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# Drug Delivery 179

NOVEMBER 5TH 2025

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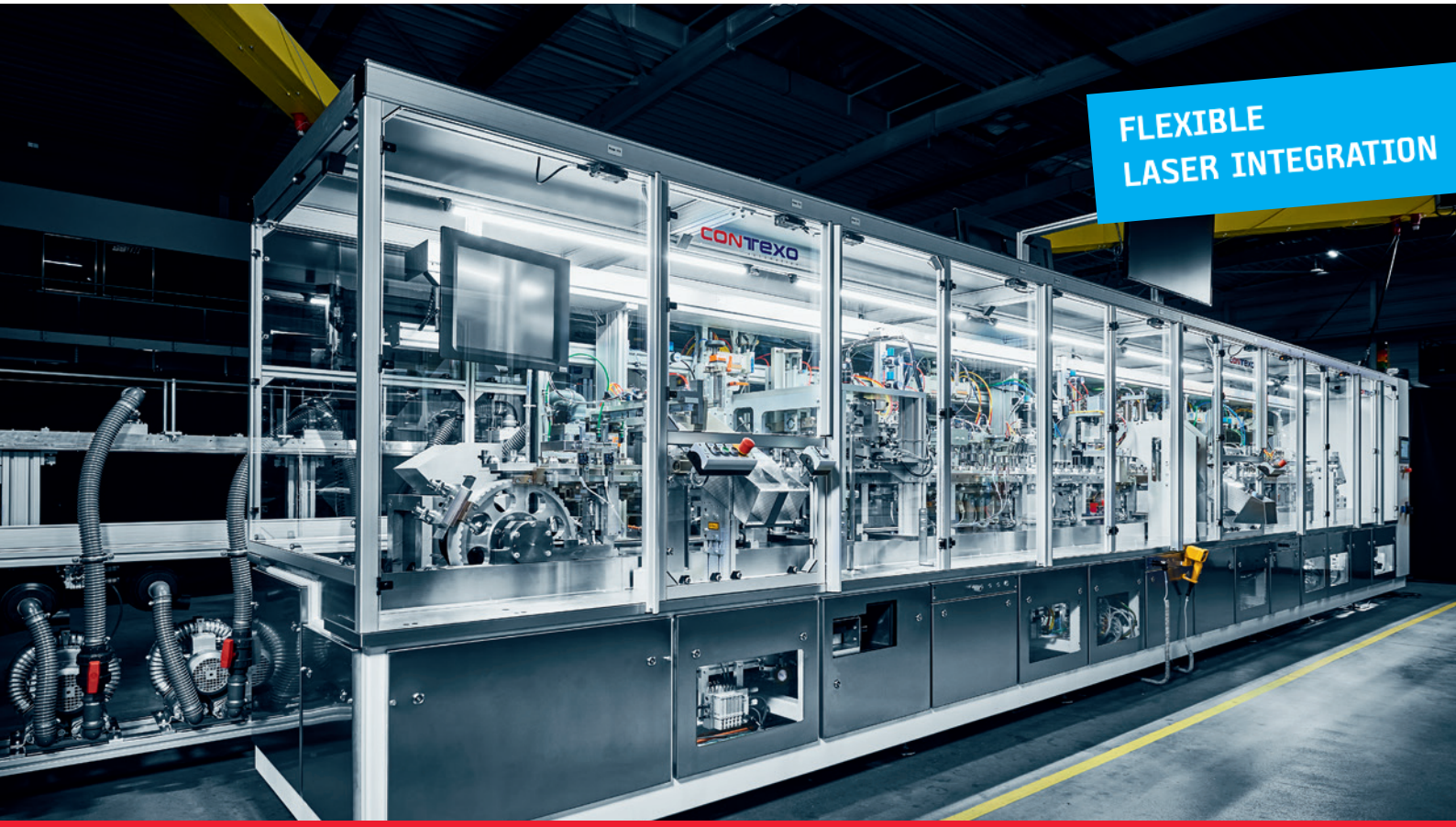


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## Contents











# SUSTAINABILITY IN DRUG DELIVERY

ONdrugDelivery Issue N° 179, November 5th, 2025


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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# Strategies for Sustainability:
## Circularity, Eco-Design and Other Approaches

With investment in environmental, social and governance issues continuing to rise and increasing regulatory pressure being applied to reduce carbon emissions across industries, sustainability remains at the front and centre for drug delivery. This topic is not constrained to a single delivery route or device category, with each sector facing its own challenges and seeking appropriate solutions to ensure that the ambitious emissions targets being set across the industry are met.

This issue begins with an article from **Ypsomed**, our Outstanding Sponsor for this issue (Page 8), which focuses in on how to reduce the carbon footprint of injectable therapies from the device side by implementing circular design principles. As an example of this approach, the company introduces its new YpsoLoop platform, which has been designed from the ground up to enable scalable disassembly and material recovery, making a significant contribution to the development of a circular economy for injectable devices.

A key topic of interest within sustainable drug delivery is the adoption of lower global warming potential propellants for metered dose inhalers, replacing the HFAs that are currently in use and a major contributor to the carbon footprint of the healthcare system as a whole. This issue features two CDMOs at the forefront of this change, with **Kindeva** (Page 16) and **Bespak** (Page 52) both offering their perspectives on this crucial step for the pulmonary sector.

Turning to pharma's perspective, the **Subcutaneous Drug Development & Delivery Consortium** presents the results of a study conducted with its member organisations (Page 20), reporting the ambitions of major pharmaceutical players and the progress they are making with regards to their sustainability commitments. Broadening the discussion, we also feature an exclusive interview with **Aptar Pharma** on eco-design principles (Page 28) and an article from **PCI Pharma Services** on the implementation of electronic batch records as a key component of digitising the company's operations (Page 38).

Rounding out the issue, we have a trio of articles offering insight into sustainability approaches across other aspects of drug delivery. First, **Lonza Capsugel** looks at progress towards sustainability targets through the lens of capsule manufacturing (Page 34). Moving on to metal springs and stampings, **Lesjöfors** discusses its approach to implementing circular design principles (Page 44). Finally, **Recipharm** tackles sustainability from a packaging perspective, considering aspects such as material choice and labelling (Page 48).

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# CLOSING THE LOOP: DESIGNING THE FUTURE OF SUSTAINABLE DRUG DELIVERY DEVICES

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**Thuysi Dao** of **Ypsomed** outlines a two-pronged approach to improving the sustainability profile of drug delivery devices, combining sustainable device design with real-world take-back and recycling initiatives, and explores how Ypsomed's new YpsoLoop autoinjector platform embodies this vision.

As the pharmaceutical industry accelerates its drive towards net zero, the environmental impact of drug delivery devices is coming sharply into focus. Scope 3 emissions dominate company footprints and end-of-life processing represents a significant proportion of a device's carbon dioxide ($CO_2$) emissions. This makes it essential to rethink device design and end-of-life processes.

## CARING FOR PATIENTS, IMPACTING THE PLANET

With the purpose of protecting and enhancing human health, the healthcare sector plays a vital role in society. However, it is also a substantial contributor to the climate crisis, which is increasingly recognised as one of the greatest health threats of the modern era.[1] This paradox places the industry in a unique position – while delivering essential care, it must also confront and reduce the environmental impact of its own activities. The healthcare sector is responsible for 4.4% of net global greenhouse gas emissions – a footprint so large that it would rank as the fifth biggest climate polluting country. The pharmaceutical industry is a major contributor to this, and without decisive change, the sector's carbon impact is projected to triple by 2050.[2]

Many global pharmaceutical companies have committed to ambitious, science-based targets verified by the Science Based Target initiative (London, UK). These aim to significantly reduce Scope 1 and 2 emissions by 2030 and to reach net zero emissions

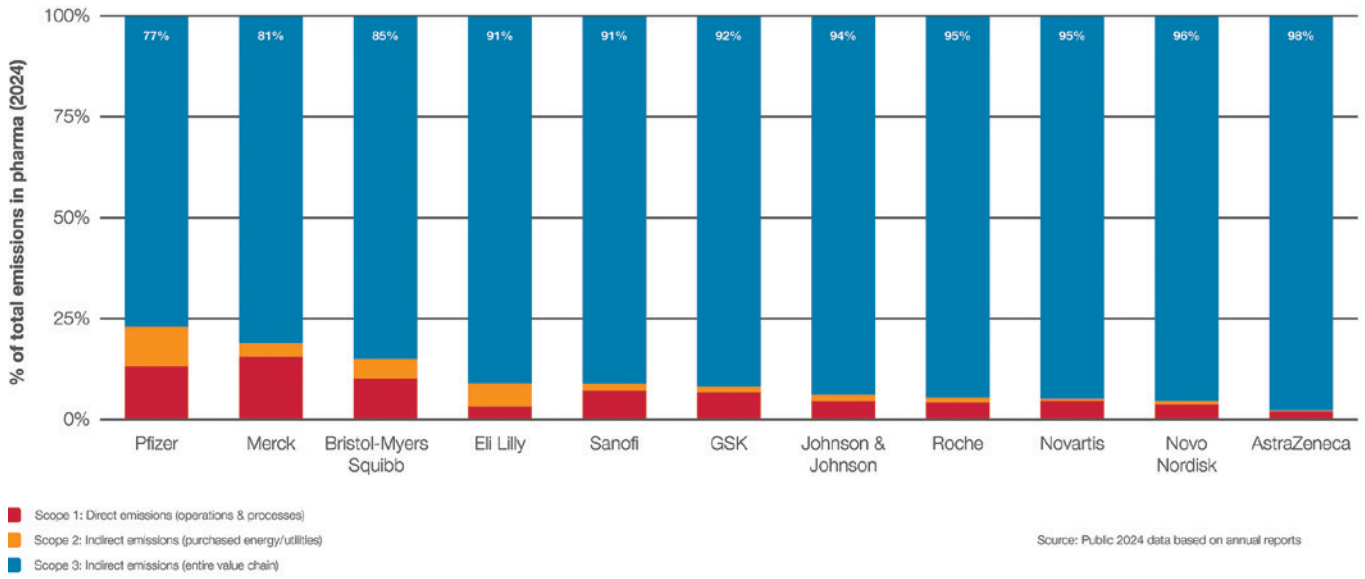


Figure 1: Breakdown of Scope 1 to 3 emissions in leading pharmaceutical companies.

across all scopes by 2050 at the latest.[3] Such commitments are vital in aligning the industry's core mission of safeguarding health with the equally urgent need to protect the planet.

Recent disclosures from major pharmaceutical companies consistently show that Scope 3 emissions – those generated indirectly across the value chain – account for between 77% and 98% of their total emissions, far exceeding Scopes 1 and 2 (Figure 1). Within Scope 3, the lion's share of emissions clearly lies within the categories of purchased goods and services (41–48% in biotech, pharma and medtech) as well as the use of sold goods (29%).[4]

## THE DEVICE LENS: A TANGIBLE LEVER FOR $CO_2$ REDUCTION

At the pharmaceutical product level, devices represent a significant source of $CO_2$ emissions and, consequently, a major opportunity for Scope 3 reduction as pharma works with suppliers to meet ambitious climate targets. The environmental footprint of injection devices extends from the extraction of raw materials to their final disposal. A lifecycle assessment of a disposable 1 mL autoinjector shows that raw materials (40%) and end-of-life disposal (20%) are the largest individual contributors to emissions, followed by packaging (15%). The remainder results from manufacturing processes, transportation and waste handling (Figure 2).[5]

**"RECENT DISCLOSURES FROM MAJOR PHARMACEUTICAL COMPANIES CONSISTENTLY SHOW THAT SCOPE 3 EMISSIONS – THOSE GENERATED INDIRECTLY ACROSS THE VALUE CHAIN – ACCOUNT FOR BETWEEN 77% AND 98% OF THEIR TOTAL EMISSIONS, FAR EXCEEDING SCOPES 1 AND 2."**

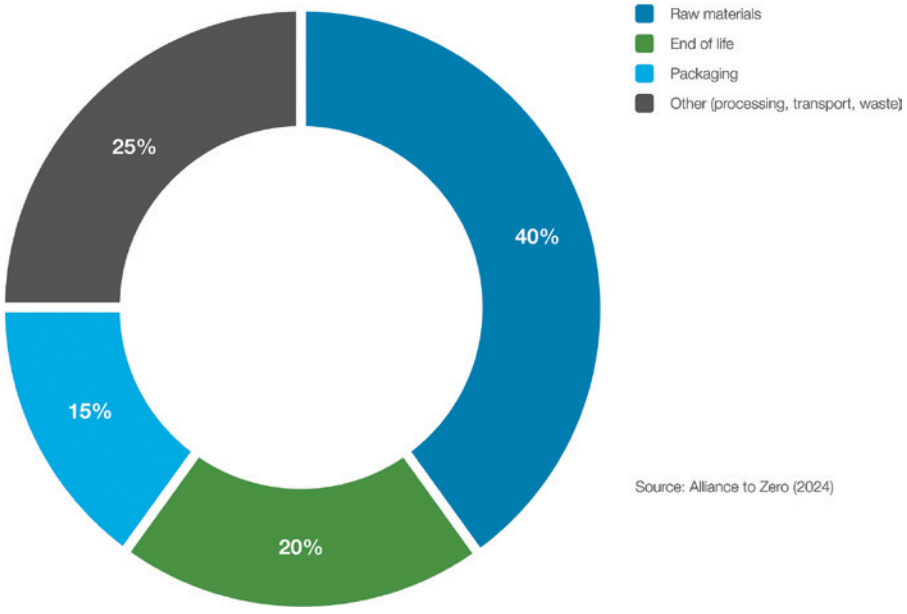


Figure 2: $CO_2$ emissions breakdown of a disposable 1 mL autoinjector.

Reducing this footprint requires action to deal with the major contributing factors. For raw materials, this includes, among other measures, selecting lower-impact alternatives, sourcing responsibly and minimising material use where possible.

For end-of-life, the current approach is almost entirely limited to high-temperature incineration or landfill disposal, with recycling not yet a significantly explored pathway. This "hidden cost of disposability" highlights the need for sustainable innovation that addresses not only material choice but also the design of the devices for recycling and disassembly, ensuring compatibility with emerging recovery systems. It is also necessary to advance these systems themselves to enable them to handle medical devices and capture resources at scale.

## TWO PERSPECTIVES FOR IMPACT: WHY DEVICE DESIGN AND END-OF-LIFE MATTERS

Addressing these drivers requires action from two complementary angles:

- **Circular Design:** Designing devices with sustainability in mind from the outset
- **Closing the Loop:** Building the systems needed to collect, recycle and reintegrate device materials.

One without the other leaves potential circularity untapped. To move from open-loop recycling towards true closed-loop systems, sustainable device design and take-back initiatives must evolve hand in hand (Figure 3).

### Perspective 1: Designing for Circularity

Circularity starts long before a device is produced – it begins at the drawing board. Design decisions made during the initial concept stage can determine up to 80% of a product's environmental footprint.[6] Therefore, integrating sustainability principles from the outset involves adopting the "R-strategies" as a design philosophy rather than an afterthought:

"DESIGN DECISIONS MADE DURING THE INITIAL CONCEPT STAGE CAN DETERMINE UP TO 80% OF A PRODUCT'S ENVIRONMENTAL FOOTPRINT."


Figure 3: Circularity requires sustainable product design and end-of-life recovery solutions.

- **Reduce:** The first and most impactful step involves selecting materials with the lowest possible environmental footprint, minimising the number of different polymers used and reducing the overall material volume. This directly lowers embedded carbon and resource use.

- **Reuse:** The second step focuses on extending a product's lifecycle, allowing it to remain in service for longer, thereby reducing the need for new materials and additional manufacturing.

- **Recycling:** The third and final step closes the loop by ensuring that materials can be recovered and reprocessed. However, this is only viable when the product is designed for disassembly and material separation, as well as being made compatible with available recycling infrastructure.

Ypsomed has embedded these principles into its eco-design guidelines, translating them into concrete ambitions. These include reducing weight and material, minimising material types, prioritising recyclable mono-materials, incorporating certified bio-based feedstocks where possible and ensuring that products are designed for disassembly from the outset. By integrating these strategies into the concept phase, Ypsomed aims to maximise circularity, ensuring that, when recovery systems are ready, the devices will be too.

### Perspective 2: Closing the Loop

Take-back schemes are gaining traction in the pharmaceutical industry. Programmes such as Johnson & Johnson's SafeReturns and Novo Nordisk's ReMed and returpen demonstrate that collection is possible, albeit on a modest scale. Beyond the environmental benefits, many companies across various industries also see potential economic value – over 70% of those engaging in circularity initiatives expect a positive financial impact by 2027/2028.[7]

However, moving from today's practices to full circularity is a multistep process. Due to regulatory limitations, devices are still produced using 100% virgin-grade plastics. Some progress is being made through recovering production waste, wherein clean moulding scrap is reintroduced or recycled into non-medical applications, and open-loop recycling, in which post-user plastics are recovered and downcycled into non-medical components. Nevertheless, the ultimate goal for many is

closed-loop recycling, meaning the recovery of used devices and decontaminating and reprocessing them into medical-grade components. Most projects currently stop at open-loop solutions, so the transition to closed-loop is both a challenge of innovation and an opportunity for leadership.

However, scaling up these circularity initiatives for self-injection devices presents several challenges:

- **Technical**: Devices are complex assemblies of mixed materials that are often contaminated with biological residue. Current recycling technologies struggle to separate these components safely, reliably and efficiently.

- **Regulatory**: Used injection devices are classified as medical waste, which restricts transport and processing. Regulations around the use of recycled materials in medical devices are still evolving, creating uncertainty for manufacturers.

- **Systemic/Infrastructure**: Collection systems for medical devices are fragmented or absent in most markets. Building them requires investment, alignment between stakeholders and, often, pre-competitive collaboration across the industry.

- **Commercial and Scale**: Many pilot programmes remain geographically limited and achieve relatively low return rates. Uncertainty regarding financial viability, actual $CO_2$ reduction potential at scale and the industry's long-term direction may hinder investment and commitment.

While these challenges are significant, they are not insurmountable. Addressing them requires long-term planning, clear policy direction and partnerships across the healthcare ecosystem. This collaborative environment provides an opportunity to develop, implement and trial value-added solutions that transcend compliance, establishing companies as pioneers in sustainable innovation and laying the groundwork for scalable, industry-wide systems.

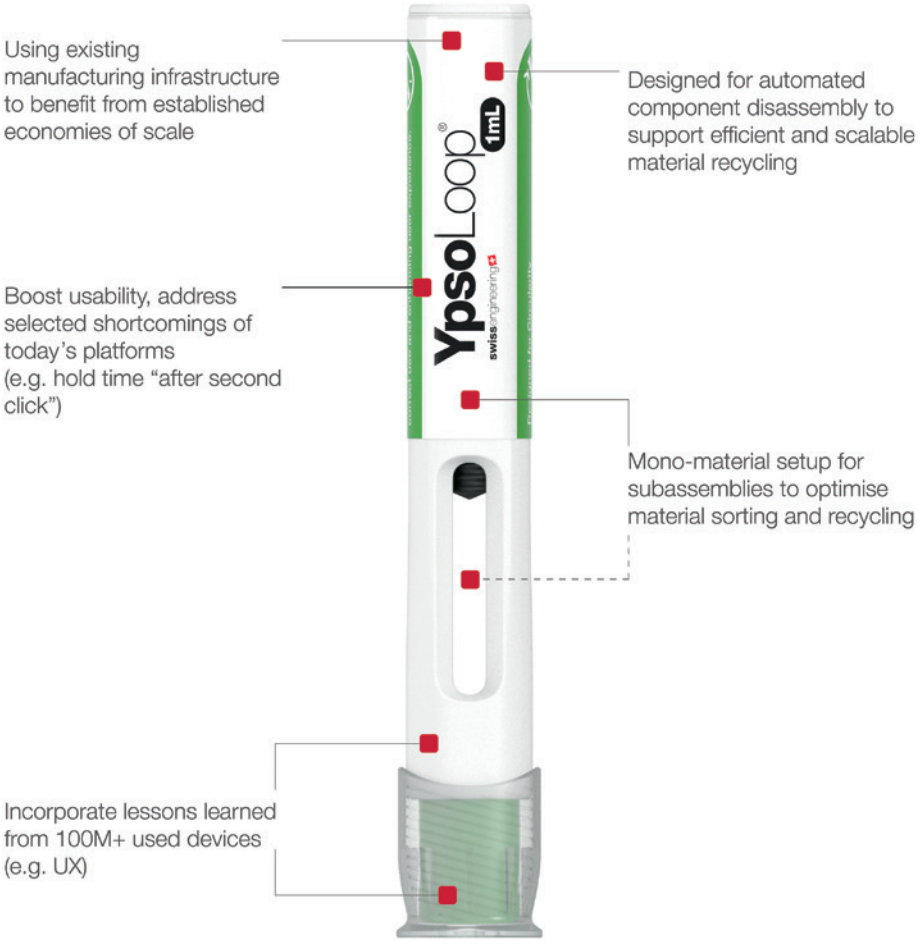


Figure 4: Ypsomed's new YpsoLoop platform.

> "YPSOLOOP, YPSOMED'S NEW PREFILLED AUTOINJECTOR PLATFORM, IS ONE EXAMPLE OF THIS APPROACH, EMBODYING BOTH SIDES OF THE CIRCULAR INNOVATION LOOP."

## YPSOLOOP: RETHINKING PLATFORM DESIGN FOR SCALABLE DISASSEMBLY AND EFFICIENT MATERIAL RECOVERY

Solutions that work in both dimensions are required to bring together the principles of circular design and the need for real-world recovery systems. YpsoLoop, Ypsomed's new prefilled autoinjector platform, is one example of this approach, embodying both sides of the circular innovation loop (Figure 4).

Developed under eco-design principles embedded in Ypsomed's ISO 14001-certified processes, YpsoLoop is able to achieve a significantly lower material $CO_2$ footprint. It uses bio-based plastics and is built around two mono-material subassemblies that allow for easy material separation. Its design for disassembly architecture is the first of its kind to enable scalable, automated component separation, making cost-efficient material recovery in take-back schemes a realistic possibility, paving the way for closed-loop recycling.

Positioned to set a new benchmark for sustainable drug delivery platforms, Ypsomed's ambition goes beyond offering a sustainable product. The company's goal is to deliver a solution that connects sustainable device innovation with real-world recovery systems and accelerates circularity across pharma. Ypsomed is driving this forward by working with partners and consortia to proactively embed

YpsoLoop into take-back programmes, while also exploring new pathways and concrete solutions that make circularity more scalable. The aim is to lower the hurdles for pharmaceutical clients to adopt circularity and help move the industry from today's linear status quo towards open- and, ultimately, closed-loop recycling, ensuring that device design and recovery infrastructure advance together (Figure 5).

## A CALL TO ACTION FOR THE INDUSTRY

Circularity in drug delivery devices is within reach, but only if the industry is prepared to make sustainability a primary requirement rather than a secondary consideration. It is, above all, the internal decisions around device design and architecture that will determine how far the industry progresses. The industry must consider how willing it is to reduce complexity in favour of recyclability, since this is an area it can influence directly. This requires a willingness to accept recycled content where it is safe and compliant, to prioritise recyclability over colour customisation and to collaborate pre-competitively on shared material standards and infrastructure. Investing in collection and recycling systems alongside product innovation is also essential to ensure that sustainability gains can be realised at scale.

The question is whether the industry is ready to radically rethink its approach to devices to meet sustainability ambitions. As Albert Einstein observed, one cannot solve their problems with the same thinking used when creating them. For the pharmaceutical and medtech sectors, this means challenging long-held assumptions and approaches about design, customisation, manufacturing and end-of-life management. By keeping valuable materials in circulation and reducing the environmental impact of drug delivery, the industry can continue to provide life-changing therapies while safeguarding the health of the planet. For Ypsomed, this ambition is set and circularity is already a central principle of its innovation, guiding the choices it makes right now.

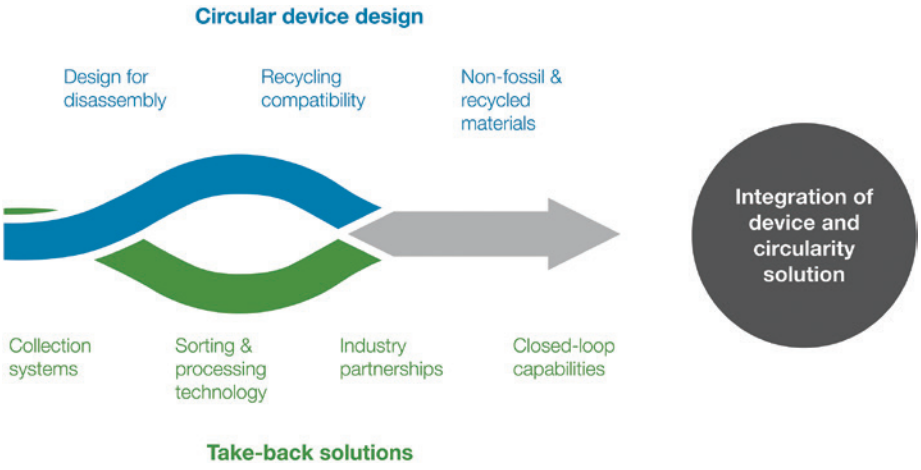


Figure 5: Joint progress in circular device design and take-back solutions, which are needed to advance circularity.

**Thuysi Dao**

Thuysi Dao, Sustainability Innovation Lead, Associate Director, joined Ypsomed's Innovation Team in early 2025, where she leads sustainability and net-zero innovation. In this role, she drives the transition towards a circular economy in future drug delivery solutions. She began her career as a sustainability consultant at umlaut/Accenture and holds a master's degree in international management with a specialisation in sustainability and innovation management.

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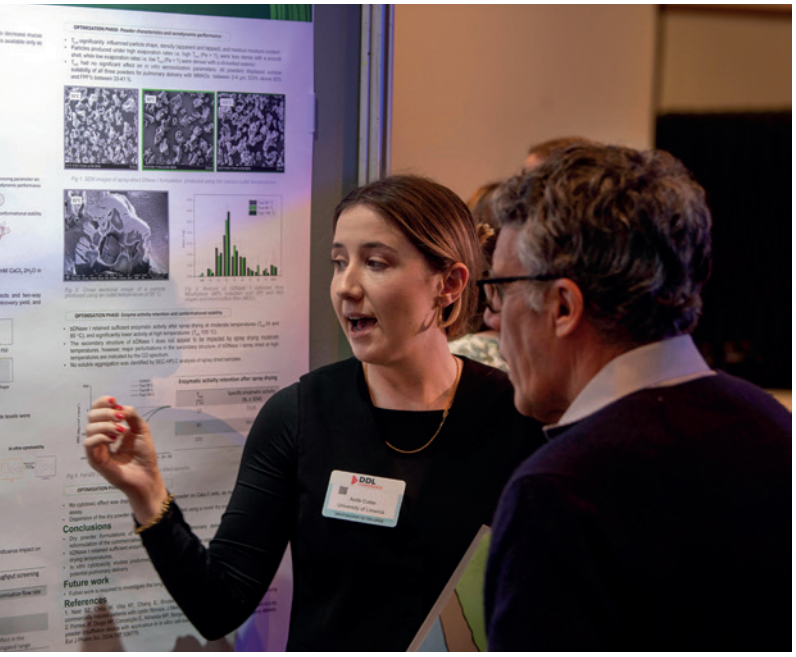

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# A BREATH OF FRESH AIR: PHARMA'S PUSH FOR SUSTAINABLE pMDIs

Kindeva

**Andy Burns** of **Kindeva** considers the driving factors for the transition to more sustainable propellants, as well as explaining the benefits and challenges of these next-generation propellants in terms of compatibility, performance, safety and global warming potential.

The pharmaceutical industry is in the midst of a green revolution, with a growing emphasis on sustainability and environmentally conscious manufacturing. A key area of focus for this transformation is the development of pulmonary and nasal drug delivery devices. For decades, pressurised metered-dose inhalers (pMDIs) have been a cornerstone of respiratory therapy, however, the propellants that power them are currently under legislative scrutiny for their environmental impact.

The change is driven by global and national regulations across Europe, the UK and the US stemming from the Kigali Amendment to the Montreal Protocol. This mandates a phasedown of the current generation of high global warming potential (GWP) hydrofluorocarbons (HFCs) to 85% of present levels in terms of tonnes of carbon dioxide equivalent. Building on this, the EU in particular has included a phaseout of HFCs by 2050 in its own regulations written to achieve the goals of the Amendment.

As these legislative changes come into effect worldwide, they are driving a period of focused innovation in inhalation drug development. Pharmaceutical companies must now reformulate their products to remain efficacious for patients while making them compliant with these new regulations and sustainable for the planet. This challenge requires a fundamental re-evaluation of the pMDI as an entire system, from its formulation and device components to its manufacturing.

This industry-wide shift, propelled by an evolving regulatory landscape and a shared commitment to sustainability, presents significant technical hurdles. This article will explore these challenges, the pivotal role expert CMDO partners play in navigating the transition and what these vital changes mean for the future of sustainable respiratory drug delivery.

## THE GLOBAL MANDATE FOR GREENER PROPELLANTS

The driving force behind the transition to greener propellants is the Kigali Amendment to the Montreal Protocol – a global agreement that compels signatory nations to phase down the production and consumption of HFCs, such as HFA 134a and HFA 227, which are potent greenhouse gases with high GWPs. The agreement sets an ambitious schedule, requiring a first group of nations (including the US, UK and all EU member states) to achieve an 85% phasedown by 2036.[1]

This international treaty is now being implemented through national and regional laws:

- **European Legislation**: The EU's updated F-Gas Regulation (EU 2024/573), which took effect in March 2024, is a primary driver. It accelerates the HFC phasedown and will eventually remove the previous medical-use exemption for pMDIs.

- **UK Legislation**: Post-Brexit, the UK has retained and continues to enforce its own F-gas regulations that align with the goals of the Kigali Amendment, pushing the industry toward lower-GWP alternatives.[2]

- **US Legislation**: The American Innovation and Manufacturing Act directs the Environmental Protection Agency (EPA) to phase down HFCs in line with the Kigali schedule. The EPA is now establishing a framework for this transition, which includes managing HFCs for essential uses such as pMDIs while encouraging the shift to next-generation technologies.[3]

To understand the drive for change, it is crucial to consider the scale of the impact. The use of some traditional pMDIs can have a carbon footprint equivalent to a car journey of over 100 miles.[4] This is due to the high GWP of HFC propellants, which disproportionately contribute to global warming when released into the atmosphere. For pharmaceutical companies, the implications are clear – to keep pMDI products on the market, they must find and validate next-generation propellants (NGPs) with lower GWPs to replace traditional gases and reformulate their products to be both safe and efficacious.

> "PHARMACEUTICAL COMPANIES MUST NOW REFORMULATE THEIR PRODUCTS TO REMAIN EFFICACIOUS FOR PATIENTS WHILE MAKING THEM COMPLIANT WITH THESE NEW REGULATIONS AND SUSTAINABLE FOR THE PLANET. "

## NAVIGATING NEXT-GENERATION PROPELLANTS

Finding a replacement for established HFCs in pMDIs is far more than a simple swap of the propellant gas, as it is in non-pharmaceutical applications, such as in heating, ventilation and air conditioning systems. This transition presents a unique set of technical challenges, including:

- **Compatibility with pMDI Devices**: The new propellant must be chemically and physically compatible with all device components, from the metal canister to the elastomer valve seals. This includes a thorough assessment of extractables and leachables to ensure that the propellant's unique properties do not introduce new impurities that could compromise the stability of the formulation.

- **Compatibility with Drug Formulations**: The propellant is a critical part of the drug formulation itself. It must be compatible with the API and any excipients, ensuring that the drug remains stable and deliverable over the product's shelf life.

- **Patient Safety**: Any new propellant must undergo rigorous toxicological testing to prove that it is safe for inhalation. This safety assessment must also extend to any new compounds identified during compatibility testing, ensuring that the final delivered dose is free from potentially harmful impurities.

- **Administration Performance**: The reformulated product must demonstrate bioequivalence to the original, meaning that it delivers the same therapeutic effect to the patient. This requires extensive testing to ensure that metrics such as particle size and plume geometry result in the correct drug deposition in the lungs.

- **Manufacturing and Safety**: While leading candidates such as HFA-152a are classified as flammable, this is a manageable engineering challenge. It can be addressed through the implementation of expert safety protocols and the use of specialised, ATEX-compliant manufacturing facilities.

- **Regulatory Approval**: Switching propellants will require a thorough assessment and approval by regulatory authorities, necessitating the generation and submission of a comprehensive package of technical data, and possibly clinical data, on the reformulated product.

The search has narrowed to two primary low-GWP NGP candidates: HFA-152a from Orbia Fluor & Energy

> "TO UNDERSTAND THE DRIVE FOR CHANGE, IT IS CRUCIAL TO CONSIDER THE SCALE OF THE IMPACT. THE USE OF SOME TRADITIONAL pMDIs CAN HAVE A CARBON FOOTPRINT EQUIVALENT TO A CAR JOURNEY OF OVER 100 MILES."

Materials (Boston, MA, US) and HFO-1234ze from Honeywell (Charlotte, NC, US). Both offer environmental benefits and have potential as near-term solutions for reformulating many existing pMDI products.

The choice comes down to a trade-off between formulation science and key factors such as manufacturing safety and environmental performance. HFO-1234ze has an exceptionally low GWP and is non-flammable, but its chemical properties may make it a poor solvent for some respiratory drugs, creating challenges with reformulation – particularly for solution -based formulations. In contrast, HFA-152a has a higher GWP and is flammable, but is more similar chemically to the currently used HFA-134a, which may provide a more direct route to achieving a stable and effective product.

## WHO IS PROPELLING THE TRANSITION TO NGPS?

The scale and complexity of the propellant transition mean that many pharmaceutical companies will turn to expert partners for support. A CDMO with specialised expertise in inhalation and sustainable propellants can significantly de-risk and accelerate the transition to NGPs.

An expert CDMO can offer several key advantages to its partners:

- **Legacy of Inhaled Innovation:** A long history of formulating and developing complex inhalation products can provide the scientific foundation needed to tackle reformulation challenges.

- **Purpose-Built Infrastructure:** A proactive CDMO partner will have already invested in the specialised infrastructure needed to safely handle flammable propellants such as HFA-152a. This can save pharmaceutical companies significant time and capital expenditure, removing a major barrier to entry.

- **Regulatory Expertise:** Decades of experience in bringing inhalation products to market can provide the regulatory insight needed to navigate the complex filing process for reformulated pMDI products across global agencies.

**"THE SCALE AND COMPLEXITY OF THE PROPELLANT TRANSITION MEAN THAT MANY PHARMACEUTICAL COMPANIES WILL TURN TO EXPERT PARTNERS FOR SUPPORT. A CDMO WITH SPECIALISED EXPERTISE IN INHALATION AND SUSTAINABLE PROPELLANTS CAN SIGNIFICANTLY DE-RISK AND ACCELERATE THE TRANSITION TO NGPs."**

- **Integrated Combination Product Development:** A pMDI is a combination product, and its success will depend on the seamless integration of the drug formulation, the components and the device. A CDMO with in-house expertise in both areas can co-optimise the entire system, ensuring consistent, effective drug delivery while accelerating the overall development timeline.

Successfully integrating this deep scientific knowledge, regulatory insight and application-specific infrastructure is where working with an experienced partner becomes essential.

Kindeva brings a legacy of pMDI innovation that stretches from inventing the world's first pMDI in 1956 to leading the industry's last major environmental shift with the first chlorofluorocarbon-free inhaler. This deep heritage, particularly the expertise gained during that first propellant transition, provides an unmatched understanding of the intricate interplay between formulation, device and manufacturing. Today, this expertise is focused on the next generation of sustainable inhalers, with significant investment in new commercial-scale manufacturing lines to support the transition to green propellants.

## GREENER TOMORROWS ARE IN THE MAKING

The mandated phasedown of high-GWP propellants marks a pivotal moment for respiratory medicine. The journey is not merely about compliance but about fundamentally re-engineering a cost-

**Andy Burns**

Andy Burns is the Vice-President of Business Development for the MDI (Metered Dose Inhaler) platform and is a member of the senior leadership team of Kindeva. He has been with the company since its inception in 2020 and is responsible for transitioning the current portfolio of MDI products to the more sustainable and lower-GWP alternatives that will be entering the market over the coming years. Before joining Kindeva, he spent 27 years in the Drug Delivery Systems Division of 3M, where he held various positions, including Process and Optimisation Operations Engineer and Business Unit Manager for the Conventional Dosage Platform. Mr Burns holds a bachelor's degree in Manufacturing Engineering and Management from Loughborough University.

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effective, critical and patient-preferred drug delivery platform for a sustainable future. The pMDI platform remains the ideal pulmonary platform from a cost-efficiency point of view, so it is essential to address this propellant issue as quickly as possible.

While the transition to NGPs presents significant technical and manufacturing challenges, it is also a powerful catalyst for innovation. This transition is driving change across the entire pMDI system, demanding a more integrated approach to formulation, device compatibility and manufacturing. The long-term impact of this shift will be substantial. It will dramatically reduce the carbon footprint of these inhaled therapeutics and align the pharmaceutical industry with global climate goals. Most importantly, this will be accomplished without sacrificing the high standards of patient safety and efficacy that have made pMDIs a cornerstone of respiratory care.

Successfully navigating this complex landscape requires both deep technical capability and a new level of collaboration. The journey to the next generation of pMDIs will be built on strategic partnerships between pharmaceutical innovators and experienced CDMOs who have the scientific legacy and the purpose-built infrastructure to turn these new propellants into approved, life-sustaining products. This shared commitment is both a regulatory necessity and the foundation for the future of sustainable respiratory care.

"WHILE THE TRANSITION TO NGPs PRESENTS SIGNIFICANT TECHNICAL AND MANUFACTURING CHALLENGES, IT IS ALSO A POWERFUL CATALYST FOR INNOVATION. THIS TRANSITION IS DRIVING CHANGE ACROSS THE ENTIRE pMDI SYSTEM, DEMANDING A MORE INTEGRATED APPROACH TO FORMULATION, DEVICE COMPATIBILITY AND MANUFACTURING."

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# ADOPTION OF SUSTAINABILITY PRACTICES WITHIN SUBCUTANEOUS DRUG DELIVERY: INDUSTRY INSIGHTS

**Conor O'Neill**, **Duncan Paterson** and **Dr Monica Adams** of the **Subcutaneous Drug Development & Delivery Consortium** come together to discuss a recent study conducted by the Consortium among its member organisations, digging into the pharmaceutical industry's progress and priorities when it comes to improving the environmental impact of subcutaneous medicines.

The pharmaceutical industry is making substantial efforts to reduce its environmental impact and contribute towards global climate goals. Most pharma companies are aligned with international initiatives such as the Paris Agreement and the United Nations' "Race to Zero" campaign, and have made public commitments to reduce carbon emissions across the entire value chain by 2045, with interim targets set between 2025 and 2030 to ensure progress, according to a survey of various company websites.

While there is a clear drive for change, realising pharma companies' ambitions will require greater collaboration and industry alignment towards implementation of sustainability efforts across the subcutaneous (SC) product value chain, from raw materials through to end use. Currently, environmentally oriented solutions are limited and often only occur at the local product or company level, thereby minimising the opportunities available and their effectiveness.

Against this backdrop, the Sustainability Sub-Team of the Subcutaneous Drug Development & Delivery Consortium (SC Consortium) conducted a study of its member organisations to benchmark

"THE OBJECTIVES OF THE STUDY WERE TO INFORM FUTURE INITIATIVES OF THE SUSTAINABILITY SUB-TEAM, AS WELL AS TO IDENTIFY OPPORTUNITIES FOR BROADER COLLABORATION ON ENVIRONMENTAL SUSTAINABILITY EFFORTS ACROSS THE BIOPHARMA AND PHARMACEUTICAL INDUSTRIES."

| SC Consortium Member Organisations (N=12) | Survey Respondents (N=12) | Interview Participants (N=29) |
|---|---|---|
| AstraZeneca | 1 | 3 |
| BD | 1 | 3 |
| Biogen | 1 | 1 |
| Boehringer Ingelheim | 1 | 2 |
| Bristol Myers Squibb | 1 | 3 |
| GlaxoSmithKline | 1 | 3 |
| Halozyme | 1 | 1 |
| J&J Innovative Medicine | 1 | 4 |
| Merck | 1 | 3 |
| Novartis | 1 | 3 |
| Pfizer | 1 | 1 |
| Sanofi | 1 | 2 |

Table 1: Number of representatives for each SC Consortium member organisation participating in the sustainability benchmarking study.

environmental sustainability-related commitments, ambitions and perspectives across the industry. The objectives of the study were to inform future initiatives of the Sustainability Sub-Team, as well as to identify opportunities for broader collaboration on environmental sustainability efforts across the biopharma and pharmaceutical industries.

The study was conducted in two phases. The first was an online quantitative pre-work questionnaire completed by representatives from each member organisation (with the support of subject matter experts within their organisations as needed). The second phase involved in-depth, qualitative, discussion-based interviews with the respondents of the first phase together with other expert representatives of each participating company.

The discussion was designed to collect qualitative, contextual information about the quantitative ratings provided in the first phase and more generally about adoption and implementation of sustainability improvement practices within the member companies. Responses from individual interview participants were then reviewed and consolidated to achieve industry insights. While the majority of respondents were employed in packaging or device development functions within their companies, experts from environmental sustainability, drug development, commercial and regulatory affairs were also included. Companies varied with regard to the number of individuals providing responses (Table 1).

## COMMON THEMES ABOUT SUSTAINABILITY COMMITMENTS AMONG MEMBER ORGANISATIONS

Strong, corporate-level sustainability commitments aimed at achieving major reductions in environmental impact have been made across the SC Consortium's member organisations. However, the study results indicate that, despite this corporate-level commitment, the transition to less environmentally impactful practices is lagging across all participating companies (Figure 1).

Qualitative discussions suggested that, to date, most member companies have concentrated their sustainability efforts on areas that are comparatively easier to address, such as secondary and tertiary packaging. In contrast, more complex domains – such as drug product formulation, device redesign and supply chain transformation – remain less advanced. A second theme concerned the regulatory environment, which participants described as both a challenge and an enabler; regulations can create prohibitive burdens for implementation, yet they are also viewed as essential for establishing a level playing field and compelling the industry to adopt more difficult but necessary changes.

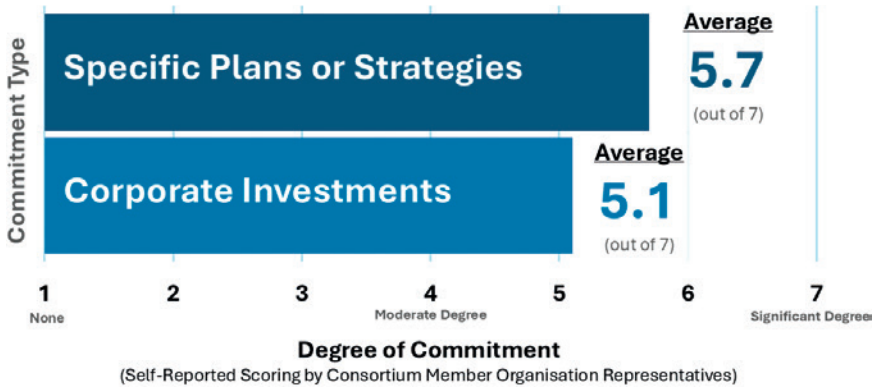


Figure 1: Existing commitments of Consortium member organisations towards future implementation of sustainable practices in product development.

**"QUALITATIVE DISCUSSIONS SUGGESTED THAT, TO DATE, MOST MEMBER COMPANIES HAVE CONCENTRATED THEIR SUSTAINABILITY EFFORTS ON AREAS THAT ARE COMPARATIVELY EASIER TO ADDRESS, SUCH AS SECONDARY AND TERTIARY PACKAGING."**

Companies have identified that packaging is an area where environmental improvements can be implemented with lower complexity and risk compared with the drug product or manufacturing processes (Table 2), which can serve as an enabler for broader sustainability

| Product Development Process | Degree to Which Sustainable Transitions Are On Track* |
|---|---|
| Product Development Overall | 5.6 |
| Packaging | 5.8 |
| Procurement | 5.5 |
| Supply Chain | 5.3 |
| Product Development – Devices | 5.2 |
| Manufacturing – Devices | 5.1 |
| Product Development – Formulation | 4.7 |
| Manufacturing – Formulation | 4.7 |

Table 2: Degree to which Consortium member organisations self-assess being on track with future transitions towards more sustainable practices. *Average score on scale from 1 (not at all on track) to 7 (completely on track).

transitions. Furthermore, respondents scored packaging transitions highest in terms of the degree to which they were on track with corporate sustainability goals and targets.

Table 3 highlights that secondary and tertiary packaging are the areas where green credentials are most likely to be considered compared with other aspects of product development. Table 4 shows that energy consumption, supplier selection and waste reduction are the key factors influencing selection decisions during development and process selection.

## CONFLICTING PRIORITIES IMPACT IMPLEMENTATION OF REUSABLE AND MULTIDOSE DEVICES DESPITE ACKNOWLEDGED ENVIRONMENTAL BENEFITS

The study confirmed that the environmental benefits of reusable and multidose SC delivery devices over single-use devices are widely recognised because of the significant reduction in material use, waste and emissions per dose. However, despite these compelling benefits, there is not yet widespread adoption of these more complex devices, especially of those that require additional training or operational steps. Study responses confirmed that Consortium member organisations are hesitant to adopt these technologies because of the possible use-related risks they are perceived to bring. Furthermore, when considering reusable devices, factors such as the intervals between doses and use-risks – such as "memory-decay" known to occur after training with more complex systems – are barriers to adoption.

## ALTERNATIVE MATERIALS AND PROCESS APPROACHES TO REDUCE ENVIRONMENTAL IMPACT

The study indicates that alternative approaches to achieving sustainability goals are seen as easier to adopt, such as adjustments to material selection and sources of energy for the production of glass, plastic and metal components. Alternative plastics, for example, bio-sourced resins, can be used for packaging and device components to reduce environmental impact; however, to date, member

| Product Development Process | Degree to Which Green Credentials Are Considered* |
|---|---|
| Secondary/Tertiary Packaging | 5.2 |
| Devices – Product Design | 4.3 |
| Primary Packaging | 4.1 |
| Devices – Manufacturing Processes | 3.9 |
| Drug Product – Formulation Development | 3.9 |
| Drug Product – Manufacturing Processes | 3.9 |

Table 3: Degree to which green credentials are considered in Consortium members' product development processes. *Average score on scale from 1 (not at all considered) to 7 (significant consideration).

| Green Credential Selection Factors | Importance When Selecting Green Credentials* |
|---|---|
| Energy Consumption | 5.5 |
| Supplier Selection | 5.5 |
| Waste Reduction | 5.3 |
| Device Material Selection | 5.1 |
| Container Selection/Primary Packaging | 4.8 |
| Drug Product Formulation Ingredients | 4.4 |
| Selection of Excipients | 4.3 |
| Automation | 3.7 |

Table 4: Perceived importance of factors when selecting product development and manufacturing processes with green credentials. *Average score on scale from 1 (not important) to 7 (highly important).

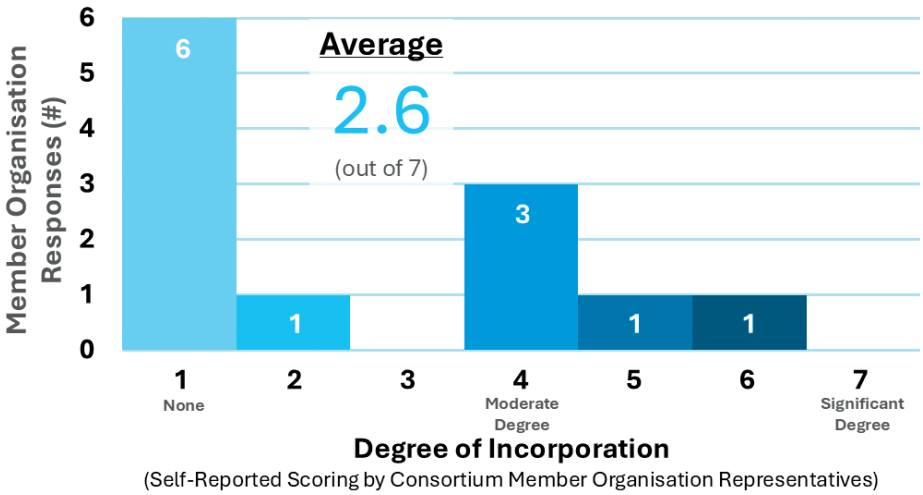


Figure 2: Current incorporation of non-fossil-derived or recycled polymers in Consortium members' SC delivery devices.

| Polymer Type | Importance for Achieving Sustainability Goals* |
|---|---|
| Bio-based Polymers | 5.2 |
| Virgin Petrochemically-Derived Polymers | 5.2 |
| Biomass Polymers | 4.5 |
| Chemically Recycled Polymers | 3.8 |
| Carbon-Captured Polymers | 3.7 |
| Mechanically Recycled Polymers | 3.0 |

Table 5: Importance of plastic material types for achieving Consortium members' sustainability goals. *Average score on scale from 1 (not important) to 7 (highly important).

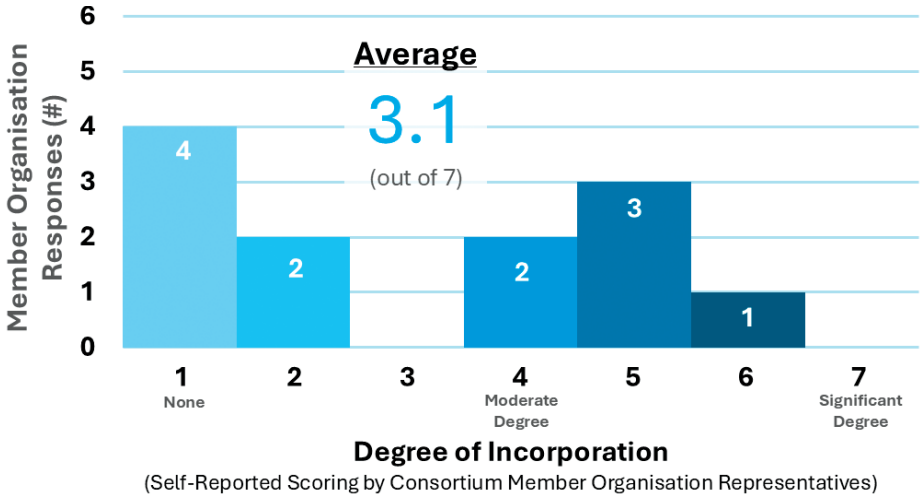


Figure 3: Current incorporation of circularity in Consortium members' product-development processes.

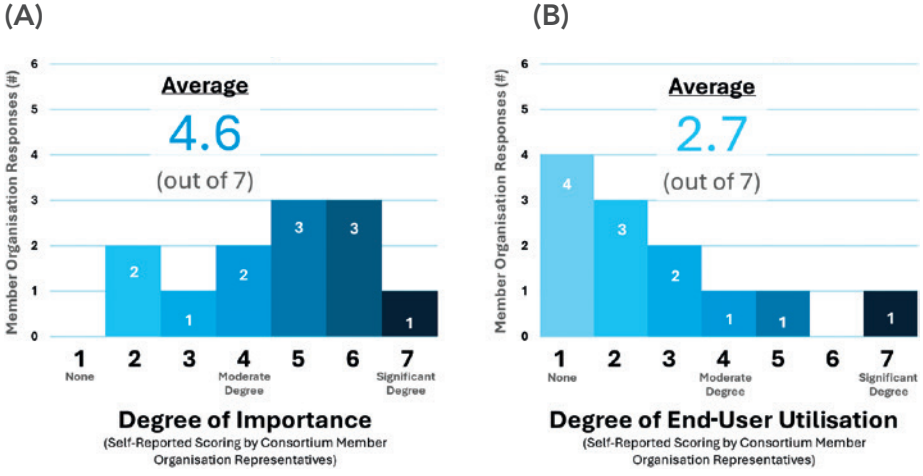


Figure 4: (A) Importance of take-back programmes to achieving Consortium members' sustainability goals; (B) Current end-user use of Consortium members' take-back programmes.

organisations report limited incorporation of non-fossil-derived or recycled polymers in their products (Figure 2). These changes can be challenging to implement, given the regulatory implications, stringent safety and quality requirements, and concerns related to ethical sourcing. However, study responses indicate that alternatives to petrochemical-derived resin materials are considered to be important for achieving sustainability goals (Table 5).

Lower scores for the importance of certain available polymer options may be down to a lack of familiarity or experience with these newer materials or feedstock flows. Moreover, qualitative responses indicated that companies remain cautious due to supplier dependency and uncertainties related to quality and consistency, as well as broader environmental impacts, including biodiversity and land use.

The qualitative responses from the second phase of the study indicate that companies consider the ethical concerns that accompany bio-derived feedstock sources for bio-based plastic resin production, specifically including risks related to the displacement of agricultural land at the expense of food production and of impacts to rainforests. Nevertheless, there is some expressed interest from companies in the introduction of lower-impact plastics through alternative hydrocarbon sources or mechanical recyclate. Provided that outstanding concerns related to consistent material quality control, relative availability, cost and true environmental benefit can be addressed, we may start to see a reduced reliance on non-renewable resources in the industry.

## Circularity

Consortium member organisations are conscious of the loss of high-value materials contained within injection devices upon disposal. However, most struggle to translate circularity ambitions into real action to prevent loss to landfill or incineration (Figure 3).

Safe retrieval of used devices for reprocessing of materials is important to achieving circularity, but study responses indicate that perspectives on take-back schemes are mixed (Figure 4). Consortium member organisations

generally acknowledge that successful implementation of reverse-logistics schemes can prevent material losses, but they also point out that they are challenged by high implementation costs and the need to take on greater downstream responsibilities that are beyond the typical reach of pharma companies, including redefining relationships with waste management organisations.

Historically, the success rate of medical device take-back schemes has been low,[1] and study participants commented that achieving greater return rates requires substantial upfront investment, making it difficult to make a sound business case to support their implementation. However, despite these challenges, some Consortium member organisations are interested in pursuing take-back schemes, especially if there is a stronger and more collaborative push across the industry.

| Product Development Process | Importance of Eco-Design Considerations* | Formal Incorporation of Eco-Design Criteria** |
|---|---|---|
| Product Development Overall | 5.3 | 4.8 |
| Packaging | 5.8 | 5.3 |
| Product Development – Devices | 5.7 | 4.9 |
| Procurement | 5.3 | 4.8 |
| Manufacturing – Devices | 5.1 | 4.2 |
| Supply Chain | 4.8 | 4.0 |
| Product Development – Formulation | 4.7 | 4.6 |
| Manufacturing – Formulation | 4.6 | 4.3 |

Table 6: Importance versus formal incorporation of eco-design criteria in various Consortium members' product-development processes. *Average score on scale from 1 (not important) to 7 (highly important) **Average score on scale from 1 (not implemented) to 7 (significantly implemented).

## LCAs and Eco-Design Principles

Although lifecycle assessments (LCAs) are conducted for fewer than half of Consortium members' products, study participants confirm that these assessments are currently used to both assess environmental impact and inform decisions. During development, some Consortium member organisations use internal tools to identify and evaluate opportunities for sustainability improvements. Results from these internal tools are generally not externally reportable but are intended to support decision-making during product design and development phases.

Comprehensive LCA methodologies are typically employed retrospectively for fully defined commercial products, when the overall environmental impact can be calculated and reported. At the time of the study, some Consortium members were not yet conducting LCAs for SC delivery devices. This may present a barrier to these organisations with respect to future collaboration opportunities, including learning best practices from other organisations and aligning on common industry practices for analyses and reporting.

Eco-design – a product-development approach that considers (and aims to reduce) environmental impact throughout a product's lifecycle – is a noteworthy approach for promoting environmental sustainability. Embedding good eco-design principles in product development can broadly improve sustainability outcomes when designing or updating subcutaneously delivered medicines, including enabling the adoption of less impactful materials; facilitating product recovery, disassembly and recycling; and establishing aligned LCA reporting across the supply chain.

Results from the study revealed that eco-design considerations are seen by Consortium members as important levers for packaging, drug delivery devices and procurement activities, but application of these considerations to formulation design and defining the supply chain is perceived to be more challenging (Table 6). Qualitative responses indicated that applying eco-design principles to drug products and delivery devices is perceived as more complex than it is for packaging, due to regulatory requirements, the need for changes in fill-finish operations, and the inherent difficulty of adapting biologics and other formulations. Participants emphasised that such changes require more time, phasing and investment to implement compared with secondary or tertiary packaging.

## Regulatory

Sustainability-led transitions must be managed within the context and constraints of existing and emerging regulatory frameworks. Study participants expressed that Consortium member organisations generally have good understanding of and compliance with regulations for topics such as zero emissions targets and pharmaceuticals in the environment, as these have been established for many



 

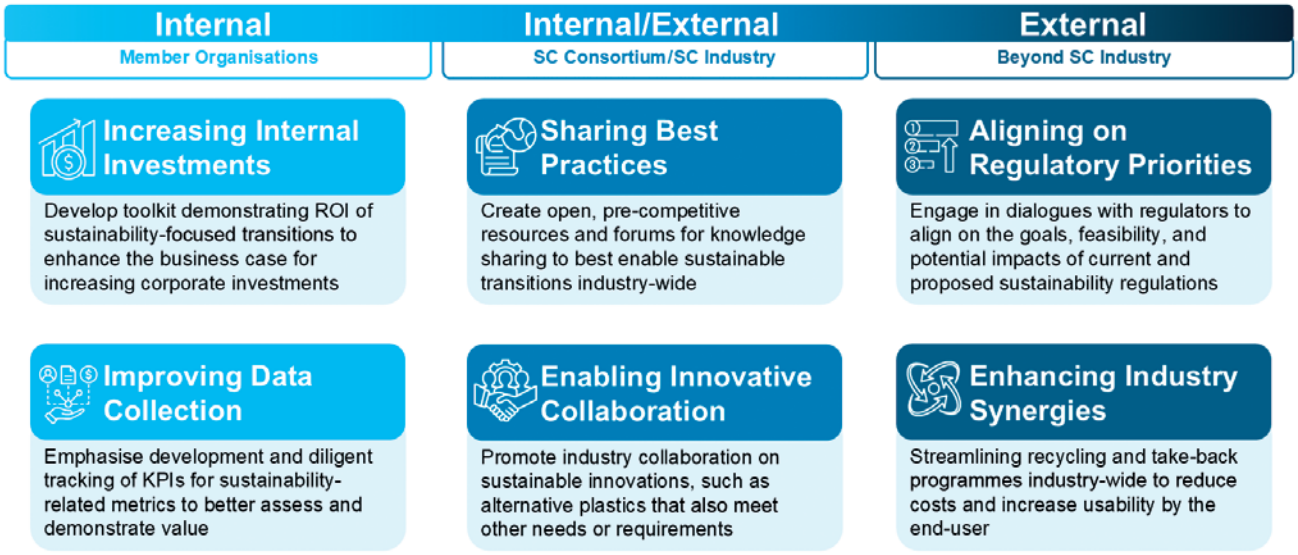


Figure 5: Recommendations following the SC Consortium sustainability benchmarking initiative.

years.[2,3] On the other hand, greater difficulties can be experienced managing compliance with newer legislation and usage restrictions related to problematic materials, such as PVC and per- and polyfluoroalkyl substances.[4,5]

The pace of regulatory change is increasing within the pharmaceutical industry and has the potential to impact shared supply chains. Newer regulations, such as the Packaging and Packaging Waste Regulation in Europe, are not always fully compatible with medical and medical device regulations.[6] While temporary derogations can provide additional time for achieving compliance, these are typically time-limited and, ultimately, the industry must find ways to meet the growing environmental regulatory requirements. The study results suggest that environmental regulations are seen as either a positive stimulant for industry-wide progress towards environmental sustainability or as significant additional complexity for the industry to manage.

## CONCLUSION

The sustainability benchmarking initiative led by the Sustainability Sub-Team of the SC Consortium found that there is strong commitment to sustainability among the Consortium's membership. However, while there is a measurable desire to achieve impact – from enhancing packaging sustainability to exploring bio-based materials and circularity – notable challenges remain. Many companies face a gap between ambitious corporate targets and the internal investment required to embed sustainability practices in SC product development, especially when balancing regulatory demands and patient needs. Moving forward, the Consortium will prioritise collaborative efforts towards industry-wide best practices, focus on aligning strategic sustainability ambitions with practical implementation, and encourage targeted investments to overcome the complex challenges of transitioning to less environmentally impactful SC drug products (Figure 5). This collective approach will be essential for achieving meaningful environmental progress while continuing to innovate for improved patient outcomes.

"MANY COMPANIES FACE A GAP BETWEEN AMBITIOUS CORPORATE TARGETS AND THE INTERNAL INVESTMENT REQUIRED TO EMBED SUSTAINABILITY PRACTICES IN SC PRODUCT DEVELOPMENT, ESPECIALLY WHEN BALANCING REGULATORY DEMANDS AND PATIENT NEEDS."

## ACKNOWLEDGEMENTS

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## ABOUT THE COMPANY

The Subcutaneous Drug Development & Delivery Consortium was established in 2018 to fundamentally improve subcutaneous drug development and delivery. Motivated by this shared goal, the organisations within the Consortium's membership have come together to address key issues in the subcutaneous industry and expand subcutaneous technology use to improve patient outcomes.

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PharmaED RESOURCES, INC

## Cleaning Validation Summit 2026
February 24-25, La Jolla, CA

## Connected Devices & Digital Health 2026
March 24-25, Philadelphia, PA

## Extractables and Leachables 2026
April 14-15, Raleigh, NC

## Combination Products Summit 2026
May 13-14, Philadelphia, PA


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

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

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

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

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# **Interview:** A Structured Approach to the Eco-Design Process

In this exclusive interview, **Fabien De Coninck** and **Bruno Morchain**, discuss **Aptar Pharma**'s eco-design philosophy with ONdrugDelivery's Guy Furness. In a thorough conversation, they cover how Aptar Pharma has implemented lifecycle assessments as a key tool to elucidate the environmental footprint of the company's rubber components for primary packaging for injectable systems, including how they tackled the unique challenges presented by the complex, proprietary formulations involved in elastomer component design.

**Q What is Aptar Pharma's strategy when it comes to sustainability?**

BM As a part of AptarGroup, Aptar Pharma places sustainability at the core of its business strategy, integrating environmental, social and economic considerations into its policies and operations. The aim of this approach is to create long-term benefits for the company and its employees, while being mindful of conserving and protecting resources.

Aptar's corporate sustainability strategy is built around three key pillars – care, collaboration and circularity. Based on this strategy, we focus on employees, communities and the environment by continuously improving our impact and reducing our carbon footprint. Furthermore, we seek to design our products with people and the planet in mind, while also incorporating eco-design principles to contribute to a more circular economy. This means understanding the key lifecycle impacts of our products and innovating to deliver optimal performance throughout the value chain.

Aptar Pharma has embraced this strategy as evidenced by the continued development of new products within our Futurity™ sustainable solutions platform. The Futurity™ platform meets the growing need for recyclable packaging and drug delivery solutions in the pharmaceutical industry, supporting our customers as they improve circularity for their products.

**Q How does Aptar Pharma's injectables segment align with the wider company's global sustainability strategy?**

BM Our injectables primary packaging components – stoppers for vials; and plungers and tip closures, including rigid needle shields, for prefilled syringes – are made from rubber (Figure 1). Working with this type of material requires a specific process, notably including the compounding of several raw materials, such as synthetic elastomers, mineral fillers, curing agents and pigments, to form a hardened cross-linked polymer. This makes it difficult to recycle in existing recycling streams.

In addition to this, primary packaging components are often in direct contact with the drug and must be used in conjunction with glass containers. As glass containers and elastomeric closure components come into direct contact with patients – whether via the intravenous, intramuscular or subcutaneous route – packaging solutions for injectable drugs are considered biohazardous waste and treated as such.

Under the current pharmaceutical waste management paradigm, rubber components are unlikely to enter any recycling stream after being used. Therefore, we have had to

Figure 1: Aptar Pharma's moulded rubber stoppers.

find other levers to fulfil our sustainability objectives. As there are challenges with changing the design or implementing recycling for these specific types of products, we have turned to looking at our corporate environmental footprint to make tangible progress. Within the company, we've implemented dedicated initiatives to reduce the environmental footprint of our sites, which can, in turn, help our customers reduce their Scope 3 emissions.

All of Aptar Pharma's injectables manufacturing sites are certified as landfill free by our internal certification programme. To obtain and maintain the certification, sites are required to prove that they reuse or recycle at least 90% of their operational waste through a third-party audit. Aptar's landfill-free programme contributes to environmental sustainability by aiming for continuous improvement in waste reduction. Within Aptar Pharma sites, we have worked to establish a dedicated recycling network for vulcanised rubber waste, enabling us to recycle at least 90% of our rubber waste annually.


## Bruno Morchain

Manager of Innovation & Scientific Affairs

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Bruno Morchain is the Manager of Innovation & Scientific Affairs for Aptar Pharma's Injectables division. He holds a Mechanical Engineering degree from the University of Technology of Compiègne (France) and has over 20 years of experience in the injectable pharmaceutical industry, supporting new production capabilities implementation and elastomeric closure development. Since joining Aptar Pharma in 2012, Mr Morchain has held various positions within the company's R&D organisation. He is a member of the Pharma Sustainability Council at Aptar Pharma and actively contributes to ISO committee TC76/WG4, focusing on elastomeric components for primary packaging in injectable drug delivery.

Additionally, all of the electricity we use within our injectables sites comes from renewable sources. Most importantly, as part of our global expansion, we have been implementing energy-saving initiatives, aiming to reduce natural gas consumption at our facilities worldwide. For example, by implementing a state-of-the-art steam boiler in our Granville (France) factory, modernising utilities and implementing heat-recovery mechanisms, we've reduced the consumption of energy for building heating and production.

**"AS PART OF OUR GLOBAL EXPANSION, WE HAVE BEEN IMPLEMENTING ENERGY-SAVING INITIATIVES, AIMING TO REDUCE NATURAL GAS CONSUMPTION AT OUR FACILITIES WORLDWIDE."**

Turning to our product development strategy, we have proactively launched an initiative to integrate eco-design into our development process, anticipating future regulatory changes, such as perfluoroalkyl substance restrictions and future packaging regulations. The first milestone in this approach is conducting a lifecycle assessment (LCA) of our products.


## Fabien de Coninck

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Fabien de Coninck is the Ecodesign R&D Engineer for Aptar Pharma's Injectables division. He graduated in 2019 with a degree in Manufacturing Engineering from the National Institute of Applied Sciences of Rouen (France). With over four years of experience in the rubber industry, Mr de Coninck has contributed to both production support and innovation initiatives. Since joining Aptar Pharma in 2024, he has led the development of lifecycle assessment methodologies tailored to the Injectables segment, driving sustainability-focused product development and supporting strategic eco-design projects.

**Q** **What does a lifecycle assessment consist of?**

**FDC** Conducting an LCA of existing products is a key step in developing a robust eco-design strategy. LCAs provide a comprehensive evaluation of a product's environmental impacts across its entire lifecycle – from raw material extraction to end-of-life disposal (Figure 2). By identifying the most impactful stages and processes, we can then prioritise areas for improvement.

This initiative is part of Aptar Group's company-wide strategy to conduct LCAs systematically for every new development project. In our case, we have implemented


Figure 2: Scope of a cradle-to-gate LCA.

an advanced cradle-to-gate LCA, covering all stages from raw material production to delivery to the customers for each product range. This approach enables us to accurately identify environmental "hotspots" and guide our eco-design actions more effectively.

In the field of rubber components for injectable devices, this is particularly innovative – our rubber formulations are proprietary, and our manufacturing processes are complex. As a result, the generic datasets present within existing LCA software and methodologies are not representative of our products. Therefore, we have adapted our LCA tools to consider the specificities of each rubber formulation we use and the steps of our manufacturing process.

**Q How did you ensure that the LCA of your products was implemented effectively?**

FDC Aligned with ISO 14040 and 14044 guidelines for LCAs, we conducted our study using the well-known Sphera® LCA FE software, previously named "GaBi" (Sphera, Chicago, IL, US). We focused on a cradle-to-gate scope, which includes the product lifecycle steps from raw materials production to final delivery to the customer, so it covers our production steps, the secondary packaging materials and supply transport. Our approach was to build a flexible and customisable LCA model, considering various scenarios and parameters to enable it to match the lifecycles of our various injectables products. An automatic report with standard environmental results was linked to the model to facilitate fluent analysis. Following our own initial analysis, we are now preparing for an LCA review by a third party in early 2026.

**"THE RAW MATERIALS USED IN OUR RUBBER FORMULATIONS ARE THE MAIN CONTRIBUTORS TO OUR CARBON FOOTPRINT, ACCOUNTING FOR UP TO 75% OF THE OVERALL ENVIRONMENTAL IMPACT OF OUR COMPONENTS."**

**Q What were the main challenges you encountered during the LCA process?**

FDC Throughout this process, data inventory was a challenging step. It required a significant time investment to ensure our analyses were based on truly reliable data. The development of our LCA tool was a six-month full-time project led by an eco-design engineer and supported by a multidisciplinary team, primarily from the R&D, environment, health and safety, maintenance and procurement departments.

Initially, the lack of supplier data and the challenges in accessing it proved to be a barrier to our approach. Nevertheless, we observed a genuine awareness among all stakeholders in our ecosystem about the importance of assessing their environmental impact. Thanks to specific confidentiality agreements, we were able to initiate constructive exchanges to share environmental impact data and align data transfer practices that supported a robust and detailed LCA.

**Q What are the key conclusions from the LCA of your products?**

BM Based on our preliminary results (Figure 3), the conclusions are clear – as we had expected. The raw materials used in our rubber formulations are the main contributors to our carbon footprint, accounting for up to 75% of the overall environmental impact of our components. Among these, elastomers alone represented an average of 85% of the rubber compounding impact. Overall, we observed a carbon footprint ranging from 4–7 kg carbon dioxide equivalents ($CO_2$eq) per kilogram of rubber components.

As an example, let's consider a 13 mm stopper for a standard 2R borosilicate glass vial to compare the carbon dioxide emissions within our defined cradle-to-

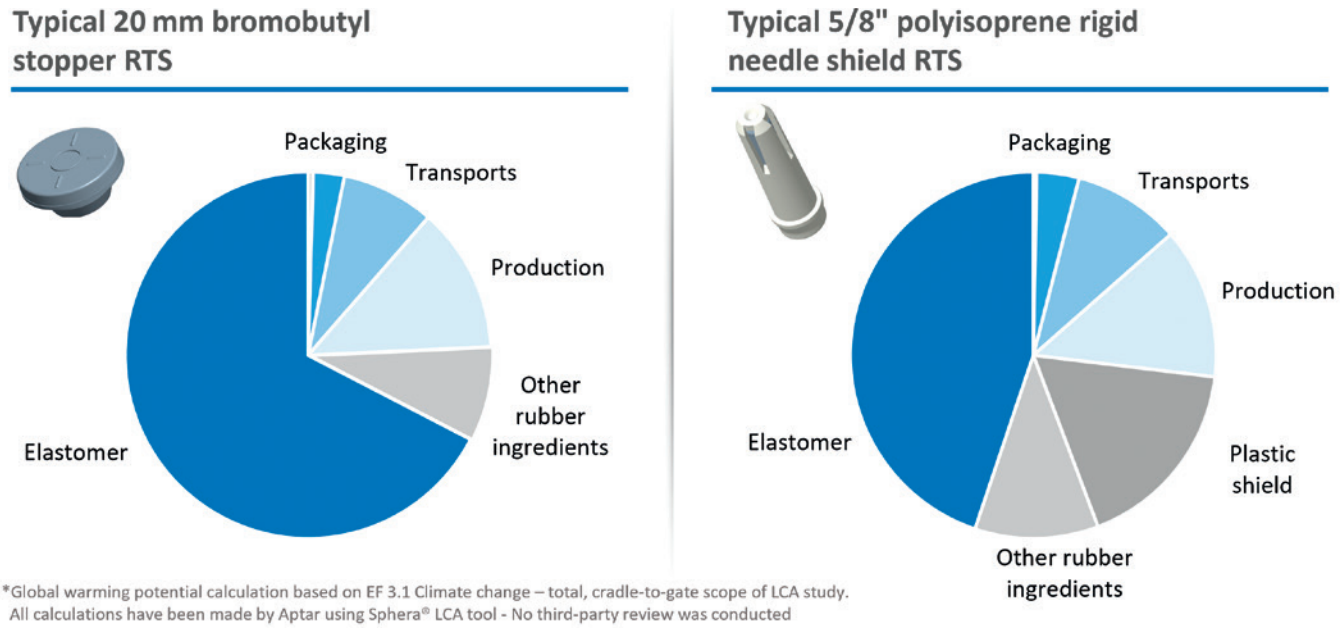


Figure 3: Global warming potential of elastomeric closures (RTU: Ready-To-Sterilise).

gate scope. The global warming potential for this rubber stopper is evaluated to be around 3 g $CO_2$eq per unit and the glass vial around 28 g $CO_2$eq per unit, based on the preliminary LCA and estimations. Data on the glass component was obtained from Corning (Corning, NY, US) based on their optimised Viridian™ vials.

The impact of our manufacturing process, primarily energy and resource consumption, on the carbon footprint remains moderate, thanks to the various measures implemented at our production sites in recent years, such as the use of renewable energy and water-saving initiatives. Other impact categories – including transport, packaging and non-product-contact materials such as the polypropylene shell of rigid needle shields – have a limited footprint but still present interesting short-term opportunities for improvement. This insight is now driving our material innovation efforts towards lower-impact alternatives, without compromising the stringent regulatory and functional requirements of parenteral applications.

**Q How does the LCA help you define or validate your eco-design strategy?**

FDC We keep a strong commitment to eco-design at the heart of our materials strategy. Every new development is evaluated for environmental impact – reducing material usage, lightweighting, enhancing durability and replacing high-impact components. Our LCA tool now enables us to quickly assess the environmental impact of various product development scenarios within our innovation projects.

Putting this into practice, we primarily focus on the hotspots identified through the LCAs, combining both short and long-term initiatives. The LCA results highlight the need to address raw materials as the primary contributor to carbon footprints. This is a critical area where development and implementation timelines with pharmaceutical partners tend to be long, as it may affect their product validation and stability studies.

Our R&D sustainability roadmap is structured around four key pillars: raw materials, waste management, process improvement and secondary packaging. In terms of materials, we're currently exploring initiatives related to the use of renewable mass balance certified materials. We're aiming to reduce the use of fossil-based materials and have launched research into alternative materials to make this reduction easier. Notably, we are participating in a multi-partner research project on bio-based materials in the rubber sector, called Bioproof 2, led by Elanova (Vitry-sur-Seine, France).

We have other initiatives underway to reduce material usage by optimising component design, all while maintaining critical functions such as tightness performance, container closure integrity and functional properties during piercing.

**"OUR LCA TOOL NOW ENABLES US TO QUICKLY ASSESS THE ENVIRONMENTAL IMPACT OF VARIOUS PRODUCT DEVELOPMENT SCENARIOS WITHIN OUR INNOVATION PROJECTS."**

**"WE ARE PARTICIPATING IN A MULTI-PARTNER RESEARCH PROJECT ON BIO-BASED MATERIALS IN THE RUBBER SECTOR, CALLED BIOPROOF 2, LED BY ELANOVA."**

**Q How does this approach support Aptar's customers?**

BM Firstly, calculating the environmental impact of a product is becoming essential. In some industries, this process is mandatory and well-regulated. In the pharmaceutical sector, there isn't a legal obligation yet, but requests from our customers are becoming increasingly frequent. Aptar's emissions are accounted for as Scope 3 emissions in our customers' greenhouse gas inventories, so we need to understand the full value chain impact to take action where it can be the most impactful.

Current customer requests are often focused on calculating a product's global warming potential and understanding where progress can be made in reducing these potential impacts. We believe that restricting LCAs to emissions alone for rubber components does not provide a sufficiently accurate picture, due to the unique characteristics of the material and the specifics of the production process. Therefore, we consider additional environmental impact categories, such as primary energy demand and fossil resource depletion, to provide a more comprehensive assessment.

Additionally, some clients now request detailed environmental impact categories based on specific methodologies, such as the European Environmental Footprint. It is therefore crucial to be prepared to meet these specific needs and to stay up to date with evolving industry trends. As a supplier, we play a vital role in creating a complete and accurate LCA of the final product that covers all stages of its lifecycle.

Secondly, understanding the LCA results of our products, coupled with our own internal corporate sustainability strategy, allows us to quickly initiate actions that contribute to reducing the environmental impact of the final product. It empowers us to take a proactive approach to manufacturing more responsibly and prioritising our eco-design strategies in alignment with a shared goal of our clients, reducing the negative environmental impact of products.

**Q What are the upcoming steps in your process?**

BM We plan to include a critical review phase of our LCAs by a third party before sharing data externally. Additionally, we aim to leverage the full potential of LCAs as a decision-making tool to help prioritise our eco-design projects. This will also enable us to quantify and highlight the improvements made to our manufacturing processes more accurately.

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# Expert View

# SUSTAINABILITY AS STRATEGY: HOW PHARMA IS DRIVING CLIMATE INNOVATION

**Dr Sofia Sotiropoulou** of Lonza Capsugel discusses the increasing emphasis that pharma companies are putting on sustainability metrics, and how they are extending this emphasis to their entire supply chains, placing expectations on design and manufacturing partners to participate in meeting sustainability targets.

"A RECENT CYTIVA REPORT FOUND THAT NEARLY TWO-THIRDS OF SURVEYED PHARMA AND BIOPHARMA PROFESSIONALS RANK SUSTAINABILITY AS THEIR NUMBER ONE PRIORITY FOR THE NEXT FIVE YEARS."

Drug development traditionally places intense demands on resources, time and energy, with advanced manufacturing and supply chain networks in place all over the world. As a result of this globalisation, the drug development value chain is a significant contributor to climate change, specifically by generating greenhouse gas (GHG) emissions. Drug development stakeholders – biotech, pharmaceutical and nutraceutical companies alike – are working to decarbonise their supply chains and lower their GHG emissions by making their processes more sustainable. In fact, a recent Cytiva report found that nearly two-thirds of surveyed pharma and biopharma professionals rank sustainability as their number one priority for the next five years.[1] To advance sustainability and efficiency, drug developers and their partners are focusing on the following areas:

- **Climate:** Climate change is putting pressure on upstream supply chains. As its effects become more visible, drug developers and their supply and manufacturing partners are cutting their carbon footprints and lowering their emissions. Many are also aiming to transition to renewable energy sources, such as solar, wind or hydroelectric power, as a way to reduce their Scope 1 and 2 emissions.

- **Resource Use:** Drug developers and manufacturers are putting a greater emphasis on efficiency, with water being a prime example. Pharma companies are not only conserving water as a scarce resource but also preserving its quality, monitoring its use during production and guarding against discharge of effluent that may contaminate water sources. According to the Cytiva report, 58% of the surveyed biopharma professionals said that they have reduced water consumption.[1]

- **Waste Reduction:** Companies are rethinking packaging and materials to reduce excess waste and becoming more vigilant about complying with regulations and guidelines. These firms are employing creativity and innovation to make pharmaceutical packaging lighter or ensure that it can be reused or recycled.

"ON THE DOWNSTREAM SIDE, MANY CONSUMERS ARE BECOMING INCREASINGLY AWARE OF CLIMATE CHANGE AND ITS DETRIMENTAL ENVIRONMENTAL EFFECTS."

These areas of focus are especially pertinent for an already strained upstream supply chain, where resources and material shortages are common. On the downstream side, many consumers are becoming increasingly aware of climate change and its detrimental environmental effects. The rise of eco-conscious consumers is driving demand for products with clear environmental benefits, transparent sustainability performance and recognised certifications related to climate, water or circularity, including those that are upcycled.

As a result, drug developers and their partners are more actively engaging in efforts to enhance the sustainability of their manufacturing practices. This shift is not only in response to customer demand and the growing environmental consciousness movement but also to safeguard operations and supply chains, making them more resilient to climate change and related effects.

## PURSUING SUSTAINABILITY IN CAPSULE MANUFACTURING

In the pharma and excipients sector, sustainability innovation has led many companies to improve their manufacturing practices and reduce their environmental impact. Ever more companies are incorporating eco-design principles into capsule manufacturing, which offers numerous sustainability benefits, including lower carbon emissions. Eco-designed products are manufactured using less energy, preferably with renewable electricity, and with ingredients and materials sourced from a responsible and transparent supply chain.

Additionally, considerations such as the use of bio-based materials are increasingly important. Capsules, as oral delivery forms, are inherently bio-based – a key differentiator from injectables – and can help pharma manufacturers transition to lower carbon products.

## PARTNERING TO ADDRESS GHG EMISSIONS

Several pharma players, guided by the industry's ambition for collective positive impact, are adopting emission reduction targets. Many organisations have joined the Science Based Targets initiative (London, UK), a global corporate climate action organisation that develops standards, tools and guidance to help companies set GHG emissions reduction targets with the goal of reaching net-zero carbon emissions by 2050.

"THESE COMPANIES EXPECT A CERTAIN LEVEL OF 'SUSTAINABILITY MATURITY' FROM THEIR SUPPLIERS AND INSIST THAT SUPPLIERS ALIGN WITH THEM ON ENVIRONMENTAL VALUES, INCLUDING MEASURING, TRACKING AND MINIMISING THEIR CARBON FOOTPRINT."

As a result, pharma and biotech companies are asking prospective supply chain partners to participate in their sustainability targets. These companies expect a certain level of "sustainability maturity" from their suppliers and insist that suppliers align with them on environmental values, including measuring, tracking and minimising their carbon footprint. These companies' sustainability requests fall into four broad categories:

- **Public Commitment to Sustainability:** When drug developers choose a manufacturing or design partner, they essentially invite the partner to join them on their sustainability journey. Therefore, they expect their partners to have the same level of commitment to sustainability goals, including global standards such as the Paris Agreement.
- **Renewable Electricity Supply:** Drug developers often request that manufacturing facilities be powered by renewable sources such as solar or wind-generated electricity. As these methods of delivery become more affordable, they are increasingly viewed as beneficial for both business and the environment.
- **Responsible Sourcing:** Being a reliable partner in sustainable business practices means maintaining tight control over the entire supply chain, beginning with the origin of raw materials. Tracking suppliers' sustainability efforts is essential to building a resilient supply chain and minimising risks. Just as drug developers align responsible sourcing with their corporate ethics and fair practices, manufacturers are applying the same principles when dealing with their own suppliers.
- **Transparency:** Drug developers now expect suppliers to share their sustainability goals openly in annual reports, including commitment to the principles of eco-design and green chemistry. These goals and measurable progress towards them must be clearly stated as part of a supplier's public profile.

The adoption of global sustainability metrics signals a more energised pharmaceutical and biotech industry that prioritises partnerships that align with their sustainability values, responding more directly to customer expectations and sharing data more proactively to demonstrate the impact of sustainability initiatives. Concurrently, many companies are establishing units dedicated to managing and advancing their sustainability initiatives.

## THE FUTURE OF SUSTAINABILITY IN DRUG DEVELOPMENT

Pharma and biotech companies and their suppliers no longer see sustainable manufacturing as a "nice-to-have" but as essential to how they operate. Increasingly, they view sustainable value creation as an ethical, social and commercial imperative and a responsibility shared across the global community.

That responsibility also shapes which partners drug developers choose to support in their sustainability journey. Manufacturers that embed sustainability throughout their processes and equip customers with the capabilities, knowledge and expertise to adopt sustainable materials and methods will be best prepared to succeed in an ever-evolving pharma industry.

**Dr Sofia Sotiropoulou**

Sofia Sotiropoulou, PhD, is Senior Director, Sustainability and Climate Innovation at Lonza Capsugel. Since joining Lonza Capsugel in December 2024, she has focused on sustainability as a key strategic initiative to drive customer value and transform organisations. Dr Sotiropoulou has over 15 years of experience in R&D and strategic innovation, having led the successful launch of more than 20 products in the fast-moving consumer goods and chemical industries.

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## ABOUT THE COMPANY

Lonza Capsugel is a global healthcare manufacturing organisation, delivering capsule design, development and manufacturing technology for the pharmaceutical and biotech industries. The company produces more than 236 billion capsules annually, supporting drug developers from preclinical research through clinical trials to commercial production.

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# 2025/26 Editorial Calendar



## NOV
Pulmonary & Nasal Drug Delivery

DEADLINE PASSED

## DEC
NEW ISSUE TOPIC

Delivering Gene & Cell Therapeutics

DEADLINE: **Nov 6, 2025**

## JAN 2026
Prefilled Syringes & Injection Devices

DEADLINE: **Dec 4, 2025**

## FEB
Skin Drug Delivery: Dermal, Transdermal & Microneedles

DEADLINE: **Jan 8, 2026**

## MAR
Ophthalmic Drug Delivery

DEADLINE: **Feb 5, 2026**

## APR
Pulmonary & Nasal Drug Delivery

DEADLINE: **Mar 5, 2026**

## APR/MAY
Sustainability in Drug Delivery

DEADLINE: **Mar 19, 2026**

## MAY
Delivering Injectables: Devices & Formulations

DEADLINE: **Apr 2, 2026**

## MAY/JUN
Oral Drug Delivery

DEADLINE: **Apr 16, 2026**

## JUN
Connectivity in Drug Delivery

DEADLINE: **May 7, 2026**

## JUL
Industrialising Drug Delivery

DEADLINE: **May 21, 2026**

## SEP
Wearable Injectors

DEADLINE: **Aug 6, 2026**

## SEP/OCT
Dual-Chamber Delivery Systems

DEADLINE: **Aug 20, 2026**

## OCT
Prefilled Syringes & Injection Devices

DEADLINE: **Sep 3, 2026**

## OCT/NOV
Sustainability in Drug Delivery

DEADLINE: **Sep 17, 2026**

## NOV
Pulmonary & Nasal Drug Delivery

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20 YEARS ON drugDELIVERY

# FROM PAPER TO PLANET: REVOLUTIONISING ENVIRONMENTAL RESPONSIBILITY IN PHARMA

pci PHARMA SERVICES

**Lori Jackson** and **Tim Hansen**, both at **PCI**, look at the rise of electronic batch records and the role they play in environmental sustainability in the pharmaceutical landscape.

In the current pharmaceutical landscape, environmental sustainability has moved beyond being a competitive edge to become a fundamental expectation. Amid tightening regulatory frameworks, mounting environmental, social and governance (ESG) pressures, and a rapidly evolving digital ecosystem, the pharmaceutical industry finds itself at a critical juncture. One of the most transformative elements of this shift is the rise of electronic batch records (EBRs). More than a tool for quality assurance or operational efficiency, EBRs are now serving as the digital backbone for sustainability efforts across the sector. However, the true power of EBRs is only beginning to emerge with the integration of artificial intelligence (AI), which is redefining what it means to manufacture intelligently, efficiently and responsibly.

Although the concept of EBRs has existed for decades, their adoption has

**"AS DIGITAL MATURITY GROWS AND AI CAPABILITIES BECOME MORE ACCESSIBLE, COMPANIES ARE BEGINNING TO SEE EBRs NOT MERELY AS DIGITAL REPOSITORIES, BUT AS ENGINES OF SUSTAINABILITY."**

Figure 1: Production runs for large-scale commercial packaging can yield lengthy, complex batch records. Manual paper-based processes consume more resources and are not environmentally sustainable.

been slow, particularly among CMOs and CDMOs. Barriers such as high implementation costs, complex enterprise resource planning integration and the perceived workflow disruption have slowed progress on this front. Yet, as digital maturity grows and AI capabilities become more accessible, companies are beginning to see EBRs not merely as digital repositories but as engines of sustainability (Figure 1).

## THE PAPER TRAIL PROBLEM

Historically, batch recordkeeping has been a paperwork-intensive process, with each production run involving extensive documentation, including manufacturing instructions, quality control checks, packaging records, deviation logs, training certifications and more. For large CDMOs, this can translate into millions of pages of printed records annually.

This is not just a storage or labour problem. According to the Environmental Paper Network, 0.9 tonnes of office paper (about 200,000 sheets) consumes approximately 24 trees, 75,708 L of water and 4,100 kWh of energy to produce. This production emits over 2,581 kg of carbon dioxide equivalent ($CO_2e$) when factoring in lifecycle emissions (as calculated by the Environmental Paper Network's Paper Calculator).

Applying those figures to a mid-sized pharmaceutical manufacturer using 10 million pages annually, the environmental cost includes the destruction of over 1,200 trees, consumption of 3,785,412 L of water and the release of over 225 tonnes of carbon dioxide into the atmosphere.

For a global enterprise operating across multiple facilities, the impact escalates dramatically. Add to that the emissions associated with transporting physical records, the energy used to store and archive them and the inevitable waste from misprints and documentation errors, and it becomes clear – traditional batch documentation is environmentally unsustainable.

## ENTER EBRS: SUSTAINABILITY BY DESIGN

EBRs digitise every element of the batch manufacturing process. By eliminating physical paperwork, companies can not only reduce their carbon footprint but also enable broader process improvements.

In 2020, PCI implemented MasterControl's Qx suite, which was a significant step forward in the company's digital transformation. Since then, PCI has deployed six modules across 14 of its 17 global sites, as well as successfully training

> "PCI'S COMMITMENT TO ENVIRONMENTAL STEWARDSHIP GOES BEYOND COMPLIANCE – IT IS ABOUT BUILDING SMARTER, LEANER AND MORE SUSTAINABLE SYSTEMS."

over 7,500 users worldwide. The Qx suite was the foundation for PCI to move forward with EBR. Key environmental benefits from this transition include:

1. **Elimination of Physical Documents:** Each batch record, often hundreds of pages long, is now fully digital. For one product run, PCI consolidated 13 paper batch records supporting 120 stock-keeping units into just two digital production records.
2. **Reduced Shipping and Storage Emissions:** By eliminating the need to transport, archive and retrieve physical documents, PCI minimises emissions associated with document handling logistics.
3. **Fewer Reprints and Errors:** Digital workflows mean fewer batch failures due to paperwork errors, reducing rework and material waste, which is a notable environmental gain in high-volume manufacturing.
4. **Less Hardware Waste:** As legacy systems are consolidated, redundant servers, scanners and printers are phased out, reducing e-waste and power consumption.

PCI's commitment to environmental stewardship goes beyond compliance – it is about building smarter, leaner and more sustainable systems. EBRs eliminate waste at the source, laying the foundations for advanced tools like AI and predictive analytics that will redefine sustainable manufacturing.

## EBRS AS A CATALYST FOR SYSTEMATIC DIGITAL ACTION

As the pharmaceutical industry continues its shift towards sustainability and operational excellence, the advancement of Pharma

4.0™ offers a powerful lens through which to view this transformation.[1] According to the ISPE 7th Pharma 4.0 Survey (2023), organisations are rapidly progressing beyond early-stage planning and into actionable, integrated digital practices. The proportion of companies reporting they had "not started" with Pharma 4.0 initiatives dropped from 31.2% in 2021 to 15.1% in 2023. Simultaneously, those engaged in "pilots" or "systematic ongoing actions" rose significantly, now representing 58.1% of respondents.

This upwards maturity trend represents an industry-wide commitment to embedding digital tools into the very core of pharmaceutical manufacturing. The report shared that 50% of manufacturing and engineering respondents identified EBRs as a main focus area and foundational for achieving operational consistency, regulatory compliance and sustainability.

EBRs exemplify the type of digitisation that transitions Pharma 4.0 from aspiration to execution. Digitised systems reduce the dependency on paper, streamline batch record review cycles, improve deviation handling and ensure real-time data traceability, all of which contribute to enhanced process control and resource efficiency. For organisations moving from pilot to systematic implementation, EBRs are often among the first large-scale digital tools to be operationalised, offering an immediate return on investment in terms of quality and operational agility.

By embedding EBRs into their transformation roadmap, pharma companies are not just digitising records, they are laying the groundwork for a more integrated, sustainable and intelligent future of manufacturing (Figure 2).

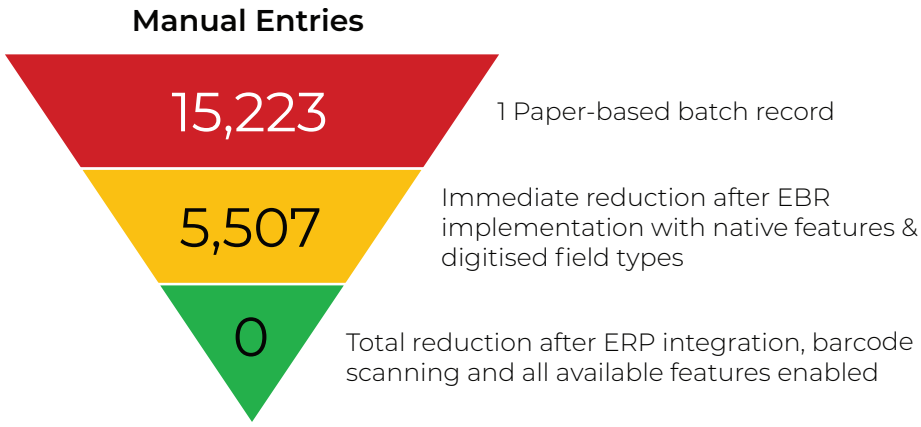


Figure 2: One batch record required over 15,000 manual entries, but that number immediately reduced upon EBR implementation.

## DIGITAL FOUNDATIONS ENABLE AI AND OPTIMISATION

While EBRs provide the structure and data integrity needed for compliance and efficiency, AI adds the intelligence layer that unlocks continuous improvement. Through the application of machine learning, predictive analytics and natural language processing, pharmaceutical manufacturers can convert vast repositories of batch data into actionable insights. AI can identify patterns and correlations that would be nearly impossible to detect manually, enabling a shift from reactive to proactive manufacturing.

For example, AI algorithms can analyse digital batch records to detect deviations in real time and even predict potential process failures before they occur. This not only reduces downtime but also minimises the risk of batch failures, which are notoriously resource intensive. Every failed batch means wasted raw materials, lost production time and unnecessary energy consumption – all of which contribute to a larger environmental footprint. By catching these issues early, AI can help ensure that manufacturing runs more smoothly and sustainably.

AI also enables optimised material usage. Historical data can inform smarter formulation decisions, helping manufacturers to reduce overages, balance inputs more precisely, and minimise solvent and water use. These micro-optimisations, applied consistently across thousands of batches, result in macro-level environmental savings. Moreover, the use of AI to fine-tune manufacturing parameters can improve yield and reduce the frequency of out-of-spec batches, further cutting waste.

In addition to process optimisation, companies such as PCI are using AI for operational efficiency in training and global compliance. PCI is currently testing AI-powered tools for automated document translation and exam generation, significantly reducing the time and complexity involved in onboarding staff across its global sites in Germany and Spain. These technologies lower the language and training barriers that often slow digital adoption, ensuring more rapid deployment of sustainable practices.

## CHALLENGES: TIME, RESOURCES AND CULTURE

Of course, implementing EBR systems and layering AI on top is not without its challenges. Time and resources, rather than resistance to change, are the primary barriers to adoption. For companies navigating frequent mergers and acquisitions, harmonising systems across facilities is particularly complex. PCI has addressed this by avoiding a "big bang" roll-out and instead adopting a modular approach, tailoring onboarding checklists and deployment strategies to the unique needs of each site. This

"PCI IS CURRENTLY TESTING AI-POWERED TOOLS FOR AUTOMATED DOCUMENT TRANSLATION AND EXAM GENERATION, SIGNIFICANTLY REDUCING THE TIME AND COMPLEXITY INVOLVED IN ONBOARDING STAFF ACROSS ITS GLOBAL SITES IN GERMANY AND SPAIN."

phased methodology has proven effective in reducing disruption while still moving the organisation steadily towards full digital maturity.

## REGULATORY AND STRATEGIC ALIGNMENT

From a regulatory standpoint, the shift towards digital documentation is also gaining traction. Guidelines such as the US FDA's 21 CFR Part 11 and the EMA's GxP reflection papers strongly advocate for electronic systems that support data integrity, real-time traceability and audit readiness. EBRs meet these criteria by offering tamper-evident digital trails, time-stamped approvals and secure storage, reducing the risk of incomplete or lost records.

What is particularly compelling is how this regulatory alignment dovetails with environmental goals. As pharmaceutical companies face increasing scrutiny from investors, regulators and consumers alike, tools that enhance both compliance and sustainability offer a rare and valuable convergence of interests. The ability to demonstrate traceable, verifiable environmental responsibility is becoming just as important as showing product quality or regulatory adherence.

## LOOKING AHEAD: A GREENER PHARMA INDUSTRY

The integration of EBRs with broader enterprise systems promises even greater impact. PCI envisions a future where EBRs connect seamlessly with ERP platforms, laboratory information management systems and environmental monitoring systems. This kind of connectivity will enable real-time carbon tracking, dynamic resource allocation and continuous improvement loops driven by AI. Instead of reacting to inefficiencies after the fact, companies will be able to course-correct in real time, reducing their environmental impact with each batch produced.

EBRs are no longer just digitised file cabinets, but are foundational elements of a smarter, more sustainable pharmaceutical manufacturing model. When augmented with AI, EBRs become powerful tools for process optimisation, environmental stewardship and strategic alignment. As companies like PCI lead the way, it is becoming increasingly clear that the path to a greener industry is not paved with paper. It is driven by data, powered by intelligence and guided by a deeper commitment to both operational excellence and planetary health.

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**Lori Jackson**

Lori Jackson, Senior Director, Global Digital Quality and Program Management, is a dynamic and solutions-oriented project leader with over 25 years of experience driving operational excellence and regulatory compliance in highly regulated manufacturing environments. Ms Jackson leads enterprise-wide digital transformation and quality initiatives that ensure adherence to cGMP, FDA standards and business continuity. Her deep expertise spans strategic planning, process improvement, risk mitigation and cross-functional project execution – skills that have earned her a reputation for delivering complex initiatives on time and within budget, even in fast-paced, evolving landscapes.

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**Tim Hansen**

Tim Hansen, Director, Sustainability, is a seasoned sustainability professional with nearly 15 years of experience in ESG programme development, strategy, engagement and reporting. He joined PCI in 2024 and is responsible for driving the company's ESG strategy to achieve its sustainability goals. Drawing from a diverse background in healthcare, legal and ESG, Mr Hansen brings a unique perspective to integrating ESG principles into business strategy, fostering accountability and engaging key stakeholders to promote actionable change.

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# CIRCULAR DESIGN FOR SPRINGS AND PRESSINGS IN DRUG DELIVERY DEVICES

LESJÖFORS
Springs & Pressings

**Bianca Plankenhorn** of **Lesjöfors** discusses how sustainability is becoming an increasingly prominent and important part of the drug delivery industry, and how collaboration across the value chain – including steel spring and stampings manufacturers such as Lesjöfors – is critical for the industry to achieve its climate and emissions goals.

Throughout 2025, the number of discussions and events focused on circularity and sustainable solutions have multiplied – the concept of a circular economy is gaining momentum. However, despite the growing attention, Circle Economy's (Amsterdam, the Netherlands) Circularity Gap Report for both 2024 and 2025 highlights that concrete initiatives remain limited.

For manufacturers working with steel materials and components, there are already opportunities to embrace more circular approaches. Innovation and collaboration between customers, suppliers and the broader value chain are essential to unlocking this potential.

## CIRCULARITY AND GLOBAL BUSINESS

In today's environment of complexity, volatility and uncertainty, efficiency and careful management of finite resources are becoming critical. Building resilient supply chains with a long-term perspective is now a key strategic priority. Equally, the urgency

"FOR MANUFACTURERS WORKING WITH STEEL MATERIALS AND COMPONENTS, THERE ARE ALREADY OPPORTUNITIES TO EMBRACE MORE CIRCULAR APPROACHES."

of moving towards fossil-free or low-carbon alternatives is accelerating the shift from linear to circular value streams.

Circularity is no longer a fringe idea – it is increasingly embraced by both producers and consumers. Across multiple industries, businesses are developing mature strategies that link circular solutions to economic value creation. Within the EU, the circular economy is a core element of the European Green Deal. The EU's Circular Economy Action Plan (2020) explicitly connects business competitiveness with the transition to environmentally friendly products and services.

Figure 1: Lesjöfors has embedded sustainability as a core aspect of its products.

## THREE PILLARS OF CIRCULARITY

At its core, circularity is built on three pillars – reduce, reuse, recycle. From another angle, it can be viewed as efficiency, sufficiency and consistency. Circularity encompasses a wide range of actions, from eco-design in production and consumption, to renewable energy use, biodiversity protection and more. By shifting from the traditional take-make-waste model to a circular approach, businesses can create value while protecting nature and benefiting society through collaboration and innovation.

For industry as a whole, the circular economy is set to be a gamechanger. However, progress remains slow, with secondary materials accounting for only 6.9% of global consumption in 2025.[1] In the healthcare sector, opportunities are particularly evident in eco-design, waste reduction, longer material use, reduced reliance on single-use plastics, renewable resources and value-chain take-back programmes.[2] Some of the main areas of focus for circularity include:

- **Carbon Footprint:** Inventory and target setting for reducing carbon dioxide emissions across the value chain and product lifecycle
- **Waste Handling and Recycling Streams:** Holistic waste management and creation of new value-added streams by reusing or recycling residual materials
- **Supplier Development and Co-operation:** Strategic push-and-pull effects along the value chain, supported by targets and project-based collaboration
- **Circular Design:** Implementing eco-design strategies and principles in daily practice
- **Innovation:** Encouraging new ideas through co-operation, knowledge-sharing and synergies.

## LESJÖFORS' APPROACH

As a supplier to the medical device and drug delivery systems sector, Lesjöfors has embedded circularity into its sustainability strategy, with innovation, resource efficiency and circular design being integral to its sustainability focus areas (Figure 1). Lesjöfors does not use the term "environmental, social and governance activities", instead using the term "sustainability focus areas". This makes it easier to engage with the company's employees internally and its partners externally about what it wants to achieve. Key milestones that Lesjöfors has met so far include:

- Validation of near-term science-based targets in April 2024, making Lesjöfors the first in its industry to achieve this milestone
- Recognition in sustainability ratings such as CDP (London, UK) and EcoVadis (Paris, France), which support its continuous improvement processes
- Conducting its first lifecycle assessments in 2023 and 2024 (Figure 2), leading to the creation of its own methodology for carbon footprint calculations at the product level.

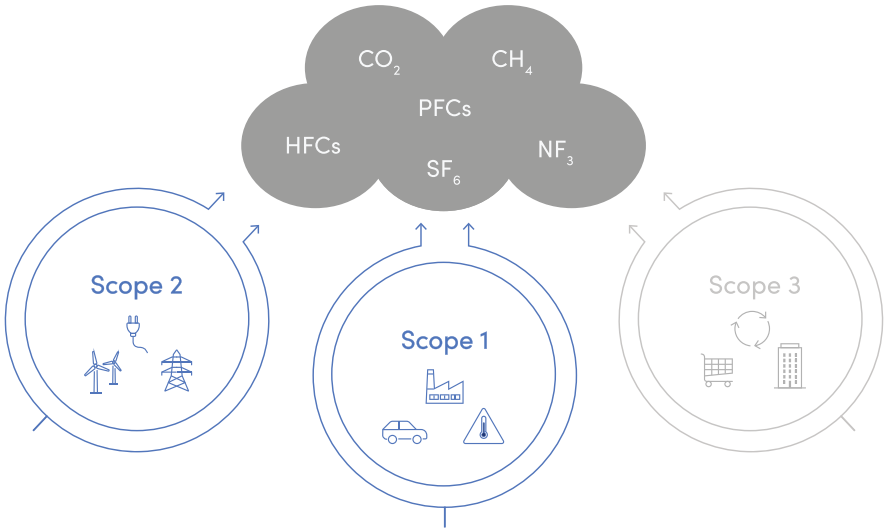


Figure 2: Carbon emission scopes for a lifecycle assessment.

Lesjöfors operates more than 50 locations worldwide. Each site is addressing emissions reduction, renewable energy adoption and opportunities for collaboration in procurement, waste, recycling and transport. The company's product carbon footprint (PCF) methodology uses a bottom-up approach, with calculations based on specific product emissions, building on data gathered during the Science Based Targets initiative's (London, UK) validation process.

## ECO-THOUGHT PRINCIPLES

At Lesjöfors, sustainability is integrated from the outset of product development, regardless of customer demand. The company treats this mindset as standard practice and a prerequisite for achieving its ambitious emissions reduction goals, while also positioning itself as a leading supplier of springs and pressings for drug delivery systems.

This mindset is reinforced by Lesjöfors' eco-thought principles, rooted in decades of technical expertise and aligned with the frameworks of the Ellen MacArthur Foundation (Crowes, UK) and EU Circular Economy Action Plan. The company's engineers also account for practical factors such as application requirements, installation space and customer-specific needs (Figure 3). Trade-offs are often necessary – for example, reducing weight may lower transport emissions but could compromise component longevity.

Figure 3: Lesjöfors ensures that practical considerations are taken into account, such as installation space and customer-specific requirements.

Together, eco-thought principles and PCF calculations enrich Lesjöfors' product offering, adding value for customers, supporting more informed conversations with suppliers and opening opportunities for joint sustainability initiatives. By modelling scenarios for PCF improvements, Lesjöfors not only advances its own climate transition plan but also helps

"TOGETHER, ECO-THOUGHT PRINCIPLES AND PCF CALCULATIONS ENRICH LESJÖFORS' PRODUCT OFFERING, ADDING VALUE FOR CUSTOMERS, SUPPORTING MORE INFORMED CONVERSATIONS WITH SUPPLIERS AND OPENING OPPORTUNITIES FOR JOINT SUSTAINABILITY INITIATIVES."

customers to reduce emissions and improve supply chain sustainability. Collaboration between the company's buyers and sales teams ensures that these efforts are embedded in practice.

## THE ROLE OF STEEL AND COLLABORATION

Although steel products initially appear to have a higher environmental impact, they are inherently circular, being up to 100% recyclable. Steel is energy-intensive to produce and heavier than plastic alternatives, but its recyclability, supported by its magnetic characteristics, makes it a key circular material.

Currently, recycling rates for standard steel products remain too low and must be improved. By comparison, plastics are lighter and highly functional but present significant recycling challenges.

As a steel and metal component provider, Lesjöfors plays a critical role in advocating for a greater proportion of recycled content in raw materials and supporting the development of sustainable, circular steel solutions. When considering the carbon footprint of Lesjöfors' products, the highest impact typically comes from raw materials, followed by emissions from production, external processes and transport.

Figure 4: Collaboration is a key part of achieving emission reduction goals for drug delivery devices.

Lesjöfors has built platforms for action with its strategic suppliers, requiring data on sustainability strategies and PCFs, as well as solutions with higher recycling shares and lower emissions. Early successes from the approach include customer projects with clear targets for emission reductions (Figure 4).

## DRIVING SUSTAINABILITY IN DRUG DELIVERY SYSTEMS

In drug delivery system projects, Lesjöfors addresses sustainability through PCF calculations, hotspot identification and collaborative eco-design. These conversations create opportunities for joint value creation with customers and suppliers alike. The company aims to be number one in its industry for a more sustainable future, and that means being at the forefront of sustainable innovation.

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# Expert View

# SUSTAINABLE DRUG DELIVERY SYSTEMS: COLLABORATIVE INNOVATION TO SHRINK PHARMA'S PACKAGING FOOTPRINT

**Maria Riccius** and **Dr Uwe Hanenberg** of Recipharm explore how CDMOs are playing a pivotal role in driving drug delivery's transformation towards sustainability, examining the most promising advances and highlighting why collaborative innovation is essential to achieving measurable environmental gains, both within organisations and across the pharmaceutical value chain.

"BALANCING SUSTAINABILITY WITH PERFORMANCE IS NO SMALL FEAT – PACKAGING MUST PROTECT SENSITIVE DRUG PRODUCTS FROM MOISTURE, OXYGEN AND LIGHT; MAINTAIN SHELF LIFE; AND MEET STRINGENT REGULATORY AND PATIENT SAFETY REQUIREMENTS."

As the pharmaceutical industry increasingly considers sustainability factors as a key facet of its products, drug delivery systems have emerged as a crucial, yet complex, area for environmental innovation. While small in form, components such as blister packs, vials, leaflets and tamper-evident seals have a disproportionately large environmental footprint, not only because of the materials used, but also due to the energy-intensive processes required to manufacture and assemble them.

Balancing sustainability with performance is no small feat – packaging must protect sensitive drug products from moisture, oxygen and light; maintain shelf life; and meet stringent regulatory and patient safety requirements. Traditionally, this has driven the use of robust, non renewable materials such as polyvinyl chloride (PVC) and aluminium foil. These materials, while highly functional, present recycling andemission challenges.

However, innovation is accelerating. Across the pharmaceutical ecosystem, drug developers, technology innovators and CDMOs are coming together to reimagine drug delivery systems through a sustainability lens. From transitioning to recyclable and lower-impact materials to re-engineering manufacturing processes to cut emissions, these efforts are starting to reshape the environmental profile of drug packaging.

## THE PACKAGING PARADOX: SAFETY VERSUS SUSTAINABILITY

Pharmaceutical packaging is fundamentally engineered to protect. It shields medicines from degradation and contaminants; ensures correct dosage and safe administration; and provides critical regulatory and safety information to patients and healthcare providers. However, these life-saving functions often come at an environmental cost, resulting in a packaging paradox – the very materials that ensure product safety and patient wellbeing are often those least compatible with sustainability goals, for example:

- **PVC:** PVC is commonly used in blister packs and tamper-evident labels due to its strong barrier properties and transparency, which allows patients and healthcare providers to visually confirm the contents without opening the packaging. This visibility can help reduce errors and support product identification at the point of use. However, the high chlorine content in PVC contributes to persistent pollutants during both manufacturing and disposal, raising concerns over its long-term environmental impact.

- **Aluminium Foil:** Aluminium foil remains a staple in pharmaceutical packaging, especially for protecting sensitive formulations from light, oxygen and moisture. Despite its functional benefits, its production is energy-intensive, resulting in a substantial carbon footprint. This makes it one of the more problematic materials when evaluating packaging sustainability.

- **Paper-Based Leaflets and Labelling:** Leaflets and labels are vital for meeting regulatory requirements and

supporting the safe use of medicines, particularly by providing clear dosage instructions and warnings. However, in multilingual regions such as the EU, the need to include multiple languages often inflates leaflet size and packaging volume, generating excess material and increasing emissions from a production and distribution standpoint. As a result, even these seemingly minor components can carry a considerable environmental burden.

Beyond environmental concerns, the path to more sustainable packaging is further complicated by regulatory scrutiny. Any change to primary or secondary packaging, even if it is environmentally motivated, must undergo rigorous testing and receive regulatory approval to demonstrate that the new material maintains product stability, does not interact adversely with the formulation and continues to ensure patient safety. This can create long timelines and risk-averse mindsets around innovation, especially in global markets where regulatory harmonisation is limited.

However, stakeholders across the pharmaceutical sector are increasingly recognising that sustainability and safety do not have to be mutually exclusive. By investing in materials science, forging closer partnerships between innovators and CDMOs and aligning packaging innovations with evolving regulatory frameworks, the industry is beginning to tackle this paradox head-on.

## KEY INNOVATIONS IN DRUG PACKAGING

Across the sector, drug developers and CDMOs are introducing new ways of enhancing sustainability without compromising on safety or regulatory compliance. These innovations are reshaping both primary and secondary packaging, and in many cases, delivering added value in the form of streamlined operations, reduced costs and improved patient experience.

One of the most visible areas of innovation is the shift away from traditional high-carbon materials. Companies are actively seeking alternatives to long-established packaging components such as PVC, polystyrene and aluminium foil – not only due to environmental concerns but also in response to emerging regulations on plastic use and recyclability.

For example, polyethylene, which generates less carbon dioxide than other polymers during manufacturing due to its simpler structure and lower processing temperatures, is being explored as a lower-impact substitute for tamper-evident seals and some types of blister packs. Polyethylene terephthalate (PET) is also being trialled as a replacement for polystyrene in blister packaging, due to its superior environmental profile. Furthermore, there is an ongoing search for an effective replacement for aluminium foil, which is one of the most carbon-intensive materials still widely used for barrier protection.

Lower-impact substrates are also replacing PVC in certain packaging components such as labels, with paper-based alternatives offering a more recyclable and less pollutive profile. However, this shift comes with important caveats – simply switching to paper does not eliminate waste. This is where digital innovation becomes an important complement to material change. In particular, the transition to electronic product information (ePI) is helping reduce the volume of printed material required in pharmaceutical packaging.

## MINIMISING LABELLING WASTE WITH DIGITAL TOOLS

Printed leaflets, especially those required to meet multilingual regulatory mandates, can be a major source of paper waste and packaging bulk. To mitigate this, many pharmaceutical developers are collaborating with CDMO partners to implement ePI, a digital alternative that replaces physical leaflets with scannable QR codes. Patients can access dosage instructions, warnings and safety guidance on their mobile devices, ensuring the same level of regulatory compliance while drastically cutting down on printed material.

Beyond material reduction, ePI also offers operational advantages. Updates to product information can be made centrally

**"COMPANIES ARE ACTIVELY SEEKING ALTERNATIVES TO LONG-ESTABLISHED PACKAGING COMPONENTS SUCH AS PVC, POLYSTYRENE AND ALUMINIUM FOIL –NOT ONLY DUE TO ENVIRONMENTAL CONCERNS BUT ALSO IN RESPONSE TO EMERGING REGULATIONS ON PLASTIC USE AND RECYCLABILITY."**

and in real-time, helping manufacturers stay compliant across markets without the need for costly and wasteful reprinting. As regulatory support for ePI grows, particularly in the EU, where agencies are actively piloting digital labelling frameworks, it is becoming an increasingly viable strategy for improving packaging sustainability without compromising patient access to vital information.

## ENHANCING RESOURCE EFFICIENCY IN PRODUCTION

Sustainability in packaging goes hand-in-hand with smarter manufacturing. CDMOs are investing in cleaner energy sources, upgrading infrastructure and optimising processes to reduce the total environmental footprint of drug production, from raw material handling to packaging line output. Examples of this include:

- Installing solar panels and pellet heating systems to power packaging lines with renewable energy
- Upgrading water purification and recycling systems to reduce water consumption in cleaning and cooling
- Introducing process automation and smarter equipment calibration to reduce waste, increase yields and lower energy intensity
- Developing closed-loop solvent recovery systems to capture and reuse production materials that would otherwise become hazardous waste.

By embedding environmental responsibility into everyday operations, CDMOs can create packaging workflows that are both more sustainable and more economically efficient. In doing so, they can create benefits that can be passed on to their pharmaceutical partners.

## CDMOs AS SUSTAINABILITY PARTNERS: THE POWER OF CO-DEVELOPMENT

For pharmaceutical companies navigating the transition to more sustainable drug delivery systems, the road is rarely straightforward. Internal capacity constraints, evolving regulatory requirements, budget pressures and the imperative to maintain product safety all create barriers to swift or unilateral change, particularly for smaller or mid-sized firms. Against this backdrop, the role of CDMOs becomes not just supportive, but transformational.

CDMOs operate at the intersection of formulation, development and commercial manufacturing, making them uniquely placed to embed sustainability initiatives across the entire product lifecycle. Their infrastructure, technical expertise and cross-functional oversight can enable them to assess the environmental implications of material selection, optimise production processes to reduce waste and energy use and help sponsors interpret the regulatory pathways for implementing greener solutions. When involved early on in product planning, CDMOs can shape more sustainable drug production from the outset.

## ALIGNING WITH VERIFIED CLIMATE TARGETS

As this strategic role evolves, CDMOs are also under increasing pressure to demonstrate their own environmental performance. In response, many are aligning with independently verified frameworks, such as the Science Based Targets initiative, which requires companies to commit to measurable emission reductions across Scopes 1, 2 and 3. For sponsors seeking trustworthy partners, such commitments signal a proactive and credible approach to sustainability.

For example, CDMOs participating in such initiatives are already making meaningful progress:

- **Scope 1 (Direct Emissions)**: Reductions are being driven through facility upgrades, increased energy efficiency and low-carbon equipment investments.
- **Scope 2 (Purchased Energy)**: Many CDMOs are moving towards full reliance on renewable electricity, with some on track to achieve Scope 2 neutrality by the end of the decade.
- **Scope 3 (Value Chain Emissions)**: These efforts often include supplier engagement, changes to packaging material sourcing and optimising logistics to reduce downstream impact.

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What makes these efforts meaningful is not just the internal impact, but the tangible benefits that progress like this can offer to pharma partners. Through co-development models, CDMOs can work alongside sponsors to identify opportunities for emission reductions within specific product pipelines – such as designing out PVC, streamlining packaging formats or implementing ePI. These initiatives are not add-ons but integral to the way projects must be scoped and delivered.

Crucially, sustainability must be embedded into internal governance. Environmental performance should be assessed within project management and change control alongside traditional metrics such as quality, cost and delivery timelines. This ensures that emission reductions are considered a strategic priority from day one, not a downstream retrofit.

By embedding these practices, CDMOs can help sponsors implement meaningful sustainability initiatives without needing to build the expertise or infrastructure in-house. As industry expectations around environmental performance continue to rise, collaboration at this level may become not only a differentiator but a prerequisite for bringing greener drug delivery systems to market.

## INTEGRATING SUSTAINABILITY INTO EVERY DOSE

As the pharmaceutical industry moves toward a more sustainable future, drug delivery systems – and the materials and processes that support them – offer an immediate and high-impact opportunity for change. From rethinking packaging substrates to embracing digital labelling and cleaner production methods, progress is being made. However, scale and speed will depend on collaboration. With their operational breadth and technical insight, CDMOs are set to play a pivotal role in accelerating sustainable innovation across the product lifecycle. By embedding sustainability into the earliest stages of product development and ensuring that it runs through to commercial manufacture, industry can make meaningful strides in reducing its environmental footprint without compromising the quality, safety or accessibility of the therapies it delivers.

## ABOUT THE COMPANY

Recipharm provides manufacturing services for pharmaceuticals in various dosage forms, including sterile fill-finish, oral solid dosage and biologics; clinical trial material development and manufacturing services; and pharmaceutical product development. Its Advanced Bio Division develops and commercialises advanced therapy medicinal products, performs preclinical to clinical projects, and offers commercial development and manufacturing for new biological modalities.

# SCALING LOW-CARBON pMDI PRODUCTION WITHOUT DISRUPTING PATIENT ACCESS

**Simon Gardner** at **Bespak** looks at how the pharmaceutical industry is scaling up production of low-carbon pressurised metered dose inhalers to cut emissions without disrupting patient care. The article considers the challenges faced by the industry, as well as the role of CDMOs in creating sustainable, scalable solutions.

Commitment to protecting the environment is transforming many industries, and pharma is no exception. For the inhalation sector, this has resulted in increased scrutiny of the carbon footprint associated with inhalers and a drive for change – particularly when it comes to pressurised metered dose inhalers (pMDIs). These devices are designed with a propellant gas that acts as a carrier for drug particles, constituting approximately 90% of drug formulations. Current high global warming potential (GWP) propellants are the main source of pMDI carbon emissions. Next-generation low-GWP propellants are now available, but switching to low-carbon pMDI production at scale can be complex.

As a specialist inhalation CDMO, Bespak is working to streamline the development and scale-up of low-carbon pMDI production without disrupting patient access to vital therapeutics.

**"THE CHALLENGE FOR PMDI MANUFACTURERS NOW IS NOT HOW TO DECARBONISE, BUT HOW TO DO IT QUICKLY AT SCALE WITHOUT RISKING SUPPLY SHORTAGES FOR MILLIONS OF PATIENTS."**

"IN LIGHT OF CHANGING REGULATIONS, SUPPLY CHAIN CONCERNS, CORPORATE SOCIAL RESPONSIBILITY GOALS AND AN OPPORTUNITY TO GAIN A CORNER IN THE MARKET, MAJOR PHARMACEUTICAL COMPANIES ARE ALREADY FORGING AHEAD WITH NEXT-GENERATION PROPELLANTS."

## MARKET CHALLENGES

Many patients rely on pMDIs, which represent an estimated 71% of all inhalers used in Europe and 87% in North America.[1] Given that pMDIs make up the majority of respiratory drug delivery devices, transitioning to new propellants that reduce their carbon footprint is a massive project with many moving parts. Two next-generation propellants have proven feasibility and a low GWP: HFA-152a and HFO-1234ze. With these alternatives ready to be adopted, the challenge for pMDI manufacturers now is not how to decarbonise, but how to do it quickly at scale without risking supply shortages for millions of patients.

To this end, there is a need for manufacturing facilities that are compatible with the new propellants. For example, HFA-152a is flammable, which together with other controls, necessitates ATEX-certified facilities to ensure safety. Handling flammable aerosols at scale is not an issue in and of itself – mass-produced consumer products using flammable propellants can be found in the cleaning and personal care aisles of any supermarket. However, this change marks a new era for pharma and requires clear guidance to ensure safe handling during manufacturing, storage and transportation.

Additionally, pMDI device components, such as actuators and valves, must be optimised to be compatible with the chemical and physical properties of next-generation low-GWP propellants. These too must be made available across the entire industry from development to commercial-scale projects.

The landscape is further complicated by evolving regulations, which has resulted in some pharma companies being hesitant to take the plunge. Nonetheless, the direction is clear – it is not a question of whether industry will transition, but how quickly and smoothly that transition to low-carbon pMDIs will take place and how companies can work together to effectively drive change.

## REGULATORY AND SUPPLY CHAIN DRIVERS

In the EU, the F-gas Regulation of 2024 has been published, which lays out the required phase-down of currently used high GWP hydrofluorocarbon (HFC) propellants starting from 2027 and a total phase-out by 2050.[2] Importantly, the exemption for HFCs used in pMDIs under the previous 2014 EU F-gas Regulation has been removed. HFCs are being phased down in the UK by 79% by 2030 compared with average use between 2009 and 2012 under the Fluorinated Greenhouse Gases Regulations 2015. While pMDIs are currently exempt from this, the guidance may change with the next revision, anticipated during 2026.

Meanwhile, in the US, the Environmental Protection Agency is implementing a phase-down of HFCs under the AIM Act. While an application-specific allowance was renewed for pMDIs over 2025–2030, as lower GWP alternatives gain momentum, it will become imperative to transition before legislation mandates it.[3]

One reason to get ahead of regulation changes is the progressively diminishing supply of currently used propellants. This is occurring because propellant supply feeds a broad industrial base beyond pharma. In fact, pharmaceutical applications of propellants are just the tip of the iceberg, accounting for less than 10% of propellant use, while over 90% of propellants are used for other industry applications, such as refrigerants, air conditioning in automobiles and firefighting.[4] The transition to next-generation alternatives is more advanced in these industries. For instance, the use of the traditional propellant HFA-134a in new EU cars was banned in favour of next-generation propellants in 2011. There have also been HFA-134a industrial-grade plant closures in Europe, and next-generation propellant alternatives to the traditional propellant HFA-227ea have been developed for firefighting.

In light of changing regulations, supply chain concerns, corporate social responsibility goals and an opportunity to gain a corner in the market, major pharmaceutical companies are already forging ahead with next-generation propellants. AstraZeneca has recently obtained regulatory approval for the first inhaled respiratory therapy delivered with a low-carbon pMDI in the UK: Trixeo Aerosphere.[5]

## THE ROLE OF CDMOs IN SCALING PRODUCTION

CDMOs play a vital role in expanding the production capacity for low-carbon pMDIs across the pharmaceutical industry. Bespak, for instance, has invested heavily in its manufacturing capabilities for pMDIs using next-generation propellants, embarking on an expansion project to enable clinical and commercial manufacture of low-carbon pMDIs incorporating either HFO-1234ze or HFA-152a. This investment addresses a major market gap and will support both large pharma companies – who want to move fast and take major market positions – and small-to-mid-size pharma companies without the resources to invest in the updated manufacturing equipment needed for both new propellants.

Additionally, Bespak has redesigned pMDI components, including its range of valves to ensure compatibility with low-GWP propellants. A new hybrid valve developed by Bespak builds on the highly successful BK357 pMDI valve, incorporating materials suitable for HFA-152a and HFO-1234ze – specifically ethylene propylene diene monomer seats and a bromobutyl neck gasket in contact with a polybutylene terephthalate core. These changes are essential to reduce propellant leakage from the inhaler,

presenting a robust barrier internally and externally to moisture ingression. The first low-carbon pMDI product using a Bespak valve has received regulatory approval and is expected to be on market before the end of 2025.

Bespak has also investigated the effect of actuator design on low-carbon pMDIs. One study investigating the suspension of fluticasone propionate in HFA-152a and HFO-1234ze revealed that the spray orifice diameter of the actuator affected the inhaled droplet and average particle size.

These optimised designs are crucial for widespread adoption of next-generation propellants, ensuring the quality and reliability of pMDIs are maintained.

## BUILDING PARTNERSHIPS TO ACCELERATE THE TRANSITION

CDMOs can help to address a major market gap by investing in low-carbon pMDI production, but a full transition necessitates collaborations across the value chain. Beyond its own investment in manufacturing infrastructure, Bespak has forged partnerships with major industry players to ensure all the pieces are in place for the green transition. This includes collaborations with Orbia Fluor & Energy Materials (Boston, MA, US), suppliers of the next-generation propellant HFA-152a and Honeywell (Charlotte, NC, US) for HFO-1234ze supply. At the same time, Bespak is working with H&T Presspart (Blackburn, UK) to facilitate pMDI pilot-scale filling capabilities, OzUK (Chippenham, UK) on the feasibility of pMDI formulations, DH Industries (Basildon, UK) on the supply of its advanced Pamasol pMDI production lines, and the Medicines Evaluations Unit (Manchester, UK) to streamline clinical trials for low-carbon pMDIs. Additionally, Bespak has seats on the board of the International Pharmaceutical Aerosol Consortium (IPAC) and the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS), allowing the company to both influence and communicate the latest regulatory changes that impact low-carbon pMDIs.

> "CDMOs CAN HELP TO ADDRESS A MAJOR MARKET GAP BY INVESTING IN LOW-CARBON pMDI PRODUCTION, BUT A FULL TRANSITION NECESSITATES COLLABORATIONS ACROSS THE VALUE CHAIN."

These collaborations have created a cluster of excellence in pMDI development and manufacturing in the UK – particularly in the Northwest of England. This helps to shorten and strengthen the pMDI supply chain, as well as providing the opportunity to reduce the carbon emissions that arise from the transportation of goods between sites.

## BEYOND LOW-CARBON CAPABILITIES

Moving away from high-GWP propellants has taken the spotlight when it comes to reducing the inhalation industry's carbon footprint. However, total environmental impact goes beyond the GWP of propellants. A truly low-impact device also depends on the energy, materials, processes and ecosystems connected with its production.

As low-carbon pMDI efforts are scaled up, a holistic approach that considers sustainability across the entire value chain is needed to meet ambitious emission reduction targets, such as those set out by the Paris Agreement. Acknowledging this, Bespak is working to ensure environmental, social, and governance principles are embedded across every level of its business operations.

From a product perspective, Bespak is conducting lifecycle assessments to find new ways to reduce greenhouse gas emissions and resource consumption. Additionally, it is seeking to incorporate renewable electricity, recycled materials and waste reduction wherever possible. Across its two manufacturing sites in the UK, Holmes Chapel and King's Lynn, 97.5% of the electricity is obtained from renewable sources, with 2,300 solar panels installed. Bespak recycles over 65% of waste at Holmes Chapel and over 86% of waste at King's Lynn. Through its partnership with Collecteco (Bristol, UK), Bespak donated decommissioned office furniture and equipment to local charities, avoiding ~26,857 kg $CO_2$e and diverting ~8,193 kg of waste.

> "TO AVOID PLASTIC WASTE, BESPAK IS ENGAGING ITS CUSTOMERS AND DISTRIBUTION PARTNERS IN CIRCULAR ECONOMY PARTNERSHIPS."

To avoid plastic waste, meanwhile, Bespak is engaging its customers and distribution partners in circular economy partnerships. It is also exploring a mechanical recycling process that will create product delivery trays with up to 80% recycled polymers.

Biodiversity and local environmental health are also emerging factors in pharma sustainability strategies. Bespak is working to understand and improve its impact on local ecosystems, especially the green space surrounding its Holmes Chapel headquarters. On-site biodiversity assessments have been conducted by Bespak at both its sites and these will be used to develop Biodiversity Management Plans. Applying the World Wide Fund for Nature Biodiversity Risk Filter will further help Bespak to identify biodiversity priorities and ensure efforts are targeted towards these.

These initiatives are crucial to build a sustainable foundation for low-carbon pMDIs that will support the inhalation industry in achieving wider environmental goals.

## A PARTNER FOR THE FUTURE

Increased environmental awareness, evolving regulations and a diminishing supply chain for currently used HFC propellants have combined to create demand for low-carbon pMDIs. Scaling up production to meet this demand is no

mean feat, and getting ahead of the curve is crucial to ensure the infrastructure is in place to transition smoothly to low-carbon pMDIs without disrupting the supply of essential medicines. By investing in a strong industry network, strategic manufacturing expansions and low-carbon pMDI expertise – and by embedding sustainability across its operations – Bespak is paving the way for a greener tomorrow.

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**Simon Gardner**

Simon Gardner, Business Development Director at Bespak, is a chemical engineer by training. He has over 25 years of experience in the global pMDI industry, including process engineering, plant management and business management roles in the medical propellants sector. He is a subject matter expert in propellant market dynamics and environmental regulation, and now focuses on supporting Bespak's customers to transition to low-GWP propellants. Mr Gardner is also an IPAC Board Member.

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With over 40 years of experience, **Ypsomed**'s comprehensive drug delivery device platforms consist of autoinjectors for prefilled syringes, disposable pens, reusable pen injectors, ready to-use prefilled wearable patch injectors and injection devices for drugs in dual chamber cartridges. Ypsomed is well equipped to tackle digital healthcare challenges and has strategically invested in the development of connected solutions and therapy-agnostic digital device management services.

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To learn more, see **Page 08**

## Kindeva

**KEY SPONSOR**

**Kindeva Drug Delivery** is a global CDMO focused on drug-device combination products. The company develops and manufactures products across a broad range of drug-delivery formats, including pulmonary and nasal, injectable and transdermal. Its service offerings span early-stage feasibility through to commercial-scale drug product fill-finish, container closure system manufacturing and drug-device product assembly.

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To learn more, see **Page 16**

## Aptar pharma

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**Aptar Pharma** offers proven drug delivery solutions and services that support pharmaceutical companies worldwide to develop safe, efficient and compliant medicines. Aptar Pharma's drug delivery systems, components and active material solutions serve the widest range of delivery routes, Aptar's digital healthcare solutions help improve patient adherence and Aptar Pharma Services helps accelerate and derisk development.

To learn more, see **Page 28**

## BESPAK

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**Bespak** is a specialist inhalation CDMO with established capacity and ongoing expansions to enable the development and manufacture of pMDIs with low-GWP propellants. The company provides a fully integrated service encompassing early-stage feasibility, analytical and formulation development, product development and clinical supply, through to full-scale cGMP batch production.

To learn more, see **Page 52**

## CONTEXO automation

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

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## DCA

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

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LESJÖFORS
Springs & Pressings

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**The Lesjöfors Group**, founded in 1675 with spring production since 1852, is a manufacturer of in springs and pressings. Among the world's largest spring manufacturers, its extensive product portfolio includes springs, gas springs and pressings across a wide range of wire sizes.

To learn more, see **Page 44**

OWEN MUMFORD
Pharmaceutical Services

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

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pci
PHARMA SERVICES

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

To learn more, see **Page 38**




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