20
A Calculated Move: Putting Environmental Assessment Data to Wider Use

38
The Overlooked Sustainability Lever: Human Factors in Drug Delivery

48
The Sustainability Escape Room: How Primary Packaging Tries to Get Out of the EU Regulatory Maze

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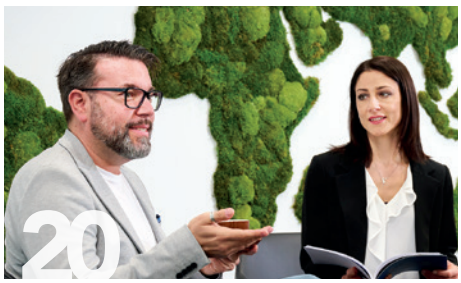
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Contents









08 Bringing Pharmaceutical Elastomer Waste into a Circular Economy
Aptar Pharma / Moine Recyclage

14 Non-PTFE, NIA-PFAS Polymers for Liquid Drug Delivery Devices
SABIC

20 A Calculated Move: Putting Environmental Assessment Data to Wider Use
Ypsomed

26 Designing with Sustainability in Mind: Engineering Low Carbon pMDIs from the Component up
Bespak

30 Manufacturers' Role in Delivering Essential Respiratory Healthcare During the Transition to Low-GWP pMDIs
Orbia Fluor & Energy Materials

34 Expert View
Designing for a World Under Strain: The Role of Eco-Design in Improving Sustainability and Supply-Chain Security
DCA Design International

38 Expert View
The Overlooked Sustainability Lever: Human Factors in Drug Delivery
Cambridge Design Partnership

44 Expert View
Bioplastics in Drug Delivery: Sustainable Solution or Substitution Trap?
Owen Mumford

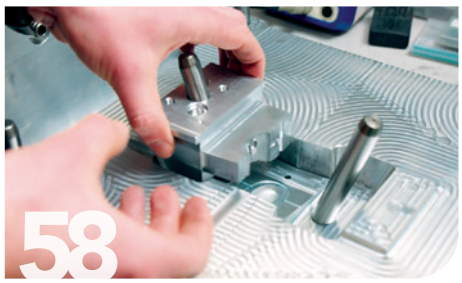
48 Expert View
The Sustainability Escape Room: How Primary Packaging Tries to Get Out of the EU Regulatory Maze
West Pharmaceutical Services

54 Expert View
Why the Greenest Polymers Never Reached Scale
Gelatex Technologies

58 Expert View
Reducing Commercialisation Risk in Drug Delivery Development
MGS

64 Company Showcase
Grand River Aseptic Manufacturing

66 Company Spotlights
Index of Sponsors and Advertisers





SUSTAINABILITY IN DRUG DELIVERY

ONdrugDelivery Issue N° 192, October 26th, 2026

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

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Tackling Sustainability at Every Level:

How to Approach a Sector-Wide Challenge

As the industry's understanding of sustainability has grown and matured, it has become increasingly clear that there is no single, simple solution to reducing product and process global warming potentials and implementing sustainable practices. In this issue of ONdrugDelivery, we look at how sustainability is being approached holistically across the drug delivery sector, with both tight focus on specific aspects, such as low global warming potential propellants for metered dose inhalers and new sustainability regulations, and a more holistic view of integrating sustainability as a key factor throughout practices and processes from the very start of development.

Beginning the issue, our Outstanding Sponsor, **Aptar Pharma**, and its partner, **Moine Recyclage**, focus on the challenges of recycling medical-grade elastomers and how looking to partners outside the drug delivery industry can provide feasible routes to reduce the amount of waste going to landfill (Page 8). Alongside them, our Key Sponsor, **SABIC**, introduces its new grades of advanced polymers for medical applications, including how bio-renewable content can provide a significant reduction in carbon footprint (Page 14). Broadening the perspective, our second Key Sponsor, **Ypsomed**, goes on to discuss how it has expanded on its lifecycle assessments and carbon footprint analyses to make use of the gathered insights across its entire value chain (Page 20).

Zooming in on metered dose inhalers, **Bespak** considers the optimisations the company has been able to achieve in designing for the different physical characteristics of low global warming potential propellants using computational modelling and simulation (Page 26). Continuing on the subject, **Orbia Fluor & Energy Materials**, developer of HFA-152a, contribute an in-depth look at the status and expectations of the propellant transition and what that means for device manufacturers (Page 30).

Next, we put various aspects of how to integrate sustainability into the design process under the spotlight. Here, **DCA Design International** provides an overview of how to apply eco-design principles to drug delivery device development (Page 34); **Cambridge Design Partnership** considers how human factors can play into the sustainability profile of a device and how they affect drug wastage (Page 38); **Owen Mumford** puts forward the idea that bio-based plastics are not a complete solution to the industry's dependence on virgin materials (Page 44); and **West Pharmaceutical Services** lays out the maze of requirements set out by the EU's sustainability regulations and how to navigate through it (Page 48).

Rounding out the issue, **Gelatex Technologies** discusses how advanced manufacturing processes possess the potential to deliver novel bio-based polymers at commercial scale (Page 54), and **MGS** investigates how early design decisions and cross-functional communication inform downstream production (Page 58). Finally, **Grand River Aseptic Manufacturing** presents a Showcase on its fill-finish capabilities (Page 64).

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BRINGING PHARMACEUTICAL ELASTOMER WASTE INTO A CIRCULAR ECONOMY

Yann Fromont of **Aptar Pharma** and **Clovis Saunier** of **Moine Recyclage** discuss the companies' partnership and explain how clean elastomer production scrap from the manufacture of injectable components is recovered and repurposed for durable technical applications.

As pharmaceutical companies extend their decarbonisation commitments into the supply chain, the environmental footprint of primary packaging, including the elastomeric components that are in direct contact with injectable drugs, has moved firmly onto the agenda. For Aptar Pharma's injectables division, addressing this footprint is both a scientific challenge and a responsibility to the drug developers the company partners with.

Elastomeric components for the primary packaging of injectable drug products must meet particularly demanding quality requirements, yet their manufacture generates vulcanised scrap that is difficult to recover and reintroduce into conventional processes. Working with Moine Recyclage, Aptar Pharma has established a dedicated process to divert this material from incineration and recover it for durable applications. This is a step towards a long-term goal – regenerating rubber to replace a proportion of new material in compounds.

PHARMACEUTICAL ELASTOMERS: ESSENTIAL, HIGH-PERFORMING AND DIFFICULT TO RECYCLE

Vial stoppers, prefilled syringe plungers, needle shields and other sealing components used for injectable drug products are designed to protect formulations that may be highly sensitive. They must maintain container closure integrity, limit gas exchange, withstand washing and sterilisation processes, and meet stringent requirements for particles, extractables and leachables.

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"LIKE ALL DIVISIONS WITHIN THE COMPANY, APTAR PHARMA'S INJECTABLES DIVISION PLAYS A KEY ROLE IN MEETING THE COMPANY'S CLIMATE AND DECARBONISATION GOALS."

Rubber meets these needs through complex formulations combining an elastomer with mineral fillers, pigments, curing agents and other additives. After mixing and moulding, vulcanisation creates a crosslinked three-dimensional network that gives the component its elasticity and stability. That same structure, however, is an obstacle to recycling; unlike a thermoplastic, vulcanised rubber cannot simply be remelted and reshaped.

End of life introduces a further constraint. Once used, components that have been in contact with a drug product or patient enter dedicated healthcare-waste streams and, under current conditions, cannot be considered a source of recyclable material. Therefore, the most accessible opportunity to recycle these components lies upstream, in the clean production scrap generated during manufacturing, before any pharmaceutical use.

USING LCA TO GUIDE A MULTI-LEVER REDUCTION STRATEGY

Aptar has set emissions-reduction goals that are validated by the Science Based Targets Initiative. These targets for Scope 1 and 2 emissions reductions are in line with the goal to keep global warming to 1.5°C by 2030. In addition to these, Aptar has established Scope 3 emissions and renewable electricity targets. As with all divisions within the company, Aptar Pharma's injectables division plays a key role in meeting the company's climate and decarbonisation goals. The division has placed a focus on sourcing electricity from renewable sources, improving energy efficiency and heat recovery, reducing water consumption, and optimising secondary packaging, material reduction and formulation development.

To prioritise these actions, the division developed a cradle-to-gate lifecycle assessment (LCA) model covering everything from raw material extraction and production through to customer delivery. Built using Sphera® LCA for Experts (Sphera, Chicago, IL, US) and aligned with the principles set out in ISO 14040 and ISO 14044, the model can be adapted to different formulations, geometries, manufacturing steps, packaging formats and logistics scenarios.

Initial results showed that raw materials were the largest contributor to the global warming potential of elastomeric components, accounting for up to 75% of the total. Within the rubber compound itself, the elastomer represents, on average, approximately 85% of the compound's climate-change impact. Depending on the component and its level of preparation, the observed cradle-to-gate footprint is around 4–7 kg CO_2eq per kilogram of component. These results are based on Aptar LCA modelling and have not been independently verified by a third party.

To make progress on reducing the carbon footprint of these products, action is needed both now and in the future. In the longer term, the greatest reductions will likely come from raw materials: non-fossil alternatives, mass-balance approaches, compound optimisation and, where regulatory requirements allow, qualified recycled feedstocks. In the shorter term, manufacturing scrap can be diverted from incineration and directed into a material loop – this is the operational initiative presented here.

MOINE RECYCLAGE: A DEDICATED ROUTE FOR TECHNICAL RUBBER

Implementing such a material loop requires a partner capable of identifying chemical families, segregating streams and ensuring reproducible preparation. Aptar Pharma's injectables division decided to partner with Moine Recyclage, a specialist in recycling technical rubber that processes approximately 20,000 tonnes of industrial production scrap and end-of-life products per year.

When it comes to injectable component scrap, it is not only volume that matters but discipline – incoming material must be sorted by chemical family before granulation, which consists of grinding rubber into small, uniform granules. This process ensures that different elastomer types are never mixed. This matters because the value and safety of any recovered rubber depend first on knowing precisely what the feedstock is.

The division's pharmaceutical production scrap, which is clean, homogeneous and fully documented, is particularly well suited to this controlled approach. Beyond preparing the material, Moine Recyclage also gives it a defined second life, engineering the recovered rubber into technical surfaces. The scrap is therefore not simply collected, but performs a real function in a new application – a credible first step towards circularity.

BACKTOMOINE®: ORGANISING THE MATERIAL'S NEXT LIFE

Aptar Pharma and Moine Recyclage's partnership addresses a stream of up to approximately 600 tonnes of clean rubber production scrap per year. After pre-shredding and separation according to formulation, the material is transferred to Moine Recyclage's authorised Installation Classified for the Protection of the Environment (ICPE) facility, where it is granulated and prepared for a new technical function, notably as a shock absorbing underlayer for playgrounds and sports surfaces. The approach begins with this controlled transfer – a known, homogeneous industrial feedstock is kept in material use rather than being sent for disposal or incineration.

"BEYOND PREPARING THE MATERIAL, MOINE RECYCLAGE ALSO GIVES IT A DEFINED SECOND LIFE, ENGINEERING THE RECOVERED RUBBER INTO TECHNICAL SURFACES."

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Figure 1: The Aptar–Moine BackToMoine® loop.

BackToMoine® keeps this first cycle from being an end point. The granulated rubber is bound into durable sports and leisure surfaces – playground and multisport flooring, athletics tracks, tiles and underlayers – where it performs a defined mechanical function, rather than serving as low-grade filler.

In addition, these surfaces can be recovered at end of life, subject to acceptance and sorting criteria, potentially keeping the material in use across successive cycles. Each returned surface is assessed on arrival and directed to the most suitable recovery pathway, then cleaned and reprocessed into new secondary raw material; only the fractions that cannot be recovered as material are sent to energy recovery. Across the programme, around 97% of collected material is recovered as secondary raw material, with only 3% directed to energy recovery, helping retain material value over successive cycles.[1]

Although regenerated material is not currently authorised for use in pharmaceutical components, this application helps retain the material's value over several cycles and contributes to the technical knowledge needed to explore potential higher-value uses in the future, subject to the applicable qualification, safety and regulatory requirements (Figure 1).

QUANTIFYING AVOIDED EMISSIONS

In an initial environmental analysis, the estimated annual climate benefit of granulation was compared with an incineration end-of-life scenario. For 600 tonnes of scrap, the emission factor for incineration was 2.66 kg CO_2eq/kg, whereas the granulation scenario was estimated at 0.20 kg CO_2eq/kg. On this basis, the associated emissions would be 1,596 tCO_2eq and 120 tCO_2eq, respectively – a difference of approximately 1,476 tCO_2eq for the annual volume considered (Table 1). These results are based on Aptar LCA modelling and have not been independently verified by a third party.

This value represents the difference between two treatment scenarios using the assumptions currently available. A critical review of the study is underway and may lead to further refinement of the system boundary, background datasets, allocation rules, transport assumptions and, where applicable, benefits associated with material substitution.

FROM MICRONISATION TO DEVULCANISATION: RETAINING MORE MATERIAL VALUE

Granulation and micronisation make it possible to use vulcanised rubber as a solid fraction in certain compounds. However, incorporation rates are generally limited, often to approximately 5–10% for a simple micronised material,[2] because the original crosslinked network remains intact.

Moine Recyclage's CEC process (Caoutchouc Économie Circulaire/Circular Economy Rubber) is designed to lift

Scenario	Climate factor	Result for 600 t per year	Difference versus incineration
Incineration	2.66 kg CO_2eq/kg	1,596 tCO_2eq	Reference
Granulation	0.20 kg CO_2eq/kg	120 tCO_2eq	−1,476 tCO_2eq

Table 1: Environmental comparison of granulation versus incineration.

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that ceiling through thermomechanical devulcanisation; by selectively breaking part of the sulphur crosslinks while preserving the polymer backbone, it restores a material that can be compounded and revulcanised again. This opens the way to higher incorporation rates and to partial substitution of conventional elastomer, which has already been explored for technical parts in the automotive sector (Figure 2).

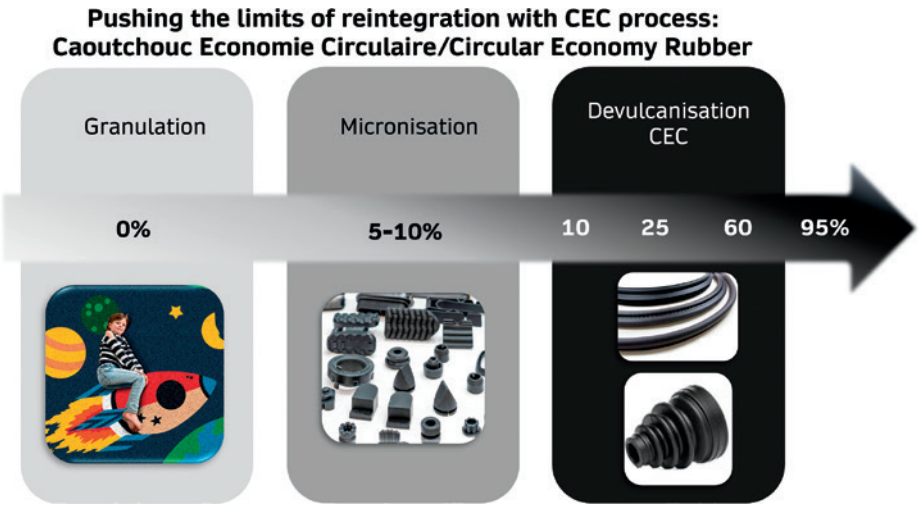


Figure 2: The CEC process.

TOWARDS REINCORPORATION: A PROGRESSIVE AND CONTROLLED PATHWAY

Reusing regenerated rubber in a sports surface is one thing; bringing it back into a pharmaceutical component is another. For injectable applications, the regenerated material could not simply be added to a formulation – it would need to be qualified as a raw material, with a defined and traceable feedstock, agreed specifications and a full quality-control plan. In practice, that would mean demonstrating consistent behaviour on the parameters that govern component performance: how the rubber flows and cures (rheology and Mooney viscosity), how evenly it disperses, its mechanical strength and sealing behaviour (compression set) and, critically for parenteral use, tight control of extractable substances.

Due to these requirements, progress must be gradual and evidence-based. The first stage is qualifying the process using homogeneous, well-characterised streams. The second stage involves demonstrating the reproducibility of the regenerated material and its ability to replace a fraction of conventional elastomer in non-pharmaceutical technical applications. The third stage involves investigating Aptar Pharma's specific compounds and components while verifying that functional performance, quality and safety remain fully preserved.

This is a long-term pathway, but its value today is in building the knowledge base. It puts the experience gained from production scrap to work, deepens understanding of how the regeneration process shapes formulation and properties, and lays the technical groundwork for higher-value circularity.

A FIRST CONCRETE INITIATIVE WITHIN A BROADER STRATEGY

Reducing the environmental footprint of elastomeric components does not depend on a single solution. Site energy efficiency, renewable electricity sourcing, material reduction, logistics optimisation, secondary packaging, non-fossil elastomers and compound improvement are all valuable strategies that can be pursued.

What sets the Aptar Pharma–Moine Recyclage loop apart is that it takes a stream that was previously difficult to recover – clean manufacturing scrap that would otherwise be incinerated – and keeps it in productive use, with a defined route for recovering it again over successive cycles. Aptar Pharma's internal LCA provides an initial sense of the benefit, with a critical review underway intended to ensure that the benefit is interpreted rigorously rather than overstated. For a drug developer, this is a tangible example of how a packaging partner can help reduce the Scope 3 emissions embedded in a finished product.

Devulcanisation represents the next step – moving from recovered waste to regenerated material capable of replacing new feedstock so that the sector retains more of the value embedded in rubber and moves closer to a genuine circular economy. For pharmaceutical applications, the pathway will necessarily be progressive, in materials science, industrial control and close collaboration between recyclers, compounders, manufacturers, regulatory authorities and pharmaceutical partners. It is a direction where Aptar Pharma is working to make progress, in close partnership with customers and the industry working towards similar goals.

"WHAT SETS THE APTAR PHARMA–MOINE RECYCLAGE LOOP APART IS THAT IT TAKES A STREAM THAT WAS PREVIOUSLY DIFFICULT TO RECOVER – CLEAN MANUFACTURING SCRAP THAT WOULD OTHERWISE BE INCINERATED – AND KEEPS IT IN PRODUCTIVE USE, WITH A DEFINED ROUTE FOR RECOVERING IT AGAIN OVER SUCCESSIVE CYCLES."

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NON-PTFE, NIA-PFAS POLYMERS FOR LIQUID DRUG DELIVERY DEVICES

Dr Erik Schwartz, **Dirk van Oevelen** and **Anton Petrov**, all of **SABIC**, discuss the company's range of NIA-polyfluoroalkyl polymers and introduce the company's fully functional autoinjector prototype, which uses the latest generation of resins and compounds from different polymer families.

As demand for safe and efficient drug delivery devices for self-administration and at-home settings continues to rise around the world, SABIC has developed a range of high-performance thermoplastic polymers targeting a growing number of applications, including liquid medication pens and autoinjectors. In addition to complying with medical regulations, these advanced materials also address concerns over formulations based on polytetrafluoroethylene (PTFE) and/or products containing per- or polyfluoroalkyl substances (PFASs). Furthermore, SABIC's portfolio of medical-grade resin and copolymer compounds can help manufacturers to achieve CO_2 reductions, as well as the optional use of bio-renewable content.

Ageing populations across all industrialised and developing countries rely on medication to address the growing burden of chronic and geriatric ailments, such as diabetes, arthritis, asthma, osteoporosis and cardiovascular diseases. Education and a growing trend towards managing these conditions in more convenient and lower cost settings outside of medical centres have created an increasing demand for at-home and self-administered therapies. Next to a vast number of established solid, oral, nasal and ophthalmic products, the highest growth rates in this market are attributed to liquid formulations administered subcutaneously through spring-loaded pens, autoinjectors or wearable injectors.

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Figure 1: Prototype autoinjector developed by SABIC highlights the benefits of using high-performance medical-grade copolymers and compounds for delivering liquid formulations.

ADVANCED MATERIAL SOLUTIONS FOR RELIABLE HIGH PERFORMANCE

The production of drug delivery devices for liquid formulations requires materials capable of supporting designs that improve usability, reliability and the patient experience while also being compliant with strict regulations. SABIC, a global leader in the chemical industry, and its Specialties business unit are spearheading this segment with a broad portfolio of dedicated medical-grade polymer resins and compounds. To showcase the high-performance potential of these materials, the company has developed a fully functional autoinjector prototype that uses the latest generation of resins and compounds from different polymer families (Figure 1).

The autoinjector features body and vial components that use globally available LNP™ copolymer technology, specifically including LEXAN™ HPX and CYCOLOY™ HCX resins. These thermoplastic materials help to maximise impact strength, including low-temperature impact strength, to store and deliver heat-sensitive products to end users, with excellent aesthetics and customisable colourability or transparency. The chassis and structural parts are moulded in LNP THERMOCOMP™ polycarbonate (PC) compounds, which deliver the strength and modulus required for metal replacement without compromising flatness or dimensional stability.

> "THE PRODUCTION OF DRUG DELIVERY DEVICES FOR LIQUID FORMULATIONS REQUIRES MATERIALS CAPABLE OF SUPPORTING DESIGNS THAT IMPROVE USABILITY, RELIABILITY AND PATIENT EXPERIENCE WHILE ALSO BEING COMPLIANT WITH STRICT REGULATIONS."

While all of these materials are optionally available with bio-renewable content for enhanced sustainability, several pen components can also be manufactured with LNP ELCRIN™ iQ polybutylene terephthalate (PBT) resins based on bio-renewable and/or chemically upcycled sources to further minimise their carbon footprints. The PBT content in upcycled LNP ELCRIN iQ resins is derived from post-consumer polyethylene terephthalate (PET) sources, such as discarded bottles.

The formulations can include up to 30% of recycled pre-consumer short glass fibres. The resulting compounds exhibit consistent high-quality physical properties, custom colourability and processability, and have been used successfully as drop-in solutions for incumbent virgin PBT materials. To further support these sustainable designs, the LNP copolymer technology also enables the production of thin-walled parts. An example of the sustainability benefits of certified bio-based LNP ELCRIN HCX1640B resin is shown in Figure 2.

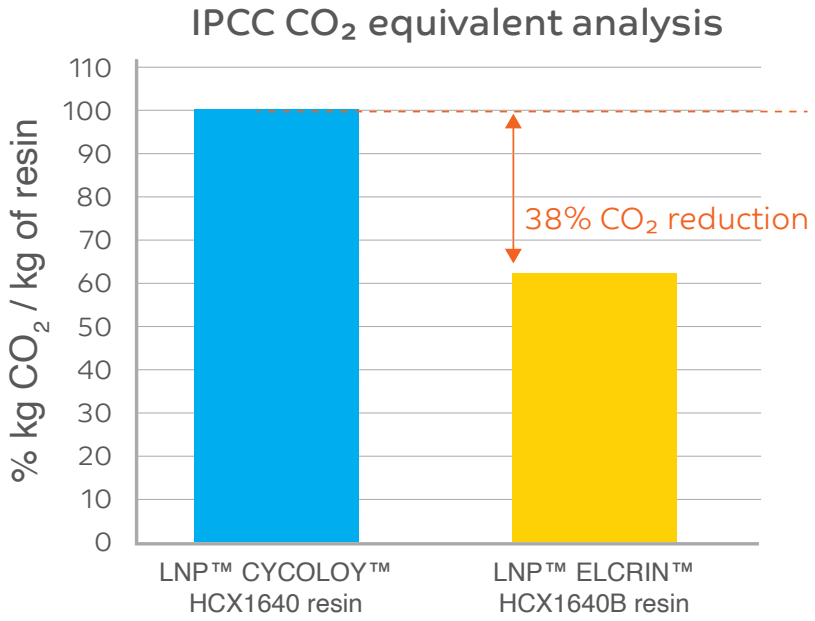


Figure 2: LNP ELCRIN HCX1640B resin containing third-party certified bio-renewable content via the mass balance approach can reduce the carbon footprint by up to 38% versus traditional LNP CYCOLOY HCX1640 resin grade (calculated according to the general principles of a lifecycle assessment as outlined in ISO 14040. IPCC; Intergovernmental Panel on Climate Change).

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"ONE OF THE MAJOR CHALLENGES IN THE DESIGN OF PENS AND AUTOINJECTORS IS TO ENSURE THE RELIABLE AND REPEATABLE LOW-FRICTION MOTION OF MOVING PARTS, WHICH IS CRITICAL FOR PRECISE DOSING."

FINE-TUNED LUBRICITY

One of the major challenges in the design of pens and autoinjectors is to ensure the reliable and repeatable low-friction motion of moving parts, which is critical for precise dosing. Especially in homecare and self-administration settings, friction can severely impact the perceived value and adoption of drug delivery devices, as it may result in a higher amount of force needing to be applied on the mechanism, which typically includes sliders, bushings and spring-loaded plungers.

Adding an internal lubricant to compounds can effectively minimise the coefficient of friction (COF) between parts, whether contact is plastic-on-metal or plastic-on-plastic. Historically, LNP LUBRICOMP™ grades based on PTFE have been the workhorse grades for lubricated solutions.

However, as regulations become more stringent and discussions on the use of PFASs and brominated compounds increase, there is growing demand for alternatives to PTFE-based compounds. In response to this, SABIC has developed a new series of internally lubricated LNP LUBRILOY™ compounds. These formulations are designed without PTFE and use non-halogenated alloy systems, offering a sustainable solution while maintaining good tribological performance.

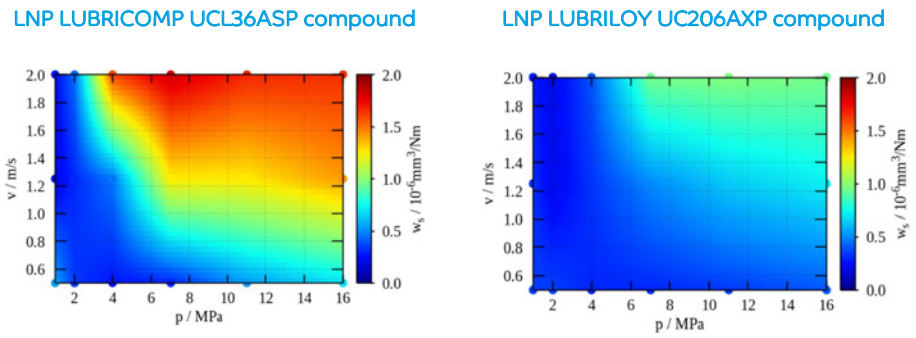


Figure 3: Wear performance of LNP LUBRILOY UC206AXP compound versus PTFE-based reference material (UCL36ASP) tested in a dry sliding 100Cr6 block-on-ring set-up (surface finish roughness average = 0.189 µm), specific wear rate (ws) in 10^{-6} mm^3/Nm with velocity (v) in m/s and pressure (p) in MPa.

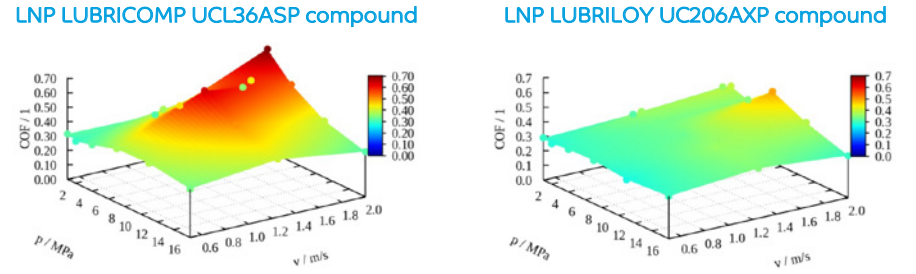


Figure 4: Friction performance – LNP LUBRILOY compounds with proprietary lubrication (UC206AXP) can significantly minimise the COF while avoiding the use of PTFE-based compounds such as UCL36ASP (tested under the same conditions as in Figure 3 in a dry sliding 100Cr6 block-on-ring setup).

Medical-grade LNP LUBRILOY formulations with inherent lubrication have been shown to provide good tribological performance while avoiding the use of PTFE, which is listed among the PFAS-containing materials that may soon be banned or restricted from use in medical devices under EU regulations.

For structural components such as rotary locks, SABIC has developed an offset carbon-reinforced polyphthalamide (PPA) compound to its PTFE-based LNP LUBRICOMP UCL36ASP, namely the non-PTFE-based LNP LUBRILOY UC206AXP. In a block-on-ring test, the new LNP LUBRILOY non-PTFE grade (UC206AXP) offers similar or better wear (Figure 3) and friction performance over a wider range of pressures and velocities compared with PTFE-based references (Figure 4).

LNP LUBRILOY compounds also offer the benefit of lower specific gravity, which enables weight-reduction opportunities while maintaining mechanical properties largely equivalent to those of PTFE-based systems. Table 1 summarises the availability of SABIC's lubricated compounds for healthcare applications.

STRICT MANAGEMENT OF CHANGE POLICY AND APPLICATION SUPPORT

To ensure the consistent quality, availability and supply of its medical-grade compounds, SABIC maintains a strict management of change policy across its manufacturing and compounding sites. Beyond offering a wide range of material solutions for healthcare, including biocompatible compounds, SABIC supports medical customers with a complete suite of value-added services from design and mould-flow analysis to predictive engineering, testing and compliance approvals. Concept studies and prototype designs complement a focused market approach, which is based on many years of innovative collaboration with leading industry players.

The market of self-administered medication is rapidly growing, and this can be a significant key to success when

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Resin Base	Healthcare Grade
ABS	AI001XXH
PC	D2000AXH
	DI001PXH
	DL003EH
PC-GF	DF206XXH
	DFL34H
PEI-GF	EFL34HL
POM	K2000XXH
	KP004AH
PA66	RF206AXH
	RFL36XXJ
PBT	WI001H
	WX07423H
	W8000



PTFE and/or Si modified (LNP™ LUBRICOMP™ compound grade)
Proprietary alloy (LNP™ LUBRILOY™ compound grade)

Table 1: Lubricated compounds for use in healthcare applications with moving parts.

it comes to designing and implementing new drug delivery devices, such as prefilled syringes and wearable injectors. With liquid therapies for osteoporosis treatment, hormone replacement, pain relief and other therapeutic applications on the rise, the right partner and material choice can accelerate time to market and provide an important competitive edge.

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A CALCULATED MOVE: PUTTING ENVIRONMENTAL ASSESSMENT DATA TO WIDER USE

YPSOMED SELFCARE SOLUTIONS

Cristin Konkart and **Shawn James** of **Ypsomed** investigate the importance of the underlying methodologies and expertise behind product carbon footprints and lifecycle assessments, drawing on Ypsomed's accrued organisational expertise to demonstrate how these processes are evolving and providing greater value to the company and its partners.

Across the medical device and pharmaceutical industries, the need for reliable environmental data is growing. Pharmaceutical companies increasingly require information from across their supply chains to fully understand the carbon footprint of their products and to support their own sustainability reporting and targets. Device manufacturers therefore need to provide robust, product-specific carbon footprint information. Product carbon footprint (PCF) assessments provide this information by quantifying the greenhouse gas emissions associated with a product. However, the resulting PCF figure is only as robust and useful as the data, methodology and expertise behind it.

Ypsomed has been conducting PCF assessments since 2020, building up practical experience, established processes and internal expertise. Its current assessments focus on CO_2 emissions, while full lifecycle assessments (LCAs) consider a broader range of environmental impact categories. As standards and regulatory expectations evolve, this established competence provides an important foundation for expanding lifecycle thinking.

> "THE RESULTING PCF FIGURE IS ONLY AS ROBUST AND USEFUL AS THE DATA, METHODOLOGY AND EXPERTISE BEHIND IT."

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Combined with expertise across the organisation and Ypsomed's active participation in industry consortia, this accumulated experience enables more rigorous assessment of environmental impacts and contributes to the development of evolving methodologies and standards. Increasingly, that competence also creates opportunities to bring environmental assessment further upstream into product development, while design choices can still be influenced.

SHOW YOUR WORKING: WHAT LIES BEHIND THE FINAL FIGURE

Six years ago, not all device components were backed by supplier-specific data. PCF calculations therefore relied more heavily on secondary datasets and assumptions based on literature searches. Today, most device components are assessed using primary data from suppliers, significantly improving the robustness and specificity of these calculations.

However, ensuring that supplier data remains current and transparent is a challenge across the industry. Supplier-specific calculations may still be based on older versions of the ecoinvent (Zürich, Switzerland) database – a widely used source that provides comprehensive environmental data for materials, energy, transport and industrial processes. When only the final PCF value is shared, without information on the underlying datasets, assumptions and calculation methodology, it can be difficult to determine when an assessment needs to be updated.

This becomes increasingly relevant as LCA databases evolve. Newer versions of the ecoinvent database provide more detailed and technologically relevant datasets, meaning calculations can better reflect the current industrial reality. Keeping supplier data and background datasets up to date therefore requires knowledge of both the data itself and the methodologies behind the calculations.

Supplier data is also becoming increasingly available within environmental impact categories beyond CO_2 emissions. This is particularly relevant as emerging frameworks, such as PAS 2090, the first global set of product category rules for pharmaceutical products, move towards broader environmental assessment requirements across the pharmaceutical value chain.

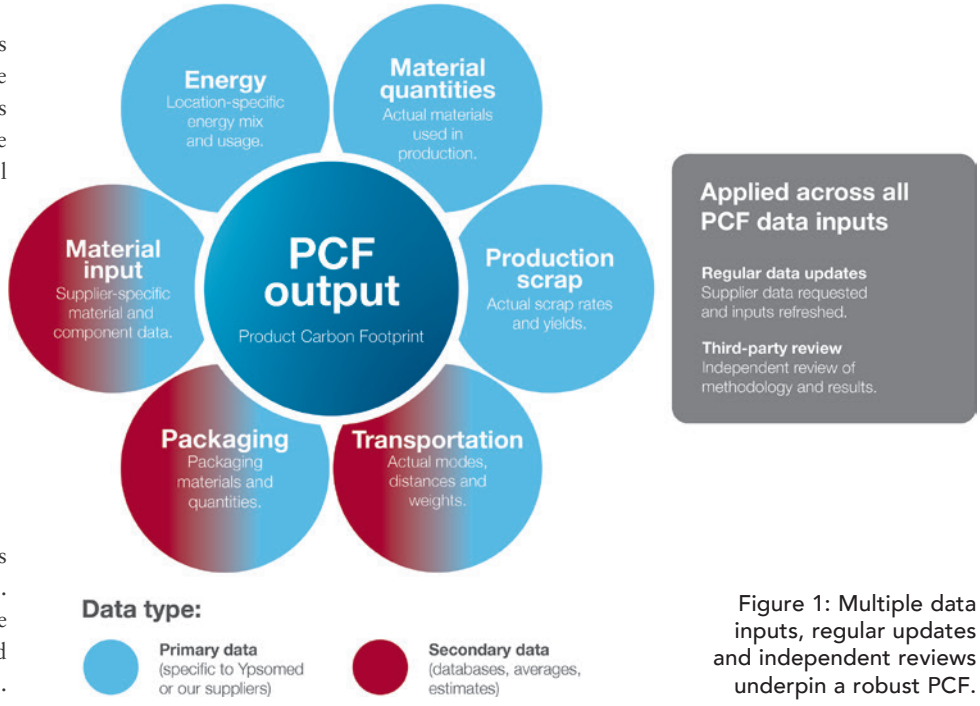


Figure 1: Multiple data inputs, regular updates and independent reviews underpin a robust PCF.

Ypsomed's approach also extends beyond supplier data. The company's assessments draw on location-specific energy data, actual material quantities, production scrap rates, packaging and transportation data to reflect the product and its production conditions as closely as possible. As a result, the same device manufactured at different locations can have different PCFs.

Clear system boundaries and assumptions are equally important. Ypsomed provides pharmaceutical customers with cradle-to-gate PCF data for use in their own calculations, while also including an end-of-life scenario to provide a broader view of the PCF. Transparency around the scope of the assessment, the underlying assumptions and the balance between primary and secondary data is therefore an important part of the methodology.

Maintaining this level of rigour is not a one-off exercise, but an ongoing commitment. Ypsomed regularly reviews supplier data and periodically recalculates PCFs as supplier, energy, material and production data change. Ypsomed also works with an external LCA consulting partner that provides third-party review of PCFs and LCAs, adding independent scrutiny of the methodology and results (Figure 1).

CONNECTING THE DOTS: BRINGING EXPERTISE TOGETHER

A key strength of Ypsomed's matrix organisation is its ability to bring different perspectives together. Production, procurement, materials specialists, product managers and sustainability experts, among others, each contribute a different view of the same product. PCF assessments create a framework in which these perspectives can meet and in which environmental considerations can be discussed alongside technical, operational and commercial requirements.

When PCF activities began at Ypsomed, the results were used mainly to support sales communication and provide customers with information about the environmental footprint of the company's products. Over time, the role of PCFs has expanded. Environmental data are increasingly brought into discussions around materials, packaging, sourcing and product development, where it can help to identify the decisions and trade-offs that have the greatest potential to influence environmental impact. In this way, PCFs become a tool for understanding where meaningful change may be possible.

One useful reference point for this evolution is the Brundtland definition of sustainable development, published in Our Common Future: "Sustainable development

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is development that meets the needs of the present without compromising the ability of future generations to meet their own needs."[1] Applied to product development, this raises a practical question – how can decisions made today also take the needs of tomorrow into account? PCFs and LCAs provide part of the answer by enabling different future scenarios to be explored and compared.

By modelling different scenarios, the potential impact of alternative materials, recycled content, reuse concepts, recycling systems or changes in production and energy infrastructure can be explored. These scenarios do not predict the future, but allow assumptions to be questioned, alternatives compared and potential opportunities identified.

The data and expertise needed for a robust assessment are distributed across the organisation. Production teams contribute knowledge of manufacturing processes and scrap rates, materials and polymer specialists provide expertise on sustainable alternatives, individual sites contribute energy data, procurement provides supplier-specific information, and packaging and logistics expertise supports the assessment of packaging and transportation (Figure 2).

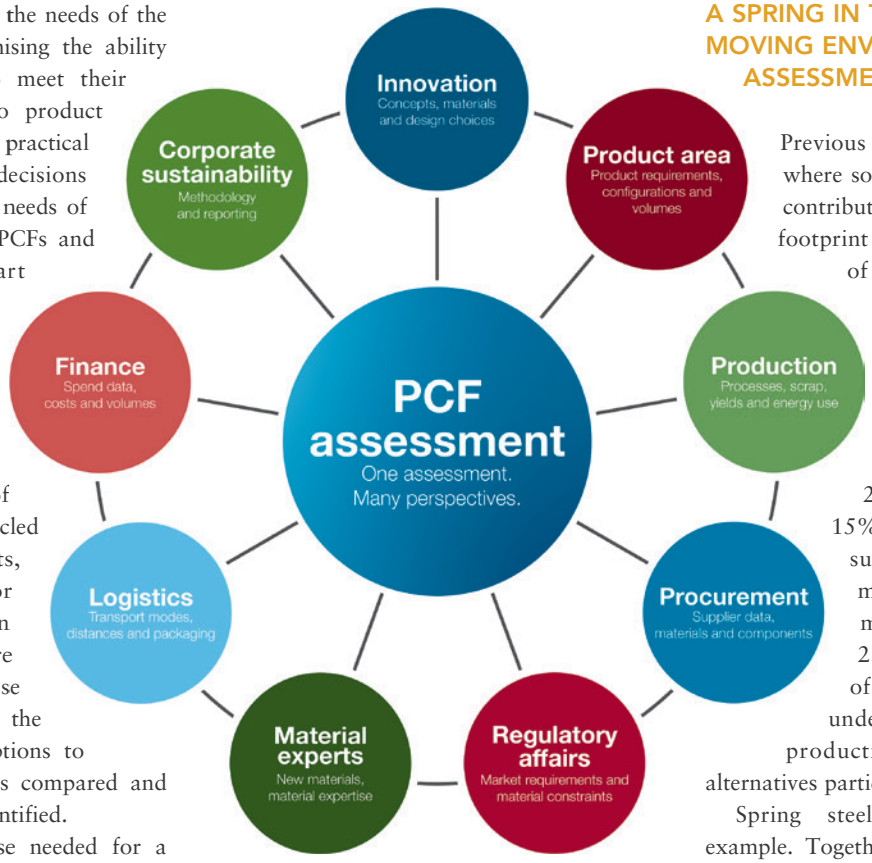


Figure 2: Robust PCF assessment combines data and expertise from across business functions.

> "AS MATERIALS AND METHODOLOGIES EVOLVE, CLEAR RESPONSIBILITIES, KNOWLEDGE SHARING AND CONTINUOUS LEARNING HELP TO KEEP PCF ASSESSMENTS AND LCAs ROBUST AND USEFUL."

This becomes particularly important when assessing newer materials and approaches. Thermoplastics, including bio-based materials and mass-balance approaches, can require specialist understanding of allocation rules, assumptions and data quality. As materials and methodologies evolve, clear responsibilities, knowledge sharing and continuous learning help to keep PCF assessments and LCAs robust and useful.

Robust assessment can also require expertise from beyond Ypsomed. Suppliers contribute increasingly specific information on materials and processes, while external LCA specialists provide methodological proficiency. Combined with expert knowledge within Ypsomed, these different perspectives can provide a more complete understanding of what sits behind the environmental data. Connecting these assessments with the people making product and design decisions also creates opportunities to put it to use.

A SPRING IN THE STEP: MOVING ENVIRONMENTAL ASSESSMENT UPSTREAM

Previous PCF analyses illustrate where some of the most significant contributions to a device's carbon footprint can arise. An analysis of an YpsoMate 1 mL autoinjector from July 2024 showed that raw materials accounted for around 40% of CO_2 emissions, with end-of-life contributing around 20%, packaging around 15%, and other contributions, such as transport and manufacturing processes, making up the remaining 25%.[2] The prominence of raw materials makes understanding their origin, production and potential alternatives particularly important.

Spring steel provides a concrete example. Together with an external LCA consulting partner, Ypsomed initiated a study to better understand the supply chain of the steel used for device springs. The study set out to answer three questions:

- Where does the steel used in the springs originate?
- Which energy mixes are used by the producers?
- Where are the opportunities for optimisation?

Gathering this information required a supplier survey to better understand the processes behind the material supply. Steel is one of the remaining significant materials for which calculations still rely on generic ecoinvent data rather than primary supplier data.

An external LCA consultant can provide methodological know-how, but cannot have detailed knowledge of every production process. In this case, expertise within Ypsomed's sustainability matrix, including previous experience in the steel industry, helped to translate the LCA findings into a more detailed understanding of the underlying production processes. Robust assessments therefore require

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Figure 3: A PCF assessment was applied during the development of Ypsomed's reusable mechanical autoinjector.

not only methodological expertise, but also detailed knowledge of the physical, chemical and engineering aspects of the processes being assessed.

This provided a basis for exploring optimisation opportunities, including reducing the number or weight of steel components and considering recycled steel. Translating these findings into changes in the physical product and supply chain was the next step.

The same competence can also be applied earlier in the design process, while product concepts and designs are still being developed. Ypsomed's ecodesign principles provide a framework for considering environmental aspects during innovation and development, while PCFs and LCAs can help to quantify the potential effects of different choices. The development of a reusable mechanical autoinjector (RMAI) concept provides one example (Figure 3). Here, the central question shifts from "Where does a material come from?" to "At what point does reuse actually pay off environmentally and economically?".

Instead of disposing of the complete device after each injection, the RMAI concept retains high-value components for reuse over multiple injection cycles, while only a limited number of components require replacement or disposal. Different scenarios were modelled for the reusable device and its minimal disposable components to understand how many use cycles would be required before the concept could provide a carbon footprint and cost-of-goods advantage compared with a single-use device (e.g. YpsoMate 1 mL, based on a PCF conducted in August 2026). In the indicative PCF assessment, the reusable concept achieved a lower calculated carbon footprint after fewer than ten injections. This allowed factors such as materials, reuse cycles and end-of-life assumptions to be explored before the concept was locked in.

This example illustrates the complementary roles of ecodesign principles and environmental assessments. Ecodesign principles provide direction, while LCAs can compare scenarios and quantify the potential effects of different design choices. For the RMAI concept, this LCA work fed directly into concept-phase decisions (Figure 4).

MAKING THE DATA COUNT: A MORE INTEGRATED APPROACH

Bringing environmental assessment earlier into product development represents a broader evolution in its role, from primarily measuring environmental impact to increasingly influencing it. The next stage is naturally to move from predominantly individual PCF and LCA studies towards a more integrated and continuously usable capability, and Ypsomed is committed to exploring this evolution.

Parameterised LCA models, supported by increasingly detailed product, supplier and manufacturing data, could allow environmental impacts to be assessed more dynamically during product development and decision making. The question then shifts from "What is the footprint?" to "How does the footprint change if another material, supplier, production location, reuse concept or end-of-life scenario is selected?".

The challenge is not only to build better models, but also to make environmental information understandable and useful for the different teams involved in product development. Therefore, knowledge sharing and cross-functional collaboration will remain important as environmental information becomes more widely used across an organisation.

At the same time, PCF and LCA methodologies, standards and regulatory expectations will continue to evolve. Ypsomed's established governance and cross-functional network of specialists enable continuous exchange and collaboration

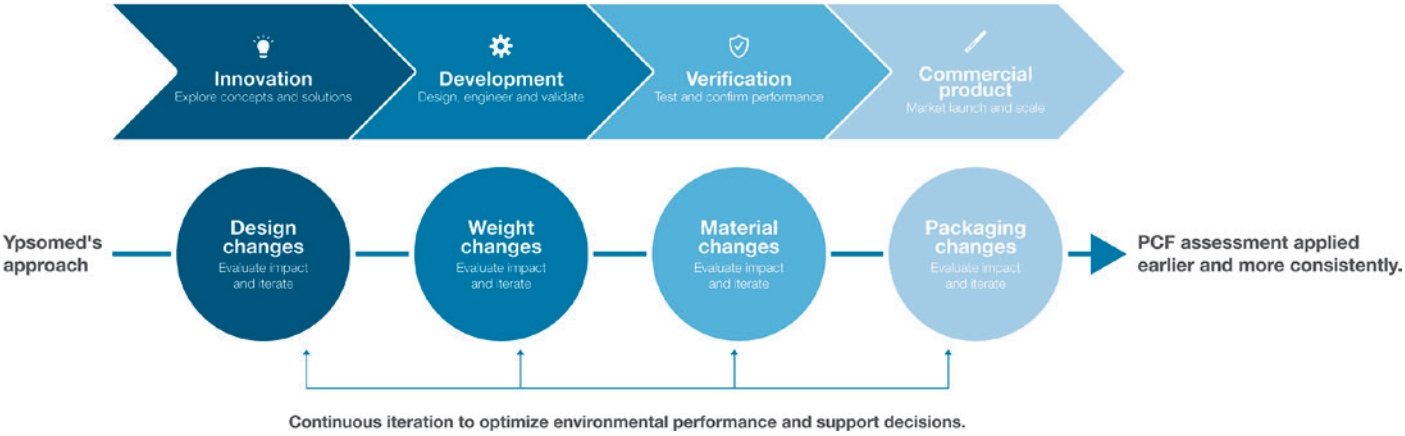


Figure 4: Applying environmental assessment earlier allows design options to be evaluated while they can still be influenced.

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Figure 5: Ypsomed's self-injection platforms with available PCFs.

across relevant technical and sustainability disciplines, helping the company to keep its approach aligned with evolving developments.

Years of PCF experience have built a capability that Ypsomed can now apply earlier and more systematically across product development, giving pharmaceutical partners more robust environmental data to understand trade-offs, compare options and make informed choices while there is still scope to influence the outcome (Figure 5).

For details on product carbon footprints, bio-based plastics, ecodesign principles and other sustainability-related information, please visit: ***www.ypsomed.com/sustainability-services***

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DESIGNING WITH SUSTAINABILITY IN MIND: ENGINEERING LOW CARBON pMDIs FROM THE COMPONENT UP

Tony Mallett and **Richard Turner** of **Bespak** explain the environmental strategies that shape inhalation device development and commercial manufacture when designing for propellants with low global warming potential, allowing patients to receive safe and effective treatment with lower environmental impact.

For the next generation of pressurised metered dose inhalers (pMDIs), sustainability and performance need to be considered hand in hand. As the Kigali Amendment to the Montreal Protocol drives the phasedown of propellants with high global warming potential (GWP), the pMDI industry is transitioning towards low-GWP alternatives, including HFA-152a and HFO-1234ze(E).

However, this transition is about far more than replacing one propellant with another. Low-GWP propellants have different physical and chemical properties that can affect how formulations interact with the device, influencing critical aspects of performance and meaning that components, such as valves, need to be redesigned and optimised.

At the same time, reducing the environmental impact of a pMDI does not stop at the propellant. Materials, manufacturing processes, supply chains and product development also contribute to its overall carbon footprint. Understanding these impacts – and identifying opportunities to reduce them – requires sustainability to be considered from the earliest stages of development and at every level of the device.

As a specialist CDMO for inhaled and nasal drug delivery, Bespak is investing across its capabilities to support this transition, from component engineering and computational modelling to lifecycle assessments (LCAs), increased manufacturing capacity and supply-chain engagement. Together, these capabilities

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are helping customers to develop low-carbon pMDIs while maintaining the quality, safety and reliability of the device that patients depend on.

BUILDING CAPABILITY FOR THE NEXT GENERATION OF pMDIs

The transition to low-carbon pMDIs will require not only new technologies but also the manufacturing capacity, environmental insight and supply-chain capability to bring them into commercial supply. Bespak is investing across each of these areas.

The company's commercial-scale infrastructure has been expanded to support both HFA-152a and HFO-1234ze(E), creating the capacity to manufacture next-generation pMDIs at scale. This investment will be essential as demand for low-carbon pMDIs grows. However, the concept of a low-carbon pMDI starts long before commercial manufacture is considered – every component must be studied and understood to make sure that the device and formulation work together as expected whenever any changes to the drug-device system are made.

Alongside this, Bespak is developing a broader understanding of the environmental impact of its products and processes. LCAs are helping to identify environmental hotspots and opportunities for improvement, while supply-chain assessment and engagement are helping the business to understand and address impacts beyond its own operations.

At the component level, Bespak has dedicated years of collaborative R&D to optimise its market-trusted pMDI valve for low-GWP propellants. This work culminated in the BK357 valve becoming the world's first market-approved valve for a low-GWP propellant in May 2025. Bespak is also introducing its next-generation integrated dose counter, ready for low-GWP propellant pMDIs.

"THE TRANSITION TO LOW-CARBON pMDIs WILL REQUIRE NOT ONLY NEW TECHNOLOGIES BUT ALSO THE MANUFACTURING CAPACITY, ENVIRONMENTAL INSIGHT AND SUPPLY-CHAIN CAPABILITY TO BRING THEM INTO COMMERCIAL SUPPLY."

Building on this component expertise, Bespak combines engineering with computational modelling and simulation (CMS) to understand how next-generation propellants can affect device performance and how device components can be optimised in turn.

BUILDING NEXT-GENERATION pMDIs WITH COMPUTATIONAL MODELLING

Bringing a low-carbon pMDI into commercial manufacture starts with understanding how the device needs to perform with the new propellant. HFA-152a and HFO-1234ze(E) have sufficiently different physical and chemical properties from existing propellants that nothing can be taken as read.

For Bespak, CMS is an important part of this process. Combined with component engineering and materials expertise, it enables engineers to understand how changes in the propellant affect device behaviour, explore how different design and manufacturing variables influence performance and refine component designs before moving into extensive physical prototyping.

Two examples demonstrate this approach. Bespak has used computational fluid dynamics (CFD) to understand how different propellants affect valve refill, while finite element analysis (FEA) and meta-modelling have been used to map the wider valve design space.

Understanding the Propellant: CFD Modelling of Metering Chamber Refill

Immediately after a pMDI is actuated, the metering chamber inside must refill ready for the next dose. If it does not refill fully and consistently, the device can deliver an inconsistent dose. As this event takes place inside a sealed metal assembly in under 300 milliseconds, it is challenging to observe directly.

To address this, researchers at Bespak and the University of Hertfordshire (UK) have developed an advanced computational model to study the critical refill phase inside pMDI valves.[1] The team simulated the flow behaviour of four propellants: the legacy propellants HFA-134a and HFA-227ea, and the next-generation alternatives HFA-152a and HFO-1234ze(E).

The findings clearly highlighted that the unique physical properties of the propellant directly dictate how quickly the valve refills. For instance, HFA-152a demonstrated the fastest refill speed, achieving over 88% liquid fill within 300 milliseconds, while HFA-227ea proved to be the slowest. These variations correlated with each propellant's specific saturated vapour pressure and liquid density.

The important point from a design perspective is that these differences can be addressed at the component level. By adapting the geometry of the metering valve, engineers can compensate for differences in refill behaviour and support consistent patient dosing regardless of the propellant chosen. The CFD model therefore provides a way to understand a process that is difficult to observe experimentally and use that understanding to inform component design earlier in development.

"THIS WORK CULMINATED IN THE BK357 VALVE BECOMING THE WORLD'S FIRST MARKET-APPROVED VALVE FOR A LOW-GWP PROPELLANT IN MAY 2025. BESPAK IS ALSO INTRODUCING ITS NEXT-GENERATION INTEGRATED DOSE COUNTER, READY FOR LOW-GWP PROPELLANT pMDIs."

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Understanding the Component: FEA and Meta-Modelling

Understanding propellant behaviour is one part of the challenge. But the pMDI valve itself is a complex assembly, with more than 100 design inputs potentially influencing more than 20 performance outputs.[2]

Traditionally, understanding how these variables affect performance would require extensive physical prototyping and testing. To explore this design space virtually instead, Bespak used FEA and statistical learning techniques, allowing the engineers to assess the potential impact of different dimensions, materials and manufacturing variations without producing a physical prototype for every combination.

The resulting model was validated against measured manufacturing data, with differences of less than 5% across the performance parameters. This gives engineers greater confidence in using the model to explore design changes and run sensitivity or "what if" studies without repeatedly producing physical prototypes.

While physical prototyping remains essential, particularly for a highly regulated product, the environmental benefit of using CMS to reduce unnecessary prototyping is significant. In one recent application of this approach, Bespak avoided producing prototypes that would have consumed up to 5 tonnes of plastic. By using simulations to explore and refine designs before committing to physical prototypes, engineers can reduce material use while enabling a more efficient and informed development process.

LCAs: LOOKING BEYOND THE PROPELLANT

As the industry moves beyond the immediate challenge of transitioning to low-GWP propellants, there is an increasing need to understand the environmental impact of the materials and processes that make up a device. This is where LCAs can provide valuable insight.

By gauging the environmental impact associated with the production of a component, LCAs can help to identify hotspots and focus efforts where they can have the greatest impact. In May 2025, Bespak completed a cradle-to-gate LCA of its BK357 pMDI valve in collaboration with Tunley Environmental (Leeds, UK). The independently verified assessment examined emissions associated with raw materials, upstream transport and manufacturing.[3]

The findings demonstrated the value of taking a component-level approach to sustainability. Rather than making assumptions about where emissions may come from, understanding the footprint of an individual component enabled previously overlooked environmental hotspots to be identified and targeted.

Customers are increasingly seeking transparent environmental data and credible reduction pathways; therefore, by undertaking a verified LCA and publishing a clear decarbonisation strategy, Bespak was able to demonstrate proactive leadership within the inhalation sector. The methodology can also be applied across different devices, processes and portfolios, providing a scalable framework for sustainability-led innovation throughout the pharmaceutical supply chain.

Increasingly, the value of LCAs lies in their integration into product development. When applied early in the design process, LCAs enable sustainability to become a decision input rather than an output, supporting more sustainable design outcomes from the outset.

WORKING ACROSS THE VALUE CHAIN

Reducing the footprint of a pMDI cannot be achieved by engineering alone. The materials used in individual components come from wider supply chains, making collaboration with suppliers an important part of the process.

Bespak carried out a supply chain assessment to better understand the environmental impacts across its supplier base and identify priority areas for

"TO EXPLORE THIS DESIGN SPACE VIRTUALLY INSTEAD, BESPAK USED FEA AND STATISTICAL LEARNING TO ALLOW THE ENGINEERS TO ASSESS THE POTENTIAL IMPACT OF DIFFERENT DIMENSIONS, MATERIALS AND MANUFACTURING VARIATIONS WITHOUT PRODUCING A PHYSICAL PROTOTYPE FOR EVERY COMBINATION."

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engagement. The assessment highlighted key hotspots for carbon emissions and biodiversity impacts, enabling the business to focus its efforts where they can deliver the greatest value. Building on these insights, Bespak hosted its first supplier engagement workshop, bringing together strategic suppliers to share the findings and discuss evolving sustainability expectations.

This builds on the collaborative approach already seen in Bespak's development work. Its research with universities has brought together academic expertise and practical experience to pMDI component development, while the BK357 valve LCA combined Bespak's understanding of its component and manufacturing processes with the specialist environmental expertise from Tunley Environmental.

Collaboration also extends beyond individual projects. Bespak's Holmes Chapel site is positioned within the Northwest of England's established pMDI R&D and manufacturing cluster, bringing together specialist expertise and capabilities across the inhalation sector for global applications. This creates a strong foundation for knowledge sharing and innovation, while enabling Bespak to develop solutions, capabilities and best practices that can support the global transition to low-carbon pMDIs. Through its work with customers, suppliers, academic partners and others across the value chain, Bespak is helping to turn sustainability ambitions into practical, scalable solutions, strengthening its position as a trusted innovation partner for the global pharmaceutical industry.

MAKING SUSTAINABILITY PART OF THE DESIGN

The development of low-carbon pMDIs illustrates a broader shift in how sustainability can be approached within inhalation drug delivery. Environmental considerations can be addressed alongside engineering, manufacturing and supply-chain decisions, rather than only being considered once a product has already been designed. For Bespak, this means bringing together component engineering, computational modelling, LCAs and collaboration across the value chain to support better-informed decisions throughout development and manufacturing.

This forms part of Bespak's wider environmental, social and governance strategy, supported by validated science-based emissions targets and actions across its operations. The aim is to make sustainability a practical consideration in the decisions that shape products, processes and partnerships.

The result is a more integrated approach to pMDI development. It is not simply a question of which propellant is used, but of how the device is engineered, what it is made from, how it is manufactured and how those choices affect its overall footprint. For Bespak, that means designing sustainability from the component up.



Richard Turner

Richard Turner is Senior Commercial Director at Bespak, with more than 25 years' experience in the respiratory drug delivery industry and particular expertise with pressurised metered-dose inhaler (pMDI) technologies. Mr Turner works with pharmaceutical companies globally on the development, industrialisation and commercialisation of pMDI platforms. A long-standing participant and key opinion leader in the respiratory community, Mr Turner brings a commercial perspective grounded in his extensive experience of translating emerging inhalation technologies into robust, scalable and commercially viable drug delivery solutions.



Tony Mallett

Tony Mallett is a Platform Development Group Manager at Bespak with over 23 years of experience within medical device development, covering all aspects of CDMO solutions. Mr Mallett's expertise encompasses all stages of new product introduction, servicing many products such as pMDIs, dose counters, dry powder inhalers, *in vitro* diagnostics, patch pumps, gas- and spring-powered autoinjectors, nasal devices and nicotine replacement therapy devices.

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"THE DEVELOPMENT OF LOW-CARBON pMDIs ILLUSTRATES A BROADER SHIFT IN HOW SUSTAINABILITY CAN BE APPROACHED WITHIN INHALATION DRUG DELIVERY."

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MANUFACTURERS' ROLE IN DELIVERING ESSENTIAL RESPIRATORY HEALTHCARE DURING THE TRANSITION TO LOW-GWP pMDIs

orbia
Fluor & Energy Materials

Darren Bromley-Davenport of **Orbia Fluor & Energy Materials** discusses the transition from current hydrofluoroalkane propellants to lower global warming potential alternatives for use in metered dose inhalers, highlighting the services that the company can offer the industry via its GMP facilities and wealth of experience to ensure that the transition is as smooth as possible.

As environmental fluorinated gas (F-gas) regulations increasingly target the climate impact of medical propellants, manufacturers of pressurised metered dose inhalers (pMDIs) must transition towards lower-global-warming-potential (GWP) alternatives. However, replacing the propellant is only one part of the challenge; manufacturers must now simultaneously manage reformulation, device compatibility, regulatory compliance and manufacturing readiness while ensuring that patients continue to have reliable access to essential respiratory medicines.

THE INDUSTRY'S CURRENT POSITION

With an estimated 43 billion pMDI doses delivered annually worldwide, and demand continuing to increase, the dosage form remains a critical treatment option for many patients.[1] The propellant-driven delivery mechanism enables consistent drug delivery independent of inspiratory effort,

"AS THE INDUSTRY TRANSITIONS TO LOWER-GWP TECHNOLOGIES, MAINTAINING CLINICAL PERFORMANCE, PRODUCT AVAILABILITY AND SUPPLY CONTINUITY IS ESSENTIAL."

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making pMDIs an important option across respiratory care. Therefore, as the industry transitions to lower-GWP technologies, maintaining clinical performance, product availability and supply continuity is essential.

One of the leading low-GWP propellant candidates is HFA-152a (Zephex® 152a), developed by Orbia Fluor & Energy Materials, which offers an approximately 90% reduction in carbon footprint compared with current propellants. Industry leaders, such as Chiesi (Parma, Italy), have already secured MHRA approval for an HFA-152a-containing pMDI, while other manufacturers await regulatory decisions following their own submissions.[2] These developments reinforce that the transition has already begun.

LESSONS LEARNED FROM THE PREVIOUS PROPELLANT TRANSITION

The previous transition from chlorofluorocarbon propellants to hydrofluoroalkanes (HFAs) in the 1990s demonstrated the complexity of changing propellant systems. What was initially expected to be a relatively straightforward substitution ultimately required substantial redevelopment work because of differences in the physical and chemical properties of the new propellants. In some cases, these challenges contributed to development delays and supply pressures.

Manufacturers face similar considerations today. Transitioning to HFA-152a requires a detailed understanding of interactions between the propellant, API, excipients, device componentry and materials, including valves, elastomers and canisters. Reformulated products must continue to deliver consistent performance throughout their entire lifecycle while meeting regulatory expectations for quality, safety and efficacy. Achieving this requires comprehensive development programmes capable of validating inhaler performance under real-world conditions.

THE IMPORTANCE OF EARLY DEVELOPMENT WORK

Technical readiness will be critical to the smooth introduction of low-GWP pMDIs. Compatibility assessments, formulation optimisation, performance testing and long-term stability studies can help identify potential challenges early in development. Evaluating parameters such as delivered dose uniformity, aerodynamic particle size distribution, shot weight and leak rate can provide confidence that reformulated products will continue to perform as intended (Figure 1).



Figure 1: A dose-uniformity sampling apparatus for collecting delivered doses for delivered dose-uniformity testing.

For manufacturers, identifying potential issues early is significantly less disruptive than addressing them during scale-up, clinical development or regulatory review. As increasing numbers of manufacturers pursue low-GWP reformulation programmes, access to development expertise, analytical capability and specialist testing infrastructure will become increasingly important.

> "ACCESS TO DEVELOPMENT EXPERTISE, ANALYTICAL CAPABILITY AND SPECIALIST TESTING INFRASTRUCTURE WILL BECOME INCREASINGLY IMPORTANT."

To support developers through this process, Orbia Fluor & Energy Materials has invested in capabilities spanning compatibility testing, formulation development, performance evaluation and GMP clinical manufacturing. These capabilities exist to help organisations navigate the transition to low-GWP propellants, from early research through to clinical supply and commercial readiness, calling upon over three decades of expertise.

MANUFACTURING AND REGULATORY READINESS

Alongside formulation development, manufacturers must prepare for evolving manufacturing and regulatory requirements. Specialist infrastructure is often required to support the development and handling of low-GWP propellants, including ATEX-rated facilities designed for flammable formulations, analytical capabilities for pMDI characterisation, and expertise in analytical chemistry and materials science.

Access to GMP manufacturing capacity is equally important for generating the data required to support development programmes and regulatory submissions. Since obtaining its Investigational Medicinal Products licence in 2023, Orbia Fluor & Energy Materials has produced GMP batches from its production facility,

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providing pharmaceutical companies with access to MHRA-approved clinical manufacturing capabilities that would otherwise require significant investment.

At the same time, regulatory compliance is becoming increasingly complex. Since January 2025, the EU hydrofluorocarbon (HFC) quota system has applied to HFC compounds manufactured or imported for use in pMDIs, as well as imported finished products. Manufacturers therefore need to navigate not only technical development challenges but also F-gas quota administration, compliance requirements and associated authorisation processes. Cross-industry collaboration with experienced partners that offer support in these areas is now a critical element of any successful propellant transition strategy, particularly for organisations operating globally.

"ULTIMATELY, THE INDUSTRY'S CHALLENGE IS ENSURING THAT REFORMULATED PRODUCTS CAN BE DEVELOPED, VALIDATED AND COMMERCIALISED AT SUFFICIENT PACE TO MAINTAIN PATIENT ACCESS TO ESSENTIAL RESPIRATORY THERAPIES."

LOOKING AHEAD

With the 2030 F-gas milestone approaching, there is increased pressure on manufacturers to reformulate, validate and commercialise lower-GWP inhalers while maintaining uninterrupted access to essential respiratory therapies worldwide. Organisations that establish robust development strategies early, supported by the necessary technical, manufacturing and regulatory expertise, are likely to be better positioned to manage risk and maintain development timelines.

To support this transition, Orbia Fluor & Energy Materials delivers a holistic approach to propellant compatibility testing for production-area modifications within a single development pathway, incorporating APIs, componentry and compliance.

Ultimately, the industry's challenge is ensuring that reformulated products can be developed, validated and commercialised at sufficient pace to maintain patient access to essential respiratory therapies. The manufacturers that successfully combine technical readiness, regulatory planning and manufacturing capability will be best positioned to deliver a smooth transition while supporting the long-term sustainability of respiratory care.



Darren Bromley-Davenport

Darren Bromley-Davenport, Technical Manager at Orbia Fluor & Energy Materials, has more than 30 years' experience in medical and pharmaceutical device markets, specialising in new product introduction, process development and regulatory compliance. He holds over 50 global patents and has developed and commercialised numerous products, including pioneering nanocoating technology designed to prevent drug adhesion in asthma inhaler canisters. In his current role, Mr Bromley-Davenport draws upon his extensive industry expertise to provide authoritative insights into the technical workings of respiratory propellants, their interaction with medicines and the implications for patient care.

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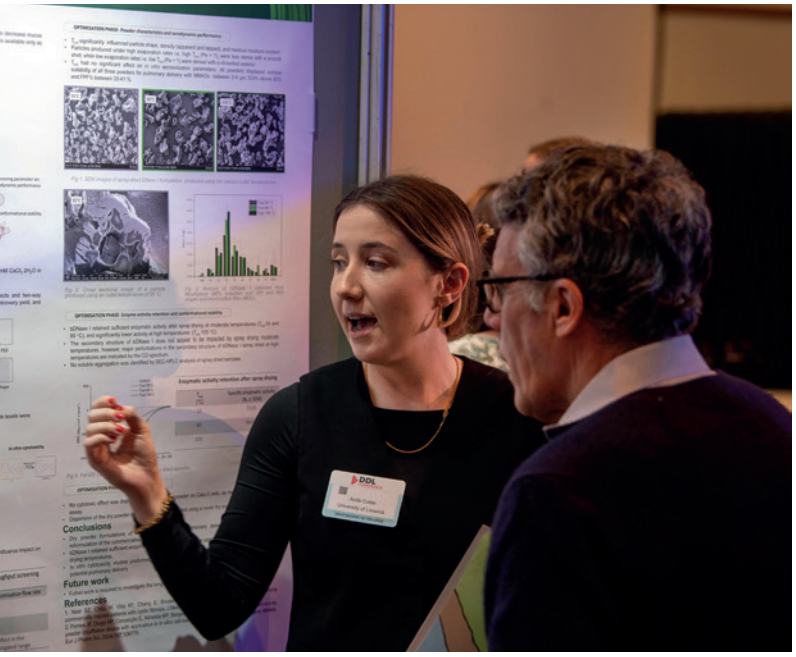
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Expert View

DESIGNING FOR A WORLD UNDER STRAIN: THE ROLE OF ECO-DESIGN IN IMPROVING SUSTAINABILITY AND SUPPLY-CHAIN SECURITY

Rob Veasey of DCA Design International discusses the core concepts of eco-design as applied to drug delivery devices, examining how sustainability principles can improve not only the environmental impact of the industry's products and processes but also how they can contribute to better supply-chain robustness and resilience.

Designing a new drug delivery device involves balancing a complex set of design inputs. Two of the broadest and most challenging drivers of these are environmental sustainability and supply-chain security. Their importance is rising fast, reflecting a global landscape marked by energy price shocks, geopolitical volatility, transport instability, resource constraints, climate-related disruptions and public health crises. These factors collectively ensure that sustainability and supply-chain resilience are likely to influence future corporate decision-making at the highest level.

These challenges do not simply influence procurement or operational decision-making; they shape the format and function of new products. In the pharmaceutical and medical device context, where post-approval changes are notoriously difficult, the stakes are even higher. Once a device is validated, changing materials or manufacturing processes can be prohibitively costly and time-consuming. This means that future vulnerabilities must be anticipated early, not retrofitted later. This article explores how an intelligent approach to product development can address both sustainability and supply-chain risks, focusing particularly where solutions naturally align.

"THESE TRENDS CARRY CLEAR IMPLICATIONS FOR ENVIRONMENTAL SUSTAINABILITY BUT ALSO HAVE SIGNIFICANT CONSEQUENCES FOR SUPPLY CHAINS."

THE TREND TOWARDS COMPLEX DISPOSABLE DRUG DELIVERY DEVICES

Most drug delivery devices today are single-dose or multi-dose disposable products, and for good reason. Disposable formats typically require fewer operating steps and are inherently easier to keep sterile and safe than reusable systems. They are less vulnerable to wear or contamination, and many self-disable at end of life, supporting adherence and reducing the risk of adverse events. As self-administered therapies have expanded to wider populations, disposability has become a dominant feature across most major device categories, including autoinjectors and dry powder inhalers.[1,2]

As drug delivery devices have gained new applications and adopted disposable formats, annual sales volumes have also risen significantly.[3] At the same time, efforts to improve usability, safety and performance have driven greater device sophistication. Early dry powder inhalers, such as Diskhaler® (GSK) and Spinhaler® (Fisons Pharmaceuticals), contained fewer than ten components, whereas more recent designs comprise around 30.[4,5] Designers have also used an expanding array of polymer grades, often enhanced with specialised additives to improve performance.

These trends carry clear implications for environmental sustainability but also have significant consequences for supply chains. They have unfolded in a business environment where global corporations have spent decades optimising their supply chains for efficiency. In many cases, this has produced geographically dispersed networks of companies involved in manufacturing, storing and distributing each device.

Whilst globalisation has delivered major benefits in cost and quality, it has also increased exposure to disruption when trade flow is interrupted. Recent events have made these vulnerabilities more visible, which is especially concerning for manufacturers of drug delivery devices that millions of people rely on. As a result, it is to be expected that there will be greater

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"WHILE ECO-DESIGN STRATEGIES HAVE GAINED TRACTION IN HELPING TO REDUCE THE ENVIRONMENTAL IMPACT OF NEW PRODUCTS, THEY CAN ALSO PLAY A ROLE IN IMPROVING SUPPLY-CHAIN ROBUSTNESS AND RESILIENCE."

focus on strengthening both the robustness (the ability to cope with external change) and the resilience (the ability to recover from shocks) of supply chains for future generations of drug delivery devices.

THE ECO-DESIGN FRAMEWORK

As one of the fundamental pillars of the "circular economy", the concept of environmentally conscious design – also known as eco-design – seeks to define development strategies that can be followed to minimise environmentally destructive impacts when creating new products. IEC 62430:2019 provides a framework covering eco-design strategies across five stages of a product lifecycle, as illustrated in Figure 1.

While eco-design strategies have gained traction in helping to reduce the environmental impact of new products, they can also play a role in improving supply-chain robustness and resilience. Structured by the eco-design framework, this article will discuss some key strategies that can be deployed to improve both sustainability and supply-chain security of drug delivery devices.

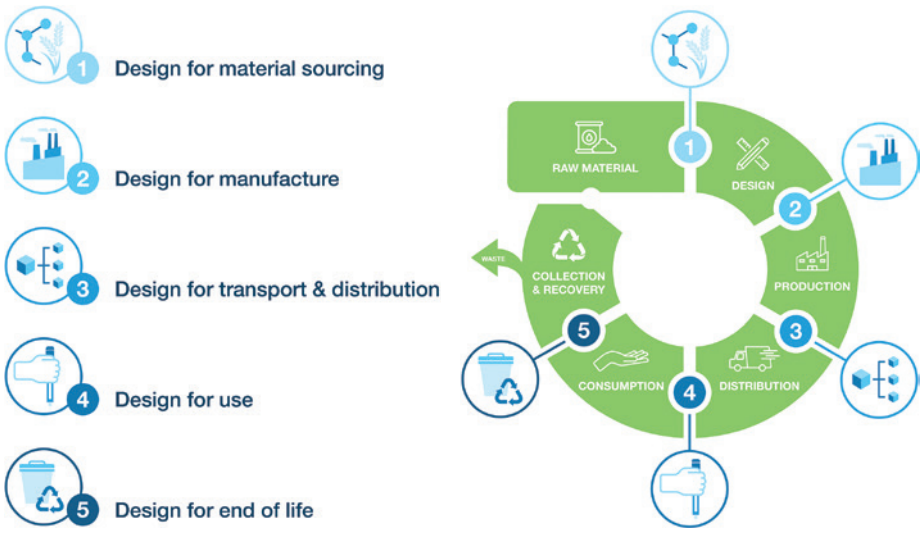


Figure 1: Eco-design strategies.

Design for Material Sourcing

Designing drug delivery devices with environmentally conscious material strategies begins with understanding the landscape of viable polymer options. Although there is an enormous range of polymer types and grades available, two categories of polymers are most suitable for drug delivery applications when sustainability, regulatory compliance and security of supply are taken into account: polymers manufactured from renewable feedstocks and low-energy polymers.

Polymers manufactured using renewable feedstocks include grades derived from non-food-competing bio-sources, chemically recycled polymers or oils, and carbon-capture processes. Many suppliers now offer such materials as medical-grade, with certification under the "ISCC PLUS" mass-balance scheme, enabling verifiable sustainability claims. Because these grades are chemically and mechanically identical to their fossil-derived equivalents, they can often be adopted with minimal design or manufacturing changes, though typically at a modest cost premium.

Depending on the proportion of renewable content, these materials can often deliver 30–60% reductions in global warming potential (GWP) per component compared with conventional polymers. However, the benefits vary significantly between grades, especially where renewable feedstock percentages are low. Published lifecycle assessments (LCAs) from major polymer producers indicate that switching from fossil-derived polymers to ISCC PLUS-certified bio-attributed materials reduces cradle-to-gate GWP by approximately 30–60%. SABIC (Riyadh, Saudi Arabia) reports a 61% reduction for its renewable polycarbonate grades, Celanese (Irving, TX, US) documents GWP reductions of around 35–45% for its ISCC PLUS-certified engineered polymers and LyondellBasell (Houston, TX, US) shows 30–40% lower CO_2e for its bio-attributed intermediates compared with fossil-based equivalents.

A second strategy is to specify polymers that inherently require less energy to produce and process. Commodity polymers such as polypropylene (PP) and high-density polyethylene (HDPE) typically have substantially lower embodied energy than engineering polymers such as polyamide (PA), polybutylene terephthalate (PBT), polyoxymethylene (POM) and polycarbonate (PC). In theory, this can yield a reduction in GWP of around 50% per unit mass; published LCAs show that commodity polymers such as PP and HDPE have cradle-to-gate GWPs of roughly 1.5–2.2 kg CO_2e/kg, whereas engineering polymers commonly used in drug delivery devices, such as POM, PA, PBT and PC, typically fall in the 3–9 kg CO_2e/kg range. However, the trade-off is mechanical performance. PP and HDPE offer lower strength and stiffness, making them less suitable for some components and device architectures.

Environmentally conscious material choices can also strengthen supply-chain robustness. Reducing reliance on fossil-derived polymers helps limit exposure to volatility in oil and gas markets. Commodity polymers, such as PP and HDPE, offer the additional advantages that they are easier and cheaper to manufacture and more widely available. This increases opportunities for local sourcing, shortens supply chains and reduces dependency on geographically dispersed suppliers.

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Design for Manufacture

Reducing the size, mass or component count of a product is a common strategy for minimising resource consumption in manufacture. However, for mature drug delivery device formats, such as injection pens and autoinjectors, large reductions in these attributes are difficult to achieve without altering the primary pack or compromising robustness and usability. When material content cannot be significantly reduced, switching to renewable energy sources for manufacturing processes can still deliver substantial environmental gains, potentially cutting the GWP of some components by up to about 30%. Injection-moulding-related CO_2 emissions can be reduced by 0.2–0.9 kg CO_2 per kg of moulded plastic when switching from average grid electricity to renewable electricity, depending on regional grid intensity and machine efficiency.

Another environmentally conscious design for manufacture strategy with major implications for supply chain resilience is reducing the number of material types used within the device. This approach not only supports recycling goals, which will be discussed later, but also creates opportunities for dual sourcing. Dual sourcing allows manufacturers to substitute one material for another if supply becomes constrained. Although common in many industries, dual sourcing is rare in drug delivery devices because each potential material combination typically requires separate performance verification. For complex, multicomponent devices, this quickly becomes impractical.

The scale of the challenge can be illustrated with a simple example. Consider a device with four components; if each part uses a different material, dual sourcing each material creates 16 unique component combinations (i.e. 4^2), each of which may require separate verification. In contrast, if all components are made from a single material, dual sourcing produces only two potential combinations, dramatically reducing the verification burden and making this strategy far more feasible.

Design for Transport and Distribution

For most drug delivery devices, there is substantial potential to reduce the size of secondary packaging. Device and packaging development are often handled by separate teams, which can lead to conservative decisions and missed opportunities. For example, most devices are engineered to withstand freefall impact and significant static loads, yet complex trays and oversized cartons are still widely used to provide additional protection during transport.

In the case of some autoinjectors, the volume of the secondary pack exceeds the volume of the medicine contained within by more than a factor of 1,000, highlighting the level of over-packaging that exists. Reducing pack size is especially important for injectable products that are distributed via cold chain, where significant energy is required to maintain temperature stability. For many such devices, doubling, or even quadrupling, packaging density appears achievable without compromising device protection. Doing so would enable major reductions in shipping volume and the energy consumed during refrigerated transport, improving both environmental impact and supply-chain efficiency.

Design for Use

A major determinant of the environmental sustainability of a drug delivery device is its effective lifetime. For disposable devices with a non-replaceable primary pack, this is defined by the number of doses contained within it. A prefilled syringe-based device typically delivers a single dose, which means that, where the dose regimen and product stability allow, shifting to an injector with a multidose pack could significantly reduce the carbon footprint of a therapy. For example, a once-weekly therapy currently delivered via single-use autoinjectors could transition to a four-dose pen, cutting device-related material use and associated carbon emissions by around 75%. This would also reduce supply-chain complexity by dramatically reducing the manufacturing and distribution capacity required to support the therapy.

Reusable injection devices offer even greater potential to reduce both carbon impact and supply-chain burden. In the same once-weekly scenario, a single reusable injector could replace more than 100 single-use devices over the course of a two-year treatment. However, these benefits come with important considerations. Reusable devices are only suitable for long-term or chronic therapies, and they typically introduce additional user steps to exchange the primary pack and reset the device. Some primary packs, such as prefilled syringes, are not optimised for reusable devices, adding complexity that, if managed poorly, may affect adherence.

Design for End of Life

The concept of the circular economy depends on recovering materials from products at the end of their life so that they can be reused in future applications. For products predominantly made from polymers, two main recycling pathways are used: mechanical recycling and chemical recycling. Both rely on rapidly evolving technologies, but mechanical recycling is by far the more established and cost-effective option today.

Mechanical recycling separates parts by material type until waste streams are sufficiently pure for reuse. Although theoretically suited to high-quality polymers, this method is not widely applied to drug delivery devices due to safety risks and the difficulty of separating the diverse materials used in their construction. This raises the question, "how can mechanical recycling be made easier for drug delivery devices?"

DEEP DIVE INTO TOMORROW'S DRUG DELIVERY INNOVATIONS

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A priority is developing safe and effective return schemes that minimise adverse events such as needlestick injuries. Several pharmaceutical companies have initiated such programmes,[6,7] though adoption remains limited. Despite added operational complexity, such schemes could generate exceptionally pure, high-value waste streams.

Mechanically recycled materials cannot yet achieve the purity required for reuse in drug delivery applications, but maximising recyclate quality remains important for value in other markets. Selecting polymers that are widely recycled and supported by established end-markets is therefore beneficial. Conveniently, low-energy polymers, such as HDPE and PP, are among the most commonly recycled materials, making them strong candidates for new "recycle-ready" devices.

Recyclability can be further improved by limiting the number of polymer types used in a device, ideally to one or two that are easy to separate, such as PP and POM. This simplifies mechanical separation and increases the likelihood of producing high-value recyclate. Removing pigments is also advantageous, as colourants cannot be separated mechanically and reduce the quality and market value of recycled material.

CONCLUSION

It is impossible to make blanket claims about how much environmental improvement or supply-chain resilience eco-design can deliver – the gains depend entirely on specifics such as device complexity, manufacturing geography, use regimen, drug characteristics and the constraints of existing infrastructure. But one thing is clear – the stakes are high. The industry is in a period of significant growth in demand for complex drug delivery devices, and this growth has the potential to collide head-on with unprecedented environmental pressures. At the same time, the drug delivery device industry remains deeply tied to the global polymer sector, which itself is dependent on fossil fuel markets that are increasingly exposed to geopolitical and economic shocks.

These factors combine to create a simple reality – the next generation of devices should target a smaller carbon footprint and lower vulnerability to supply-chain disruptions. While eco-design principles will not solve everything, they offer practical tactics that can make a real difference, enabling companies to make informed design choices to shape the environmental impact and supply-chain robustness of drug delivery systems for decades to come.

ABOUT THE COMPANY

DCA Design International 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.

"THE GAINS DEPEND ENTIRELY ON SPECIFICS SUCH AS DEVICE COMPLEXITY, MANUFACTURING GEOGRAPHY, USE REGIMEN, DRUG CHARACTERISTICS AND THE CONSTRAINTS OF EXISTING INFRASTRUCTURE."



Rob Veasey

Rob Veasey, Senior Sector Manager – Medical and Scientific at DCA Design International, leads development projects within DCA's medical sector, bringing over 30 years of experience in engineering, device design and cross-functional leadership. He has played a central role in advancing drug delivery platforms from initial feasibility to market launch, with expertise covering mechanical and electromechanical architectures. His work spans pen injectors, autoinjectors, wearable injectors, dry powder and soft mist inhalers, intranasal spray systems, topical applicators and pharmaceutical packaging solutions.

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Expert View

THE OVERLOOKED SUSTAINABILITY LEVER: HUMAN FACTORS IN DRUG DELIVERY

Adrian Segens and **Robin Huedepohl** of Cambridge Design Partnership consider the effects of device design choices on environmental impact, looking at how design decisions can be optimised to reduce drug or device wastage, improve benefits for patients and ultimately minimise carbon footprints.

"EACH INSTANCE OF DEVICE MISUSE – WHETHER THAT BE A DOSE THAT IS STORED INCORRECTLY, NOT FULLY DELIVERED OR DISCARDED IN AN UNUSED DEVICE – ERODES THE ENVIRONMENTAL COST-BENEFIT TRADE-OFF BEHIND THE PRODUCTION OF THE DRUG, PRIMARY CONTAINER, DEVICE, PACKAGING, TRANSPORT AND STORAGE."

Injectable therapies have been moving out of the clinic and into the home at pace for over a decade and the shift shows no sign of slowing. Biologics that once required administration by a healthcare professional are now supplied to patients for subcutaneous self-administration, and the growth of glucagon-like peptide-1 therapies has made combination products available to an unprecedented number of largely untrained users.

There is arguably an environmental benefit to this shift. At-home administration removes the need for journeys to the clinic, reduces clinical contact time and, where it improves disease control, avoids the frequency of flare-ups and hospital admissions. That argument depends on a condition that may seem obvious – the treatment must be delivered as intended, whether through patient compliance, treatment regimen adherence or correct use of the delivery device.

Each instance of device misuse – whether that be a dose that is stored incorrectly, not fully delivered or discarded in an unused device – erodes the environmental cost-benefit trade-off behind the production of the drug, primary container, device, packaging, transport and storage. Misuse is not a user failure; it arises from interactions between the user, device (including its training offering, labelling and packaging) and use environment, and can represent opportunities to improve design.

Most of the work to address sustainability currently sits upstream of dose delivery – particularly around materials, manufacturing and supply-chain environmental impacts. For example, material selection, lightweighting, manufacturing efficiency, packaging reduction and end-of-life recovery are specified, measured and compared within engineering and lifecycle assessment (LCA) processes. A broader approach is to consider the overall treatment as the functional unit, bringing both the drug and delivery device within the scope of LCAs. Even with this wider scope, models tend to focus on residual drug losses.

"MATERIAL SELECTION AND REDUCTION REMAIN IMPORTANT SUSTAINABILITY LEVERS, BUT THEIR EFFECT MUST BE CONSIDERED ALONGSIDE THE LOSSES THAT OCCUR WHEN TREATMENTS ARE NOT SUCCESSFULLY ADMINISTERED."

An LCA by ApiJect (Stamford, CT, US) modelled the remaining drug in the container after delivery but without consideration of doses lost due to device mishandling. This is a gap that needs to be addressed further. Human factors engineering is not only a safety discipline, but also a tool for understanding how much of a treatment's footprint is spent on doses that never work.

Material selection and reduction remain important sustainability levers, but their effect must be considered alongside the losses that occur when treatments are not successfully administered. The comparison that follows illustrates where design efforts can have the greatest overall benefit, rather than ranking one type of improvement over another.

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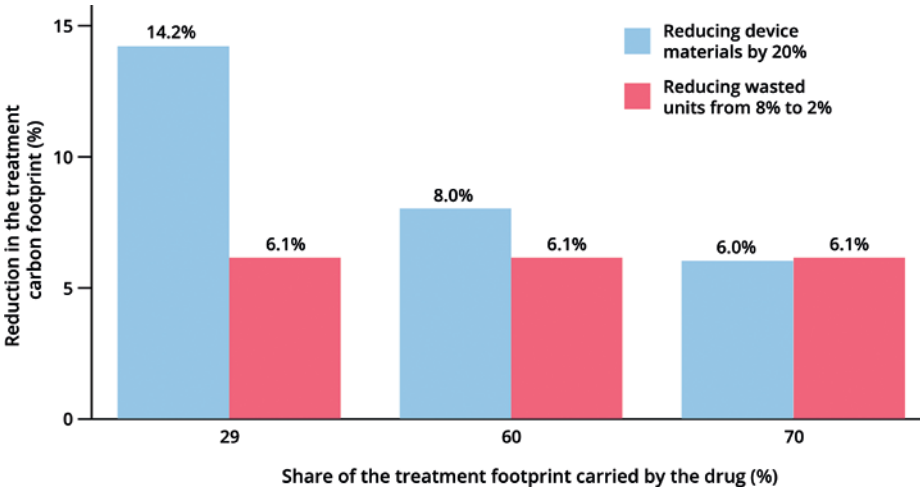


Figure 1: Impact of two improvement programmes on the carbon footprint split between drug and device, based on assumptions detailed in Table 1. As the carbon footprint of the drug increases, reducing device materials has less impact on the overall footprint. Minimising the number of wasted units reduces both drug and device losses. Reducing device materials and number of wasted units has equal impact when the drug carbon footprint is 70% of the total.[1]

HOW MUCH CARBON CAN A DEVICE DESIGN ACTUALLY SAVE?

The first question to ask is not actually "How much carbon does a sustainable device design save?", but "How much of the treatment footprint lies beyond the device?". A published LCA of the Prefilled ApiJect Injector, a single-dose device that pairs a blow-fill-seal plastic container with a double-ended needle hub, placed around 29% of the lifecycle carbon footprint on the drug and 71% on the device, packaging and manufacturing.[1]

Two details qualify these figures. Firstly, the 29% rests on a normalised drug carbon intensity of 10 kg CO_2 equivalents rather than a product-specific figure. Secondly, the drug-related share counts the residual volume left in the container, not the doses lost due to incorrect use.

The carbon footprint of a drug is neither negligible nor fixed. It rises with the carbon intensity of the API (such as low-yield synthesis routes and cold-chain storage requirements) and falls as the device and its container get heavier. Reducing the device's environmental impact is a possibility, but it is a bounded one. Materials, mass and manufacturing changes act only on part of the carbon footprint that the device occupies. That part is 71% of the ApiJect total, so a 20% reduction in it lowers the total treatment footprint by 14.2%. When the drug accounts for a larger share of the carbon footprint, the same improvement delivers even less impact (Figure 1). However, a wasted unit affects the footprint of both the drug and device.

Use-related losses are not bounded by the footprint of the device. A device with the same materials footprint but designed to reduce use-related failures may deliver more of its doses. Conversely, when a whole unit is lost without delivering a therapy, both drug and device are lost together, meaning that loss scales with the entire footprint rather than with part of it. Quantifying the environmental significance of these losses constitutes an important focus for future research, as current real-world data remains limited.

Therefore, headline device improvements to sustainability must be read against the drug footprint share. YpsoLoop (Ypsomed, Burgdorf, Switzerland), launched in October 2025, estimates an 87% reduction in material-related CO_2 emissions when compared with a conventional autoinjector, achieved through the use of bio-based and sustainable materials in a platform designed for disassembly and recycling.[2] Material-related emissions are only one aspect of the device footprint, so the effect on the overall treatment footprint is a fraction of reduced emissions, and component recovery depends on devices being returned into a managed end-of-life pathway.

HOW MUCH DOES A WASTED DOSE ADD TO THE OVERALL CARBON FOOTPRINT?

The answer depends on the composition of the footprint rather than on which impact is counted.

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Factors assessed	Conventional assessment	Assessment including use-related loss	Source
Drug share of carbon footprint	29%	29%	ApiJect LCA[1]
Device, packaging and manufacturing share	71%	71%	ApiJect LCA[1]
Functional unit	One unit manufactured	One dose successfully delivered	ISO 14044[3]
Whole-unit loss rate	Not modelled	2% low case, 8% high case	Illustrative
Environmental impact per functional unit	100%	102.0% at a 2% loss rate, 108.7% at an 8% loss rate	Calculated
Value of a 20% cut to the device materials	**14% of the total**	**14% of the total**	**Calculated**
Value of cutting whole-unit loss from 8% to 2%	**Not visible**	**6% of the total**	**Calculated**

Table 1: Two assessments of the same product, differing only in the functional unit. Illustrative values are chosen to show sensitivity, not to represent a specific product.

A single-dose case is used here as the simplest, most conservative estimate of how a wasted dose affects an overall carbon footprint. At worst, when a whole-unit loss occurs – perhaps through incorrect storage, preparation or activation by the user – drug and device are lost together, so the whole carbon footprint is carried by a single dose.

Table 1 compares two assessments of the same product using different functional units: environmental impact per unit manufactured and environmental impact per dose successfully delivered. This distinction is consistent with those allowed by ISO 14044.[3]

The conventional assessment – impact per unit manufactured – shows one environmental lever. Cutting the device share of the footprint by 20% is worth 14% of the total footprint. The second assessment reveals two levers: that same 14%, and a further 6% when cutting whole-unit loss from 8% to 2%. This second lever carries a little under half the impact of the first, which is not shown at all by a conventional assessment.

This is not to say that any single human factors intervention will deliver a reduction in a product's carbon footprint. The environmental value of a design change ultimately depends on the loss that it addresses.

Many steps that do affect the device loss rate are already addressed through human factors considerations, such as storage before use, the preparation sequence, activation and, where applicable, completing a device return.

Partial losses cause different outcomes. If 10% of injections result in a quarter of the dose lost to a wet injection, the drug wasted is 0.7% of the total footprint, against 8.7% for an 8% whole-unit loss rate (more than ten times larger).

Not all losses are entirely use-related. Overfill and priming volumes are set by the formulation and the container. Cold-chain excursions occur during distribution and in pharmacy handling. Devices fail and doses expire unused. Moreover, from a human factors perspective, foreseeable use-related losses are understood as shortcomings in the design of the system, not failings of users. Design teams can influence these losses through changes to packaging, device design, storage guidance, return systems or service design.

WHERE DOES USE-RELATED LOSS OCCUR?

While human factors is typically associated with safe and effective use,[4,5] it also influences sustainability outcomes. From a sustainability perspective, a key question is how user interactions can lead to the loss of drug, device hardware or recovery value. Selected device categories illustrate how these losses arise in different ways.

Autoinjectors, Pen Injectors and Prefilled Syringes

Across these device categories, the most costly events are whole-unit losses, where both drug and device are discarded together. Incorrect storage before use and accidental activation during preparation both consume the unit without delivering the therapy, and even over-priming a pen injector partially wastes drug.

Loss of drug during a wet injection – where the device is lifted before delivery is complete and drug escapes at the needle or leaks back from the injection site – also significantly affects the environmental impact (while its clinical impact is product specific). That impact grows as dose volumes rise. In response to this, the designs to test include packaging that presents components in the order of use, pre-prime locking, unambiguous dose progress and clear end-of-dose feedback. Similarly, a fixed multidose device specified for four doses but abandoned after two leaves its hardware carrying twice the environmental burden assumed by the per-dose assessment.

Disposable On-Body Devices

Disposable on-body devices carry more hardware per dose, often including electronics and a battery, so each unit loss costs more than a purely mechanical equivalent. Poor attachment can mean the dose is not delivered correctly, and removing the device early wastes the undelivered drug in the device or on the skin.

Digital and Connected Elements

Connected devices, apps and electronic instructions can reduce waste by improving dosing confidence, prompting returns and keeping hardware in service, but they are not automatically sustainable.

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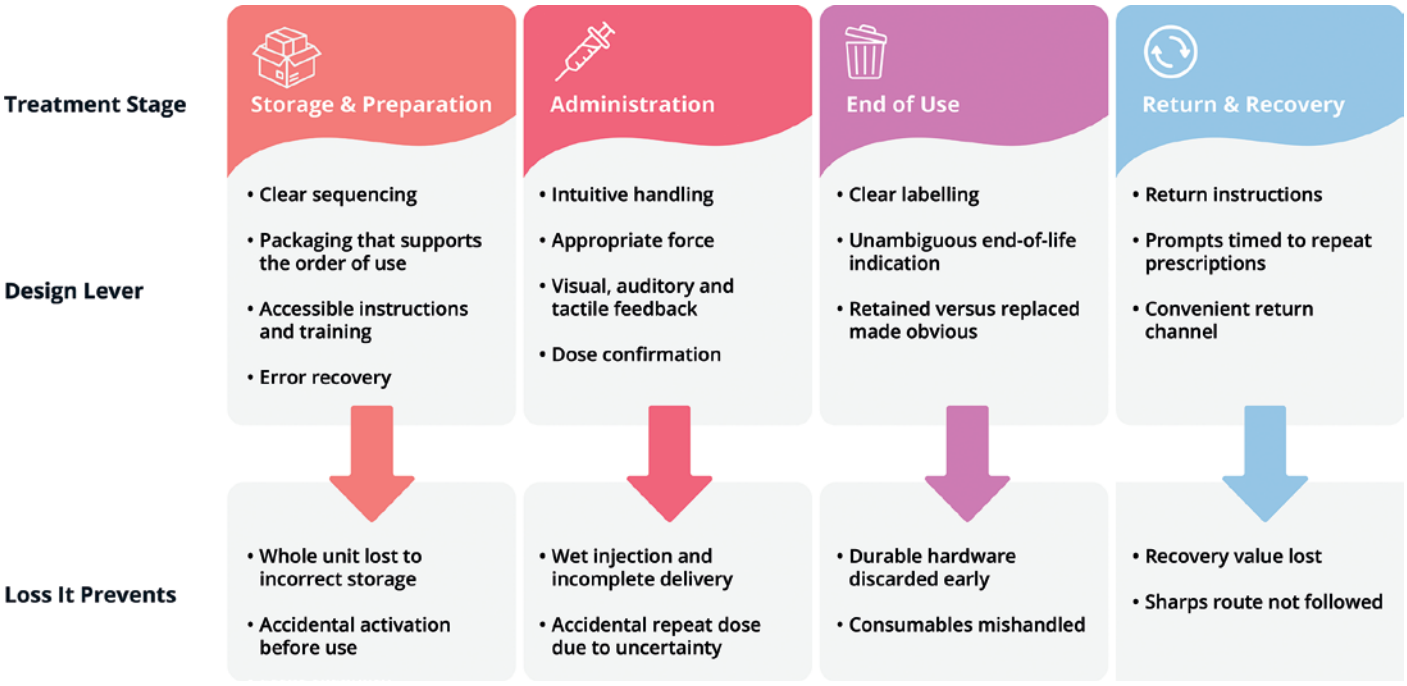


Figure 2: Design levers mapped to the treatment stage they act on and the loss that each may prevent (illustrative, not an exhaustive list).

Device category	Storage and preparation	Administration	End of use and recovery
• Autoinjector • Pen injector • Prefilled syringe • Single-dose and multidose	• Incorrect storage before use • Accidental activation during preparation • Over-priming a pen injector	• Device lifted before delivery is complete, resulting in wet injection • Ambiguous end-of-dose feedback	• Uncertainty over sharps handling • Part-used pen discarded with doses remaining • Device discarded before a return route is used, where one exists
• Disposable on-body device	• Poor skin preparation or attachment • Incorrect storage of the filled unit	• Premature removal wastes the undelivered drug • A misread status indicator may prompt disposal of a working unit	• Electronics and battery leave the recovery stream • Unit abandoned before the end of its intended use life
• Digital or connected element	• Set-up or pairing not completed	• Alerts ignored or misinterpreted • Untrusted dose record prompts an unnecessary replacement	• Electronics enter general waste • App abandoned, so return prompts are never seen

Table 2: Examples of use-related waste mechanisms by device category (not an exhaustive list).

Electronics, batteries, sensors and data infrastructure add environmental impact at a time when global e-waste is rising by around 2.6 million tonnes a year, with only about a fifth formally collected and recycled.[6]

The question is targeted – "Which waste mechanism does this digital element remove, and is the reduction in footprint larger than the environmental impact that the element adds?". Misread status indicators may prompt a patient to discard a working unit, though how often this happens is not well documented. Adhesion, a clear wear-time signal and status indicators that distinguish a fault from a completed dose are all levers which may reduce avoidable losses.

DESIGN LEVERS ACROSS DEVICE CATEGORIES

Across all discussed device categories, the design levers are familiar. The sustainability lens asks, "Which lever affects the most environmentally significant part of the treatment system?". Figure 2 maps each lever to the stage it acts on and the loss it

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may prevent. Table 2 sets out where the losses arise in each category.

ADHERENCE MAGNIFIES EFFECTS AT LARGER SCALES

The same principle applies at larger scales for non-adherence to chronic therapies. Non-adherence is a substantial field of study, with a large set of psychological and behavioural literature behind it. The difficulty is in isolating the device-attributable part rather than explaining the whole effect.

A treatment manufactured, distributed and dispensed but never used produces its full carbon footprint with no patient benefit. Adherence to long-term therapies for chronic illness in developed countries averages around 50%,[7] and unused or wasted prescription medicines cost the NHS in England around £300 million per year.[8]

Non-adherence is influenced by many factors, including side effects, access to treatment and clinical support. However, some barriers are directly affected by device design, including needle anxiety, uncertainty that a dose has been successfully delivered, packaging and treatment routines that are difficult to integrate into daily life. When these barriers lead to treatment abandonment, the sustainability outcome is ultimately the same: resources are consumed without delivering the intended therapeutic benefit.

MAKING WASTE VISIBLE IN EXISTING HUMAN FACTORS WORK

The questions already asked under IEC 62366-1 and equivalent human factors guidance can be extended to sustainability with little additional effort.[4,5] At each stage of the treatment journey, designers can ask:

- What could be wasted – drug, device hardware, packaging, consumables or recovery value?
- Which user behaviours could cause that loss and are they reasonably foreseeable?
- Which design features, instructions, training, packaging cues or services could reduce environmental impact?
- What evidence is needed to understand and quantify environmental impact?

Formative human factors studies already identify foreseeable use errors and the design causes behind them. The same output could answer a second question: "What environmental impact could each of those errors have?".

Summative studies have then provided the evidence that design changes have reduced the occurrence of critical use-related errors in the intended context of use, providing data that could inform assumptions, modelling and scenarios within an LCA.

LOOKING AHEAD

Sustainability assessments routinely examine the environmental cost of producing and delivering therapies but have historically omitted the impact of lost therapies – when not used as intended. As injectable therapies continue to move into patients' homes and hands, these losses become increasingly relevant to the environmental performance of the overall treatment system.

Human factors are usually discussed in terms of improving the safety and effectiveness of drug delivery devices,



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but many of the same use-related failures that these considerations prevent also reduce the loss of drug product, device hardware and recovery value.

Incorporating human factors considerations and data into environmental assessments, such as LCAs, has the potential to identify environmental impacts that are currently overlooked. Combining these two perspectives – manufacturing footprint and improved usability – could reveal the true environmental impact of a treatment system and where improvements can be made.

ABOUT THE COMPANY

Cambridge Design Partnership (CDP) is an end-to-end innovation partner focused on helping clients grow. Some of the world's largest companies trust CDP to design and develop their most important innovations within drug delivery and also diagnostics, surgical equipment and other health-related products. Located in Cambridge (UK) and Raleigh (NC, US), CDP specialises in the consumer, healthcare and industrial markets. Its multidisciplinary teams have expert knowledge to identify opportunities and overcome challenges throughout the product development and manufacturing process.

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Expert View

BIOPLASTICS IN DRUG DELIVERY: SUSTAINABLE SOLUTION OR SUBSTITUTION TRAP?

Serena Grace and **Alex Fong** of Owen Mumford Pharmaceutical Services

examine the environmental and supply-chain limits of bio-based plastics in drug delivery, arguing that material substitution alone cannot address the sector's deep dependence on virgin plastics. They consider how reducing raw material dependence can contribute not only to lowering carbon footprints but also to increasing supply-chain resilience, and highlight the importance of assessing, not assuming, impact.

"BIOPLASTICS ARE CLEARLY A PROMISING ALTERNATIVE TO FOSSIL-DERIVED POLYMERS, BUT MANUFACTURERS CANNOT AUTOMATICALLY CONSIDER THEM THE MOST MEANINGFUL – OR WORSE, THE ONLY – SUSTAINABILITY INTERVENTION."

A PROMISING ALTERNATIVE

As the pharmaceutical industry increases its focus on the environmental impact of drug delivery devices, bio-based plastics have emerged as one of the most visible responses to the sector's well-documented dependence on fossil-derived raw materials. Replacing fossil-based polymers with materials made from renewable biological feedstocks offers an attractive proposition: reduced reliance on finite resources and, potentially, lower greenhouse gas emissions.

It is also a relatively straightforward intervention to communicate both internally and externally and, in some cases, to implement. "Drop-in" bioplastics can retain the same chemical structure as their fossil-based counterparts, allowing established manufacturing processes and recognised device architectures to be maintained.[1]

Some bioplastics are already used in the medical device industry, to differing degrees. Polylactic acid (PLA) is a bioabsorbable polymer commonly used in orthopaedic implants, providing comparable fixation to traditional implants while eliminating complications associated with retaining non-biodegradable materials.[2] Polyhydroxyalkanoates (PHAs) are also used in medical implants, with further applications, such as wound dressings, currently being explored.[3] Cellulose, the most abundant natural biopolymer on Earth, has garnered particular interest due to its biodegradable, biocompatible, non-cytotoxic and non-genotoxic properties, making it a leading candidate for a range of medical and pharmaceutical applications.[4] The range of potential biomaterials will continue to expand as research unveils new biological feedstocks and manufacturing routes.

For drug delivery, however, material substitution is rarely straightforward. Devices must deliver a therapy accurately and reliably over time, while maintaining mechanical performance, dimensional stability, drug compatibility, usability, shelf life and patient safety over long commercial lifecycles. Any material change must therefore satisfy demanding engineering and quality requirements as well as the regulatory expectations of a highly controlled industry. Bioplastics are clearly a promising alternative to fossil-derived polymers, but manufacturers cannot automatically consider them the most meaningful – or worse, the only – sustainability intervention.

THE LIMITS OF FEEDSTOCK SUBSTITUTION

Overestimated Impact

The fundamental point is simple – "bio-based" describes what a polymer is made from, not the overall environmental impact of the material. Replacing fossil-derived feedstocks with biological sources may reduce dependence on petroleum, but this is only one element of the wider sustainability question. Depending on the feedstock and the production pathway, bioplastics may not have as low an environmental impact as is often assumed. Land use, water consumption and impact on biodiversity must all be taken into account to avoid overestimating the total product-level benefit. There are also concerns that crop-derived feedstocks may compete with food and fuel production for limited resources, including land and water.[5]

This is driving interest in second-generation feedstocks, which use non-food biomass and waste-derived streams such

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as agricultural residues and industrial biowaste. These could reduce some of the pressures associated with dedicated agricultural production, while creating value from materials that might otherwise be discarded. However, second-generation materials must be submitted to the same scrutiny as any other material, and they may not solve the wider problem if their use creates a new point of dependency and competition with other sectors.

Scalability

European Bioplastics (Berlin, Germany) estimates that the global bioplastics production capacity will roughly double to approximately 4.69 million tonnes by 2030.[5] Yet this remains a fraction of the total plastics demand, raising practical questions about the reliability of long-term supply, particularly if multiple sectors turn to bioplastics as their preferred route for decarbonisation. Smaller production volumes can also contribute to higher material costs when compared with established fossil-based polymers, although increasing production capacity, technological development and incentives could narrow the gap over time.[6]

For drug delivery device manufacturers, this is particularly relevant, given the long commercial lifecycles of many products. Devices can remain on the market for many years, making consistent material availability, quality and validated supply important considerations. Introducing a material that is readily available today but dependent on a relatively immature supply chain could create a different form of vulnerability.

Waste Management

Bioplastics is a broad term that can be applied to polymers that are bio-based, biodegradable or both. Indeed, approximately half of current bioplastics are not biodegradable,[7] and even those that are biodegradable or compostable can pose end-of-life issues, including microplastic formation and the need for specific industrial conditions that are not available through conventional waste management systems.

As RecycleLab (Chipping Norton, UK) founder, Danielle Stephens, explains, "What we see is that the material itself rarely makes the difference. It comes down to how the item is disposed of. Whether a part is bio-based or fossil-based, if it goes in the clinical waste bin, it ends up in the same place, and any saving which was intended to be made will be neutralised. If we want to realise the benefit that we set out to get, we must change where the plastic goes at the end, not just what it's made of." RecycleLab specialises in recycling laboratory consumables made of single-use plastics.

> "FOCUSING ON THIS 'QUICK AND EASY' INTERVENTION RISKS OBSCURING THE DEEPER ISSUE: DEPENDENCE ON VIRGIN PLASTIC."

To fully realise the potential environmental impact of bioplastics, existing recycling strategies and waste management systems must be reconsidered to ensure that the intended end-of-life benefit is not lost to incineration or landfill.[8] The implication here is not that bio-based plastics have no value. It is that changing the feedstock does not, by itself, guarantee the most sustainable or resilient route forwards.

BEYOND THE SWAP

Given the highly regulated nature of the medical device industry, a drop-in material can appear significantly less disruptive than changing the architecture or lifecycle of a device. However, focusing on this "quick and easy" intervention risks obscuring the deeper issue: dependence on virgin plastic. Whether the feedstock is fossil-based or biological, a device manufactured from virgin polymers leaves the manufacturer exposed – this exposure is both environmental, as producing a new polymer requires resources and energy, and commercial, as the manufacturer remains dependent on the availability, quality and price of a newly produced polymer.

Polymer supply chains are complex and international, regardless of feedstock. The OECD (Paris, France) notes that international trade plays a significant role at multiple stages of the plastics value chain,[9] creating exposure to fluctuations in raw material availability and energy costs. Trade restrictions, geopolitical tensions and competing demands from other sectors can also increase vulnerability. Recent supply chain disruptions have demonstrated how quickly these factors can affect the availability and price of industrial materials.[10–12]

For drug delivery, the consequences can be particularly significant. Devices are often designed and validated around specific polymers, grades and processing characteristics, and may remain commercially available for many years. As a result, a material cannot simply be substituted whenever market conditions change – changes to material type, formulation, processing or source may require additional assessment and validation to prove that the device continues to meet its safety and performance requirements, adding both cost and complexity.

Reducing the quantity of virgin material required in the first place therefore offers a different kind of resilience; rather than simply seeking alternative sources of virgin polymer when supply becomes constrained, manufacturers can reduce their exposure altogether. This changes the question from "Can we swap this material?" to "How can this device be as sustainable and resilient as possible across its lifecycle?".

DESIGNING FOR CIRCULARITY

Systems that require fewer materials and remain in use longer offer a more structural approach to reducing resource dependence. Material efficiency should be an early design consideration, examining how to reduce parts, lighten components and simplify architectures without compromising performance, usability or safety. Other possibilities include modular or platform-based systems, appropriate reuse, reprocessing and remanufacturing, and designing elements for disassembly and recovery.

While sterility, contamination risk, product stability and patient safety are legitimate concerns with regard to reuse and reprocessing, they should not prevent consideration of circularity during development. Designing for material efficiency or future recovery does not

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necessarily mean creating a reusable product if this is not appropriate. It can simply mean avoiding unnecessary complexity, reducing material demand or making valuable materials easier to recover at end of life.

The potential benefits are not only environmental. By using fewer virgin materials, manufacturers can reduce their exposure to volatile supply chains, constrained feedstocks, rising material costs and future regulatory or procurement pressures. More efficient use of resources can therefore contribute to resilience as well as sustainability.

Circularity does not render bio-based plastics irrelevant. Where virgin materials remain necessary, a lower impact feedstock can still be valuable. However, the impact may be far greater if material substitution is reframed as one potential intervention within a broader strategy, rather than the sole strategy itself.

"THE IMPACT MAY BE FAR GREATER IF MATERIAL SUBSTITUTION IS REFRAMED AS ONE POTENTIAL INTERVENTION WITHIN A BROADER STRATEGY, RATHER THAN THE SOLE STRATEGY ITSELF."

ASSESSING NOT ASSUMING

The challenge for device developers is therefore not simply to identify a material with a better sustainability profile; it is to determine which interventions can truly and measurably deliver the greatest benefits. As sustainability claims are now coming under the same scrutiny as safety and performance claims, this must be demonstrated, not presumed.

Lifecycle assessments (LCAs) provide a framework to compare the environmental performance of different material and design choices across a product or portfolio's lifecycle, looking not only at fossil-based emissions but also land use, land use changes, water use, resource depletion and other environmental indicators.

This is particularly important for bio-based materials, as a reduction in one impact can result in an increase elsewhere, an effect known as "burden shifting". For example, a material may reduce fossil resource consumption or greenhouse gas emissions while creating greater land use impacts. Conversely, a material with a different feedstock may enable lighter components, generating a number of benefits across the product lifecycle, including reduced transport weight, which would be missed if the polymer was considered in isolation.

For instance, a validated, independently reviewed ISO LCA commissioned by Owen Mumford showed that swapping certain fossil-based components of a new reusable autoinjector for PLA-based parts offered only a marginal reduction in the overall product environmental footprint. This highlights the importance of using a consistent and transparent methodology when comparing potential interventions.

For drug delivery, the value of an LCA is not just in establishing whether a bio-based plastic is "better" than a conventional one. It provides a common basis for assessing material substitution, material reduction, modular design, reuse, reprocessing and recovery against the same objective: delivering the required clinical function with the lowest overall environmental burden, while maintaining technical and regulatory feasibility and supply-chain resilience. This also helps to prevent burden shifting, by allowing developers to identify impacts elsewhere in the product lifecycle.

CONCLUSION

Bioplastics have a legitimate role to play in making drug delivery devices more sustainable. In appropriate applications, particularly where drop-in materials can reduce environmental impact without compromising device performance or regulatory requirements, they offer a simple and credible route to improvement.

However, material substitution should not obscure the greater opportunity to reduce the amount of virgin material a device requires throughout its lifecycle.

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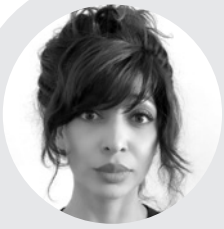
"RETHINKING DEVICE DESIGN CAN SUPPORT BOTH ENVIRONMENTAL GOALS AND SUPPLY-CHAIN RESILIENCE BY REDUCING THE QUANTITY OF NEW MATERIAL THAT THE SECTOR NEEDS TO SOURCE, MANUFACTURE AND ULTIMATELY DISPOSE OF."

Rethinking device design can support both environmental goals and supply-chain resilience by reducing the quantity of new material that the sector needs to source, manufacture and ultimately dispose of. This is why the industry should move beyond asking whether a plastic is bio-based and instead ask whether a device is more sustainable and resilient as a result of its use.

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ABOUT THE COMPANY

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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Expert View

THE SUSTAINABILITY ESCAPE ROOM: HOW PRIMARY PACKAGING TRIES TO GET OUT OF THE EU REGULATORY MAZE

Dr Bettine Boltres, **Joe Monfort** and **Dana Smith**, all of West Pharmaceutical Services, break down the key EU regulatory layers affecting primary pharmaceutical packaging authorisations and explain why sustainability decisions require lifecycle thinking rather than single-attribute claims.

"LCA AND PRODUCT CARBON FOOTPRINT CALCULATIONS ARE BECOMING ESSENTIAL TO SUPPORT DEFENSIBLE DECISIONS, CREDIBLE CLAIMS AND MEANINGFUL COLLABORATION ACROSS THE VALUE CHAIN."

Sustainability in pharmaceutical packaging is often reduced to familiar ideas: less material, more recyclability and more recycled content. For prefilled syringes (PFSs), vials and cartridges, the challenge is more complex. Primary packaging is part of a regulated drug delivery system, and regulators consistently prioritise patient safety and product quality.

In the EU, this creates a sustainability "escape room". The Green Deal sets the ambition – the Packaging & Packaging Waste Regulation (PPWR), Corporate Sustainability Reporting Directive (CSRD) and chemical, water and industrial emissions rules add operational requirements; medical device, medicinal product and good manufacturing practice (GMP) rules define what can actually be changed (Figure 1).

There is rarely one simple exit. Recyclability matters, but it may not always be the most feasible or highest-impact option for sterile systems, such as when a recyclable material option increases sterilisation burden or lacks a viable clinical waste collection pathway. Lifecycle assessment (LCA) and product carbon footprint calculations are therefore becoming essential to support defensible decisions, credible claims and meaningful collaboration across the value chain.

This article considers the escape room door by door, breaking it down into a structured approach. Behind every policy pillar the current status is indicated as follows:

- I – Information
- R – Regulation (automatically binding)
- D – Directive (needs to be translated into national law)
- P – Proposed.

DOOR ONE: THE GREEN DEAL SETS THE RULES OF THE GAME

The first door is the broadest: the European Green Deal. It sets the direction for the EU economy – lower greenhouse gas emissions, circular material use, reduced pollution and safer chemicals. For primary pharmaceutical packaging, this matters because many requirements down the line flow from this policy agenda. Three related policy pillars are important for primary packaging:

1. **EU Climate Law (R)**: Turns the 2050 climate-neutrality objective and 2030 emissions-reduction target into a legal framework.
2. **Circular Economy Action Plan (I)**: Pushes product design, packaging prevention, recyclability and waste reduction higher on the agenda.
3. **Chemicals Strategy for Sustainability (I)**: Increases pressure to identify, control and, where possible, substitute substances of concern.

Taken together, these policies create the framework for more detailed rules on packaging, reporting, chemicals, water and industrial emissions.

DOOR TWO: CORPORATE ACCOUNTABILITY MOVES SUSTAINABILITY INTO THE VALUE CHAIN

The second door is corporate accountability. Under the CSRD, sustainability moves from voluntary messaging into structured reporting.

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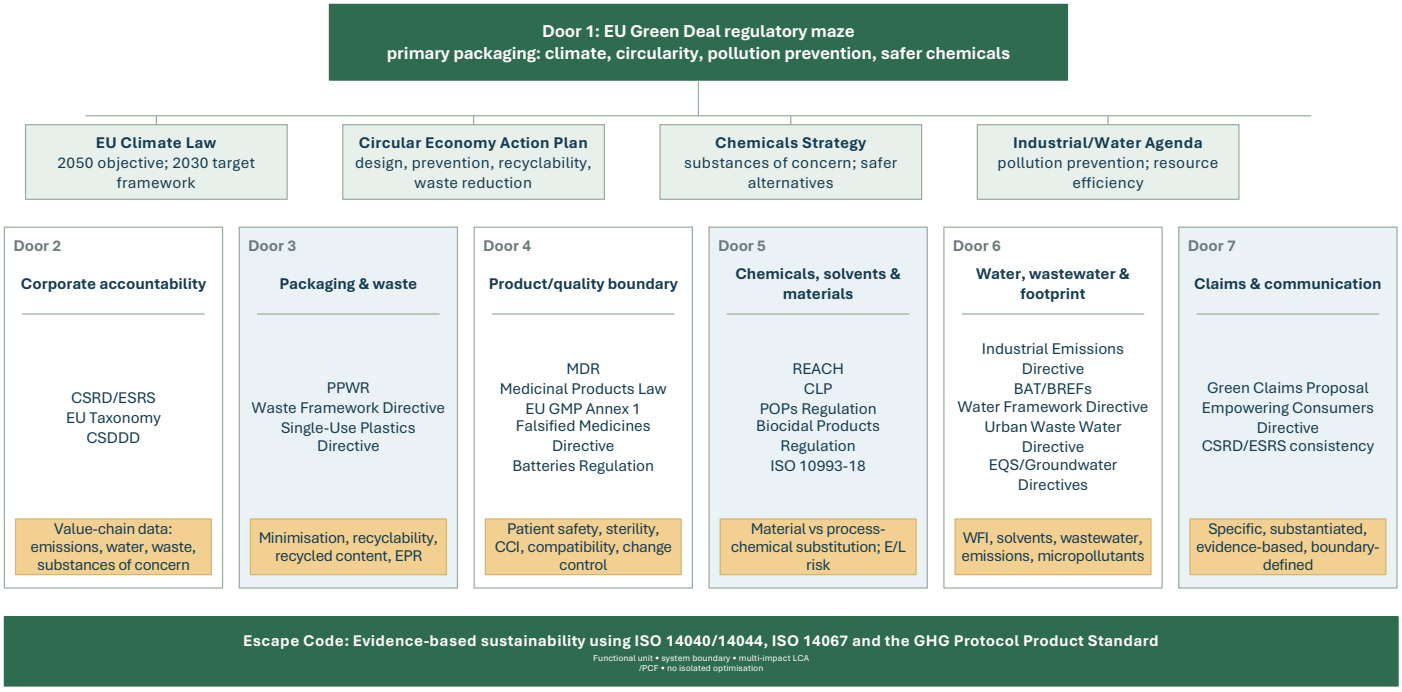


Figure 1: Overview of the sustainability escape room in Europe.

Companies in scope must disclose material impacts, risks and opportunities across metrics such as climate, pollution, water, resource use and circular economy. Therefore, companies must assess and understand both their upstream and downstream risks and impacts. For primary packaging suppliers, this means that customers are increasingly requesting more detailed data on materials, energy, emissions, water, waste and substances of concern. Three related frameworks are important for primary packaging:

1. **CSRD (D) and European Sustainability Reporting Standards (ESRS) (R):** Require structured sustainability disclosure, including value-chain information for packaging materials.
2. **EU Taxonomy (R):** Defines the criteria for environmentally sustainable economic activities and influences investor-facing reporting.
3. **Corporate Sustainability Due Diligence Directive (D):** Increases expectations to identify and address environmental and human rights impacts within value chains.

Taken together, these rules make gathering sustainability data part of commercial readiness. The next competitive advantage will be credible supplier-level evidence, not generic green messaging (which will be discussed in the seventh door).

DOOR THREE: PACKAGING RULES MEET PHARMACEUTICAL REALITY

The third door is packaging-specific regulation. The PPWR strengthens EU expectations on packaging waste prevention, recyclability, recycled content, labelling and extended producer responsibility. For primary pharmaceutical packaging, this is where the maze becomes more complex – syringes, vials and cartridges are not only designed to contain a product but to protect drug sterility, stability and patient safety. Three related frameworks matter for primary packaging waste:

1. **PPWR (R):** Sets requirements on packaging minimisation, recyclability, recycled content, labelling and waste obligations, with applicability and exemptions to be assessed carefully.
2. **Waste Framework Directive (D):** Establishes the waste hierarchy and extended producer responsibility principles.
3. **Single-Use Plastics Directive (D):** Reinforces policy pressure to minimise avoidable single-use plastic waste (though applicability to sterile primary pharmaceutical packaging is limited or conditional, customer perception and public policy pressure can still influence sustainability expectations for single-use healthcare packaging).

Taken together, these rules make recyclability important, but not automatically the highest-impact or most feasible route. For sterile drug delivery systems, packaging choices must be assessed against safety, performance and lifecycle evidence.

DOOR FOUR: PRODUCT DESIGN CANNOT IGNORE DEVICE AND MEDICINAL PRODUCT RULES

The fourth door is the product regulatory boundary. Any sustainability-driven change to a syringe, cartridge, vial system, stopper, plunger, seal, coating or connected delivery system may affect performance, compatibility, sterility, usability or regulatory status. Consequently, material reduction, recycled content use or design-for-recyclability concepts must be evaluated against pharmaceutical and

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device requirements before implementation, meaning that any changes must be handled through an established change-control process like any other regulated product or validated process. Five related frameworks matter for primary packaging quality:

1. **Medical Device Regulation (R)**: Applies where the syringe or delivery system has a device function or is part of a combination product.
2. **EU Medicinal Products Legislation (D)**: Governs quality, safety, efficacy and container-closure expectations for medicines.
3. **EU GMP Annex 1 (Regulatory Guidance)**: Defines requirements for sterile manufacturing, contamination control and validated processes.
4. **Falsified Medicines Directive (D)**: Affects safety features, tamper evidence and verification for certain medicines.
5. **Batteries Regulation (R)**: Relevant only for connected injectors or smart delivery systems containing batteries.

Taken together, these rules explain why primary packaging cannot follow consumer packaging logic directly. Sustainability improvements must be compatible with patient safety, product quality and regulatory change control.

DOOR FIVE: CHEMICALS, SOLVENTS AND MATERIALS ARE UNDER THE SPOTLIGHT

The fifth door is chemical safety. Primary packaging and its manufacturing processes involve polymers, elastomers, coatings, lubricants, adhesives, inks, cleaning agents, disinfectants and solvents. Sustainability improvements therefore need consideration of not only carbon and waste but also hazardous substances, worker exposure, emissions and potential impacts on extractables and leachables. Material substitution and process chemicals substitution should be assessed separately, as each can have different implications for toxicology, supplier qualification, change control and validation. Four related frameworks are important for primary packaging:

1. **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (R)**: Governs registration, authorisation and restriction of chemicals, including substances of very high concern.
2. **Classification, Labelling and Packaging (CLP) Regulation (R)**: Defines classification, labelling and packaging of hazardous substances and mixtures.
3. **Persistent Organic Pollutants Regulation (R)**: Restricts persistent substances that may be relevant to material, additive or supply chain screening.
4. **Biocidal Products Regulation (R)**: Applies to disinfectants, preservatives, antimicrobial treatments and certain production-environment chemicals.

Taken together, these rules make chemical substitution an important

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sustainability option. However, any "safer" or lower-toxicity alternative must still meet pharmaceutical performance, compatibility and quality requirements (through an established change-control process) because, as already mentioned, alternative approaches do not automatically mean lower impact.

DOOR SIX: WATER, WASTEWATER AND MANUFACTURING FOOTPRINT

The sixth door is the production footprint. For primary packaging, sustainability is not only determined by the final syringe, vial or cartridge – it is also shaped by manufacturing operations using purified water and water for injection (WFI), component washing, sterilisation, cleanroom utilities, cooling systems, solvent use, wastewater treatment and process emissions. There are five related frameworks for primary packaging:

1. **Industrial Emissions Directive (D)**: Sets requirements for pollution prevention and control for certain industrial installations, including emissions, waste, water and solvent management where in scope.
2. **Best Available Techniques (BAT)/BAT Reference (BREF) documents (I)**: Define BATs that can guide reductions in water use, wastewater load, emissions and resource consumption.
3. **Water Framework Directive (D)**: Provides the overarching EU framework for protecting water bodies and managing water quality.
4. **Urban Waste Water Treatment Directive (D)**: Affects industrial wastewater entering municipal systems and strengthens focus on treatment and micropollutants.
5. **Environmental Quality Standards and Groundwater Directives (D)**: Set controls relevant to hazardous substances, discharges and contamination risks.

Taken together, these rules broaden the sustainability discussion beyond packaging design. Water efficiency, solvent recovery, wastewater quality and emissions control can be material contributors to the environmental profile of sterile primary packaging.

> "AS EU RULES TIGHTEN, ENVIRONMENTAL CLAIMS NEED TO BE SPECIFIC, SUBSTANTIATED AND CONSISTENT WITH UNDERLYING EVIDENCE."

DOOR SEVEN: CLAIMS, COMMUNICATION AND THE RISK OF GREENWASHING

The seventh door is communication. As EU rules tighten, environmental claims need to be specific, substantiated and consistent with underlying evidence. Terms such as "green", "eco-friendly", "sustainable" and "carbon neutral" can create risk if they are not supported by clear boundaries, methods, data and verification. There are three related frameworks for primary packaging:

1. **Green Claims Directive Proposal (P)**: Would require explicit environmental claims to be substantiated and communicated with defined evidence.
2. **Directive on Empowering Consumers for the Green Transition (D)**: Restricts generic or misleading environmental claims and sustainability labels.
3. **CSRD (D) and ESRS (R)**: Create consistency between public claims, corporate reporting and value-chain sustainability data.

Taken together, these rules make LCA-based decision-making more defensible than single-attribute claims. For PFSs, vials and cartridges, claims should be precise, evidence-based and limited to what the data can support.

THE ESCAPE CODE: EVIDENCE-BASED SUSTAINABILITY

To successfully step through all doors and get out of the escape room alive, device developers must always apply the escape code: the evidence base. In the pharmaceutical world, sustainability decisions should not rely on a single metric, such as weight reduction, recycled content or recyclability. Each option needs to be assessed against patient safety, product quality, regulatory feasibility and lifecycle impact. There are six assessment steps for primary packaging:

1. Define the functional unit (e.g. one sterile PFS) and system boundary, including manufacturing, sterilisation, transport, use and end-of-life
2. Apply LCA or product carbon footprint methods to compare options consistently
3. Assess multiple impact areas, including climate, water, waste, circularity, chemical safety and resource use
4. Confirm both product feasibility through stability, compatibility, extractables/leachables, performance testing and manufacturing feasibility to ensure that a product can be manufactured and run on fill-finish lines
5. Evaluate regulatory change-control implications before implementation
6. Substantiate any external claim with transparent assumptions, data quality and defined boundaries.

Taken together, these basics provide the "escape code" for the maze. The strongest sustainability position is not the loudest claim, but the one with the most robust evidence.

CONCLUSION

Escaping the maze requires prioritisation, not slogans. In 2023, the EU generated about 177.8 kg of packaging waste per person,[1] and PPWR now pushes packaging towards recyclability, waste prevention and stronger evidence. However, pharmaceutical primary packaging sits in a different risk category from consumer packaging. Changing one component or material to reduce weight or improve recyclability triggers questions on safety, stability, extractables/leachables, sterilisation, machinability, etc.

A very practical route is to build a system-level "sustainability file". For each syringe, vial or cartridge format, companies should quantify material mass, product carbon footprint, manufacturing energy, water use, WFI losses, solvent use, scrap rates, transport assumptions and end-of-

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life constraints. This is important because healthcare is estimated to contribute around 4.4% of global net greenhouse gas emissions,[2] and laboratories can use several times more energy per square metre than a typical office space. In some cases, the best first option may not be recyclability, but reducing rejects, optimising secondary packaging, switching to renewable electricity, recovering solvents, reducing cleanroom utility demand or improving supplier data quality.

The final door cannot be opened by one company alone. Waste handling is the clearest example – a component is only recyclable if collection, segregation, contamination control, waste classification, logistics and recycling capacity exist, which is particularly challenging for sharps, biohazard contaminants and clinical waste, as in the case of PFSs and other injection systems. Public take-back pilots for injection pens, such as for Novo Nordisk's (Bagsværd, Denmark) PenCycle,[3] show the direction of travel, as well as underlining the system challenge.

For PFSs and other immediate packaging formats, meaningful progress will require common industry positions, collaboration with waste handlers, clearer recycling pathways, regulator engagement and shared data standards. In this maze, the real escape code is not an individual material change choice; it is co-ordinated industry infrastructure backed by defensible evidence such as shared data standards, harmonised LCA assumptions, take-back infrastructure pilots and regulator engagement on acceptable sustainability-driven changes.



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ABOUT THE COMPANY

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

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WHERE CONTENT MEETS INTELLIGENCE ON drugDELIVERY

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Expert View

WHY THE GREENEST POLYMERS NEVER REACHED SCALE

Athanasios Garoufas and **Laura Armenio**, both of Gelatex Technologies, discuss how the sustainability profile of a material is baked-in at its production, examining how traditional methods for producing polymers fail to unify both environmentally favourable feedstock and industrial-scale production capacity, and consider the advantages that next-generation methods that bring these two key aspects together could bring to not only drug delivery but the wider industry.

Sustainability in drug delivery is usually discussed at the end of product development, when considering aspects such as packaging, the device and its disposal. The decisions that guide production, however, are made much earlier. The contribution to the carbon footprint from material selection is fixed by the way the material is manufactured. In a fibre-based product, the polymers that can be used are largely decided by the process used to turn them into a fibre.

"THESE ARE MANUFACTURING QUESTIONS, AND THEY SET THE CEILING ON EVERYTHING A SUSTAINABILITY CLAIM CAN HONESTLY SAY AFTERWARDS."

WHAT IS A SUSTAINABLE POLYMER?

From a pragmatic point of view, it can be argued that the question is not about whether a given polymer is bio-based or biodegradable – many polymers are one or both. The real question is whether or not a polymer can be turned into a fibre at all, and whether it can be done at a scale needed for a commercial product. These are manufacturing questions, and they set the ceiling on everything that can be honestly said in a sustainability claim afterwards.

It is worth being precise about what such a claim even means, because the industry is full of single-attribute statements that do not survive a lifecycle-scale view. "Bio-based" describes where the feedstock came from. "Biodegradable" describes what happens to the polymer at its end of life. Neither aspect on its own provides information about the carbon footprint per functional unit across the product's lifecycle, and neither is the same as being sustainable.

A bio-based polymer spun from an aggressive solvent, or a biodegradable one that only breaks down under industrial composting the product will never see, are no better than the incumbent polymers they might replace. The useful frame is not a label – it is the full accounting of feedstock, solvent and process; energy per unit of usable material; how much material and API are actually needed; and what happens at end of life. It makes sense to start with the manufacturing process, because this introduces a real constraint.

"THE POLYMERS WITH THE BEST SUSTAINABILITY PROFILES, THE ONES DERIVED FROM BIOLOGICAL SOURCES, ARE EXACTLY THE ONES THAT ARE UNSUITABLE FOR MELT-BASED PROCESSES."

CURRENT MANUFACTURING PROCESSES

Broadly speaking, there are currently two primary ways to turn a polymer into fibre at industrial scale. Melt-based processing includes melt-blowing, a process already operated at very high throughputs for nonwovens, up to 150 kg per hour per metre of line width.[1] Melt-blowing is efficient and uses no solvent at all, which is a real advantage. At the same time, however, this can only be a process for polymers that have a stable melt phase, which, in practice, means mostly petroleum-derived thermoplastics. The polymers with the best sustainability profiles, the ones derived from biological sources, are exactly the ones that are unsuitable for melt-based processes.

The reason why melt-based processing cannot be used with biologically derived polymers is a mechanistic one – or, more precisely, a thermal one. Proteins such as collagen, gelatin and silk, as well as polysaccharides such as chitosan, pullulan,

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carboxymethyl cellulose and alginate, simply do not have a true melt phase. They denature, degrade or char long before they get there. You cannot melt-blow gelatin, and so the scalable melt route is closed off for the whole class of natural polymers.

One thing to be mindful of, of course, is that biodegradability and biological origin are not the same property. There are synthetic biodegradable polyesters, polylactic acid (PLA) and polycaprolactone (PCL) among them, that melt and are melt-processed all the time, but they are chemically synthesised rather than extracted from a biological source, and, of the two, only PLA is even bio-based, with PCL being derived from petroleum. So the polymers that cannot be melted are the ones that genuinely come from biological sources, which happen to be the same ones with the strongest feedstock and end-of-life sustainability profiles.

What remains practical at scale for these polymers is solution spinning, in which the manufacturer dissolves the polymer, forms the fibre and then removes the solvent. There are other non-melt routes – protein self-assembly and bacterial biosynthesis among them – but they are niche or hard to scale into an engineered membrane. Solution spinning is entirely capable of handling natural polymers, and can do so using benign solvents. Gelatin, for one, can be spun from water alone, and newer solution-spinning methods can be particularly well suited to aqueous systems of this kind. And this is the critical point – the primary flaw of solution spinning in sustainability terms is the solvent, and that flaw is at its weakest right where the bio-based benefit is at its strongest.

Among the solution-spinning methods available, the most established one – electrospinning – has been around for the best part of a century, and it does not really scale. A single spinneret produces polymer at a rate of 0.01–0.1 grams per hour and, although multi-needle and needleless configurations can do better than that, throughput has remained the recognised bottleneck for industrial use.[2,3] Even a purpose-built high-throughput laboratory system tops out at a few grams per hour.[4]

Electrospinning proved decades ago that bio-based nanofibre can be made. What it never proved is that these materials can be made at the volume and cost that a commodity product needs. So, until recently, the situation was a choice between two incomplete options – melt-based methods that scale but exclude the sustainable polymers, whereas conventional solution-spinning methods include those polymers but do not scale. Neither delivered both, and that, more than any question of chemistry, is why bio-based nanofibre mainly stayed in the laboratory.

"ELECTROSPINNING PROVED DECADES AGO THAT BIO-BASED NANOFIBRE CAN BE MADE. WHAT IT NEVER PROVED IS THAT THESE MATERIALS CAN BE MADE AT THE VOLUME AND COST THAT A COMMODITY PRODUCT NEEDS."

NEXT-GENERATION SOLUTION SPINNING: SOLVING SCALE

This status quo is changing. Modern methods using advanced solution-spinning techniques are able to keep what makes a solution-based route appealing in the first place – access to the natural polymers and to the benign solvents that melt methods cannot touch, while working comfortably at production throughputs of kilograms per hour, territory that, like for like, conventional electrospinning struggles to enter. The difference is not only one of scale, though. Modern solution spinning can create finer fibres and more open, interconnected mats, rather than the dense layer produced by electrospinning. Put the two together – the scale and the morphology – and a bio-based nanofibre becomes something that pharmaceutical companies can actually build a product around.

Strictly speaking, this is not an all-green process, and it should not be presented as one. Some medical formats use polyesters that still need organic solvents, and the solvent chemistry is largely shared among solution methods, so there is no solvent advantage to claim over electrospinning as such in these cases. The differentiation is narrower than that, and more honest for it. In essence, it comes down to access to the sustainable polymers that cannot be produced using melt-based methods, combined with a scale that conventional solution methods cannot reach.

Scale also changes the energy picture because, in fibre production, energy consumption is dominated by throughput; energy per kilogram of usable material falls as output rises. In lifecycle accounting, this is one of the larger levers for improving sustainability, although it only moves once the process itself can run efficiently at volume.

There is a second consequence of solving the scale problem, and it reaches well beyond drug delivery. The same polymer family can be produced at different grades – technical, cosmetic, food, pharmaceutical – and it is the grade, not the platform, that decides which sector the material can serve. So, once a bio-based nanofibre can be made at scale, one process can address applications sitting in completely different regulatory worlds, at which point the sustainability argument ceases to be about a single product – it becomes about reach.

THE BIGGER PICTURE

In drug delivery itself, biopolymers and protein nanofibre are already well-studied and comparatively sustainable materials.[5] A nanofibre membrane does its job with a very low mass of material, and release can be tuned through polymer choice and layering, which increases the amount of API actually used, rather than lost as overage, and since the API is the largest single contributor to both cost and carbon footprint, that efficiency matters. Sustained local release from drug-eluting mats produced using next-generation solution-spinning methods has been tracked *in vivo* and modelled[6] – not just inferred from a dissolution bath – which is the level of evidence to which such a claim should be held.

The larger sustainability prize, though, may well be in the commodity sectors, where scale has always been the barrier. Take hygiene as an example. The superabsorbent material in a modern nappy

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is sodium polyacrylate – a petroleum-derived, non-biodegradable material used in very large volumes. Bio-based absorbents based on cellulose, nanocellulose and carboxymethyl cellulose are currently being investigated,[7–9] and a nanofibrous form is attractive for two distinct reasons. The high surface-to-volume ratio provides strong absorbency, and the fibre network distributes and wicks liquid better than a bed of particles, which is a significant functional gain in the acquisition and distribution layer, as well as offering improved sustainability.

What has been missing is not the chemistry but the ability to make bio-based nanofibre at hygiene-industry volumes, and the arithmetic there is simple. At that scale, even a partial substitution, a few percent, is a large absolute reduction in fossil-derived, non-degradable materials. Therefore, the realistic target is not to replace the incumbent outright – it is to make partial replacement viable at scale, which conventional methods could not do.

Filtration follows the same logic. Nanofibre-based media give high filtration efficiency at low pressure drop,[10] which also means less energy is required to push air or fluid through the filter, and a biopolymer version would be biodegradable where petroleum-based polymers are not. This is another commodity sector, and another one gated by scale rather than by the science.

Food technology is the less obvious one, and it connects to the same platform directly. Edible nanofibre scaffolds are being developed for cultivated meat, where the scaffold has to be edible and animal-free and, for anything resembling a whole cut, has to guide cell differentiation and texture rather than just support proliferation. Nanofibre and related scaffolds mimic the extracellular matrix and can support that differentiation, with fibre diameter and porosity tunable to the same end.[11,12]

CONCLUSION

In all cases, the key point is that the sustainability of a fibre-based material is set upstream by which polymers can be used and at what scale. What has been missing until now was the ability to produce sustainable polymers at an industrial scale. In drug delivery, this manifests as a more material-efficient format, in hygiene and filtration as a bio-based substitution that finally has a route to volume, and in food technology as an edible scaffold that can be made at more than laboratory quantity. Different sectors, but the same underlying principle.

It should be highlighted that there are still limits. A solution route still uses

"WHAT HAS BEEN MISSING UNTIL NOW WAS THE ABILITY TO PRODUCE SUSTAINABLE POLYMERS AT AN INDUSTRIAL SCALE."



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solvent, resorbable is not the same as compostable and a sustainability claim is only worth as much as the lifecycle accounting behind it. But the framing is the useful part – for most of the history of nanofibre materials, the sustainable polymers and the scalable process were mutually exclusive, and the field got used to treating bio-based nanofibre as a laboratory curiosity. That constraint is no longer fixed. Once the greenest polymers can be spun at scale, sustainability in these products stops being a story told at the disposal end and becomes a decision made at material selection, which is where it belonged in the first place.

ABOUT THE COMPANY

Gelatex Technologies is a materials technology company specialised in the high-throughput manufacturing of nanofibrous materials using proprietary halospinning technology, a fast and cost-effective modern solution-spinning process. It provides products for 3D cell culture and tissue engineering, and services for customised solutions.

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REDUCING COMMERCIALISATION RISK IN DRUG DELIVERY DEVELOPMENT

Dr Frank Engel Rasmussen and **Mark Ypsilantis** of MGS discuss how early decisions on functional device design affect downstream production choices, highlighting the importance of integrating scale-up considerations from the outset, across all development teams.

THE GROWING COMPLEXITY OF DRUG DELIVERY DEVICES

Drug delivery requirements are continuing to evolve alongside increasingly complex therapies. Recent research points to high-concentration biologics and larger-volume injections as key factors that are shaping the development of autoinjectors,[1] as on-body delivery systems and large-volume autoinjectors expand beyond the traditional 1–2 mL volume limitations of existing devices.[2]

For product development teams, this means balancing a growing set of requirements within a single device. Greater fill volumes and higher-viscosity formulations can introduce new technical demands, while usability, human factors and patient needs remain central to the delivery experience. Meanwhile, device platforms and delivery technologies continue to expand the options available for how and where therapies are administered.

Navigating this complexity requires more than a glance at each individual requirement. Development teams must balance product performance, patient needs, quality and speed-to-market while also considering how to ensure that individual device parts and subassemblies work together reliably when assembled with the primary packaging and as part of the final combination product.

BUILDING THE BRIDGE FROM DESIGN TO PRODUCTION

The path from a new drug delivery concept to commercial production is shaped long before a device leaves the manufacturing floor. Decisions made throughout product design and development influence not only how the device performs for the patient but, ultimately, how it can come to life through tooling, moulding and assembly (Figure 1).

"DECISIONS MADE THROUGHOUT PRODUCT DESIGN AND DEVELOPMENT INFLUENCE NOT ONLY HOW THE DEVICE PERFORMS FOR THE PATIENT BUT, ULTIMATELY, HOW IT CAN COME TO LIFE THROUGH TOOLING, MOULDING AND ASSEMBLY."



Figure 1: A commercial-scale production floor, where injection moulding and automated assembly bring device designs from development to high-volume manufacturing.

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That connection is particularly important for combination products, where product performance, usability, material selection, component architecture and manufacturing requirements are closely interconnected. Decisions made to address one requirement will most likely have implications elsewhere, making it important to balance both device performance and production requirements as designs evolve.

As therapies become more sophisticated and combination products more complex, bringing downstream considerations into development earlier can help teams to identify potential challenges before design decisions become more difficult and costly to change. Decisions on product architecture, tolerancing, materials, tooling, automation and manufacturing strategy can subsequently be made with a clearer understanding of what will be required for commercial production.

That flexibility narrows as development progresses. By the time validation is complete or production tooling has been commissioned, even relatively small design changes can have significant cost, scheduling and regulatory implications. The question, then, is not simply, "Can this device be manufactured?", it is "Are the decisions being made today creating a clearer path to commercial production?".

DESIGN DECISIONS SHAPE WHAT COMES NEXT

The foundation of successful combination product design and development is simple: every drug delivery device must perform safely and reliably. However, preparing a device for commercialisation requires development teams to consider much more than just functional performance in the hands of the end user.

In a multicomponent drug delivery device such as an autoinjector, seemingly small decisions made regarding materials, tolerances, part geometry and component architecture during the product design and development stages can have implications well beyond the performance of individual components (Figure 2). Material selection influences moulding behaviour, process capability and long-term supply chain flexibility. Part geometry affects tooling complexity, cooling performance and production cycle times. Component architecture shapes assembly strategies and automation potential. Tolerance decisions determine how consistently products can be manufactured at commercial volumes and how much process control will ultimately be required.



Figure 2: A design engineer reviews a 3D computer-aided design model of a device component, evaluating geometry, tolerances and material behaviour to assess usability, manufacturability and performance.

Viewed independently, these appear to be routine product design decisions. Viewed collectively, they establish the foundation for successful commercialisation. A design that meets its functional requirements is not necessarily ready for commercial-scale production. The same decisions that shape device performance also influence whether that device can be manufactured consistently and efficiently at the cost and volumes required for commercialisation.

The implications become clearer when individual design decisions are considered in the context of commercial production. A tolerance that appears reasonable on paper may require process controls that increase production costs or reduce manufacturing flexibility. Materials selected to optimise performance may introduce sourcing challenges, extend production lead times or respond differently to the thermal and processing demands of injection moulding. Ultimately, these challenges add up to project delays, inflated costs and missed opportunities due to costly rework and resource investments.

Assessing manufacturability is not about limiting innovation or forcing engineering compromises. Device decisions must support performance, usability and sustainability requirements while also accounting for high-volume production and assembly. Balancing those requirements throughout development can help to reduce the risk of extended validation timelines, delayed technology transfer, unplanned tooling revisions, lower manufacturing efficiency and higher total programme costs.

CONNECTING DEVELOPMENT AND TOOLING

Tooling provides a clear example of how early collaboration can positively impact both product design and development, and the path to production.

For injection-moulded drug delivery components, collaboration between designers and tooling engineers can

"THE SAME DECISIONS THAT SHAPE DEVICE PERFORMANCE ALSO INFLUENCE WHETHER THAT DEVICE CAN BE MANUFACTURED CONSISTENTLY AND EFFICIENTLY AT THE COST AND VOLUMES REQUIRED FOR COMMERCIALISATION."

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inform decisions around part geometry, material behaviour, gate location, cooling, tolerances and other factors that influence both component performance and mould design. Evaluating these factors while the product design and tooling strategies are still taking shape gives teams further opportunities to adjust designs and improve manufacturability before investing in full-scale production tooling.

The tooling strategy can also evolve alongside the programme, creating opportunities to generate manufacturing insights as device and component design take shape – hybrid tooling is one example. By combining lower-cost aluminium and high-quality steel components, hybrid tools provide injection-moulded parts under real production conditions on the path to high-volume production tooling (Figure 3). For autoinjectors and other combination products, this interim step can allow teams to evaluate usability, function and manufacturability, applying what they learn before key product and tooling specifications are finalised.

The insights gained through approaches such as hybrid tooling have value beyond immediate product design and development conversations. When design and development, tooling and automation teams work together early on, the knowledge gained during these stages can carry forwards into mould design and ultimately into manufacturing. This connection helps to reduce unnecessary hand-offs and rework while supporting a smoother path to commercial-scale production.

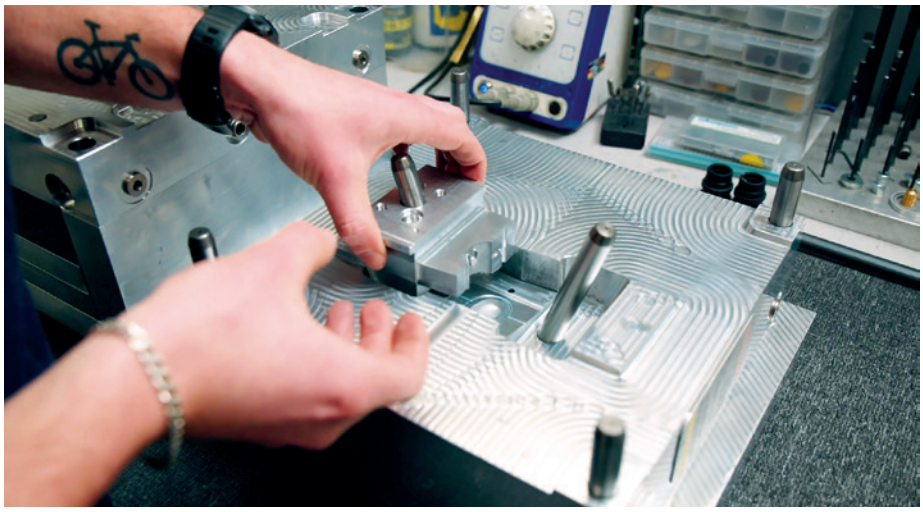


Figure 3: Hybrid tooling in action, combining aluminium and steel components to validate part performance with real injection-moulded parts produced under production-relevant conditions.

MANUFACTURING EXPERTISE HAS THE GREATEST VALUE BEFORE PROBLEMS EXIST

As device design moves forwards, the connection between development, tooling, automation and production becomes increasingly important. Manufacturing and automation teams bring additional perspectives on how components will be produced, handled, assembled and inspected at full-scale production volumes. Integrating that expertise into development can help teams to account for production requirements before they translate into manufacturing challenges or design revisions.

This insight can be applied through design for manufacturability (DFM) and design for assembly (DFA) reviews, which bring manufacturing and assembly considerations directly into the design and development process. DFM reviews evaluate mouldability, material behaviour, draft angles, wall thickness and tolerance strategies. DFA reviews examine how drug delivery device components will be oriented, handled, inspected and assembled under fully automated commercial manufacturing conditions rather than the more controlled conditions of development builds.

These activities are often viewed as manufacturing practices. In reality, they are product development practices because they influence design transfer, process validation, manufacturing efficiency and long-term scalability.

Automation brings another perspective to these early decisions. Manual assembly may support early builds and lower-volume programmes but, as drug delivery devices move towards higher production volumes, factors such as automated handling, inspection and assembly can become

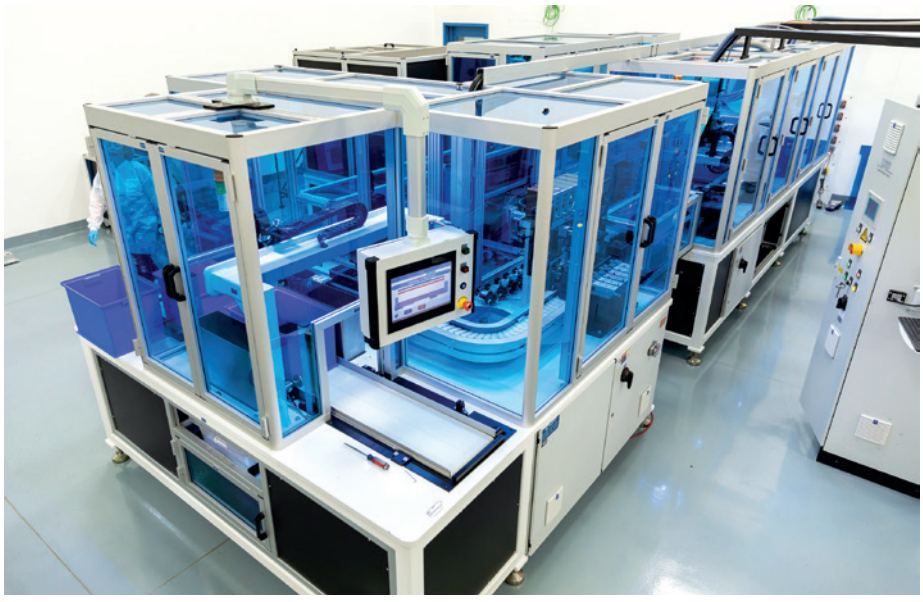


Figure 4: Automated assembly cells inspect and assemble device components with the precision, consistency and throughput required for commercial-scale manufacturing.

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increasingly important for consistency, throughput and quality (Figure 4). The real value in considering automation early on is not in teaching teams what automation can do. It is understanding how early design decisions determine whether automation is feasible, efficient or unnecessarily complex. In turn, this can have significant impacts on commercial readiness.

Together, these perspectives give development teams a more complete view of how a design will translate at the manufacturing stage. Bringing this expertise together while designs are still evolving creates more opportunities to address manufacturability, assembly and scale-up considerations before changes become too complex to implement.

INTEGRATING SUSTAINABILITY INTO DEVELOPMENT

For many single-use drug delivery devices, sustainability considerations begin with the same decisions that shape the product and its manufacturing strategy. Material selection, component architecture, manufacturing methods and packaging strategies all influence environmental impact while also affecting manufacturability, assembly and long-term production efficiency.

Each of these decisions presents opportunities to improve environmental performance while also strengthening manufacturability. Optimising material use can reduce environmental impact while supporting efficient manufacturing. Consolidating components, where technically appropriate, can streamline assembly, reduce tooling requirements and minimise opportunities for variation. Optimised mould design and cooling strategies can reduce energy consumption while lowering scrap rates and improving cycle times. Packaging decisions can influence transportation efficiency, warehousing requirements and overall patient adherence just as much as they affect environmental impact.

Evaluating these opportunities during development requires teams to consider sustainability alongside performance, usability and manufacturability rather than as a separate requirement to be addressed after design freeze. It also reinforces the value of bringing different perspectives into development as decisions are made to improve quality and accelerate time-to-market.

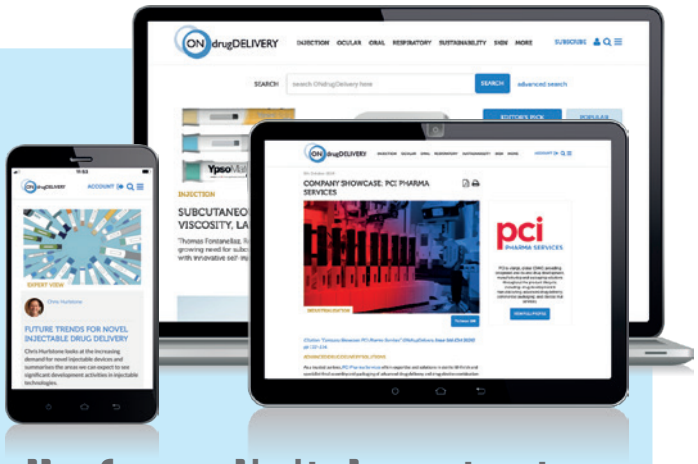
CREATING CONTINUITY FROM DEVELOPMENT TO PRODUCTION

Transferring a drug delivery device from development to high-volume production requires more than siloed expertise. It requires continuity across all aspects of development. Decisions made at design and development stages directly impact tooling design. Tooling decisions affect automation and manufacturing. Quality, regulatory, human factors, sustainability and supply chain considerations also add requirements that need to be understood holistically.

The value of cross-functional collaboration is not simply having each discipline represented. The value lies in the creation of opportunities when those perspectives inform one another as decisions are finalised. When teams share knowledge throughout product development, insights gained in one area can support decisions made in another. This creates a more complete understanding of how to efficiently

> "EVALUATING THESE OPPORTUNITIES DURING DEVELOPMENT REQUIRES TEAMS TO CONSIDER SUSTAINABILITY ALONGSIDE PERFORMANCE, USABILITY AND MANUFACTURABILITY RATHER THAN AS A SEPARATE REQUIREMENT TO BE ADDRESSED AFTER DESIGN FREEZE."

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and effectively move products towards commercial readiness – without rework.

For a combination product, the impact of that connection is particularly important. Product design engineers optimise product features for usability. Quality and regulatory teams evaluate compliance requirements; human factors specialists focus on usability; tooling specialists consider mould complexity and production efficiency; automation engineers assess assembly, inspection and packaging feasibility; manufacturing engineers evaluate process capability; and supply chain teams identify sourcing risks and long-term scalability. Individually, each competency provides a critical insight into the path to production. Together, their impact extends across the entire programme – accelerating time-to-market, protecting product quality and driving efficiency from start to finish.

A turnkey CDMO model can create this continuity within one integrated team. Rather than transferring knowledge, designs and tools between disparate partners, teams can carry insights and decisions forwards as the product progresses to production.

BUILDING FOR THE FUTURE

As drug delivery devices and combination products become more complex, development teams must balance evolving patient, product, regulatory and manufacturing requirements without compromising quality or speed.

No single decision or discipline determines whether a product will successfully reach commercial production. What matters is how those decisions and areas of expertise allow teams to work together throughout the programme. Connecting teams across design and development, tooling, automation and manufacturing with quality, regulatory, human factors and sustainability expertise enables knowledge to expand as device designs evolve.

This continuity can help teams to maintain product quality, accelerate time-to-market and move towards scale with greater confidence. For drug delivery innovators, the path to commercial production is not a series of isolated stages but a connected journey from design through manufacturing.

ABOUT THE COMPANY

MGS is a global healthcare CDMO dedicated to transforming clients' challenges into innovations that improve lives. With deep expertise and vertically integrated global capabilities, the company accelerates innovation for leading pharmaceutical, diagnostic and medtech companies, bridging the gap between imagination and realisation to drive patient outcomes.

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GRAM's Sterile Filling Facility One opened in 2020 and features production lines approved by both the EU and the US FDA. The facility has the capacity to produce over 80 million vials as well as more than 10 million syringes and cartridges per year.

"FOR PHARMACEUTICAL COMPANIES, CHOOSING A CDMO GOES BEYOND ASSESSING CAPACITY; IT IS ABOUT FINDING A PARTNER COMMITTED TO QUALITY AND INNOVATION."

Sterile Filling Facility Two is the company's newest sterile filling facility, equipped to provide over 50 million units of syringe and cartridge filling capacity annually, starting with Line 5 (Table 1). This facility includes the infrastructure needed for future expansion to support client needs and meet market demand.

For pharmaceutical companies, choosing a CDMO goes beyond assessing capacity; it is about finding a partner committed to quality and innovation. GRAM is dedicated to delivering consistent, high-quality sterile fill-finish services that empower pharmaceutical companies in their mission to improve patient outcomes. Specialising in biologics, GRAM's five filling lines serve pharma's liquid or lyophilised vial, syringe and cartridge products.

Line 1: Liquid & Lyophilised Vials	Line 2: Liquid Vials	Line 3: Prefilled Syringes & Cartridges
• Bausch+Ströbel • SKAN isolator • 4-head • IMA lyophiliser • 2R, 6R, 10R, 20R, 50R • 20 million units/yr • 6,200 lyo hr/yr • EU/FDA approved	• Bausch+Ströbel • SKAN isolator • 4-head • 2R, 6R, 10R, 20R, 25R • Up to 12,000 units/hr • 20–25 million units/yr • Identical to Line 1 • EU/FDA approved	• Bausch+Ströbel • SKAN isolator • 1/2-head • PFS: 1, 2.25, 3 mL • Cartridges: 3, 5, 10, 20 mL • 1,000–3,000 units/hr • 8–10 million units/yr • EU/FDA approved
Line 4: Liquid Vials	**Line 5: Prefilled Syringes & Cartridges**	**Available Future Space**
• Bausch+Ströbel • SKAN isolator • 8-head • 2R, 6R, 10R • External vial washer • 24,000 units/hr • 40–50 million units/yr	• Groninger • SKAN isolator • 10-head • PFS: 1, 2.25, 3 mL • Cartridges: 5, 10 mL • 24,000 units/hr • 40–50 million units/yr • Media Runs Q1 2027	Space and utilities to support three additional fill lines and client-dedicated projects 

Table 1: GRAM's fill-finish lines.



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ASEPTIC MANUFACTURING

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Image of the new sterile filling platform taken during the FAT. Source: groninger



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See **Page 02**

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

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