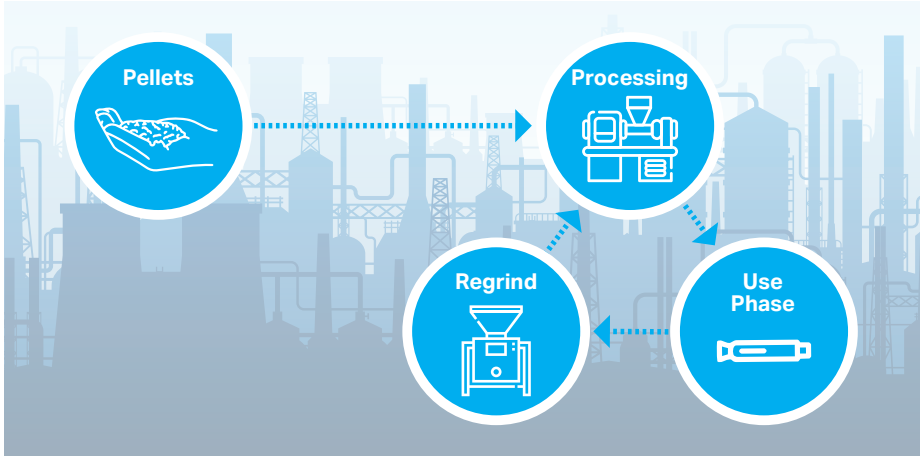

Figure 1: Mechanical recycling of mixed PC-centric waste.

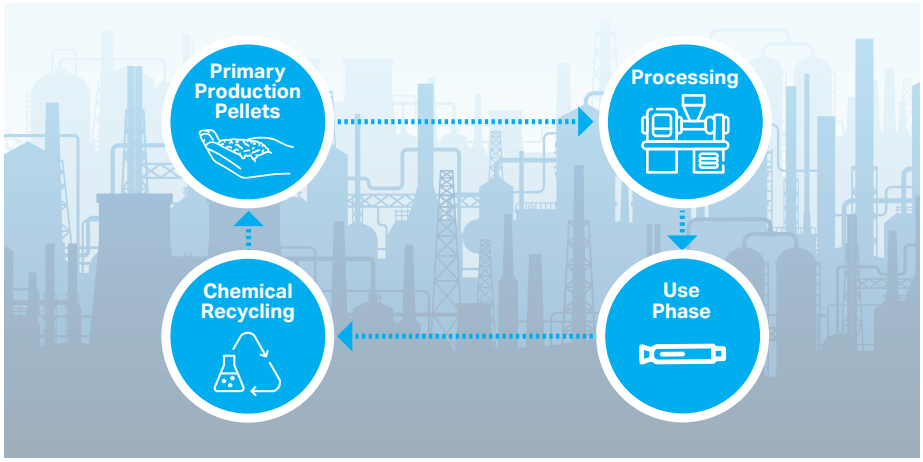

Figure 2: Future chemical recycling of mixed PC-centric healthcare devices.

reduce climate impact by up to 34%, and even 20% recycled content yielded a 7% CO_2 reduction.[10]

Closed-Loop Recycling

Healthcare presents a significant challenge for use of recyclate; however, a 2024 study by Barbaroux *et al* evaluated the mechanical recycling of single-use PC bioreactor vessels used for research in the biopharma sector. The aim of this study was to assess the feasibility of setting up a closed loop to reduce both carbon footprint and plastics waste from a sector that relies heavily on single-use plastics. After autoclaving, vessels were shredded and reprocessed to make new ones. No significant changes were noted in cell compatibility or product quality, indicating that PC could support closed-loop recycling even in sensitive bioreactor applications.[10]

Implementation of closed-loop systems (Figure 1) requires meticulous collection, decontamination and quality control protocols. However, the potential benefits can be substantial: reduced consumption of virgin raw materials, lower carbon emissions and decreased waste management costs. Several healthcare facilities have already implemented pilot programmes for closed-loop recycling of non-patient-contact plastic items, demonstrating the increasing efforts to make healthcare more sustainable.[3,10,11]

Chemical Recycling

Chemical recycling (Figure 2), which has made substantial advances in recent years, represents a complementary approach to mechanical recycling, which is particularly valuable for materials that have undergone multiple mechanical recycling cycles and begun to show degradation in properties. By returning these materials to their molecular building blocks, chemical recycling can effectively "reset the clock" on material ageing, setting the stage for circularity without quality loss.

Chemical recycling breaks polymers down into monomers or chemical building blocks that can be reused for synthesis of polymers, which are indistinguishable from virgin materials.[12,13] In certain cases, such a process can even address the challenge of multi-material devices and enable genuine circularity.

PC's outstanding retention of properties in mechanical recycling stems from the stability of the material. This stability has presented a particular challenge for chemical recycling of PC, but recent advances have made this not only possible but also scalable, energy-efficient and environmentally responsible. Covestro's new RP series marks the company's first product line linked to chemically recycled post-consumer waste, which is designed to address end-of-life expectations. The RP suffix refers to chemically recycled attributed plastics that combine high purity with the use of secondary raw materials while maintaining the performance and quality of primary fossil-based PCs.[14] Covestro incorporates two key practices into the production process: the use of alternative raw materials attributed with chemically recycled content through mass balancing, and the allocation of energy from renewable sources at selected production sites.

In addition, Covestro has developed a new chemical recycling process for PC, overcoming the last barrier to full circularity for this material and establishing a viable process to break down PC into its monomer, which can be re-polymerised to yield high-quality PCs again. Covestro has expanded beyond lab-scale and is setting up a pilot-scale facility.[15]

"BY RETURNING THESE MATERIALS TO THEIR MOLECULAR BUILDING BLOCKS, CHEMICAL RECYCLING CAN EFFECTIVELY 'RESET THE CLOCK' ON MATERIAL AGEING, SETTING THE STAGE FOR CIRCULARITY WITHOUT QUALITY LOSS."

CONCLUSION

The path to more sustainable drug delivery is clear – PC-based devices designed for recycling and material efficiency can help to reduce the healthcare sector's environmental footprint. Using bio-circular feedstocks, thin-wall smart design, mechanical recyclability and chemical recycling, manufacturers can achieve tangible carbon footprint reductions, lower plastic consumption and attain circularity at scale.

The transition to sustainable healthcare devices represents not just an environmental imperative but also a strategic business opportunity. As regulatory frameworks increasingly demand extended producer responsibility and carbon accountability, organisations that proactively embrace circular design principles will gain competitive advantages in market access, stakeholder trust and operational resilience.

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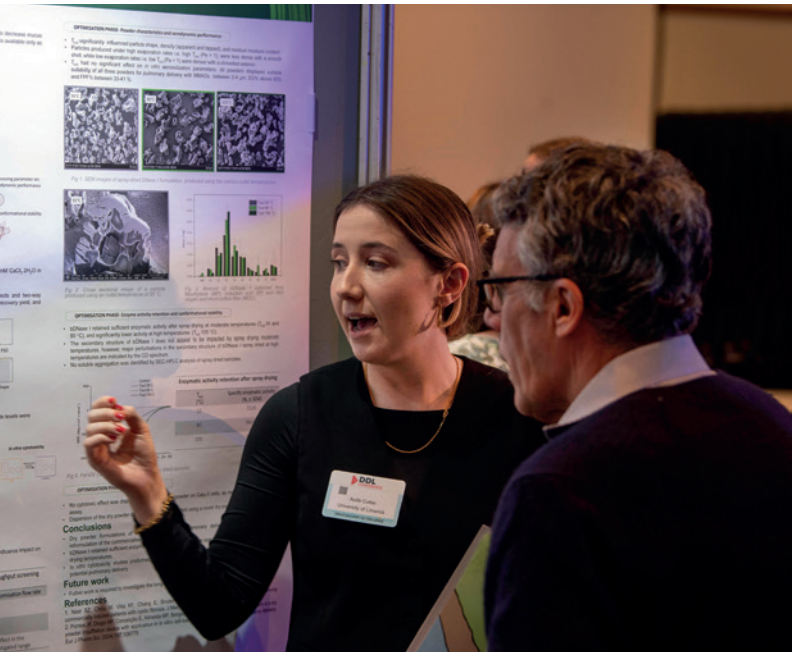
DRUG DELIVERY TO THE LUNGS



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BIO-BASED PLASTICS IN DRUG DELIVERY: FROM MATERIAL EQUIVALENCE TO SYSTEMIC DECARBONISATION

YPSOMED SELFCARE SOLUTIONS

Nadine Kaufmann and **Michael Schori** of **Ypsomed** analyse the feasibility of introducing sustainable materials within current regulatory frameworks, demonstrating this with a range of Ypsomed products and illustrating ways to further integrate sustainable principles into the value chain.

CARBON FOOTPRINTS: AN INDUSTRY TREADS CAREFULLY

The pharmaceutical industry is facing growing pressure to reduce its carbon footprint, particularly regarding Scope 3 emissions and product lifecycle impact. Combination products, including self-injection devices used in chronic therapies, are increasingly visible in this discussion, as frequent administration over many years translates into substantial material consumption and end-of-life waste. Healthcare systems, investors and procurement bodies are beginning to scrutinise not only therapeutic outcomes but also environmental performance.

At the same time, drug delivery systems operate within one of the most tightly regulated engineering environments in the industry. Materials are qualified, validated and embedded within controlled specifications, often across global markets. Any modification must be supported by biocompatibility assessments and managed under rigorous change control.

> "SUSTAINABILITY INITIATIVES MUST ACHIEVE ENVIRONMENTAL GAINS WITHOUT INTRODUCING TECHNICAL OR REGULATORY UNCERTAINTY."

This creates a structural tension: decarbonisation calls for material evolution, while regulation prioritises stability and predictability. In this context, sustainability initiatives must achieve environmental gains without introducing technical or regulatory uncertainty.

MATERIAL EVIDENCE: THE CASE FOR REGULATION

Regulatory conservatism should not be understood as reluctance to innovate, but as an integral framework designed to safeguard patient safety and product reliability. Within this environment, a material is never just a material – it forms part of a validated system that interacts with a medicinal product, interfaces with the patient and is documented across technical files and regulatory submissions.

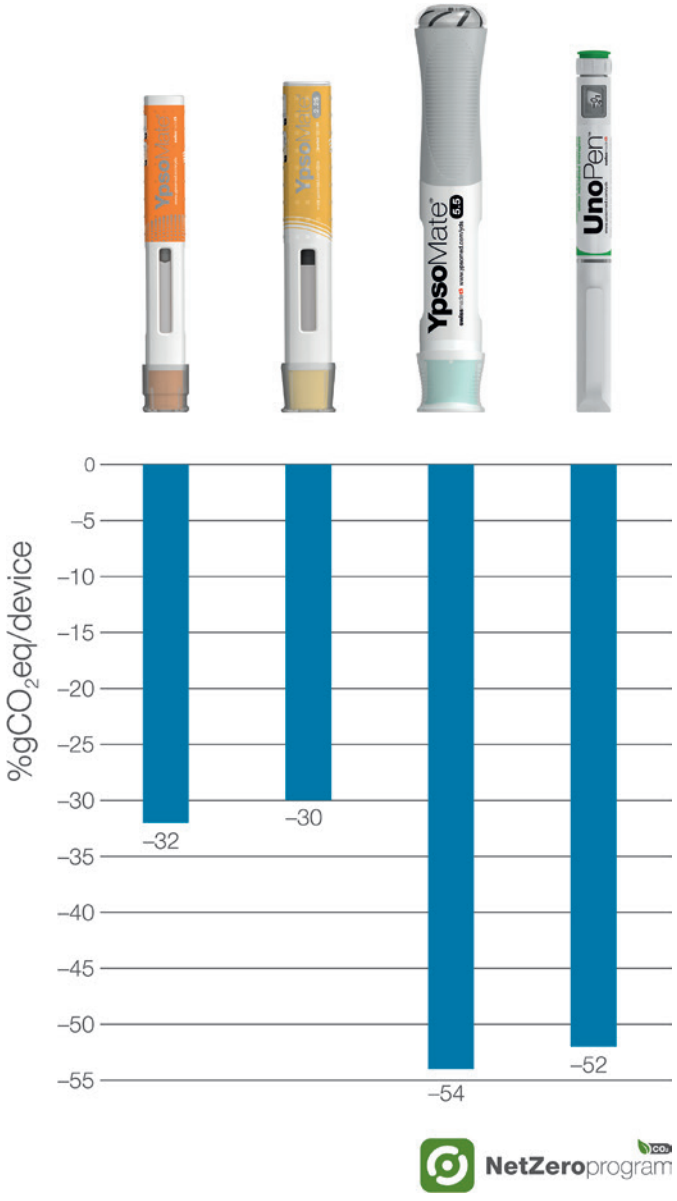

Figure 1: CO_2 reduction in device material when switching to bio-based polymers for Ypsomed's NetZero Program product platforms (cradle-to-gate, according to ISO 14067, which addresses biogenic CO_2 uptake).

Any proposed substitution, even when driven by sustainability objectives, must therefore be assessed through the same disciplined processes applied to safety and performance changes.

Combination products are particularly sensitive to material modifications. Polymer components may influence extractables and leachables profiles, sterilisation behaviour, mechanical stability and long-term ageing characteristics. Material choices are closely linked to ISO 10993 biocompatibility evaluations. Thus sustainability initiatives must operate within this governance structure. Procurement ambitions alone are insufficient; engineering, regulatory and quality functions must align on equivalence criteria, documentation expectations and lifecycle implications.

The central question is not whether a material is renewable, but whether it can be integrated without altering the validated safety and performance envelope of the device. In the last few years, several established self-injection platforms have answered this affirmatively, demonstrating that sustainability can be implemented within existing regulatory frameworks.

In practice, this approach is embedded within Ypsomed's NetZero Program, which forms part of the company's science-based emissions reduction roadmap targeting net zero across the value chain. Within this framework, selected flagship platforms, including YpsoMate 1.0, YpsoMate 2.25 and UnoPen, are available in carbon-reduced variants. These integrate bio-based plastics with International Sustainability and Carbon Certification (ISCC+) while maintaining full biocompatibility, functionality and safety. Because the polymer chemistry remains unchanged, these implementations require no additional testing or requalification. For pharmaceutical partners, this demonstrates that decarbonisation can be incorporated into established platforms without altering validated device performance or regulatory status (Figure 1).

WHAT'S THE MATTER? A QUESTION OF CARBON, NOT CHEMISTRY

Early efforts to improve the environmental profile of medical plastics are often focused on biodegradable or novel bio-derived polymers. While well intentioned, these materials have frequently introduced new chemistries with different mechanical properties, altered extractables profiles and uncertain long-term ageing behaviour, and were not compatible with existing recycling streams. In regulated drug delivery systems, such changes inevitably translated into additional validation requirements and regulatory complexity. Sustainability therefore became associated with technical risk.

> "RATHER THAN MODIFYING POLYMER CHEMISTRY, DROP-IN BIO-BASED MATERIALS RETAIN THE EXACT SAME MOLECULAR STRUCTURE AS THEIR FOSSIL-BASED COUNTERPARTS."

The current generation of bio-based polymers follows a different path. Rather than modifying polymer chemistry, drop-in bio-based materials retain the exact same molecular structure as their fossil-based counterparts. The distinction lies solely in the origin of the carbon feedstock used during production, not the chemical architecture.

Conventional polymers and engineering plastics are typically derived from fossil-based petrochemical feedstocks such as naphtha or methanol. In bio-based variants, renewable feedstocks, such as waste-based oils or other second-generation biomass, are introduced upstream in the refining process, resulting in the same essential petrochemicals as in the fossil route. Through established polymerisation routes, these inputs yield polymers with an identical molecular structure, identical additive packages and identical material specifications. Thus the resulting resin is chemically identical to the fossil-based material (Figure 2).

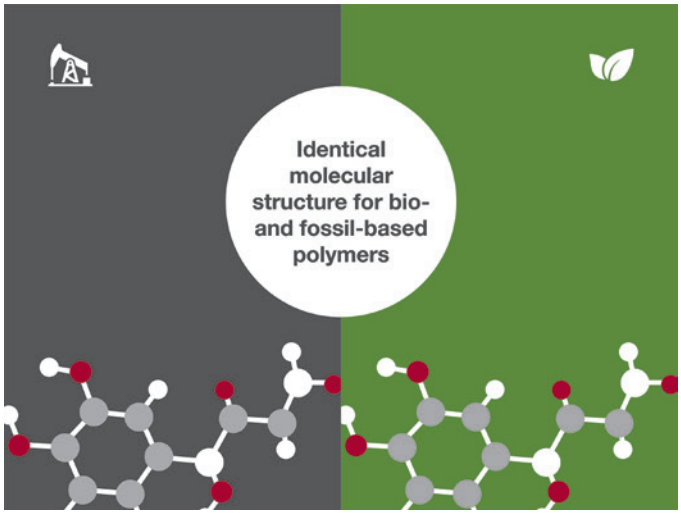

Figure 2: Identical molecular structure for bio- and fossil-based polymers.

NOTING TO DECLARE: DOCUMENTING EQUIVALENCE

If polymer chemistry and material specifications remain unchanged, the regulatory implications of transitioning to bio-based feedstock are significantly reduced. From a technical standpoint, equivalence is established through specification matching, supplier declarations and continuity of documentation. The feedstock origin does not alter the polymer structure; therefore, toxicological profiles, extractables strategies and functional performance data remain within the validated range.

Documentation discipline, however, remains essential. Extractables and leachables rationales must demonstrate that existing data remain applicable, while supplier qualification and audit documentation, particularly under ISCC+ certification schemes, must ensure traceability of renewable content claims. For platform-based devices developed within mature quality systems, this level of assessment is a familiar exercise rather than an exceptional hurdle.

PERFORMANCE REVIEW: MEETING EXPECTATIONS

Polymer performance is determined by molecular architecture, not by the origin of the carbon used to create it. With bio-based polymers, the polymer backbone, molecular weight distribution and additive formulation remain exactly the same, resulting in a material that exhibits the same mechanical strength, dimensional stability and resistance to environmental stress cracking as its fossil-based equivalent. When these parameters remain constant, functional behaviour remains constant.

> "A SHIFT IN FEEDSTOCK ORIGIN DIRECTLY REDUCES UPSTREAM CARBON INTENSITY AT ITS SOURCE, BUT REDUCTIONS MUST BE QUANTIFIED USING CLEARLY DEFINED CRADLE-TO-GATE SYSTEM BOUNDARIES TO ENSURE METHODOLOGICAL TRANSPARENCY."

For injection devices, this equivalence is essential. Structural components must retain their geometry under load, during sterilisation and throughout long-term ageing. Resistance to ethylene oxide or gamma sterilisation depends on the stability of the polymer chain rather than the feedstock source.

New platforms offer the opportunity to integrate sustainable materials from the very beginning of the design phase. However, it is equally important to continue using well-established engineering plastics with proven long-term behaviour and reliable technical performance. By transitioning these materials to bio-based feedstocks, their sustainability profile can be further improved without compromising functionality or safety. Since 2021, all of Ypsomed's new platforms, such as YpsoFlow and YpsoDot, follow this process.

Yet, material strategy alone does not define the upper limit of sustainable device design. With YpsoLoop, an award-winning autoinjector combining sustainability and patient convenience, Ypsomed advances further. It combines carbon-reduced materials comprising only two bio-based, monomaterial subassemblies with a circular design philosophy, translated into a design made for automated disassembly and efficient recycling.

PUTTING LIFECYCLE IN SCOPE

Material substitution is meaningful only when evaluated across the full product lifecycle. Product lifecycle assessments, conducted according to ISO 14040, 14044 and 14067 standards or Greenhouse Gas Protocol's Corporate Standard, provide the framework for quantifying environmental impact from raw material extraction through manufacturing, distribution, use and end-of-life.

For device manufacturers, Scope 3 emissions typically dominate the carbon footprint, particularly those associated with raw material production. Design-stage decisions therefore exert disproportionate

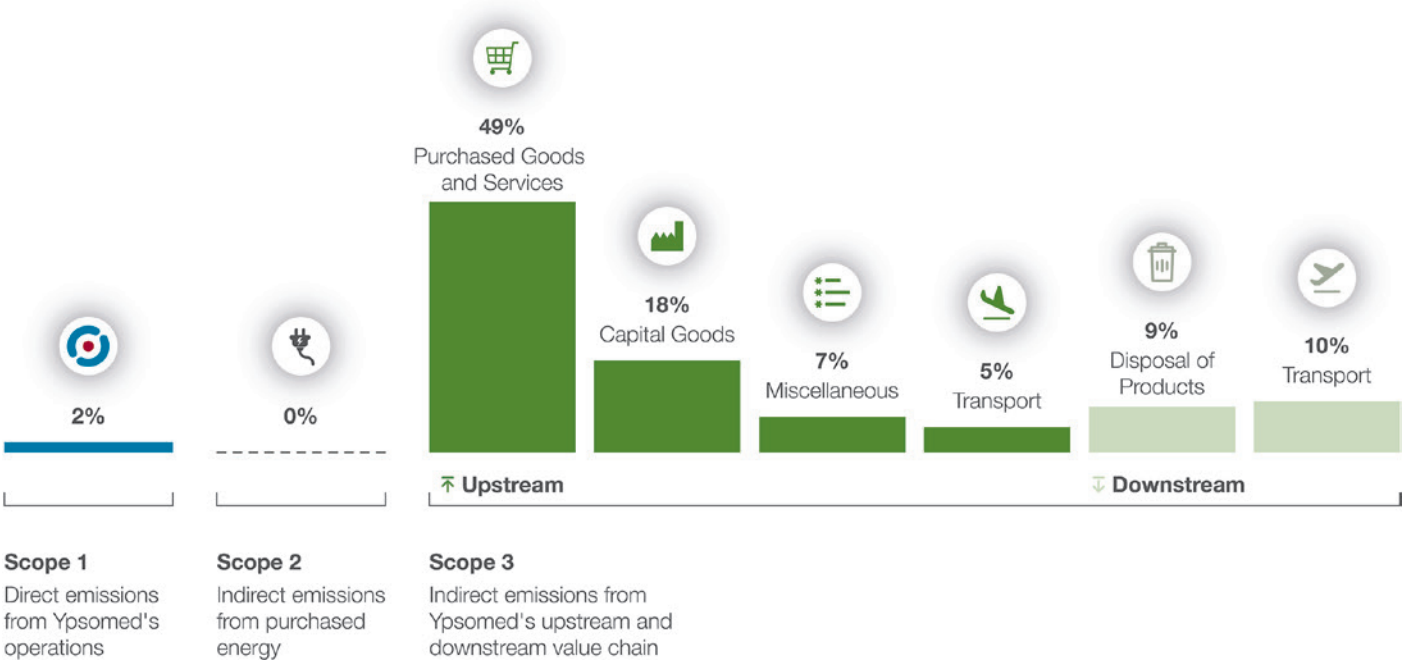

Figure 3: Carbon footprint of Ypsomed AG and its subsidiaries according to latest sustainability report.

influence over total lifecycle impact. A shift in feedstock origin directly reduces upstream carbon intensity at its source, but reductions must be quantified using clearly defined cradle-to-gate system boundaries to ensure methodological transparency (Figure 3).

BALANCING THE BOOKS AT SCALE

The transition to renewable carbon does not occur at the moulding machine. It takes place upstream, at the refinery and feedstock level, where renewable raw materials are introduced into existing petrochemical infrastructure. Because physical segregation of molecules is neither practical nor necessary, attribution is managed through a mass balance methodology.

Under this approach, renewable feedstock input is tracked and allocated to specific outputted products. Independent certification bodies verify that defined volumes of renewable content enter the system and are correctly attributed downstream. ISCC+ certification provides chain-of-custody documentation, audit traceability and standardised accounting rules. ISCC+ also ensures a high standard of sources for bio-based materials protecting high-value land, ensuring eco-friendly production, upholding labour rights and complying with laws. Responsible sourcing is central to credibility. Ypsomed prioritises waste-based feedstocks to avoid deforestation and competition with food crops. They also exclude first-generation biomass routes to minimise land-use concerns (Figure 4).

> "YPSOMED PRIORITISES WASTE-BASED FEEDSTOCKS TO AVOID DEFORESTATION AND COMPETITION WITH FOOD CROPS."

Ypsomed was first certified ISCC+ in 2023 and operates multiple certified sites globally. Net zero implementations within Ypsomed platforms rely on ISCC+ certified supply chains and standardised lifecycle assessments to substantiate carbon reduction claims. The environmental benefit lies in verified upstream carbon reduction, not in any physical difference in the moulded component.

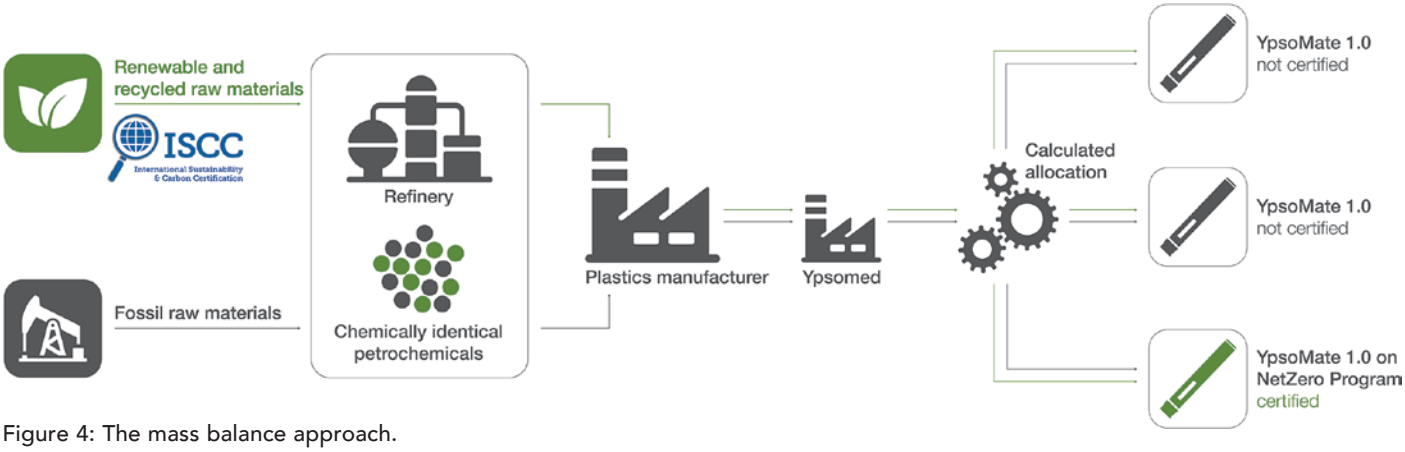

Figure 4: The mass balance approach.

CRITICAL MASS: THE GLP-1 STRESS TEST

The systemic relevance of bio-based integration becomes most visible in high-volume therapeutic areas. GLP-1 receptor agonists, widely used for type 2 diabetes and obesity, are frequently administered over extended periods, resulting in sustained high device usage across large patient populations. Millions of disposable injection devices are produced annually, each containing multiple polymer components derived from carbon-intensive feedstocks.

Lifecycle modelling of net zero variants demonstrates how per-unit reductions translate into substantial aggregate impact across global treatment volumes, reinforcing the value of integrating renewable carbon at platform scale. In such contexts, even incremental reductions in cradle-to-gate emissions per device compound rapidly at population scale. Extended dosing intervals may reduce injection frequency over time, but material intensity per device can remain similar. Therefore, decarbonising polymer input represents one of the few scalable levers available without altering clinical practice.

> "DECARBONISING POLYMER INPUT REPRESENTS ONE OF THE FEW SCALABLE LEVERS AVAILABLE WITHOUT ALTERING CLINICAL PRACTICE."

A VALUE CHAIN REACTION: THE NEED FOR SYSTEMIC ALIGNMENT

From a technical standpoint, drop-in bio-based polymers are no longer experimental. The chemistry is established, performance equivalence is demonstrable and regulatory pathways are well understood. The remaining constraints are largely systemic.

Renewable feedstocks compete with other sectors, including sustainable aviation fuels. Certification capacity must scale alongside demand. Regulatory recognition of mass balance attribution continues to evolve across jurisdictions. Pharmaceutical procurement frameworks may still prioritise short-term cost stability over lifecycle carbon metrics.

In this context, the limiting factor is not polymer science but market alignment. Decarbonisation requires a co-ordinated movement across resin suppliers, device manufacturers, pharmaceutical companies and healthcare systems. Technical feasibility alone does not guarantee adoption. Ypsomed engages with multiple stakeholders along the value chain, such as the Alliance to Zero of which it is a founding member, to collaboratively resolve outstanding questions and concerns.

GOING FULL CIRCLE

The integration of bio-based polymers represents an important step, but it is only one facet of a deeper shift in how devices are conceived, designed and evaluated. As the industry matures in its understanding of lifecycle emissions and supply-chain

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Michael Schori

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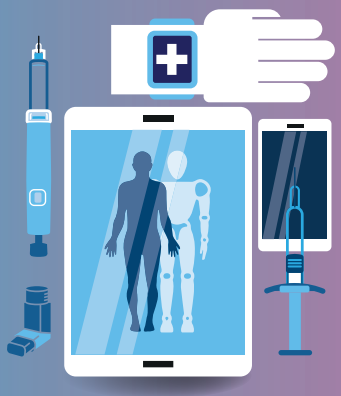
decarbonisation, attention is increasingly moving towards design strategies that address impact at both ends of the product lifecycle.

At Ypsomed, responsibility is embedded as a core pillar of long-term strategy, shaping how devices are designed, manufactured and evaluated across their lifecycle. YpsoLoop is a tangible expression of this commitment, a platform conceived with circularity principles embedded from the outset. Bio-based polymers are used as the standard, but rather than treating end-of-life as an afterthought, YpsoLoop's architecture simplifies material recovery. This is achieved through design for automated disassembly and efficient recycling, while retaining the usability and safety expected of prefilled, two-step autoinjectors. This approach acknowledges that reducing embodied carbon upstream is only part of the equation; true structural decarbonisation requires devices that are designed to feed back into material cycles once they have been used.

Future innovation in sustainable drug delivery will likely build on this template: combining low-impact feedstocks with device designs that anticipate and enable responsible end-of-life pathways. Collaboration across manufacturers, healthcare systems and recycling infrastructure providers will be essential for this next horizon of impact (Figure 5).

Figure 5: YpsoFlow, YpsoDot and YpsoLoop: Since 2021, Ypsomed has applied ecodesign principles to all new product development.



Expert View

LATE-STAGE MATERIAL SUBSTITUTION: AMBITION FOR SUSTAINABILITY OR TRANSFER-TIME RISK?

Kiara Taylor of Sanner delves into the challenges of changing materials to enhance sustainability after a design has been transferred to manufacturing, considering the reasons that might drive such a change, the issues involved and the benefits that can be gained.

"STAKEHOLDER OR CUSTOMER EXPECTATIONS MAY SHIFT LATE IN DEVELOPMENT, FAVOURING MORE SUSTAINABLE OPTIONS THAT WERE NOT PREVIOUSLY PRIORITISED."

Material selection can have a major influence on the environmental impact of a product. Ideally, the materials for a device would have been carefully considered through an environmental lens when initially selected, meaning that there is no need to change them once in production. Unfortunately, that is not the case for every product. If requirements change after design transfer, this presents an opportunity to improve the sustainability of the device, potentially by switching to an alternative material.

Any alteration made during or after transferring a design to manufacturing can have significant repercussions. This is particularly true when the change involves a material substitution, which often sits at the heart of a device's validated performance, manufacturing process and regulatory justification. In drug delivery products, where material properties directly influence mechanical function, patient safety and drug compatibility, a late-stage material change can trigger a cascade of additional work. Biocompatibility or extractables and leachables testing may need to be repeated, sterilisation compatibility may need to be reassessed and supply chains may require requalification. What might initially appear to be a straightforward substitution can therefore become a substantial engineering and regulatory undertaking.

Figure 1: Sustainability measures can include installing solar panels and wind turbines at manufacturing sites.

For this reason, best practice encourages teams to address sustainability considerations early in the design process. Involving relevant stakeholders during concept development and feasibility stages can help to ensure that material choices align with both functional requirements and environmental ambitions. Methods such as early life cycle assessments (LCAs), collaborative stakeholder engagement and multidisciplinary design reviews allow sustainability to be embedded within the design inputs themselves. When this approach is taken, environmentally preferable materials can be evaluated alongside traditional performance metrics such as durability, manufacturability and regulatory acceptability.

Despite these efforts, situations arise in which material changes become necessary down the line. For example, stakeholder or customer expectations may shift late in development, favouring more sustainable options that were not previously prioritised. This may occur following a corporate acquisition, where new leadership introduces revised environmental strategies and sustainability targets, or based on customer demand. Similarly, a late-stage LCA may reveal that an alternative material could substantially reduce the environmental burden of the product.

In one example, a company sought to improve the sustainability of a self-injection device when it scaled its operations to meet increased demand. This presented a rare opportunity to rethink the design and manufacturing methods to improve efficiency, decrease waste and reduce cost. The suggested changes eliminated the need for three components, thereby reducing material usage and manufacturing energy, as well as decreasing the cost by 16%.

These scenarios highlight a fundamental challenge for the industry – balancing sustainability ambitions with the practical realities of validated manufacturing and regulatory compliance (Figure 1). While late-stage material substitution is never desirable, it is sometimes unavoidable. Understanding how to navigate these changes effectively is therefore becoming an increasingly important skill for engineering teams working on drug delivery technologies.

Figure 2: Sustainable effervescent tubes manufactured using bio-material.

CASE STUDY

A practical illustration of this challenge can be found in a recently undertaken sustainability initiative. Anticipating consumer packaging preferences, a more sustainable option was introduced within a portfolio of tube packaging used for effervescent tablets (Figure 2). At the time this initiative began, production had already been well established for tubes manufactured from conventional polypropylene (PP), meaning that any material change would have to be implemented within an existing manufacturing framework.

The first stage of the project involved a detailed investigation of potential alternative materials. One of the most promising sustainability strategies for packaging is the incorporation of post-consumer recycled content, which supports circular material flows and reduces reliance on virgin polymers. However, regulatory restrictions still limit the use of recycled materials in food-contact packaging applications. Since effervescent tablet tubes fall into this category, the use of post-consumer recycled plastics was not considered viable within the current regulatory environment.

The team therefore explored plant-based polymer options that were already being used in certain packaging applications. These materials offered the potential to reduce dependence on fossil resources while maintaining similar functional properties to conventional plastics. However, as the investigation progressed, it became clear that adopting these alternatives would introduce significant technical challenges. Differences in material behaviour during moulding, as well as incompatibilities with existing tooling, made this option difficult to implement within the constraints of the current production system.

The tools originally used for manufacturing the tubes had been designed around the processing characteristics and shrink rates of standard PP grades. When the alternative plant-based high-density polyethylene (HDPE) material was introduced, dimensional alignment with existing specifications was no longer guaranteed due to a number of factors:

- Melt flow rates
- Degree of crystallinity and therefore packing pressure
- Mould temperature
- Shrinking
- Demoulding.

In response, the engineering team modified the tool designs to accommodate the specific properties of the plant-based HDPE. Production parameters were also carefully refined to ensure that dimensional accuracy could be maintained.

Figure 3: The polyethylene cycle.

By transitioning to plant-based HDPE, the team achieved a 15% reduction in CO_2 emissions while avoiding major disruptions to established manufacturing processes (Figure 3). This reduction applied both to the manufacturer's own operations and to the packaging footprint of its customers. Additionally, the tube's moisture barrier was increased by over 30%, leading to a longer shelf life for the tablets, thereby improving another aspect of its sustainability.

The case study demonstrated that late-stage material substitution can be successfully implemented, but only when it is approached systematically. When such changes become necessary, a formal risk management review aligned with ISO 14971 will be triggered.

RISK MANAGEMENT REVIEW

The purpose of this review is to identify which aspects of device performance and safety are sensitive to material changes. These include dose accuracy, delivery performance, creep behaviour, actuation forces and the reliability of safety mechanisms such as needle shields. Dimensional tolerances that affect the interface between the device and the drug container must also be considered.

A structured risk assessment allows engineering teams to focus their verification efforts on these critical areas. Rather than repeating every original test conducted during development, targeted testing programmes can be designed to confirm that the substituted material does not compromise essential device functions.

"BY TRANSITIONING TO PLANT-BASED HDPE, THE TEAM ACHIEVED A 15% REDUCTION IN CO_2 EMISSIONS WHILE AVOIDING MAJOR DISRUPTIONS TO ESTABLISHED MANUFACTURING PROCESSES."

The risk management review would also encompass a structured material equivalence assessment. The objective of this exercise is to identify an alternative that behaves as similarly as possible to the original material while still delivering the desired sustainability benefits.

MATERIAL EQUIVALENCE ASSESSMENT

This assessment typically examines several critical properties. Mechanical behaviour must be carefully evaluated, as changes in tribology, strength, stiffness or creep characteristics may affect product performance. Thermal characteristics also require consideration, particularly if processing temperatures differ from those originally validated. In many cases, finite element analysis (FEA) and multi-physics modelling can provide useful insights into how a new material will behave under operational loads.

Shelf-life considerations should also be reviewed, including the potential impact of moisture absorption and the role of additives or stabilisers in maintaining long-term performance. Improving the shelf life of the product can be a significant sustainability win.

Chemical composition and processing conditions are particularly important in drug delivery applications, where extractables and leachables are a critical consideration. Even minor differences in formulation and process conditions may introduce new compounds that could interact with the drug product.

Sterilisation compatibility is another common failure point in sustainable material substitutions. Many drug delivery devices rely on sterilisation processes such as ethylene oxide or gamma irradiation. Alternative materials may respond differently to these processes, exhibiting discolouration, embrittlement or changes in chemical and dimensional stability. Early screenings should therefore assess these risks, including the potential for residual absorption behaviour when ethylene oxide sterilisation is used.

"RATHER THAN REPEATING EVERY ORIGINAL TEST CONDUCTED DURING DEVELOPMENT, TARGETED TESTING PROGRAMMES CAN BE DESIGNED TO CONFIRM THAT THE SUBSTITUTED MATERIAL DOES NOT COMPROMISE ESSENTIAL DEVICE FUNCTIONS."

CONCLUSION

Ultimately, sustainable innovation in drug delivery will depend not on reactive material substitution, but on proactive design choices that integrate environmental responsibility alongside patient safety, product performance and regulatory compliance from the very beginning.

Therefore, the most effective strategy is not to manage these changes when they arise, but to anticipate them from the outset. By embedding environmental considerations within early design inputs, conducting

"DESPITE THE TECHNICAL AND REGULATORY CHALLENGES, IMPLEMENTING SUSTAINABILITY-DRIVEN CHANGES DURING OR AFTER DESIGN TRANSFER IS A VIABLE ROUTE FOR COMPANIES TO USE TO HELP MEET THEIR SUSTAINABILITY TARGETS."

robust material assessments during concept development and aligning sustainability objectives across engineering, regulatory and manufacturing teams, organisations can avoid costly retrofits later in the product lifecycle.

Despite the technical and regulatory challenges, implementing sustainability-driven changes during or after design transfer is a viable route for companies to use to help meet their sustainability targets. When approached with rigour and cross-functional alignment, material substitution can deliver meaningful reductions in environmental impact without compromising product integrity or compliance. In some cases, it may even enhance device performance through improved material properties or more efficient manufacturing processes. Rather than being viewed solely as a constraint, late-stage material optimisation should be recognised as an opportunity to strengthen both the sustainability and overall quality of drug delivery devices.

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.

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Kiara Taylor is a Consultant Design Engineer at Sanner with a keen interest in sustainability and user-centric design. Drawing from a broad understanding of engineering, design, human factors and manufacturing principles, Ms Taylor enjoys working with clients to develop innovative solutions.

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Expert View

MAINTAINING RELIABLE DRUG DELIVERY THROUGH SUSTAINABLE OPERATIONS

Henryk Badack of Vetter considers how a holistic approach to sustainability can enable CDMOs to implement efficient operations strategically – while introducing initiatives that address environmental, economic and social elements.

The rapid evolution of advanced biologics is reshaping expectations for drug delivery – and with it, the operational standards that CDMOs must meet. The need for robust aseptic processes, reliable scale-up and high-quality production has never been greater. These are areas where a specialised CDMO partner can materially benefit its biopharma customers and, ultimately, patients by reducing risk and time-to-market for drug development programmes. This alone represents a meaningful contribution to faster and safer patient access. When combined with a strategic commitment to sustainability, these capabilities gain an additional layer of resilience and long-term reliability.

Sustainability enables CDMOs to address the implicit demands associated with complexity without shifting their core focus away from their customers' development, manufacturing and packaging needs. Seasoned outsourcing partners already understand how to mitigate risk through proven processes, quality management systems and cross-functional expertise – from clinical to commercial scale and beyond. However, when pharmaceutical service providers make consistent and strategic investments in sustainability, they foster improved trust and reliability throughout the system.

THE SUSTAINABILITY GENE: STRATEGY IN PRACTICE

For experienced manufacturing partners, sustainability is a corporate responsibility. It should be rooted into a company's DNA as a critical part of its business strategy. A holistic approach to sustainability can allow CDMOs to implement efficient operations strategically throughout the company – with a focus on introducing initiatives that address environmental, economic and social elements.

"WHEN PHARMACEUTICAL SERVICE PROVIDERS MAKE CONSISTENT AND STRATEGIC INVESTMENTS IN SUSTAINABILITY, THEY FOSTER IMPROVED TRUST AND RELIABILITY THROUGHOUT THE SYSTEM."

Figure 1: PV cells can be used to generate a significant portion of a facility's electricity requirements.

"STRATEGIC FINANCIAL INVESTMENT INTO SUSTAINABLE EFFORTS WILL IMPROVE A SERVICE PROVIDER'S PARTNERSHIPS OVER TIME, AS WELL AS ITS OWN LONGEVITY AND FUTURE GROWTH."

Positive results, however, do not appear overnight; effective sustainability strategies require long-term dedication to creating and building up viable initiatives and programmes. The impact of these strategic investments can be tracked over time with measurable actions and commitments. For example, the adoption of renewable energy sources at service provider facilities can have a big impact on sustainability. Using climate-friendly energy – such as photovoltaics (PV) and biomethane – for pharmaceutical production can lead to drastic reductions in carbon utility emissions without risking drug delivery reliability (Figure 1). Energy efficiency initiatives that are both reasonable and measurable can contribute to the achievement of ambitious goals, all while avoiding compromising product quality or patient safety in their execution.

Sustainable operations, however, cannot have a one-dimensional focus. They need to be all-encompassing. A seasoned outsourcing partner's effective and comprehensive approach should include a commitment to supporting employee wellbeing through social sustainability efforts. Offering enhanced employee benefits – such as free supplementary health insurance, mental health and fitness initiatives, and mobility programmes (for example, bike leasing and public transport subsidies to encourage use of sustainable transportation) – supports a healthier, more resilient workforce, which is an essential pillar of sustainable operations.

"SUSTAINABILITY HAS MOVED FROM A VOLUNTARY INITIATIVE TO A CORE EXPECTATION FOR CDMOs."

Another element of corporate responsibility is a commitment to support biopharma customers in achieving their Scope 3 sustainability goals through these initiatives. Strategic financial investment into sustainable efforts will improve a service provider's partnerships over time, as well as its own longevity and future growth.

PROOF OF CONCEPT: THE IMPACT OF SUSTAINABILITY EFFORTS

For many manufacturing partners, determining the quality of their sustainability efforts can be difficult to navigate. How can a company confirm that they are on the right track with their sustainability strategy? Third-party validation from international campaigns can provide much needed reassurance. For example, external sustainability ratings (such as EcoVadis) and science-based climate target validations (such as the Science Based Targets initiative (SBTi)) provide transparent confirmation that sustainability strategies are both credible and aligned with global standards (Figure 2).

The SBTi validation process features a thorough analysis of emissions calculation methodology to confirm the accuracy and feasibility of the sustainability strategy. These recognitions reaffirm the real impact of effective sustainability strategy and operations based on their objectives to reduce greenhouse gas emissions and alignment with the Paris Agreement to achieve net zero emissions.

Sustainability has moved from a voluntary initiative to a core expectation for CDMOs. Aiming to reach net zero emissions in the next several decades is widely expected. Exploration into climate-friendly materials and increasing recycling rates supports the achievement of this goal.

In addition, pharmaceutical waste remains a challenging issue in the industry. Investment in waste separation and recycling efforts can alleviate the amount

Figure 2: EcoVadis ratings demonstrate a company's commitment to sustainability.

"PATIENT SAFETY AND REGULATORY COMPLIANCE MUST DRIVE EVERY SUSTAINABILITY DECISION."

of total waste that a service provider produces at its facilities. Another vital sustainability consideration for outsourcing partners is the evaluation of alternative packaging materials with customers to find approaches that work best for them – for example, paper-based or mono-material secondary packaging.

Patient safety and regulatory compliance must drive every sustainability decision. No longer a moral obligation but a quality expectation, sustainable operations can help CDMOs to win new business and foster long-lasting relationships.

SUSTAINABILITY: THE KEY TO RELIABLE DRUG DELIVERY

Sustainability in drug delivery, and in the biopharmaceutical industry as a whole, is not about choosing between climate protection and reliable operations. It is about doing both, and doing them well, to best serve customers and their patients around the world. Continuous strategic investment in sustainability builds trust with customers, in addition to providing direction for navigating risks and adjusting processes to meet evolving needs. Throughout sustainable operations, CDMOs need to be dedicated to

supporting reliability and resilience in drug delivery services with a holistic customer centric approach to address the growing demands of advanced injectables.

Clear benchmarks and long-term partnerships enable continuous progress and ensure that sustainability efforts remain measurable, credible and aligned with future industry needs. In the face of a shifting global market due to increasing complexity, sustainability will continue to help CDMOs sustain trustworthy services.

ABOUT THE COMPANY

Vetter is a family-owned CDMO with headquarters in Ravensburg, Germany, and production facilities in Germany, Austria and the US. Vetter also has sales locations in the Asia-Pacific markets of Japan, China, South Korea and Singapore. Around the world, pharma and biotech companies benefit from its decades of experience, high-quality, modern technologies, reliability and commitment of its 7,300 employees. In close collaboration with its customers, Vetter helps to enable the global supply of essential medicines. Vetter provides support from drug product development through clinical and commercial filling to a wide range of assembly and packaging services for vials, syringes and cartridges, developing prefilled drug delivery systems together with its customers to continuously improve patient safety, comfort and compliance. Vetter takes responsibility for sustainable practices and operates as a socially and ethically responsible corporate citizen. It is a member of the UN Global Compact and has Science Based Target initiative and received platinum ranking from EcoVadis.

Henryk Badack

Henryk Badack is a Managing Director at Vetter. Prior to that, he was Senior Vice President Technical Services. Mr Badack has over 20 years of experience in the pharma industry, having joined Vetter in 2003 as a Project Manager for validation and qualification projects. He later held positions of increasing importance at Sandoz in 2007–2008, before returning to Vetter in 2009.

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2026/27 Editorial Calendar

Each issue of ONdrugDelivery focuses 100% on one specific topic *within* drug delivery.

MAY Delivering Injectables: Devices & Formulations DEADLINE PASSED	**JUN** Oral Drug Delivery DEADLINE: **May 21, 2026**	**JUL** Industrialising Drug Delivery DEADLINE: **May 28, 2026**
SEP Wearable Injectors DEADLINE: **Aug 6, 2026**	**SEP/OCT** Dual Chamber Delivery Systems DEADLINE: **Aug 20, 2026**	**OCT** Prefilled Syringes & Injection Devices DEADLINE: **Sep 3, 2026**
OCT/NOV Sustainability in Drug Delivery DEADLINE: **Sep 17, 2026**	**NOV** Pulmonary & Nasal Drug Delivery DEADLINE: **Oct 1, 2026**	**DEC** Delivering Gene & Cell Therapeutics DEADLINE: **Nov 5, 2026**
JAN 2027 Prefilled Syringes & Injection Devices DEADLINE: **Dec 10, 2026**	**FEB** Oral Drug Delivery DEADLINE: **Jan 7, 2027**	**MAR** Ophthalmic Drug Delivery DEADLINE: **Feb 4, 2027**
APR Pulmonary & Nasal Drug Delivery DEADLINE: **Mar 4, 2027**	**APR/MAY** Sustainability in Drug Delivery DEADLINE: **Mar 18, 2027**	IN WHICH ISSUE SHOULD ***YOUR*** COMPANY APPEAR?

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REAL-TIME LCAs: CREATING "A SINGLE SOURCE OF TRUTH" FOR SUSTAINABILITY

Serena Grace of **Owen Mumford** and **Marina Dumont** of **PRé Sustainability** offer insight into the development of a real-time operational model for lifecycle assessments, and detail how organisations can transform these analyses into robust decision-making tools.

Pharmaceutical companies now generate more environmental data than ever, yet most still struggle to convert it into meaningful intelligence. Multiple, disconnected versions of "sustainability performance" metrics circulate within organisations, none feeding into real operational decision-making. Fundamentally, this is a systems challenge that cannot be solved through additional reporting alone. To shift sustainability from a retrospective disclosure exercise to a forwards-looking operational function, organisations need unified data structures that are capable of supporting real-time insight.

DATA-RICH BUT INSIGHT-POOR

Commercial focus on sustainability has grown in recent years, and rightly so. However, the haphazard nature of this evolution has led to a lack of co-ordination, both within organisations and more broadly across industries. Rather than

"PHARMACEUTICAL COMPANIES NOW GENERATE MORE ENVIRONMENTAL DATA THAN EVER, YET MOST STILL STRUGGLE TO CONVERT IT INTO MEANINGFUL INTELLIGENCE."

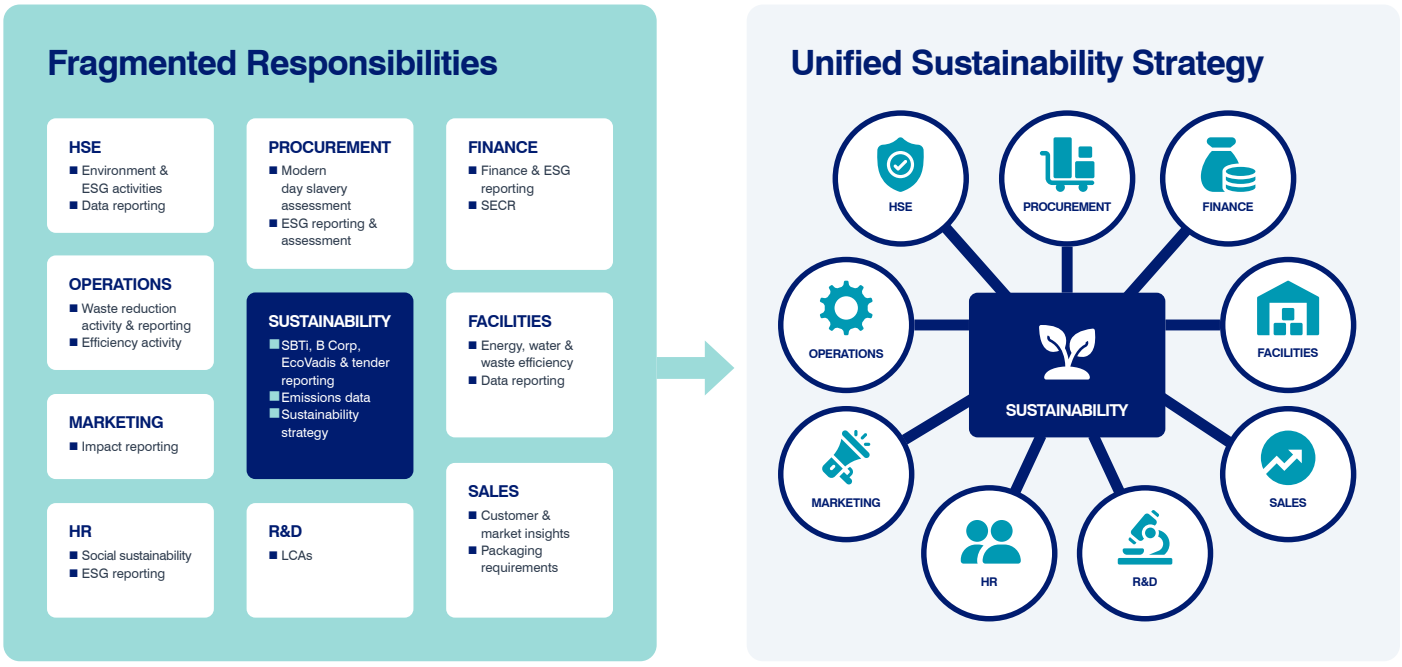


Figure 1: At present, sustainability responsibilities are dispersed among various departments, each operating with their own reporting standards, objectives and leadership. Establishing a unified strategy at the executive and board level will foster comprehensive top-down transformation.

a single, unified system, sustainability activity has emerged as a series of parallel initiatives introduced over time in response to evolving stakeholder expectations, regulatory requirements and business pressures (Figure 1).

As a result, different organisational functions assume responsibility for distinct aspects of sustainability. Each activity generates valuable environmental data, but relies on different methodologies, system boundaries, data formats and reporting cycles. Adding to this complexity, organisations frequently engage multiple external consultants to deliver individual reporting outputs, such as lifecycle analyses (LCAs) or regulatory submissions. This introduces significant cost, duplication and dependency, with each output often delivered as a standalone report rather than as part of an integrated system.

A genuine data-driven sustainability model requires a "single source of truth": a unified data architecture in which critical datasets are standardised, centrally governed and accessible across functions. This provides the foundation for a shift towards real-time insight.

"THIS COHESIVE APPROACH TO SUSTAINABILITY IS INCREASINGLY PRESSING, GIVEN THE TRANSITION FROM LARGELY VOLUNTARY DISCLOSURE TOWARDS A MORE REGULATED AND ENFORCEMENT-DRIVEN LANDSCAPE."

FROM VOLUNTARY DISCLOSURE TO REGULATORY ENFORCEMENT

This cohesive approach to sustainability is increasingly pressing, given the transition from largely voluntary disclosure towards a more regulated and enforcement-driven landscape (Figure 2). Under the EU's Corporate Sustainability Reporting Directive (CSRD), companies are required to disclose detailed, standardised information on environmental, social and governance impacts. In parallel, the Empowering Consumers for the Green Transition Directive, demands verifiable evidence to support claims such as "environmentally friendly" or "carbon neutral".

In the UK healthcare sector, regulatory and market pressures are further reinforced through procurement frameworks, most notably the UK NHS Evergreen Sustainable Supplier Assessment.

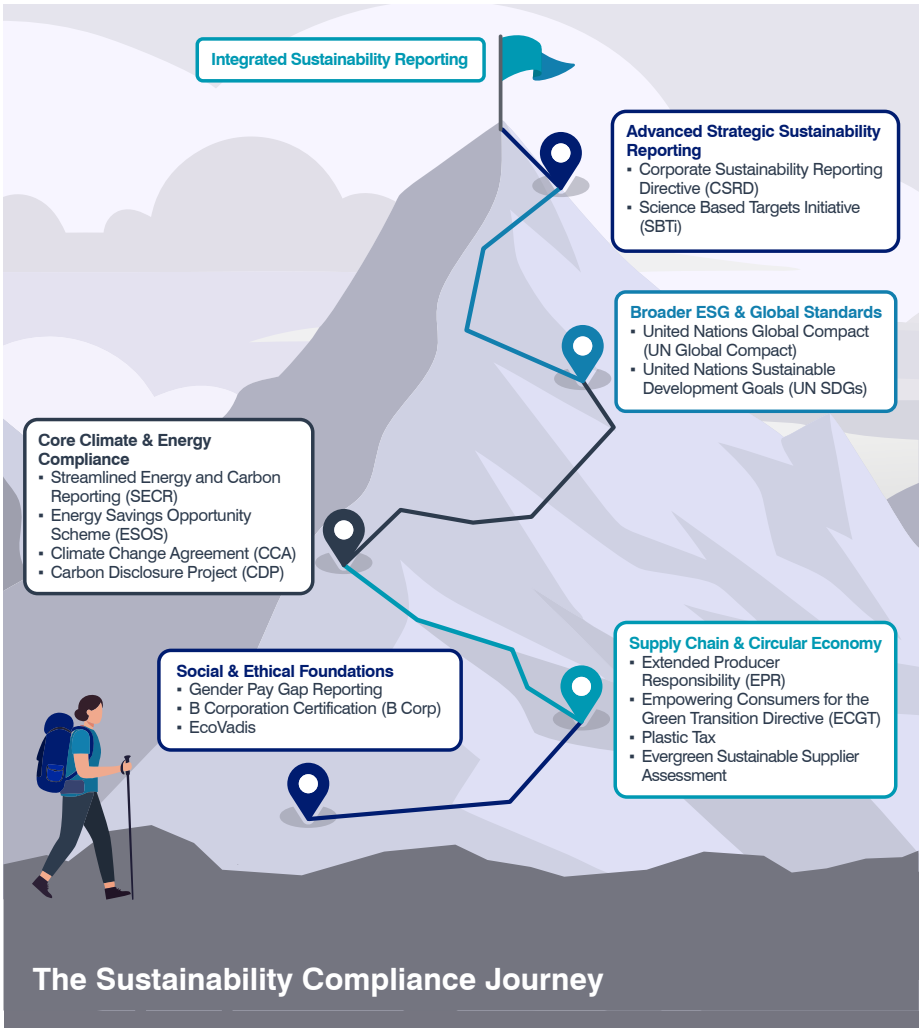


Figure 2: Globally, regulatory frameworks are expanding to require greater transparency in environmental, social and governance reporting.

Initially a voluntary self-assessment tool, the Evergreen framework is increasingly being integrated into procurement processes as the NHS moves towards its 2045 net zero target. This effectively transforms sustainability from a "nice to have" into a commercial requirement for suppliers.

For manufacturers in the pharmaceutical and medical device sectors, this shift has clear implications. Organisations must be able to provide credible, product-level environmental data aligning with NHS expectations, as well as broader regulatory frameworks, such as the CSRD. This creates a cumulative reporting burden that increasingly exceeds the capacity of existing internal systems. Traditional siloed systems cannot meet the bar, strengthening the case for standardised real-time LCA modelling.

"UNLIKE HIGH-LEVEL ESTIMATIONS OR AGGREGATED REPORTING APPROACHES, LCAs ARE DESIGNED TO CAPTURE THE FULL LIFECYCLE OF A PRODUCT, FROM RAW MATERIAL EXTRACTION THROUGH TO MANUFACTURING, DISTRIBUTION, USE AND END-OF-LIFE."

LCA AS THE FOUNDATION FOR STANDARDISATION

To create a single source of truth, organisations must therefore move towards integrated, decision-grade data architecture that can support both compliance and operational optimisation. Within the current fragmented landscape of sustainability initiatives, LCAs stand out as a foundation for this standardised, operational approach.

LCAs already provide a comprehensive and scientifically robust methodology for quantifying product-level environmental impact. Unlike high-level estimations or aggregated reporting approaches, LCAs are designed to capture the full lifecycle of a product, from raw material extraction through to manufacturing, distribution, use and end-of-life.

This methodological rigour is underpinned by internationally recognised standards, including ISO 14040 and ISO 14044, as well as sector-specific initiatives, such as PAS 2090. By aligning organisations around a common framework, such initiatives provide a foundation for harmonisation, create a more level playing field and make it easier for companies to conduct LCAs.

LCAs are more than compliance tools; they form the logical backbone for an integrated sustainability data architecture. Their rigour makes them uniquely suited to be operationalised into real time systems capable of supporting rapid decision-making. However, despite these strengths, the way in which LCAs are currently implemented within organisations presents significant limitations.

In practice, LCAs are typically conducted as discrete, point-in-time studies, often commissioned externally and delivered as detailed technical reports. However, by integrating LCA methodologies with data systems, organisations can begin to bridge the gap between fragmented data and regulatory expectations.

FROM STATIC ASSESSMENT TO REAL-TIME DECISION SUPPORT

To address this need, Owen Mumford is exploring the development of a real-time, product-level emissions model. This capability is still in development and has

not yet been implemented. The challenge is not simply to increase data availability, but to create an agile system that is capable of absorbing live updates from manufacturing, procurement and logistics, and then translating operational activity into immediately actionable insights (Figure 3). This approach has the potential to fundamentally change how sustainability is experienced within the organisation. Teams can test hypotheses, evaluate alternative materials or processes, and observe the environmental consequences almost instantly.

Environmental improvements can be directly linked to specific products, processes and decisions. For example, a change in transport mode or manufacturing efficiency can be reflected in updated product-level emissions in near real time. This feedback loop embeds sustainability within everyday operations rather than confining it to annual reporting cycles.

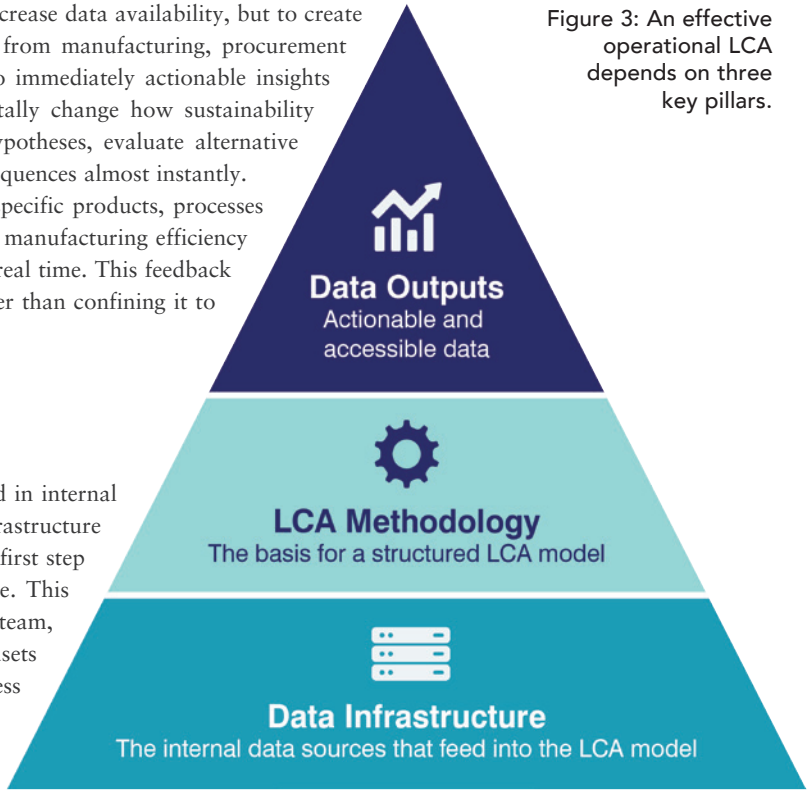


Figure 3: An effective operational LCA depends on three key pillars.

A THREE-PILLAR APPROACH TO REAL-TIME LCA

Data Infrastructure

The foundation of a real-time LCA is the primary data held in internal systems that the model draws from. Creating this data infrastructure is the most challenging part, but also the most critical. The first step is to map out and optimise the internal data infrastructure. This requires companies to map out the data collected by each team, clarify ownership and accountability, determine which datasets are needed for sustainability and LCA purposes and then assess how this information should be presented and integrated.

It must be acknowledged that no organisation will have perfect primary data across its entire value chain.

BOX 1: EMBEDDING LCAs INTO ORGANISATIONAL DECISION-MAKING

Methodological Rigour

Without a robust methodological foundation, LCA results cannot be scientifically credible, relevant for the sector or comparable. The LCA journey should begin with a structured landscape analysis of relevant standards and frameworks (and regulation, if applicable), tailored across three layers.

First, sector-agnostic standards, such as ISO 14040, ISO 14044, ISO 14067 and the Product Environmental Footprint provide the common overarching principles for LCAs. Second, sector-specific frameworks, such as PAS 2090 and other relevant pharmaceutical guidance documents, provide insights and specifications for modelling choices. This ensures that assumptions reflect industry realities, including typical production processes and data availability.

Third, supply-chain-specific requirements should be considered, aligning as much as possible with supplier data structures and client expectations. This includes integrating primary data where available, aligning with customer reporting formats and ensuring compatibility with upstream and downstream data exchanges. Mapping information from all three layers in this type of analysis creates a methodological backbone for the LCA model, future-proofing the strategic transformation.

Parameterised and Configurable LCA Models

A parameterised LCA model covers the full production process and value chain of a portfolio or organisation, situated within a suitable LCA software such as SimaPro Enterprise. Instead of fixed inputs, key variables are defined as parameters. These parameters can include material compositions, energy consumption profiles, yields, transport distances, packaging configurations and more.

This structure allows a single LCA model to generate results for multiple product variants and scales by updating parameter values. Rather than rebuilding models for each assessment, users can input product-specific data into predefined parameter fields, ensuring that all results are generated within the same consistent modelling framework. While traditional LCA studies are typically static and case-specific, limiting their usefulness in fast-paced decision-making environments, a parameterised model transforms LCAs into a dynamic tool that can be applied repeatedly and efficiently.

When implemented in an API-enabled environment, parameterised models can be directly connected to enterprise data systems (Figure 4). This enables automated data exchange, where product data, bill of materials and process information flow directly into the LCA model.

Integration with Enterprise Systems and User Interfaces

Integrating LCA models with enterprise systems ensures that sustainability information becomes accessible, up to date and actionable. Without integration, LCAs remain a siloed activity, dependent on manual data collection and limited to expert users.

Through API connections, parameterised LCA models can link directly into internal data architectures, enabling a centralised and automated data flow. This ensures that sustainability calculations are based on the most current and consistent data available within the organisation, such as product specifications, procurement data and production metrics.

On top of this integrated backend, tailored user interfaces can be developed to serve different functions. For research and development teams, interfaces can support design exploration and comparison of product alternatives. For procurement, they can provide insights into supplier impacts and support more informed sourcing decisions. For sustainability and reporting teams, they can enable the generation of consistent, audit-ready environmental metrics aligned with internal and external requirements. This combination of system integration and user-specific interfaces is essential for functional LCAs.

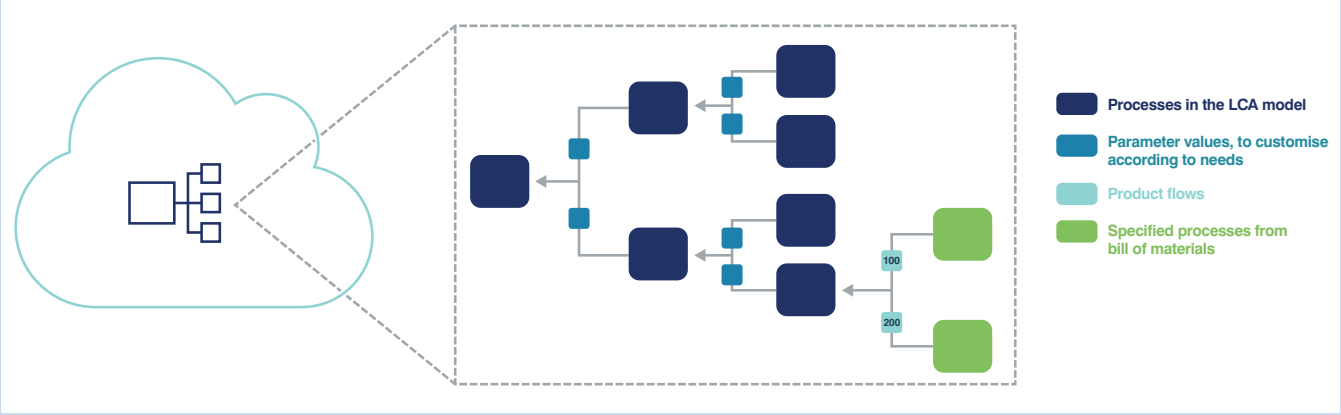


Figure 4: Configurable and parameterised LCA model (SimaPro 2026).

A pragmatic and iterative approach is required to identify the emission hotspots that drive the highest impact and to prioritise improved data quality in those areas.

LCA Methodology

The second pillar is the methodological engine (Box 1). This ensures that all calculations remain grounded in scientifically recognised frameworks, such as ISO 14040/44 or PAS 2090, while enabling scalability, scenario modelling and continuous data integration. Integrating LCAs into organisational decision-making requires a structured, scalable and methodologically robust approach that balances scientific integrity with operational usability. At Owen Mumford, this work is being led internally, with the company recognising the value of partnering with established LCA experts, such as PRé Sustainability, as this approach evolves.

Actionable Data

The third critical pillar in operational LCA design is to create a user interface with a common language. Data must be translated into clear, accessible outputs that can be understood and acted upon by non-specialist teams. A simple test of this is speed – if someone cannot understand what is happening and what it implies within a few seconds, the data will not influence behaviour. This can be addressed by designing for the least technical user, thereby removing unnecessary complexity.

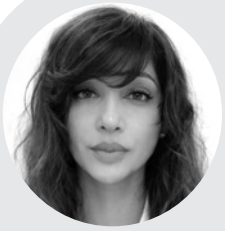
The use of familiar manufacturing processes and terminology can support this effort. As lean manufacturing methodologies are already well established in the industry, the Owen Mumford team is exploring how these can be integrated with LCA outputs. Instead of introducing a new, abstract sustainability language, the data should be structured around familiar processes, steps and constraints, reducing the cognitive translation effort.

SETTING A NEW BAR FOR SUSTAINABILITY

Obscure data also pose a broader problem for the industry. The pharmaceutical sector frequently calls for greater collaboration across supply chains, but this becomes challenging if each organisation manages its data differently. At present, companies are largely decarbonising in isolation. Even where two companies report similar metrics, such as product carbon footprints or Scope 3 emissions, the underlying methodologies may differ significantly. If organisations align on methodology and data structure, they can begin sharing comparable product-level insights with suppliers and customers.

Within the next decade, product-level carbon accounting is likely to become embedded within manufacturing systems in much the same way that financial accounting is today, fundamentally changing how environmental performance is measured and managed. Organisations that develop LCAs as a governed, repeatable capability, rather than a one-off analytical exercise, will therefore be better positioned to respond to tightening regulatory expectations, rising customer scrutiny and growing supply-chain volatility.

In developing its own real-time operational model, Owen Mumford's ambition is not only to enhance the organisation's reporting, but also to contribute to emerging best practice across the sector. As the approach matures, Owen Mumford intends to develop supporting educational materials to help drive greater standardisation in emissions reporting and enable more meaningful comparison across organisations.



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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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SimaPro BV, acting under the tradename **PRé Sustainability**, is a lifecycle assessment expert, with over 35 years of experience. Its SimaPro platform is used by over 3,000 organisations in more than 80 countries for environmental product declarations, carbon footprinting, and sustainable design. Part of the One Click LCA family, PRé combines software development with expert consulting across a wide variety of sectors, including pharmaceuticals, medtech, and manufacturing.

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ten23 health is a pharmaceutical CDMO that supports its clients in developing differentiated, stable, usable and safe injectable treatment options for patients. The company combines the latest scientific findings with proven industry and regulatory expertise to forge new paths for its clients' needs. ten23 health provides its innovative services in a fair and sustainable manner.

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