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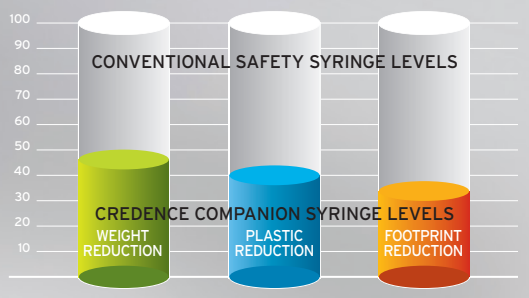

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Contents

SUSTAINABILITY IN DRUG DELIVERY

ONdrugDelivery Issue N° 171, April 29th, 2025

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

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Materials and Methods:

Making Progress Through Sustainability Across the Drug Delivery Industry

In this issue of ONdrugDelivery, we cover the topic of sustainability and how it applies to the drug delivery industry. Sustainability only becomes more relevant with each passing year, with no industry exempt from policies and regulations that aim to address this vital subject.

The issue opens with an interview with Chris Baron of **Aptar Pharma** (Page 08), discussing one of the biggest challenges faced by the pulmonary sector – the transition away from current hydrofluoroalkane propellants that, as powerful greenhouse gases, are responsible for a significant portion of the entire sector's carbon footprint, to alternatives with much lower global warming potential. The interview focuses on Aptar's contribution to this effort as a well-established supplier of components for metered dose inhalers with the development of the ZEN30 Futurity™ metering valve, which has been designed specifically with the two leading next-generation propellants in mind.

Continuing with a focus on devices, **Ypsomed** (Page 14) offers a detailed explanation of how the principles and practices of the company's Net Zero Program have been applied to its broad portfolio of autoinjectors and pen injectors. **Stevanato Group** (Page 22) further contributes to the discussion with a Product Showcase offering insights into a user preference study conducted by the company to determine how much sustainability factors feature in patient thinking and feedback.

Sustainability is not only a concern for product design, however. **PCI Pharma Services** (Page 26) goes into depth on how supply-chain practices and procurement procedures are critical aspects to address if the drug delivery industry wants to make real progress towards its sustainability targets. A similar point is made in an Expert View from **CluePoints** (Page 48) which shines a light on the oft discussed subject of artificial intelligence and how it can be applied to make clinical trials and drug discovery practices more effective and sustainable.

Starting with a discussion from **ALBIS** (Page 31) on how to bring sustainable polymers to drug delivery devices, this issue also features a strong focus on the materials that are required to make the transition to a more sustainable industry. Following that, we feature an Early Insight from **BIOVOX** (Page 36) that foregrounds the potential of bioplastics, and dispels myths about them along the way. Moving from polymers to pigments, **ELIX Polymers** (Page 41) enters the discussion with a piece highlighting the value of using pre-coloured plastic from both a sustainability and convenience perspective. Rounding out this section, **NIRI** (Page 44) contributes an Expert View article about the urgent need to address the use of PFAS and find viable alternative materials.

The issue closes as it begins, with an interview. The final word is given by Patrick Anquetil of **Portal Instruments** (Page 52) in a wide-ranging discussion with ONdrugDelivery's Guy Furness, covering topics from the key role of connectivity in the future of sustainable, reusable devices to how sound economics and environmental sustainability go hand in hand.

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Interview: The Transition to Lower-Global-Warming-Potential Propellants in pMDIs

The transition to lower-global-warming-potential (GWP) propellants in pressurised metered dose inhalers (pMDIs) will play a significant role in reducing the carbon footprint of inhaled asthma and chronic obstructive pulmonary disease medications – a key factor for meeting the environmental goals of pharmaceutical companies with a large respiratory pMDI portfolio. The hydrofluoroalkanes (HFAs) currently used as propellants have a high GWP rating and produce significant CO_2 emissions. Reducing emissions from all sources, including medicines and their delivery systems, is essential to meeting climate change goals.

Aptar Pharma's Chris Baron discusses how, in response to this challenge, the company has developed a new metering valve technology platform – ZEN30 Futurity™ – that is compatible with leading lower-GWP propellants. By collaborating with drug developers, regulators and the pMDI supply chain, Aptar Pharma aims to support the reduction of the CO_2 footprint of pMDIs while ensuring that the pharmaceutical industry's strict regulatory requirements are met or exceeded.

Q What are lower-GWP propellants and why are they needed for pMDI applications?

A Formulations for pMDIs typically consist of a defined amount of API combined with a propellant and a number of excipients, which can include surfactants, co-solvents and stabilisation systems. The propellant expels the formulation from the cannister via the metering valve, creating an aerosolised spray that is then inhaled by the patient and delivered to the lungs. The most common class of propellants currently used in pMDIs are HFAs, such as HFA134a and HFA227ea.

However, these propellants have a high GWP, leading to an undesirable CO_2 footprint. New lower-GWP propellants are being used to develop the next generation of pMDIs, which, according to current estimates, will reduce the CO_2 footprint pMDIs generate by over 90% compared with existing propellants. As pMDIs are an important and widely used technology for delivering a variety of inhaled drugs around the world, especially for rescue therapies, the adoption of these new propellants is critical for organisations that want to reach their climate goals.

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Chris Baron is Director of Business Development, Pulmonary Category at Aptar Pharma. In this role, he is responsible for the global business development activities for Aptar Pharma's inhalation drug delivery devices, as well as their respective services pertaining to the application fields of asthma and COPD. With a degree in Mechanical Engineering, Mr Baron has over 28 years' industry experience in the field of inhalation drug delivery, specifically metering valve technologies for pMDIs and their accessory peripheral device technologies, including dose indicators and breath-activated inhalers.

Q Which lower-GWP propellants are being used in pMDI development projects and what makes them different from the current HFA propellants?

A There are two main frontrunners with respect to lower-GWP propellants – Koura's (Waltham, MA, US) HFA152a and Honeywell's (Charlotte, NC, US) HFO1234ze, each offering significantly reduced CO_2 footprints. There are a number of differences between the two new propellants, including their flammability, density, vapour pressure, boiling point and dipole moments. These differences may impact the final solubility and stability of any given pMDI formulation in conjunction with any additional excipients selected.

Q How do the propellants impact pMDIs and their components?

A The use of the new propellants in pMDIs requires close attention to all aspects of the container closure system (CCS). This includes the metering valve, canister and actuator. In some cases, drug delivery device manufacturers can even integrate digital technologies, such as dose counters or breath-actuated mechanisms, to provide additional levels of patient convenience. Each component of a pMDI's CCS that comes into contact with the formulation must be strictly evaluated for

its chemical compatibility. The resulting components must also deliver the functionality and mechanical performance required for dose consistency over the entire shelf-life of the medication.

We must also consider the impact on manufacturing processes and analytical testing methods. For example, HFA152a is considered a higher risk material from a flammability perspective compared with its counterparts. Therefore, formulation mixing and filling suites must be capable of handling such materials.

Q Are there any concerns about the move to convert pMDIs to use lower-GWP propellants?

A Compatibility with existing pMDI components is a concern that should be addressed during product design. New propellants, including HFA152a and HFO1234ze, will require extensive testing and may even require the optimisation or potential redesign of the CCS' key critical quality attributes so that they can maintain product performance similar to current HFA-based formulations. The materials currently used in the construction of pMDI components, including metering valves, may or may not be compatible with the new lower-GWP propellants, so each component needs to be re-evaluated.

Any incompatibility could necessitate substantial modifications to the metering valve or other pMDI components to ensure the pMDI product's continued performance and efficacy. As some lower-GWP propellants have greater flammability risks than current propellants, the manufacturing and filling processes need to be reviewed to ensure that they are safely handled at every step of the process.

Additionally, regulatory compliance is always a major consideration when making any changes to complex drug-device combination products. One needs to assess material selection not only against today's regulations but also against anticipated or new potential regulations that could impact the future compliance of a new part or component. Ignoring these risks in the short term could result in the need for a costly and time-consuming redesign and revalidation of pMDI components in just a few years.

"NEW PROPELLANTS, INCLUDING HFA152a AND HFO1234ze, WILL REQUIRE EXTENSIVE TESTING AND MAY EVEN REQUIRE THE OPTIMISATION OR POTENTIAL REDESIGN OF THE CCS' KEY CRITICAL QUALITY ATTRIBUTES SO THAT THEY CAN MAINTAIN PRODUCT PERFORMANCE SIMILAR TO CURRENT HFA-BASED FORMULATIONS."

Finally, patient acceptance and adherence are critical concerns. Changes in propellants can affect the patient experience, which, if not handled appropriately, could lead to lower patient compliance and poorer health outcomes.

Q How did Aptar Pharma initially get involved in the transition to lower-GWP propellants in pMDIs?

A Aptar Pharma is a well-established and trusted global developer and supplier of metering valves that have been reliably used in many leading pMDI products for decades. Realising that addressing global sustainability concerns and meeting corresponding objectives for pMDIs would require a collaborative, industry-wide effort, the company took the initiative to work alongside drug developers, drug delivery device companies, equipment manufacturers, chemical suppliers, key opinion leaders and regulators to find practical solutions.

For example, Aptar Pharma organised an event in conjunction with Pharmaserve Northwest back in September 2021 that was attended by device developers, pharmaceutical companies, CDMOs and the two lower-GWP propellant suppliers to discuss common objectives and share knowledge. For some time, Aptar Pharma has been initiating developmental collaborations with customers regarding the advancement of their next-generation pMDIs using lower-GWP propellants.

This has resulted in Aptar Pharma engineering the new ZEN30 Futurity™ metering valve technology platform, designed specifically to be compatible with leading lower-GWP propellants. However, developing a new metering valve was only part of the process. Our customers led the necessary reformulation and testing effort in parallel with Aptar Pharma's development of the new metering valve to shorten the overall transition timelines for their reformulated products.

Q What are the new or pending regulations driving this change?

A Global climate change objectives are driving new regulations to help reduce CO_2 emissions. For example, the EU's new F-Gas legislation was adopted in March 2024. These regulations will impact pMDIs as they will be partially combined with the wider F-gas quota system, requiring a 15% reduction in F-gas use by 2026/27 and a complete 100% elimination of hydrofluorocarbons by 2050. These reductions are relative to a 2023/24 baseline. There are also potential future restrictions stemming from the European Union's "Registration, Evaluation, Authorisation and Restriction of Chemicals" (REACH) regulations, which aim to eliminate materials determined to pose an unacceptable risk.

"FOR SOME TIME, APTAR PHARMA HAS BEEN INITIATING DEVELOPMENTAL COLLABORATIONS WITH CUSTOMERS REGARDING THE ADVANCEMENT OF THEIR NEXT-GENERATION PMDIS USING LOWER-GWP PROPELLANTS."

These anticipated changes could eliminate the ability to use certain materials in pMDI components. As many of the materials that may be subject to a ban are already known, it is important to future-proof new pMDI part or component designs today to avoid costly redesigns later. Aptar Pharma took this into consideration when designing the new ZEN30 Futurity valve, selecting only materials that provide the required performance and that are also unlikely to fall inside the upcoming REACH elimination criteria.

In December 2024, the US FDA held a series of collaborative industry workshops with an aim of developing guidance for the implementation of new pMDIs intended for the US market using lower-GWP propellants. Aptar has been monitoring and participating in these developments to stay engaged in the latest regulations impacting pMDIs. These considerations were implemented throughout the design of the ZEN30 Futurity valve, including its material selection, to ensure compatibility with lower-GWP propellants.

Q What are the challenges and opportunities associated with transitioning to lower-GWP propellants, including supply chain restrictions? How is Aptar Pharma planning to overcome these challenges?

A Although the transition to lower-GWP propellant use in pMDIs presents a variety of challenges, including new supply chain restrictions, updated manufacturing and filling capability requirements, reformulation complications and the need for optimised device designs, this transition also offers significant new opportunities to reduce the environmental impact of pMDIs. Aptar Pharma applies ecodesign tools and lifecycle assessment approaches to design new products and services with lower environmental impacts.

Aptar Pharma's main contribution to moving pMDIs to lower-GWP propellants comes in the form of the ZEN30 Futurity metering valve. This valve was designed for compatibility and performance when used with the new lower-GWP propellants. The additional support provided by Aptar Pharma helps to accelerate the transition process for our customers. We also offer end-to-end supply chain control with the valves. This can help pharmaceutical companies avoid disruptions to business continuity and protect patients' access to potentially life-saving medicines.

"APTAR PHARMA CREATED THE NEW ZEN30 FUTURITY METERING VALVE SPECIFICALLY FOR LOWER-GWP PROPELLANTS AND RELATED FORMULATIONS."

Q Did you have to modify existing pMDI metering valves or develop new valves in order to be compatible with the new lower-GWP propellants?

A Aptar Pharma created the new ZEN30 Futurity metering valve specifically for lower-GWP propellants and related formulations. We assessed every material and critical quality attribute to ensure that the ZEN30 Futurity could stand up to the demands of new formulations that contain either of the new HFA152a or HFO1234ze propellants. As a result, we selected materials that were compatible with the new formulations and lower-GWP propellants, as well as providing the mechanical and chemical performance needed over the entire lifespan of the product.

This was supported by the data generated in multiple accelerated stability studies. We decided to eliminate some of the existing materials used in our current DF30 metering valves because they were not compatible with the new propellants. We also future-proofed the ZEN30 Futurity metering valve design against future anticipated EU REACH restrictions. Aptar Pharma was able to do this quickly based on our decades of experience as a leading pMDI metering valve developer and supplier and because of our specialised R&D capabilities located in both our Le Vaudreuil (France) and Nanopharm (Cwmbran, UK) operations. Ultimately, we were able to produce a practical, manufacturable and scalable design that is regulation-compliant and compatible with the demands of both lower-GWP propellants.

Q What is Aptar Pharma's Futurity platform and what are its objectives?

A Aptar Pharma created the Futurity platform to represent products that bring enhanced sustainability and circularity features. This includes products such as mono-material drug delivery systems designed for greater recyclability, multiuse delivery systems that reduce plastic use and the new ZEN30 Futurity metering valve as discussed earlier. All of the Futurity product lines contribute to the enhanced sustainability of critical drug products that can have an impact on patient's lives.

Q Can you tell us more about the design of the ZEN30 Futurity valve and the benefits it brings to customers?

A Our internal R&D teams worked collaboratively with customers to develop the ZEN30 Futurity metering valve. First off, we ensured that it was compatible with the needs of formulations containing HFA152a and HFO1234ze.

"THESE MATERIALS ARE DEVELOPED AND MANUFACTURED AT APTAR PHARMA'S OWN STATE-OF-THE-ART ELASTOMER FACILITY IN FRANCE TO ENSURE THE HIGHEST QUALITY, AS WELL AS TO SAFEGUARD THE SUPPLY CHAIN OF THESE CRITICAL MATERIALS."

We selected valve component materials that demonstrated chemical compatibility and enhanced mechanical performance that could provide reproducible dosing over the entire shelf-life of the pMDI.

For example, the static gasket is made from a cyclic olefin copolymer elastomer for a strong and durable seal that is resistant to degradation and provides a best-in-class moisture protection barrier, maintaining product stability. The dynamic elastomers are made from proprietary formulations of ethylene propylene diene monomer because of its durability, flexibility and resistance to degradation in various climatic zones.

These materials are developed and manufactured at Aptar Pharma's own state-of-the-art elastomer facility in France to ensure the highest quality, as well as to safeguard the supply chain of these critical materials. We also use a polybutylene terephthalate polymer for some components because of its insulative and chemically resistant properties. This combination of newly selected materials resulted in a high-performance metering valve that is compatible with both of the leading lower GWP propellants.

Q How does Aptar support its customers through the development of the ZEN30 Futurity valve and incorporating it into their pMDI products?

A Aptar has built an extensive list of additional support services that can help customers to advance their pMDI products to market in the shortest possible timeframe. Aptar Pharma's Nanopharm team provides sophisticated inhaled drug development services, including highly specialised *in vitro*, *in silico*, physiologically-based pharmacokinetic and deposition modelling, uniquely applied to pMDI and inhaled drug products. Furthermore, offering the ATEX-rated R&D pilot filling facility to support the development of customer pMDI products has meant that our customers could move their development programmes forward, avoiding the wait time to secure access to their own suitably scaled manufacturing and testing capabilities.

As experts in pMDI drug delivery, Aptar Pharma also provides extensive regulatory support, including some of the documentation our clients are expected to include in their submissions to regulatory bodies. Aptar provides customers with full Combination Packages and Art117 dossiers for our ZEN30 Futurity metering valves. Aptar's Noble group (Orlando, FL, US) provides sophisticated patient onboarding services and training kits, along with human factors studies, to get new devices into the hands of patients sooner. Aptar Pharma also provides in-person support for the integration of our drug delivery systems on to their manufacturing and filling lines for seamless implementation of technology changes.

"AS EXPERTS IN pMDI DRUG DELIVERY, APTAR PHARMA ALSO PROVIDES EXTENSIVE REGULATORY SUPPORT, INCLUDING SOME OF THE DOCUMENTATION OUR CLIENTS ARE EXPECTED TO INCLUDE IN THEIR SUBMISSIONS TO REGULATORY BODIES."

Q What are the expected impacts of the new lower-GWP propellants on patients?

A At Aptar Pharma, we try to consider the needs of the end user, the patient, as our key driver. Our products and services are designed to help our customers derisk and accelerate their pMDI development programmes. Our company's mind-set is always focused on taking customers from "formulation to patient". We see the ZEN30 Futurity metering valve as enabling patients to maintain the same convenient, preferred pMDI delivery platform and methodology to deliver their treatments.

Although there are alternative inhaled drug delivery systems, such as dry powder inhalers (DPIs), many of them require a minimal level of inhalation capability from the patient to ensure that the drug is adequately delivered. Administering drugs via some DPIs can also require the co-ordination of different preparation and inhalation steps by the patient, which can be challenging for some. Instead, the continued use of newer pMDIs driven by lower-GWP propellants means that patients can maintain their established drug administration practices while also contributing to the reduction of CO_2 emissions associated with traditional propellants.

"ONE OF THE FACTORS IMPACTING pMDI VOLUMES WILL BE THE RELATIVE ECONOMICS ASSOCIATED WITH THE TRANSITION TO NEW LOWER-GWP pMDIs AS COMPARED WITH ALTERNATIVE DELIVERY TECHNOLOGIES."

Q What future do you see for pMDIs and how does Aptar's ZEN30 Futurity valve fit into that future?

A It is expected that the new lower-GWP pMDIs will be able to maintain their place as one of the world's most widely used orally inhaled drug delivery systems. Alternative inhalation delivery technologies, such as DPIs and non-propellant liquids inhalers are available, but their combined commercial volumes still do not approach those of pMDIs.

One of the factors impacting pMDI volumes will be the relative economics associated with the transition to new lower-GWP pMDIs as compared with alternative delivery technologies. Historically, pMDIs have been one of the most cost-effective respiratory drug delivery platforms based on cost per dose. However, the cost to purchase new propellants relative to the current propellants will also become an important factor. Pharmaceutical companies must also consider the investment costs associated with upgrading mixing and filling capacity to meet the required ATEX safety guidelines for the more flammable lower-GWP propellants – HFA152a in particular.

In summary, the speed of change in a given region will depend on both market regulations and economics, which will be impacted by the levies and taxes applied to the older HFA propellants during their phase out. Ultimately, pMDIs will continue to serve the critical medical function of delivering inhaled drug products to patients in a convenient and portable package. Now, the next generation of pMDIs will be able to do so while contributing to a reduced carbon footprint with every inhalation. Designed specifically for a seamless transition to lower-GWP propellants and ensuring reliable and robust performance, the ZEN30 Futurity valve will be at the forefront of this transformation.

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

SUSTAINABLE GLP-1 DRUG DELIVERY: FUTURE-PROOFING THERAPY ADMINISTRATION FOR OBESITY AND BEYOND

YPSOMED
SELFCARE SOLUTIONS

Lorenzo Biasio and **Gloria Skibba**, both at **Ypsomed**, discuss the integration of the company's Net Zero Program into its self-injection platforms and explain how YpsoMate 1 and 2.25 mL autoinjectors have been redesigned to achieve a lower carbon footprint. With the evolution of GLP-1 therapies and the exploration of higher-dose formulations, the demand for higher-volume autoinjectors is increasing; this article explains how Ypsomed has also applied its sustainability principles to larger-volume delivery.

Almost 20 years ago to the day, the glucagon-like peptide-1 (GLP-1) era began. On the heels of basic research on the venom of Gila monsters in the preceding decades,[1] exenatide secured the first US FDA approval in the class on April 28, 2005.[2] While the prominent GLP-1 brand names are household names today, the class was off to a relatively slow start at first – five years passed before it reached blockbuster status (US$1 billion (£770 million) in sales), and another five went by before the first formal approval of a GLP-1 drug indicated for obesity became a reality.[3]

Last year saw sales for the class cross $50 billion and, with another 40% in revenue growth in store for 2025, the GLP-1 segment of the pharmaceutical industry is firmly in the rapid growth phase of the market, per Investment Bank Consensus. On the same measure, cumulative revenues across the major pharmaceutical companies alone are projected to reach close to $165 billion by 2030 (Figure 1).

While GLP-1s are mainly known for their impact on glycaemic control and weight management, they play a role beyond, with effects confirmed – or at least suspected – on cardiovascular risk, kidney disease, obstructive sleep apnoea and osteoarthritis. Even otherwise dispassionate media outlets have labelled these drugs "miracle drugs" that will "change the world". Considering the diversity of clinical trials and indications they are tested in – including the notoriously challenging Alzheimer's disease – these claims may well

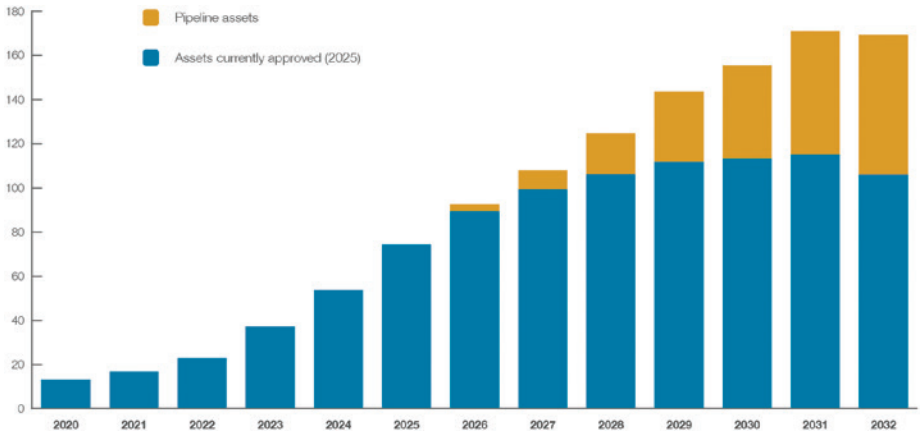

Figure 1: Projected growth of the GLP-1 market (2020–2032): Capital Market Consensus estimates in US$ billion, highlighting the contribution of currently approved assets (as of 2025) and pipeline assets expected to enter the market. Source: Investment Bank Consensus via DrugAnalyst, Company reports. Note: Does not include biosimilars.

hold a substantial amount of truth (Table 1). After all, there are over 100 originator drugs and almost as many biosimilars in the pipeline, many of which will never progress to commercialisation, but some of which will further push the boundaries on patient convenience, efficacy and indication spectrum.

Today, Novo Nordisk estimates that just under 20 million people are treated with GLP-1 drugs.[4] Given a well-stocked pipeline, a substantial global addressable population (the obese population alone is projected to exceed 1.2 billion by 2030[5]), and in light of the very beneficial clinical profile of these drugs, it is plausible that over 100 million patients worldwide will be treated with GLP-1s in the near future. Particularly with the expected adoption boost as biosimilars enter the market towards the end of the decade, affordability barriers may begin to crumble, especially in lower-income regions where GLP-1 access currently remains limited.

EXTENDED DOSING INTERVALS AS A DRIVER FOR IMPROVED SUSTAINABILITY

Native GLP-1 has a half-life that is measured in mere minutes[6] and, as such, has limited therapeutic relevance without continuous dosing. Exenatide stretched that measure to about 2.5 hours[3] – sufficient for therapy but requiring twice-daily injections that placed a significant burden on patients. Even with the improved convenience of once-daily options, the true breakthrough in adherence came with current-generation, once-weekly GLP-1 drugs.

Currently approved conditions	Conditions under clinical investigation/in registration
Cardiovascular risk reduction	Alzheimer's disease
Chronic kidney disease	Atherosclerosis
Obesity	Diabetic retinopathy
Obstructive sleep apnoea	Heart failure
Type 2 diabetes	Ischaemic stroke
	MASH
	Type 1 diabetes

Table 1: Snapshot of GLP-1 therapeutic indications – currently approved conditions and those under clinical investigation or registration. Source: Pharmacircle/Prescribing information; subject to change.

"ADVANCES IN DRUG ENGINEERING MAY ENABLE EVEN LONGER DOSING INTERVALS, WITH A SMALL BUT GROWING PERCENTAGE OF CLINICAL CANDIDATES AIMING FOR MONTHLY OR LONGER INJECTION CYCLES."

The fact that the overwhelming majority of GLP-1 administration is parenteral, combined with the preference of both drug sponsors and patients for easy-to-use device formats (typically injection pens and/or autoinjectors), presents a massive opportunity for drug delivery system manufacturers. However, on the flip side, it also introduces a significant sustainability challenge, as the current landscape is dominated by disposable devices. The projected increase in patient numbers will only magnify this issue.

The simplest step towards mitigation is shifting from single-dose autoinjector formats to multidose pens where preservability allows. However, beyond that, solutions become less straightforward. Advances in drug engineering may enable even longer dosing intervals, with a small but growing percentage of clinical candidates aiming for monthly or longer injection cycles. If successful, these options could reduce the aggregate number of devices required, which has led some industry stakeholders to consider them a sustainability lever. That said, the true impact on plastics consumption is debatable, as a single-dose monthly injection may still require similar amounts of materials as a multidose weekly injection device.

While monthly GLP-1 formulations may become commercially available soon in higher-income regions, other geographies – especially those with high expected biosimilar penetration – may continue relying on weekly-dosed drugs for the foreseeable future. This means that the

entire GLP-1 supply chain, particularly drug delivery system manufacturers, must take a proactive approach in developing more sustainable device solutions.

A DATA-DRIVEN APPROACH TO SUSTAINABILITY

Ypsomed has taken up this challenge with its Net Zero Program – a structured approach to reducing the carbon footprint of self-injection devices while maintaining ease of use and full compliance. As part of its long-term sustainability commitment, Ypsomed has joined the Science Based Targets initiative (SBTi), targeting net zero emissions across its entire value chain by 2040. This ensures that its sustainability efforts follow scientifically validated reduction pathways and deliver measurable impact.

As part of the Net Zero Program, Ypsomed conducts lifecycle assessments in accordance with ISO 14040/44 standards, using an established methodology verified by independent third parties. These assessments provide detailed insights into the carbon footprint of Ypsomed's products, identifying key areas for optimisation and immediate opportunities for improvement. With this data-driven approach, sustainability measures are targeted and effective.

ADVANCED MATERIALS FOR A LOWER FOOTPRINT

While new delivery solutions are being explored, many of today's GLP-1 therapies still rely on established autoinjector platforms. As the market continues its rapid expansion, ensuring that these widely used devices are as sustainable as possible is a key priority. With single-use systems remaining a dominant format, reducing their environmental footprint is critical to ensuring long-term viability.

To address this, Ypsomed has integrated its Net Zero Program into its proven self-injection platforms. The YpsoMate 1 and 2.25 mL autoinjectors – already in use for various biologics, including GLP-1s – have been redesigned to achieve a lower carbon footprint without requiring any changes to drug formulation, delivery protocols or device.

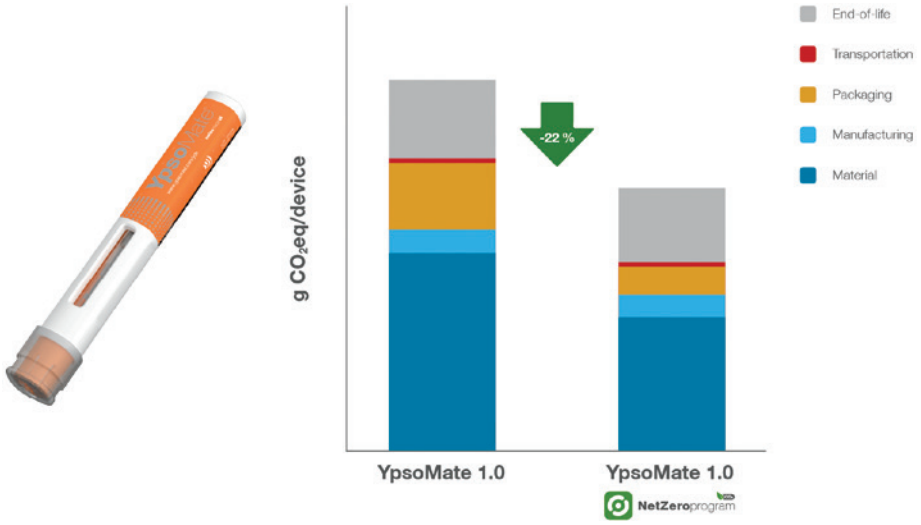

Figure 2: CO_2 reduction impact of the Net Zero Program – comparison of the carbon footprint (g CO_2eq/device) between the standard YpsoMate and YpsoMate within the Net Zero Program, highlighting a 22% carbon footprint reduction across materials, production, packaging, transportation and end-of-life (EoL) processes.

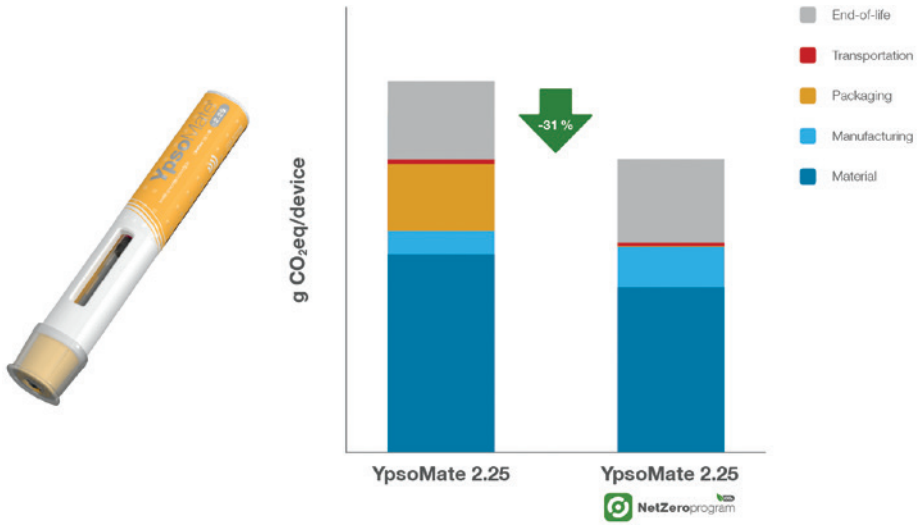

Figure 3: CO_2 emission reduction of the Net Zero Program – a 31% reduction in carbon footprint (g CO_2eq/device) for the YpsoMate 2.25 mL autoinjector when integrated into the Net Zero Program, demonstrating lower emissions across materials, manufacturing, packaging, transportation and EoL processes.

A key driver behind the 22% carbon footprint reduction of the YpsoMate 1 mL autoinjector is the shift to bio-based materials – chemically identical to conventional plastics, sustainably sourced and requiring no additional regulatory approvals or manufacturing process adjustments (Figure 2). Importantly, this transition does not necessitate any changes in formulation, stability or device function. This sustainability shift is further reinforced by ISCC+ certification, ensuring compliance with rigorous industry standards. The same approach has been applied to the YpsoMate 2.25 mL autoinjector, achieving an even greater carbon footprint reduction of 31% (Figure 3).

PLUG-AND-PLAY SUSTAINABILITY FOR PHARMA SUPPLY CHAINS

Beyond material innovations, the net zero sustainability approach extends across the entire supply chain. Since the bio-based materials used in Ypsomed's devices retain the same chemical properties as conventional

plastics, the transition requires no additional regulatory approvals or manufacturing modifications – a key advantage already outlined. This allows pharmaceutical companies to reduce their environmental footprint with minimal operational impact, a growing priority as sustainability regulations become increasingly stringent.

In addition to making products more sustainable through material selection, Ypsomed's Net Zero Program also incorporates optimised packaging solutions, which prioritise the use of recycled materials for trays and a shift to wooden pallets, minimising the overall carbon footprint while ensuring that pharmaceutical logistics maintain the highest quality and safety standards.

UNOPEN: SUPPORTING THE EXPANSION OF GLP-1 IN MULTIDOSE FORMATS

While single-dose autoinjectors remain dominant in GLP-1 delivery, multidose pen injectors also play a critical role, particularly in formulations where preservability allows. As demand for GLP-1 therapies expands, balancing injection frequency, sustainability and drug stability is becoming increasingly important. In this context, multidose devices can help reduce material consumption while maintaining flexibility in treatment regimens.

To support this transition, Ypsomed has applied its net zero sustainability principles to multidose injection systems as well. The UnoPen, a prefilled pen injector, integrates ISCC+ certified bio-based materials to achieve a 32% CO_2 reduction – offering a more sustainable alternative for therapies administered in a multidose format (Figure 4). Like YpsoMate, this sustainability shift requires no regulatory changes, making it easy for pharmaceutical companies to integrate into existing treatment protocols.

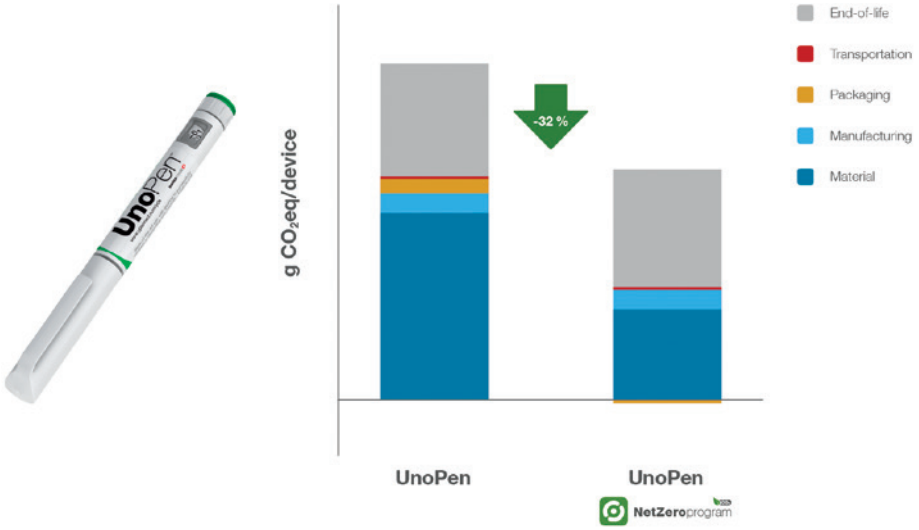

Figure 4: CO_2 emission reduction for UnoPen in the Net Zero Program – comparison of the carbon footprint (g CO_2eq/device) between the standard UnoPen and UnoPen within the Net Zero Program, showing a 32% reduction in carbon footprint (g CO_2eq/device) across materials, manufacturing, packaging, transportation and EoL processes.

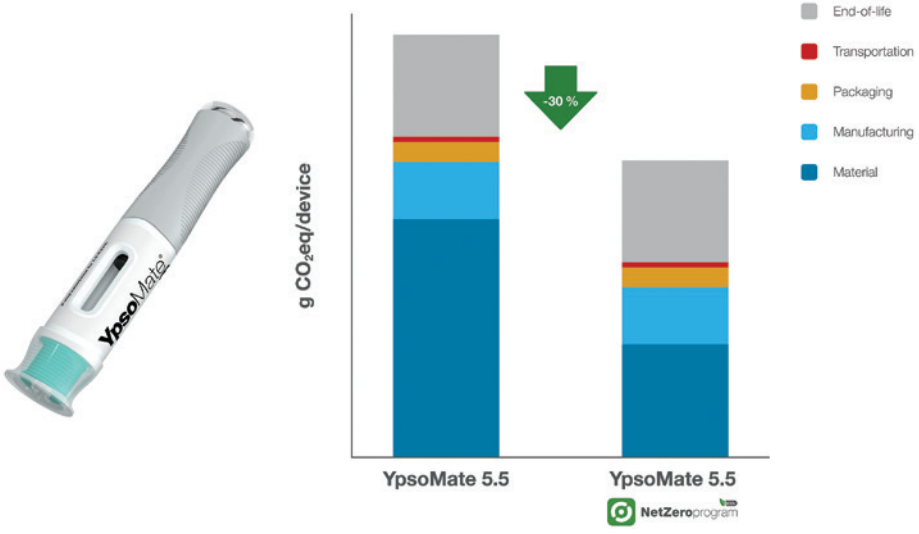

Figure 5: CO_2 emission reduction for YpsoMate 5.5 mL in the Net Zero Program – comparison of the carbon footprint (g CO_2eq/device) between the standard YpsoMate 5.5 mL and YpsoMate 5.5 mL within the Net Zero Program, illustrating significant reductions across materials, manufacturing, packaging, transportation and EoL processes.

ECODESIGN IN HIGH-VOLUME DRUG DELIVERY: YPSOMATE 5.5

As GLP-1 therapies evolve and higher-dose formulations are being explored to further reduce injection frequency, the demand for higher-volume autoinjectors is increasing to support these advancements and meet drug delivery requirements. Beyond standard-dose autoinjectors, Ypsomed has also applied its structured sustainability principles to larger-volume delivery. The YpsoMate 5.5, designed for high-volume biologics, follows ecodesign principles embedded within Ypsomed's development process. By ensuring that sustainability considerations are integrated from the earliest design stages, including material selection guided by the Ecodesign Guideline, the company can offer a CO_2-reduced variant of YpsoMate 5.5 from launch (Figure 5).

Despite its larger size, the YpsoMate 5.5 remains aligned with Ypsomed's sustainability efforts, allowing pharmaceutical companies to adopt a more environmentally responsible solution without compromising usability or performance. This approach highlights how innovation and sustainability can go hand in hand, ensuring that even as drug formulations evolve, delivery systems keep pace with sustainability goals.

"YPSOMED OFFERS TWO HIGH-QUALITY REUSABLE PEN INJECTORS, DESIGNED TO EXTEND PRODUCT LIFESPANS AND REDUCE MATERIAL CONSUMPTION OVER TIME."

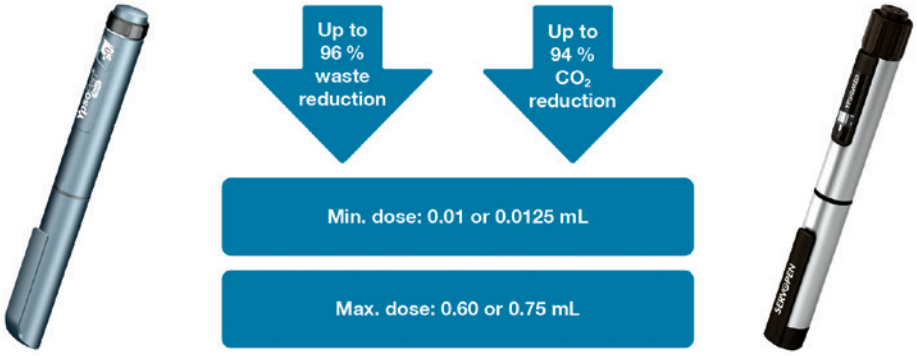

Figure 6: YpsoPen and ServoPen – Ypsomed's reusable pen injectors designed for sustainability, offering up to 96% waste reduction and 94% CO_2 reduction. These devices support precise dosing, with a minimum dose of 0.01 or 0.0125 mL and a maximum dose of 0.6 or 0.75 mL, making them suitable for long-term GLP-1 therapies (Ypsomed, internal data on file, 2024).

BEYOND SINGLE-USE: THE ROLE OF REUSABLE PEN INJECTORS

While the Net Zero Program significantly reduces the environmental impact of single-use devices, reusable solutions provide an additional pathway towards sustainability. Ypsomed offers two high-quality reusable pen injectors, designed to extend product lifespans and reduce material consumption over time. For GLP-1 therapies, switching to a reusable device can lead to a waste reduction of up to 96% and a CO_2 reduction of 94%, further amplifying the environmental benefits (Ypsomed, internal data on file, 2024; Figure 6).

The ServoPen is a premium reusable pen injector, featuring a metal housing for enhanced durability and a high-end user experience. With an in-use time of three years, this pen contributes to significant waste reduction by minimising the need for disposable components. With GLP-1 drugs being prescribed as

long-term therapies, a durable, reusable device can significantly reduce plastic waste and material consumption. This makes the ServoPen a sustainable choice for ongoing GLP-1 treatment, particularly in regions where cost effectiveness and long-term adherence are priorities.

For more cost-sensitive applications, the YpsoPen provides another reusable solution, designed for ease of use while still delivering the sustainability benefits of a multi-use system. Made from lightweight yet durable plastic, it helps expand access to GLP-1 therapies, balancing affordability with reduced environmental impact.

A PRAGMATIC PATH TO A GREENER FUTURE

The GLP-1 era is unfolding at a rapid pace, reshaping treatment landscapes for obesity and metabolic diseases. But with this progress comes responsibility – ensuring that the delivery of these breakthrough therapies aligns with the sustainability imperatives of the future. The growing demand for self-injection devices cannot be met with traditional solutions alone; the industry must evolve, adopting forward-thinking approaches that reduce environmental impact without compromising patient care.

Ypsomed stands at the forefront of this transformation. Through its Net Zero Program, the company is not only providing CO_2-reduced alternatives but also setting a new standard for sustainability in drug delivery. With a firm commitment to scientifically validated impact reduction, innovative material use and seamless supply chain integration, Ypsomed is empowering pharmaceutical companies to make meaningful strides toward greener drug administration.

The future of GLP-1 drug delivery is not just about efficacy – it is about responsibility. As the industry scales, Ypsomed is ensuring that sustainability keeps pace, proving that innovation and environmental stewardship can go hand in hand. The path to net zero in self-injection devices has been laid, and Ypsomed is leading the way.

REFERENCES

1. *Eng J et al, "Isolation and characterization of exendin-4, an exendin-3 analogue, from Heloderma suspectum venom. Further evidence for an exendin receptor on dispersed acini from guinea pig pancreas". J Biol Chem, 1992, Vol 267, pp 7402–7405.*
2. *Byetta Injection approval. US FDA, April 28, 2005.*
3. *Zheng Z et al, "Glucagon-like peptide-1 receptor: mechanisms and advances in therapy". Sig Transduct Target Ther, 2024, Vol 9, (1), p 234.*
4. *Annual Report. PDF, Novo Nordisk, 2024.*
5. *World of Obesity Atlas. PDF, World Obesity, 2023.*
6. *Hui H et al, "The short half-life of glucagon-like peptide-1 in plasma does not reflect its long-lasting beneficial effects". Eur J Endocrinol, 2002, Vol 146 (6), pp 863–9.*

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Product Showcase

UNDERSTANDING PATIENT PREFERENCES FOR SUSTAINABLE ON-BODY DELIVERY SYSTEMS

Sustainability has become a critical priority for the healthcare sector due to the growing need to address the environmental impact of medical practices and devices. Globally, healthcare accounts for approximately 4.4% of greenhouse gas emissions, with single-use medical devices and pharmaceutical packaging being major contributors. For instance, the US generated over 5.9 million tons of medical waste in 2018, much of it being non-recyclable or hazardous.[1]

On-body delivery systems (OBDS), a rapidly expanding category of drug delivery devices suitable for a wide range of therapies, face similar challenges. As the healthcare industry strives to balance safety, efficacy and environmental responsibility, understanding patient preferences for sustainable solutions is essential.

PATIENT PREFERENCES FOR SUSTAINABILITY: INSIGHTS FROM LITERATURE

Research indicates that patients are becoming increasingly receptive to sustainable healthcare solutions, provided that these maintain usability and efficacy. For example, a 2020 survey conducted under the UK NHS sustainability agenda on asthma patients revealed that, while 65% were unaware of the carbon footprint of metered-dose inhalers, 60% would be willing to switch to greener alternatives, if ease of use and safety were not compromised.[2]

While such research on OBDS is still limited, early evidence is emerging. For instance, a 2024 human factors study on an OBDS in development that collected feedback from patients and healthcare professionals regarding various product attributes – including preferences for reusable versus single-use devices – found that 93% of participants preferred reusable OBDS. The primary motivations for this preference were the reduction of waste and plastic.[3]

Regional and cultural differences also influence preferences. According to a 2024 online survey that explored patient preferences for emerging injectable obesity therapies, patients in the UK, Germany and Switzerland demonstrated stronger preferences for reusable devices, reflecting greater environmental awareness. In contrast, US patients leaned toward single-use options, prioritising usability as their main concern.[4]

Interestingly, patients often associate sustainability with visible factors, such as reduced plastic usage, but may lack awareness of the environmental impact of different materials and components, such as electronics. For example, a 2023 online survey on patient perceptions of device sustainability found that single-use electromechanical OBDS were generally perceived as having a smaller environmental footprint than single-use mechanical autoinjectors.[5] This perception likely stems from the reduced injection frequency that OBDS typically offer, rather than a comprehensive understanding of the environmental impacts of the materials and components used.

These findings highlight the importance of interconnected factors – such as user-centric design, regional preferences and material considerations – for driving patient adoption of sustainable solutions. Designing with these factors in mind offers a pathway to align sustainability with patient experience and treatment efficacy.

> "RESEARCH INDICATES THAT PATIENTS ARE BECOMING INCREASINGLY RECEPTIVE TO SUSTAINABLE HEALTHCARE SOLUTIONS, PROVIDED THAT THESE MAINTAIN USABILITY AND EFFICACY."

Stevanato Group's Preference Study

As part of its commitment to aligning sustainability with usability in OBDS, Stevanato Group conducted a preference study in July 2024 with UK patients, focusing on its Vertiva® 10 mL, a semi-reusable OBDS designed to address both environmental concerns and patient

needs. Vertiva's modular design consists of two units (Figure 1):

- A reusable electromechanical controller, which powers the device and houses its electronic components
- A single-use injection unit, comprising only mechanical components and featuring a prefilled and preloaded drug cartridge.

The study compared Vertiva with a fully disposable electromechanical OBDS. Unlike Vertiva, the comparison device involved discarding its electronics after each injection and required patients to manually load the drug cartridge before use. Both devices shared the same fill capacities and targeted similar therapeutic regimens, primarily differing in the presence or absence of a reusable module and the drug loading mechanism.

Twelve participants, representing various demographics, medical conditions and familiarity with injection devices, reviewed mock devices, printed instructions for use and demonstration videos before evaluating the two devices. They first ranked a series of product attributes by importance, then matched each attribute to the device they felt best met the criterion (Figure 2), finally expressing their overall preference for one of the two devices.

Despite most patients emphasising the importance of environmental sustainability, it ranked fifth out of the seven evaluated product attributes on average, following ease of use steps, number of use steps, device size and ease of storage. This aligns with existing literature – while patients value sustainability, usability and convenience often take precedence.

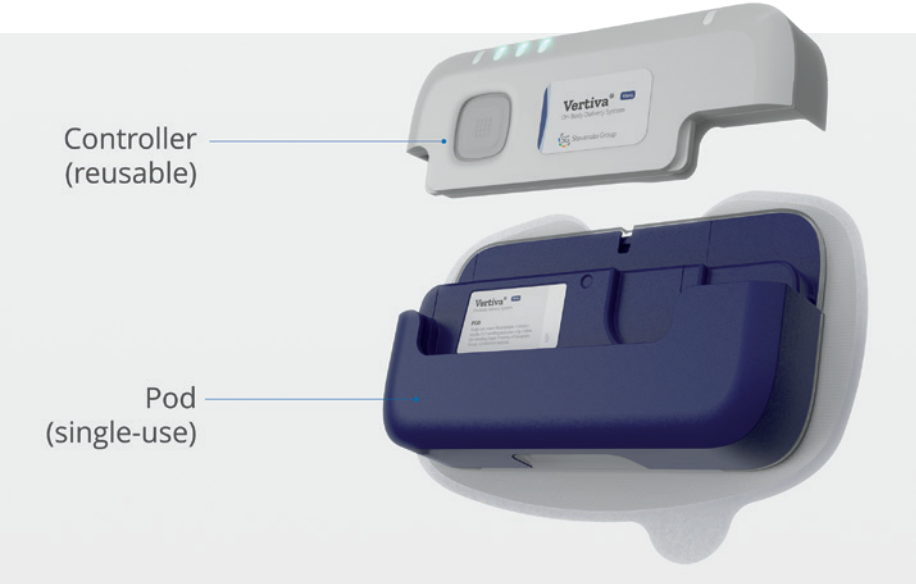

Figure 1: Stevanato Group's Vertiva® 10 mL OBDS, featuring reusable electronics.

Regarding attribute assignation, two-thirds of participants identified Vertiva as the more sustainable option, citing waste reduction thanks to its reusable unit. The remaining third perceived that both devices required disposal of a similar amount of plastic after each injection and therefore did not feel the reusable component offered a significant sustainability advantage. This also supports previous literature, which suggests that many patients equate sustainability with tangible design elements, such as reduced plastic usage, while overlooking the impact of less visible materials such as electronics (Box 1). This highlights the need for more effective communication from device manufacturers and pharmaceutical suppliers to address the gap in patient education and awareness of the broader issue of product sustainability.

Indeed, a 2023 lifecycle-analysis-based study assessing the environmental impact of a single-use electromechanical OBDS concept found that electronic components, such as processors and batteries, accounted for approximately 61% of the device's

Figure 2: A patient completing the attribute assignation task during Stevanato Group's Patient Preference Study.

BOX 1: QUOTES FROM PATIENTS

"I really like it. One of the things I feel somehow guilty about is the amount of plastic wastage, so I really like this idea of being able to reuse."

"You keep the electronic part, that's really good, because that saves a lot of plastic. Anyone with a chronic illness is aware of how much plastic waste there is."

"I have loved that, with devices that have plastics and everything, they are making you retain some of them."

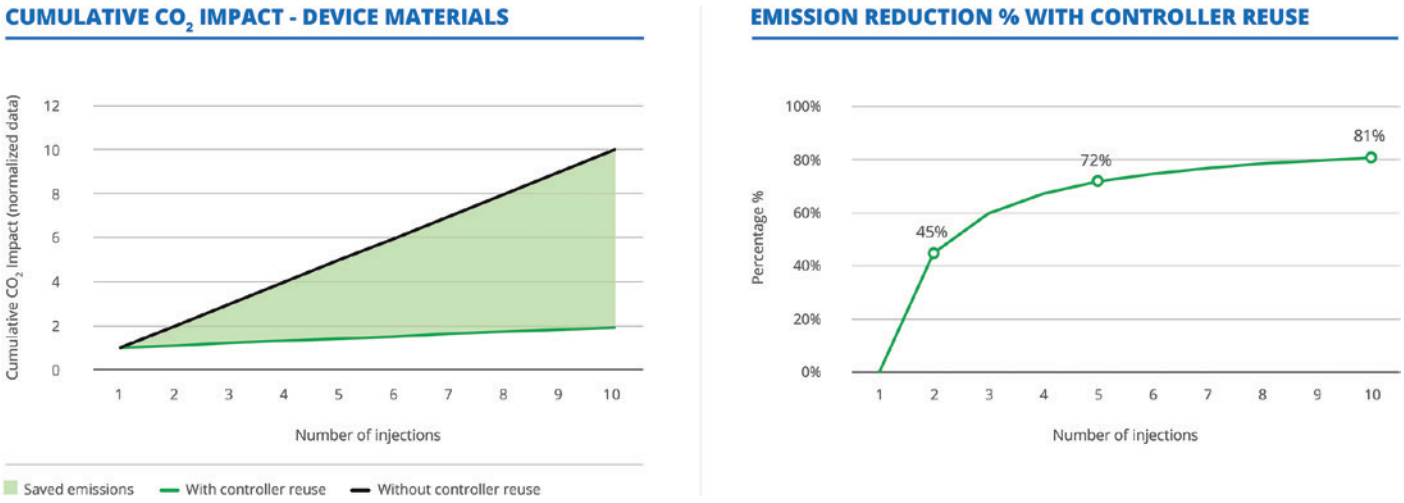

Figure 3: Preliminary material LCA on Vertiva® 3mL (analysis provided by an independent third party).

total global warming potential, compared with just 16% for plastics.[6] Based on these results, it is clear that reusable designs are key to mitigating the environmental impact of electronics. This was also found in a preliminary lifecycle analysis conducted by Stevanato Group on Vertiva, which compared emissions from its current semi-reusable design with those of a hypothetical single-use equivalent. The analysis found that emissions from device materials were nearly halved after just one reuse and reduced by approximately 70% after the fifth use (Figure 3). These findings underscore the potential of modular, reusable designs to significantly reduce the carbon footprint of a therapeutic regimen when electronics are involved.

However, one key imperative remains – sustainability must not compromise patient safety or usability. Looking back at Stevanato Group's preference study, Vertiva outperformed the comparison device in perceived usability, particularly in the ease of starting treatment. Over 80% of patients considered Vertiva easier to prepare, appreciating its preloaded and prefilled design, which eliminates the risks associated with manual drug cartridge loading. When asked about their overall device preference, eight out of 12 patients chose Vertiva, with most of these participants emphasising a perceived superiority in usability alongside its sustainability benefits. This result demonstrates that usability and sustainability can coexist when user-centric design principles guide product development.

CONCLUSION

Moving the healthcare sector towards sustainability requires a deep understanding of patient preferences to ensure adoption without compromising care. While studies consistently show that patients prioritise ease of use and reliability, sustainability is increasingly becoming a key differentiator. As the healthcare sector aligns more closely with the sustainability trends seen in other industries, its importance to patients is expected to grow even further.[7]

Insights from Stevanato Group's research demonstrate how innovations like the Vertiva® 10 mL semi-reusable OBDS can address both patient needs and environmental concerns. By promoting modular designs, along with effective patient education and clear product communication, the industry can move towards a future where sustainability and patient care go hand in hand.

Don't miss the chance to attend the PDA Miniverse on June 25–26, 2025, which will include a tour of Stevanato Group's new, state-of-the-art US hub. Subscribe to the PDA Miniverse Conference, visit Stevanato Group at booth #218 and join us in Fishers (IN, US) on June 24. ***https://www.stevanatogroup.com/en/news-events/events/pda-miniverse-2025/***

REFERENCES

1. *"Health Care's Climate Footprint: How the Health Sector Contributes to the Global Climate Crisis and Opportunities for Action". Health Care Without Harm, Sep 2019.*
2. *D'Ancona G et al, "The sustainability agenda and inhaled therapy: what do patients want?". Eur Respir J, 2021, Vol 58(Suppl 65), art PA3399.*
3. *Bürdel S, Abedian R, "The Importance of User-Centric Design When Developing Devices for Home Use." ONdrugDelivery, Issue 164 (Sep 2024), pp 36–40.*
4. *Schneider A, "Decoding the Obesity Revolution: Mapping Device Needs and Patient Preferences for Emerging Injectable Obesity Therapies". Presentation, PDA Universe of Pre-Filled Syringes and Injection Devices, Oct 2024.*
5. *Lange J, "Patient Voices in Sustainable Drug Delivery: Insights on Self-Injection Devices". Presentation, PDA Universe of Pre-Filled Syringes and Injection Devices, Oct 2023.*
6. *Natarajan P, Bavar S, Dean C, "How Lifecycle Assessment Supports Insight-Driven Sustainable Design". ONdrugDelivery, Issue 153 (Oct/Nov 2023), pp 16–19.*
7. *"2024 Global Healthcare Sector Outlook: Navigating Transformation". Report, Deloitte, Feb 2024.*

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2025/26 Editorial Calendar

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

MAY 2025 Delivering Injectables: Devices & Formulations DEADLINE PASSED	**MAY/JUN** Oral Drug Delivery DEADLINE PASSED	**JUN** Connectivity in Drug Delivery DEADLINE PASSED
JUL Industrialising Drug Delivery DEADLINE: **May 15, 2025**	**SEP** Wearable Injectors DEADLINE: **Aug 7, 2025**	**SEP/OCT** **NEW ISSUE TOPIC** Dual Chamber Delivery Systems DEADLINE: **Aug 14, 2025**
OCT Prefilled Syringes & Injection Devices DEADLINE: **Sep 4 , 2025**	**OCT/NOV** Sustainability in Drug Delivery DEADLINE: **Sep 18, 2025**	**NOV** Pulmonary & Nasal Drug Delivery DEADLINE: **Oct 2, 2025**
DEC **NEW ISSUE TOPIC** Delivering Gene & Cell Therapeutics DEADLINE: **Nov 6, 2025**	**JAN 2026** Prefilled Syringes & Injection Devices DEADLINE: **Dec 4, 2025**	**FEB** Skin Drug Delivery: Dermal, Transdermal & Microneedles DEADLINE: **Jan 8, 2026**
MAR Ophthalmic Drug Delivery DEADLINE: **Feb 5, 2026**	**APR** Pulmonary & Nasal Drug Delivery DEADLINE: **Mar 5, 2026**	**APR/MAY** Sustainability in Drug Delivery DEADLINE: **Mar 19, 2026**

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20 YEARS ON drugDELIVERY

FIVE CRUCIAL COMPONENTS OF A SUCCESSFUL SUSTAINABLE PROCUREMENT STRATEGY

Ann Cartwright and **Tim Hansen** of **PCI Pharma Services** explain the company's five key components of its sustainable procurement strategy to increase efficiency, meet regulatory demands and support business resilience and sustainability in the long term.

In recent years, sustainability has become more than just a buzzword. It is now a central element of strategic planning, particularly within the pharmaceutical industry. According to a report by EcoVadis in 2024, more than 70% of programmes state that their top procurement driver is delivering on corporate sustainability goals and commitments.[1] The demand for environmentally friendly products, coupled with increasing regulatory pressure, are additional factors that have led pharmaceutical organisations to reconsider how they source their materials, manage their suppliers and align with global sustainability goals.

A sustainable procurement (SP) strategy is not just a matter of compliance – it is a way to future-proof businesses, drive efficiencies and build long-term value for clients and patients.

FIVE KEY COMPONENTS OF A SUCCESSFUL SP STRATEGY

Clear Roadmap

Any successful SP strategy begins with a clear roadmap, which is the foundation

> "A WELL-DEFINED ROADMAP HELPS TO ALIGN SUSTAINABILITY GOALS WITH BROADER CORPORATE OBJECTIVES."

for setting realistic, measurable goals that guide the organisation towards its sustainability objectives. PCI Pharma Services recognised early on that sustainability was not just a "nice-to-have" but an essential part of the company's long-term vision. The first challenge was to outline what sustainability meant for the organisation, focusing on the nine key pillars of its overarching environmental, social and governance (ESG) strategy that would ultimately guide its efforts.

A well-defined roadmap helps to align sustainability goals with broader corporate objectives. It provides direction, ensuring that every action taken is purposeful and linked to the company's overall mission. Importantly, this strategy should not be static – regular evaluations and updates are needed to keep up with evolving sustainability practices, emerging regulations and shifting market dynamics. By doing so, organisations can adapt to new challenges and remain on track to achieve their goals.

A strong starting point is to create a comprehensive sustainability framework, informed by both internal goals and the United Nations Sustainable Development Goals (SDGs). This allows companies to break down complex sustainability concepts into tangible, actionable steps. With a roadmap in place, companies can identify key areas for improvement, track progress and adjust their approach as needed.

Environment of Partnership and Collaboration

Sustainability is not a competitive advantage – it is a collective effort. Building an environment of partnership and collaboration is crucial to the success of any SP strategy. Within the pharmaceutical industry, where procurement has traditionally focused on cost, quality and service, sustainability is now being incorporated into the purchasing and supplier evaluation process. A vendor's environmental impact, labour standards and commitment to sustainable practices should be given equal weight in procurement decisions.

PCI discovered that working together with both suppliers and clients was essential to advance its sustainability efforts. In some areas, such as sustainable packaging and renewable energy sourcing, collaboration with suppliers has been key to driving meaningful change. Rather than viewing sustainability as a competitive edge, PCI has approached it as an area where everyone can improve, learning from one another and sharing best practices.

Figure 1: Supplier engagement grounded in trust, mutual respect and shared values is at the core of PCI's SP programme.

Additionally, fostering a culture of open communication with suppliers allows organisations to understand their sustainability journey and capabilities better. PCI encourages suppliers to openly discuss their sustainability initiatives, without fear of penalties or judgement for being at different stages in their journey. By creating this collaborative environment, PCI can assess the genuine commitment of its suppliers and work alongside them to create long-term, sustainable solutions (Figure 1).

Policies and Procedures

Policies and procedures form the backbone of any SP strategy. They provide the framework for decision making and ensure that sustainability principles are consistently applied across the organisation. Effective policies should cover every aspect of procurement, from supplier selection to compliance with environmental and social best practices just to shorten sentence a bit.

"FOSTERING A CULTURE OF OPEN COMMUNICATION WITH SUPPLIERS ALLOWS ORGANISATIONS TO UNDERSTAND THEIR SUSTAINABILITY JOURNEY AND CAPABILITIES BETTER."

PCI has developed clear policies that prioritise ethical labour standards, environmental responsibility and adherence to sustainable sourcing practices. These policies guide the company's decision making and provide transparency both internally and externally. Furthermore, PCI has built a comprehensive procedure for evaluating and engaging suppliers on sustainability efforts, ensuring that it is working with organisations that align with the company's values and sustainability goals.

As sustainability continues to become more central to procurement, organisations must update their policies regularly to reflect new regulations and emerging

industry standards. For instance, as global environmental regulations evolve, companies must ensure their procurement policies are aligned with legislative changes, such as carbon reduction targets and waste management protocols.

A key element of these policies is the ability to measure compliance. Companies should incorporate clear, verifiable standards into their procedures to ensure that both they and their suppliers remain accountable for their sustainability commitments.

Data and Metrics

A data-driven approach is essential to tracking and measuring the effectiveness of any SP strategy. Without accurate data, it is impossible to understand where improvements are needed or to assess progress over time. Metrics allow organisations to evaluate the environmental impact of their procurement activities and ensure alignment with sustainability goals.

To support these efforts, PCI invested heavily in capturing data related to its sustainability efforts, specifically across the nine key pillars of its strategy. By gathering and analysing data on energy consumption, waste generation, emissions and supplier sustainability practices, PCI can identify areas for improvement and benchmark its performance against industry standards.

These metrics are essential for reporting to stakeholders, including customers, suppliers, employees, investors and regulatory bodies. They provide transparency, showcasing the tangible impact of sustainability efforts and reinforcing the organisation's commitment to responsible sourcing. As sustainability reporting becomes increasingly important, especially with rising regulatory pressure, companies must invest in tools and systems that allow them to capture, analyse and report more complex sustainability data accurately and effectively.

By aligning its metrics with the UN SDGs, PCI ensures that its procurement decisions contribute meaningfully to global sustainability efforts. Moreover, continuous tracking of its data allows the company to adjust its strategy in real-time, making improvements where necessary to ensure it is meeting its goals (Figure 2).

"BY GATHERING AND ANALYSING DATA ON ENERGY CONSUMPTION, WASTE GENERATION, EMISSIONS AND SUPPLIER SUSTAINABILITY PRACTICES, PCI CAN IDENTIFY AREAS FOR IMPROVEMENT AND BENCHMARK ITS PERFORMANCE AGAINST INDUSTRY STANDARDS."

Figure 2: PCI's internal company mission is to develop world-class, industry-leading talent by investing in its people.

A Dedicated Team

Lastly, a successful SP strategy requires the right team to drive it forwards. Building an internal team of sustainability champions is crucial for embedding sustainable practices into the fabric of the organisation. PCI has grown its team of ESG professionals to over 100 individuals across its global network. This diverse, cross-functional team spans across the organisation and is responsible for executing its ESG strategy and ensuring that sustainability is considered in every aspect of procurement.

Leadership support is essential in this regard, as it provides the resources, funding and authority needed to implement sustainability initiatives effectively. Additionally, team members should be equipped with the knowledge and tools to make informed decisions, ensuring that sustainability is at the forefront of procurement processes.

Training and awareness programmes are also important for ensuring that everyone in the organisation understands the importance of SP. By empowering employees with the knowledge to make responsible sourcing decisions, companies can integrate sustainability goals into their

"TEAM MEMBERS SHOULD BE EQUIPPED WITH THE KNOWLEDGE AND TOOLS TO MAKE INFORMED DECISIONS, ENSURING THAT SUSTAINABILITY IS AT THE FOREFRONT OF PROCUREMENT PROCESSES."

daily operations and create a culture of environmental responsibility throughout the organisation.

CONCLUSION

SP is no longer optional – it is a necessity for companies looking to stay competitive in an increasingly eco-conscious world. By focusing on these five crucial components – clear roadmaps, partnerships and collaboration, robust policies and procedures, data-driven metrics and the right team – organisations can build an SP strategy that drives efficiency, meets regulatory demands and contributes to long-term business resilience. For the pharmaceutical industry, adopting such a strategy is essential not only for compliance but also for improving corporate responsibility and building long-term sustainability.

By working together with suppliers, clients and other stakeholders, the pharmaceutical industry can create a future where sustainability is woven into every aspect of business, from product development to procurement. As we move forwards, it is essential to remember that SP is about collaboration, not competition. It is an industry-wide effort, and we are all in this together.

REFERENCE

1. *"Sustainable procurement barometer 2024". Research Report, EcoVadis and Accenture, 2024.*

Ann Cartwright

Ann Cartwright is the GSC Sourcing Systems Strategy Director for PCI, where she harmonises contracts and best practices across the global procurement space. She also heads up the Indirect Spend category globally and is heavily involved with cost-saving and continuous improvement projects. Ms Cartwright recently undertook the role of SP Lead with a team of buyers, working towards specific goals and targets aligned with the pillars of PCI's ESG strategy pillars. These include setting key performance indicators with PCI's supply partners on topics such as Scope 3 emissions, waste generation, diversity and sustainable innovations.

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Tim Hansen

Tim Hansen, Director of ESG for PCI Global, is a seasoned sustainability professional with nearly 15 years of experience in environmental, social and corporate governance programme development, strategy, engagement and reporting. He joined PCI in 2024 and is responsible for driving the ESG strategy to achieve the company's sustainability goals. Drawing from a diverse background in healthcare, law and ESG, Mr Hansen brings a unique perspective to integrating ESG principles into business strategy, engaging key stakeholders to promote actionable change and foster accountability. Mr Hansen holds a Master of Public Administration degree with certifications in sustainable business practices, equity and climate change.

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SUSTAINABILITY IN DRUG DELIVERY: INNOVATIONS IN PLASTIC COMPONENTS AND CIRCULAR DESIGN

Edwin van der Heul of **ALBIS** considers the increasing regulatory pressure on manufacturers to deliver sustainable solutions in the medical device industry. This article explores these innovations and their impact on the future of drug delivery devices.

The pharmaceutical and medical technology industries are undergoing a significant transformation, driven by the growing demand for sustainability. Drug delivery devices, including insulin pens, inhalers, nebulisers and monitoring systems, are increasingly expected to integrate environmentally friendly materials and circular design principles. As regulatory pressure mounts and consumer awareness grows, manufacturers are shifting towards sustainable solutions, such as mass balance approaches, biopolymers and advanced recycling techniques (Figure 1).

THE ROLE OF PLASTICS IN DRUG DELIVERY DEVICES

Plastics are the materials of choice for drug delivery devices due to their light weight, durability and cost effectiveness. They provide precise dosing, sterility and ease of use, making them indispensable in diabetes care and respiratory therapies. However, their perceived environmental impact, particularly in terms of waste generation and carbon footprint, has led to greater scrutiny and a growing demand for more sustainable alternatives.

"MANUFACTURERS ARE SHIFTING TOWARDS SUSTAINABLE SOLUTIONS, SUCH AS MASS BALANCE APPROACHES, BIOPOLYMERS AND ADVANCED RECYCLING TECHNIQUES."

Figure 1: Sustainable solutions are increasingly required in the drug delivery industry.

SUSTAINABLE MATERIAL INNOVATIONS

To better understand the role of plastics, consider the example of an autoinjector. These devices consist of many parts, most of which are plastic. To reduce the carbon footprint of such drug delivery devices, the following factors must be considered.

Mass Balance Approach

The mass balance approach is a widely adopted method for tracking the amount of circular and/or bio-based content in the value chain and allocating it to final products through verifiable bookkeeping. It allows manufacturers to gradually replace fossil-based raw materials with bio-based or chemically recycled content while maintaining existing production infrastructure. This approach enables a seamless transition to sustainable plastics without compromising performance, safety or regulatory compliance.

Biopolymers

Biopolymers, derived from renewable sources – such as corn starch, sugarcane or cellulose – are emerging as viable alternatives to conventional plastics. These materials offer reduced carbon footprints and, in some cases, are biodegradable. However, challenges remain in terms of mechanical strength, compatibility with drug formulations and long-term stability.

Chemical and Mechanical Recycling

- **Mechanical recycling** involves sorting, shredding and reprocessing plastic waste into new products. While effective for many packaging applications, medical-grade plastics often pose challenges due to contamination and stringent regulatory requirements.
- **Chemical recycling** breaks down plastics into their fundamental monomers, enabling the production of high-quality recycled materials suitable for medical applications. This method ensures that end-of-life drug delivery devices can be reintegrated into the supply chain without degrading performance.

DESIGN FOR CIRCULARITY VERSUS DROP-IN SOLUTIONS

Circular Design Principles

To achieve sustainability, drug delivery devices must be designed for circularity – maximising reuse, recyclability and material recovery. Key design strategies include:

- Modular components for easier disassembly and recycling
- Single-material designs to simplify sorting and processing
- Refillable and reusable systems to reduce single-use plastic waste.

Drop-In Solutions

Drop-in solutions refer to sustainable materials and processes that seamlessly replace traditional ones without requiring

"TO ACHIEVE SUSTAINABILITY, DRUG DELIVERY DEVICES MUST BE DESIGNED FOR CIRCULARITY – MAXIMISING REUSE, RECYCLABILITY AND MATERIAL RECOVERY."

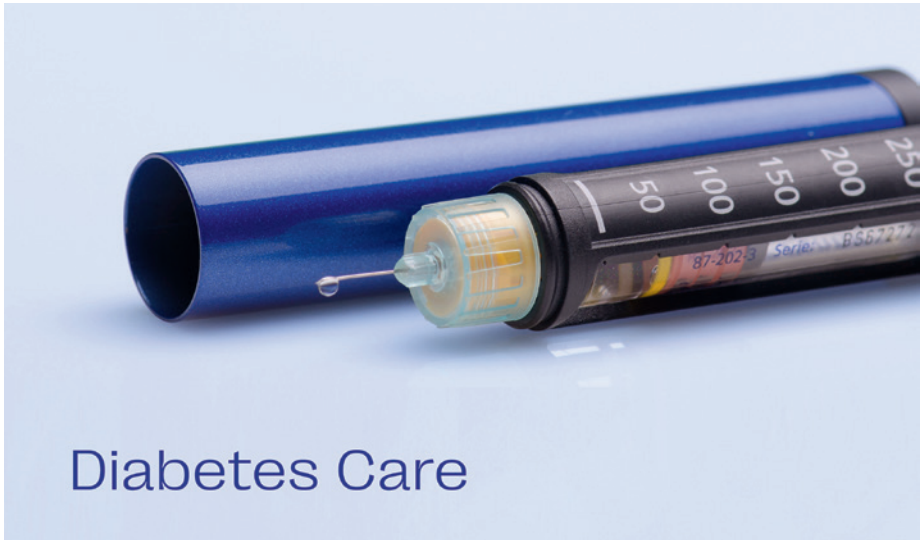

Figure 2: In diabetes care, chemically recycled plastics can replace virgin plastics in insulin pens and inhalers.

significant design or production changes. For instance, chemically recycled plastics can replace virgin plastics in insulin pens and inhalers, promoting sustainability without sacrificing quality or performance (Figure 2).

REGULATORY AND INDUSTRY CHALLENGES

The shift to sustainable drug delivery solutions must align with stringent medical regulations. Key considerations include:

- **Regulatory Approval:** Ensuring that new materials meet safety and efficacy standards set by agencies such as the US FDA and EMA.
- **Supply Chain Integration:** Scaling up sustainable materials while maintaining cost efficiency and availability.
- **Patient Adherence:** Ensuring that sustainable devices maintain usability, durability and reliability to support patient health outcomes.

"INNOVATIONS SUCH AS BIO-BASED POLYMERS, IMPROVED RECYCLING TECHNOLOGIES AND ENHANCED LIFECYCLE ASSESSMENTS WILL DRIVE THE NEXT GENERATION OF DRUG DELIVERY DEVICES."

FUTURE OUTLOOK

As sustainability becomes a growing priority, the medical technology industry is poised for further advancements. Innovations such as bio-based polymers, improved recycling technologies and enhanced lifecycle assessments will drive the next generation of drug delivery devices. Collaboration between manufacturers, regulatory bodies and research institutions will be essential in achieving long-term sustainability goals.

WHAT CAN ALBIS OFFER TO SUPPORT THESE SUSTAINABILITY GOALS?

ALBIS, a prominent, globally active distributor of thermoplastics headquartered in Germany, has been expanding its portfolio to include sustainable materials suitable for healthcare applications, including drug delivery devices (Figure 3).

ALBIS is committed to enhancing the sustainability of drug delivery devices, such as insulin pens, by focusing on drop-in solutions and single-resin designs to facilitate easier recycling. These initiatives align with the industry's shift towards environmentally friendly solutions, focusing on materials that

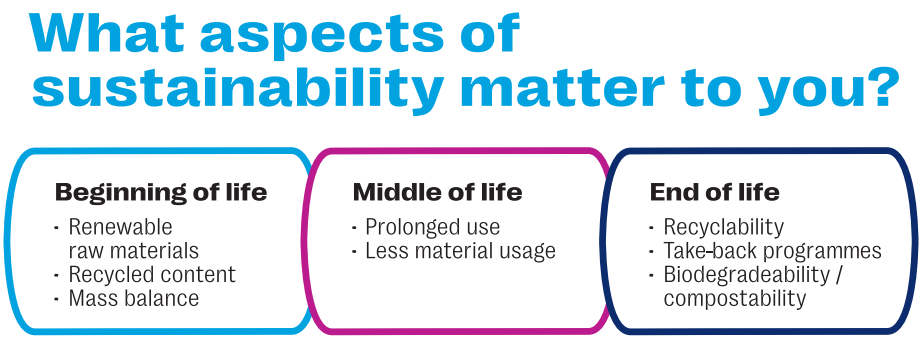

Figure 3: ALBIS offers a wide range of solutions from trusted partners to address various aspects of sustainability.

reduce carbon footprints while maintaining high performance. The question for selecting the best fit-for-use material is "What aspects of sustainability matter to you?"

SUSTAINABLE MATERIALS AND SOLUTIONS

Bio-based and Chemically Recycled PET Products

ALBIS has introduced Skypet CR and Ecozen, produced by SK Chemicals (Seongnam, South Korea), into its sustainable materials portfolio. Skypet CR is made from chemically recycled polyethylene terephthalate (PET) waste, offering a lower carbon footprint without compromising quality. Ecozen is a bio-based copolyester with excellent transparency and processability, making it an excellent fit for healthcare applications.

Bio-Based and Recycled Styrenics

Partnering with INEOS Styrolution (Frankfurt am Main, Germany), ALBIS distributes materials such as Styrolux ECO, Styroflex ECO, NAS ECO, Novodur ECO HD and Luran ECO. Derived from renewable feedstocks, such as kitchen and wood waste, these materials offer a significant reduction in carbon footprint – between 50% and 99% compared with conventional options. Their properties make them suitable for various applications, including for components in drug delivery devices.[1]

Renewable Raw Materials

ALBIS distributes CirculenRenew materials for LyondellBasell (TX, US) as part of its Purell line. These polymers are based on used cooking oil as a feedstock. The CirculenRenew product line includes polypropylene and polyethylene (high-density polyethylene and low-density polyethylene) grades of the same quality as virgin polymers that reduce the use of fossil resources. They also help lower CO_2 emissions over the product lifecycle. These renewable-based polymers maintain the same properties in terms of product performance and regulatory approval processes, making them a perfect drop-in solution for applications with high quality requirements. CirculenRenew polymers significantly reduce carbon footprints compared with their fossil-based equivalents.

Renewable-Attributed Polycarbonates

With Covestro (Leverkusen, Germany), ALBIS offers polycarbonate grades from bio-circular resources. These materials represent a significant stride in the development of intelligent circular materials; tailor-made as direct drop-in solutions for a reduced carbon footprint of the final product. Covestro's new line of healthcare-grade products – including low-friction Makrolon®, glass-filled Makrolon®, high-flow Makrolon® and Bayblend® – bring new levels of performance and sustainability to the medical device market.

To demonstrate design for circularity, Covestro has developed a concept drug delivery device that uses polycarbonate solutions, each purpose-built for medical applications. It addresses multiple challenges in building sustainable healthcare products, including reducing weight, enabling smooth and controllable operation, and maintaining toughness, rigidity and dimensional stability under spring load and after radiation sterilisation.

100% Bio-Based

Rilsan® MED PA11 products, which ALBIS recently added to its biocompatible portfolio, are manufactured by Arkema (Colombes, France). Rilsan® MED products belong to a family of long-chain polyamides, which have significantly different properties to short-chain polyamides, such as PA6 or PA66. These unique features of long-chain polyamides include resistance to chemicals, hydrolysis and hydrocarbons, as well as being lightweight and having high dimensional stability. Additional features include low- and high-temperature performance (-40°C to +130°C) and good barrier properties.

IMPLICATIONS FOR DRUG DELIVERY DEVICES

The materials distributed by ALBIS, which combine reduced environmental impact with high performance, present viable options for manufacturers aiming to enhance the sustainability of drug delivery devices. By integrating these sustainable materials, companies can address environmental concerns without compromising the safety, efficacy or quality of their products.

"THE MATERIALS DISTRIBUTED BY ALBIS, WHICH COMBINE REDUCED ENVIRONMENTAL IMPACT WITH HIGH PERFORMANCE, PRESENT VIABLE OPTIONS FOR MANUFACTURERS AIMING TO ENHANCE THE SUSTAINABILITY OF DRUG DELIVERY DEVICES."

Through strategic partnerships and a commitment to sustainability, ALBIS provides the medical device industry with materials that support the development of eco-friendly drug delivery solutions.

CONCLUSION

The transition to sustainable drug delivery solutions is not just a necessity but an opportunity to innovate and create a more environmentally responsible healthcare system. By using mass balance approaches, biopolymers, advanced recycling and circular design principles, the industry can address the increasing demand for sustainability while ensuring the safety and efficacy of life-saving medical devices.

REFERENCE

1. *"Renewable Carbon by nova-Institute". Company Web Page, nova-Institute, accessed Apr 2025.*

Edwin van der Heul

Edwin van der Heul had 29 years of plastics experience at ALBIS in various positions before he joined the ALBIS Healthcare Team in 2016 as dedicated Healthcare Business Development Manager. Recently, Mr van der Heul has contributed at ALBIS to a study of the European Kidney Health Alliance: "The European Green Deal and nephrology: a call for action" and, this year, has joined the MedPharmPlast Europe Workgroup on Sustainability. He believes that a circular economy is a joint effort and welcomes current innovations in this segment. Mr van der Heul is based in Rotterdam, the Netherlands, and his region covers the Benelux and Southern Europe in supporting his contacts in selection of the large portfolio of medical grade plastics from ALBIS and its partners, among which are some of the world's leading plastics manufacturers.

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Early Insight

BIOPLASTICS IN DRUG DELIVERY: GETTING RID OF CRITICAL SUBSTANCES AND CARBON EMISSIONS

BIOVOX

Julian Lotz of **BIOVOX** introduces bio-based solutions for drug delivery devices, excelling in quality while meeting upcoming sustainability regulations, and explores the future of bioplastics in the healthcare sector.

The sustainability and safety of materials is driven by four main factors. First, the sheer need to reduce the use of substances that harm human health and the environment, including the climate. Second, there is increasing regulatory pressure on human and environmental health. Third, the use of safer and more sustainable materials is a valid marketing advantage in many tenders across Europe. Finally, having no critical substances and a low carbon footprint is a mandatory risk management strategy for product risks. Ultimately, future-proof materials strengthen business. These four aspects will influence the materials selected for autoinjectors, inhalers, sprays and squeeze dispensers in the future (Figure 1).

The healthcare industry cannot risk drastic health problems and irreversible environmental damage that is, in turn, detrimental to the health of us all. The threat posed by critical substances is

"THE HEALTHCARE INDUSTRY CANNOT RISK DRASTIC HEALTH PROBLEMS AND IRREVERSIBLE ENVIRONMENTAL DAMAGE THAT IS, IN TURN, DETRIMENTAL TO THE HEALTH OF US ALL."

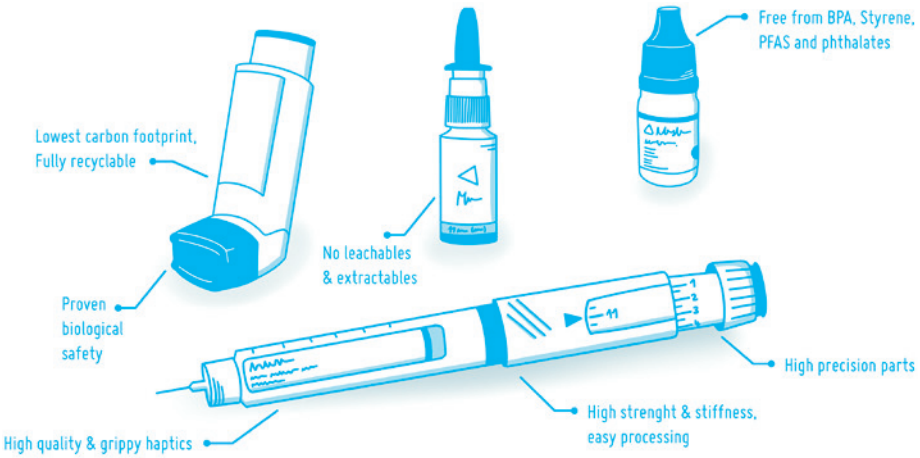


Figure 1: Medical-grade bioplastics can be used in a variety of drug delivery devices – with full safety and great sustainability.

also being recognised by legislation, such as the EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the polyfluoroalkyl substances (PFAS) ban already in place in Minnesota (US), with a similar ban proposed by the European Chemicals Agency for the EU. The healthcare industry will see the phase-out of critical substances, such as ultra-persistent PFAS, or additives and monomers that act as endocrine disrupters, causing all kinds of hormone-related health problems, often affecting sexual reproduction. Examples include not only polytetrafluoroethylene (PTFE) but also PFAS-containing additives in polyethylene (PE) grades, bisphenol A in polycarbonates (PC) or phthalates such as di(2-ethylhexyl) phthalate (DEHP) used as a plasticiser in PVC, both highly critical endocrine disruptors.

In addition to direct health risks, plastics contribute to climate change at all stages of their lifecycle. Incineration is still the most common end-of-life scenario for drug delivery devices, thus releasing the carbon from fossil-based plastics directly into the atmosphere. Some of them, such as the PC and acrylonitrile butadiene styrene (ABS) often found in drug delivery devices, are not even particularly efficient to produce, resulting in a huge overall carbon footprint of around 6 kg CO_2e per kg of PC and almost 7 kg CO_2e per kg of ABS[1] (Figure 2).

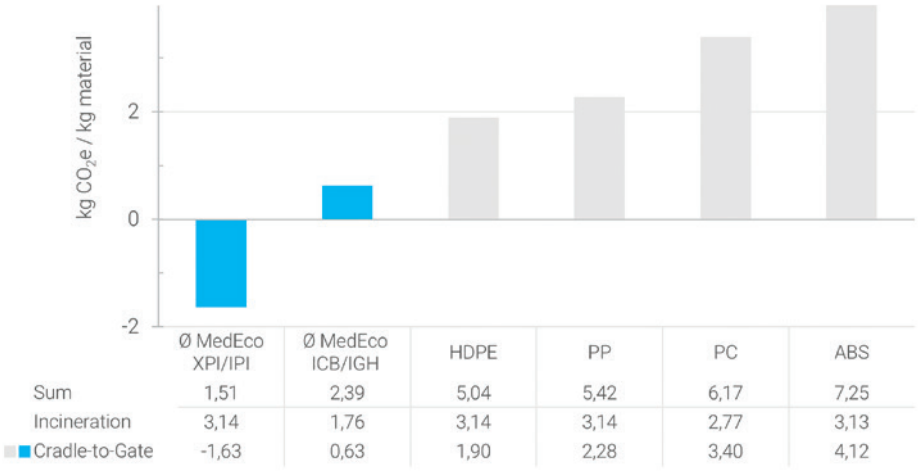
This is significant when you look at pharmaceutical companies' targets: GSK is aiming for an 80% reduction in carbon emissions by 2030, Novo Nordisk a 33% reduction in Scope 3 emissions by 2033 and Sanofi a 55% reduction in CO_2e by 2030. Additionally all three are aiming for net-zero emissions by 2045, as is Johnson & Johnson, which wants 80% of its supply chain to meet science-based targets by 2028. Pfizer is aiming for net zero by 2040.

All in all, this is slightly more ambitious than what the EU climate legislation requires. With 80% to more than 90% of emissions coming from the supply chain, the need for carbon-efficient plastics in drug delivery and packaging is clear (Figure 3).

For example, the Packaging and Packaging Waste Regulation (PPWR) will drive a number of material changes for recyclable products over the next few years, moving the industry away from fossil-based polymers currently in use. What does this mean for drug delivery devices?

FUTURE-PROOFING INJECTORS AND DRY POWDER INHALERS WITH PLA?

With bioplastics being the simplest material solution that can meet industry requirements, such as medical-grade plastics defined in the VDI 2017 Medical-Grade Plastics guideline, they can address both health and environmental risks.



	Ø MedEco XPI/IPI	Ø MedEco ICB/IGH	HDPE	PP	PC	ABS
Sum	1,51	2,39	5,04	5,42	6,17	7,25
Incineration	3,14	1,76	3,14	3,14	2,77	3,13
Cradle-to-Gate	-1,63	0,63	1,90	2,28	3,40	4,12

Figure 2: Carbon footprints of various plastics used in drug delivery devices.

Figure 3: Medical blister packaging made from MedEco XCB – a substitute for PET.

"BIOVOX'S MEDECO PLASTICS ARE PARTICULARLY SUITED TO THE HEALTHCARE MARKETS – THEY ARE NOT ONLY SUSTAINABLE BUT ALSO PATIENT SAFE AND LONG-TERM STABLE IN FORMULATION AND PROVENANCE."

Figure 4: MedEco IGH inside a dish made of the transparent MedEco ICB; one of the preferred bioplastics for autoinjectors and inhalers

With no critical substances and up to 85% lower carbon emissions, including when incinerated at the end of their life, a range of bioplastics offers the potential to meet future requirements and mitigate regulatory risks. BIOVOX's MedEco plastics are particularly suited to the healthcare markets – they are not only sustainable but also patient safe and long-term stable in formulation and provenance. BIOVOX offers comprehensive change notifications, proven biocompatibility, extensive documentation – including the effects of ageing and various sterilisation methods on the material – and development and production under ISO 13485 quality management. These are necessary prerequisites for the use of plastics in drug delivery devices but, in particular, the PLA-based MedEco ICB and MedEco IGH offer properties that are perfectly suited to the autoinjectors and inhalers of the future (Figure 4). Why is this the case?

BIOVOX's PLA-based MedEco ICB and IGH offer key benefits for drug delivery devices, such as autoinjectors and inhalers. Their high mechanical strength and stiffness ensure durable, reliable and material-efficient designs that reduce the use of plastics without compromising device integrity. Both of these MedEco grades have higher stiffness than PC or ABS and are easy-flowing, enabling thinner parts to be used that reduce cycle times and save material, while decreasing costs and environmental impact. Lower processing temperatures – approximately 50°C lower than ABS and 100°C lower than PC – also save energy. Additionally, minimal energy is required to produce PLA, with a cradle-to-gate footprint of only about 0.6 kg CO_2e per kg of MedEco ICB. The materials are fossil-free, which also reduces dependence on fossil resources from politically unstable regions.

ICB also offers excellent glass-like transparency, making it ideal for components that require visual monitoring of the drug or mechanism. In addition, low shrinkage, high surface hardness and precise detail reproduction enable the production of high-precision components, which are critical for consistent performance of drug delivery devices. The feel of a material further enhances perceived quality – IGH offers excellent grip with vinyl and nitrile gloves, both wet and dry, improving the user experience of autoinjectors. A prime example of these benefits in action is a trocar system developed and demonstrated by Röchling Medical (Baden-Württemberg, Germany).[2]

ADDRESSING PLA END-OF-LIFE AND RECYCLING MYTHS

However, the real bonus of PLA comes at the end of its life. PLA is one of the most versatile polymers when it comes to disposal. With 100% bio-based carbon, today's standard disposal – incineration – is climate neutral. The CO_2 emitted has been captured by the plants from which the polymer is made, closing the carbon cycle over a growing season.

In addition to incineration, PLA has faced a number of misconceptions in the past, particularly with regard to recycling. Recycling, such as that being set up in Denmark and France for autoinjectors, is necessary to move healthcare towards a circular economy. It further reduces the consumption of energy and raw materials, thereby reducing the carbon emissions and impact categories associated with agricultural processes.

Let's clear up a common misconception right away – yes, PLA is recyclable within existing industrial processes. For post-consumer waste, current recycling rates remain low due to limited volumes. However, as PLA adoption increases, mechanical recycling will increase for economic reasons. Post-industrial PLA waste is already being mechanically recycled today. BIOVOX has conducted tests and found that its PLA-based MedEco grades degrade only slightly over six cycles of production and regranulation – similar to medical polyolefins, such as the company's MedEco Bio-PE grades. Moreover, PLA does not interfere with the recycling of other polymers – it can be easily and reliably identified by near-infrared sorting

"BEST OF ALL, AS POLYESTERS, MEDECO ICB AND IGH CAN BE EASILY CHEMICALLY RECYCLED IN A MONOMER-RECYCLING PROCESS."

technologies and then separated using modern sorting technologies. Traces of other polymers are inevitable in any recycling process, and PLA is no more problematic than any other material.[3]

Best of all, as polyesters, MedEco ICB and IGH can be easily chemically recycled in a monomer-recycling process. With double the yield and half the energy consumption compared with pyrolytic chemical recycling, a medical-grade recyclate can be produced with half the footprint of virgin material but with 100% patient safety. BIOVOX is currently demonstrating this in research projects, including in contaminated waste streams.

Figure 5: Injection-moulded parts of surgical devices, device packaging and a syringe using BIOVOX MedEco bioplastics.

SPRAYS, DROPPERS AND PHARMACEUTICAL PACKAGING

BIOVOX is constantly researching formulations with new biopolymers and drop-in polymers to expand the possibilities for sustainable healthcare materials (Figure 5).

One promising material is bio-based PE, which is emerging as a viable option for soft packaging, tubes and ophthalmic squeeze dispensers, for example. It offers excellent barrier properties against water vapour diffusion and performs as well as its fossil-based counterpart, while significantly reducing environmental impact. Its carbon footprint is negative on a cradle-to-gate basis and releases only about 20% of the emissions of fossil-based PE in incineration scenarios – just over 1 kg CO_2e per kg PE compared with 5 kg CO_2e per kg fossil-based PE, cradle-to-grave, including incineration at end of life.

Another exciting innovation for bottles and blisters is PE furanoate (PEF) – a polymer made from renewable resources. PEF also has superior barrier properties against oxygen and other gases, making it particularly attractive for pharmaceutical packaging that requires extended shelf life and high protection against external factors. BIOVOX is always happy to start pilot projects with customers who want to be at the forefront of sustainability by using development-stage MedEco grades.

IN A NUTSHELL: FUTURE-PROOFING DRUG DELIVERY DEVICES WITH BIO-BASED MATERIALS

Transforming healthcare by using materials without critical content is an imperative for all pharma and medtech companies. Combining this effort with the transition to a sustainable, circular economy for healthcare plastics is the icing on the cake – it is not a separate issue from patient safety, it can be solved synergistically. This reduces product risk while improving image and market position.

Many will say there is no room for expensive niche materials. The facts are different – in most of its projects, BIOVOX sees a small 2–5% increase in part cost while reducing the carbon footprint by 60–85% and eliminating BPA and similar substances. In rare cases, the cost per part can be up to 10% higher, however, costs can also be reduced too. On the whole, using bioplastics is a good investment in risk mitigation and marketing.

By implementing sustainable materials such as the MedEco range, manufacturers can future-proof their products and stay ahead of the competition. With EU sustainability regulations and the industry already moving towards circularity – just look at this year's Pharmapack – now is the time to innovate.

BIOVOX is committed to being at the forefront of these advances – working agnostically with polymers to provide the best solutions for each case. BIOVOX achieves this with regulatory and technical competence, with full material safety according to the VDI 2017 Medical-Grade Plastics guideline and with minimal impact on human and environmental health.

ABOUT THE COMPANY

BIOVOX redefines plastics for drug delivery devices and pharmaceutic packaging with its medical-grade bioplastics. Its materials are free from critical substances, such as BPA, PFAS and phthalates, and offer up to 85% lower carbon footprints while ensuring full regulatory compliance and patient safety By using renewable feedstocks, adhering to ISO 13485-certified quality management and conducting rigorous biological safety testing, BIOVOX provides sustainable, high-performance alternatives for the pharma industry.

Dr Julian Lotz

Julian Lotz is Chief Executive Officer and Co-Founder of BIOVOX. With a PhD in mechanical engineering from TU Darmstadt (Germany), he specialises in fibre-reinforced plastics, lightweight design and product development. Dr Lotz did technical consulting for orthopaedics companies and led the Modular Systems department at Votih before co-founding BIOVOX. Since 2020, he has focused on advancing non-toxic, sustainable materials in the healthcare industry with BIOVOX.

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REFERENCES

1. *Rubio-Domingo G, Halevi A, "Making Plastics Emissions Transparent". Coalition On Materials Emissions Transparency, Feb 2022.*
2. *"A Single Use Medical Device Designed for Sustainability". Röchling Medical, Mar 2025.*
3. *"PLA in the Waste Stream". Fachagentur Nachwachsende Rohstoffe and Federal Ministry of Food and Agriculture, Oct 2017.*

IMPORTANCE OF PRE-COLOURED ABS IN INHALATION MEDICAL DEVICES

ELIX POLYMERS | A member of Sinochem International

Luca Chiochia of **ELIX Polymers** discusses the vital role of coloured plastics in medical devices and how the use of pre-coloured, pre-tested solutions can provide not only a significantly reduced regulatory burden for device developers and manufacturers but also a higher quality end product, going on to explain how the company is approaching the critical subject of producing more sustainable polymers.

Medical devices with bright and intense colours are relevant for patients because they stimulate a positive attitude to taking their medications, as well as helping to differentiate device parts and indicate how to use the device correctly. Additionally, distinct colours help to distinguish different types of drugs that target different disease areas.

However, despite colour in medical device applications being such a crucial property, there are strict regulatory limitations on the types of pigments permitted to be used in colour formulations and on their maximum concentrations. According to the requirements set out in ISO 10993, not only the base acrylonitrile butadiene styrene (ABS) material must be biocompatible but also all the additives compounded with the material, including the colour formulation with all its various pigments. No biocompatible pigments must be directly excluded, and maximum allowed pigment concentrations must not be exceeded.

Furthermore, special attention must be given to possible mutual interactions between different pigments, ABS and other additives. ELIX Polymers eliminates those risks for original equipment manufacturers (OEMs), processors and developers by providing a pre-coloured medical-grade ABS material formulation that includes the complete colour recipe and does not need any further material modification. As such, it is invaluable for OEMs to have access to a reviewed and pre-tested formulation that meets biocompatibility standards according to ISO 10993 and other regulatory requirements.

"PRE-COLOURED ABS IS A MUCH SAFER APPROACH FOR MEDICAL OEMS AND MOULDERS, RATHER THAN USING A MEDICAL-GRADE ABS IN NATURAL COLOUR AND COMPOUNDING IT THEMSELVES WITH A MASTERBATCH COLOUR DURING THE INJECTION MOULDING PROCESS."

PRE-COLOURED ABS

Pre-coloured ABS is a much safer approach for medical OEMs and moulders, rather than using a medical-grade ABS in natural colour and compounding it themselves with a masterbatch colour during the injection moulding process. However, the ABS market primarily offers natural ABS, forcing processors, OEMs and moulders to buy natural ABS and assume most responsibilities and risks, additional quality control costs and regulatory compliance verifications at different development and production stages.

As mentioned prior, in the case of pre-tested and pre-coloured medical ABS, the material formulation is not modified by the customer, which reduces their responsibilities, facilitating the medical device approval process and avoiding the risk of compounding mistakes during the injection moulding production process. For ELIX's pre-coloured ABS, all required medical compliance certifications can be provided with reference to the complete material formulation, including all included colour pigments, additives and related concentrations.

Regulatory compliance is a prerequisite for medical devices, but there are also other important quality properties that are strictly related to colour, including homogeneity throughout the complete device part, consistency from lot-to-lot productions and required colour target contrast in case of surface laser marking (typically for traceability reasons to comply with unique device identification regulations). In all of these cases, colour deviations are not permitted, and a pre-coloured ABS can offer advantages compared with natural materials coloured with masterbatch during the injection moulding process.

Pre-coloured ABS is obtained during a compounding extrusion process, mixing the ABS intermediate materials directly with colour pigments in powder form. Three important elements come into play at this point to optimise dispersion homogeneity in the material compound:

- The type of technology used, such as extrusion compounding
- The fact that the colour pigments are in powder form
- The mixing step that happens when the base ABS material is not already a compound but still a "set of ingredients" made of different ABS intermediates, such as the ABS rubber phase (which also comes in powder form) and the ABS matrix phase.

This combination of factors is not possible in the case of an injection moulding process, as injection moulding machines are not specifically designed to mix different ingredients together optimally, but rather to melt, feed and inject specific types of materials into a mould within a reasonable cycle time. On the other hand, extrusion compounding machines can handle powder recipes and have a specific double-screw design that optimises dispersion homogeneity. Twin-screw extruders not only have the right length, length/diameter relationship and shape of helical elements to provide adequate compound mixing and a better interaction between the ABS intermediate and raw materials, but also have a better interaction with the pigments and additives employed. In this way, pre-coloured ABS offers better colour pigment dispersion and homogeneous distribution, which is consistent from lot to lot. Furthermore, laser-marking enhancers benefit from this optimal compounding ability.

In the case of natural ABS post-coloured during the injection process, there is also an additional product needed that is not required for pre-coloured ABS: a colour masterbatch. This includes a carrier (an additional material to the ones mentioned prior) and a concentration of colour pigments. The carrier is needed to encapsulate the colour pigments and help the pigment distribution within the natural ABS during the injection moulding process. Due to the compounding limitations during the injection moulding process, the targets of colour dispersion and lot-to-lot consistency are more difficult to achieve compared with pre-coloured ABS.

Masterbatch carrier compatibility with base material and other additives must be ensured, and production personnel need additional training and competencies for colouring with masterbatch and managing possible unexpected situations, such as colour differences between different injection cycles, production stop, colour troubleshooting and specific interactions between ABS and the masterbatch carrier or colour formulation.

Even when colour targets may be achieved with a masterbatch, there remains room for doubt with regard to the biocompatibility compliance of the final compound ABS and masterbatch, due to the fact that no biocompatibility tests in accordance with ISO 10993 will have been conducted on the resulting compound. Such tests must be conducted on the final devices and not before. However, in the case of pre-coloured medical ABS,

"IN THE CASE OF PRE-COLOURED MEDICAL ABS, THE BIOCOMPATIBILITY TESTS HAVE ALREADY CONDUCTED AND PASSED ON THE COMPLETE COMPOUND OF ABS, COLOUR FORMULATION AND ADDITIVES."

the biocompatibility tests have already conducted and passed on the complete compound of ABS, colour formulation and additives.

COLOUR AND SUSTAINABILITY

When it comes to sustainable design for medical devices, colour quality turns into an even more critical and sensitive property. The demand for new, more sustainable ABS materials for drug delivery device applications is growing in the healthcare sector. Due to the risk of cross-contamination, medical regulatory compliance cannot be fully fulfilled with mechanically recycled ABS materials.

On the other hand, the novel approaches of chemically recycled and bio-based ABS materials are already available and offer the same exact chemical composition and properties of virgin medical ABS, fulfilling the same drug delivery applications along with medical regulation requirements. All the colours that are available in the virgin medical ABS version can be also used in the bio-circular version, guaranteeing not only regulatory compliance but also the availability of bright and intense colours in chemically recycled ABS formulations. These types of colours cannot be achieved in any case with mechanically recycled content.

"THE NOVEL APPROACHES OF CHEMICALLY RECYCLED AND BIO-BASED ABS MATERIALS ARE ALREADY AVAILABLE AND OFFER THE SAME EXACT CHEMICAL COMPOSITION AND PROPERTIES OF VIRGIN MEDICAL ABS, FULFILLING THE SAME DRUG DELIVERY APPLICATIONS ALONG WITH MEDICAL REGULATIONS REQUIREMENTS."

ELIX's vision is to be a driving force of the new plastics economy in the upcoming years, participating in the redefinition of plastic waste as a raw material. The company's mission is to offer top-of-the-line sustainable solutions, promoting the transformation of the value chain towards a circular economy model. Towards this goal, ELIX was the first ABS manufacturer to earn the International Sustainability and Carbon Certification (ISCC+ certification) for sustainable materials.

In pursuit of more sustainable ABS materials, ELIX has launched E-LOOP, a new brand name that covers all the company's circular economy initiatives, including a circular plastics portfolio and responsible innovation programmes. ELIX's E-LOOP ABS portfolio includes new medical and biocompatible ABS grades with chemically recycled and/or bio-based content. The certified raw materials content of ELIX M203FC and M205FC medical grades can be adapted according to the customer OEMs' sustainability targets.

ELIX's medical-grade ABS formulations with chemically recycled and/or bio-based content have been approved by the US FDA for the inclusion in the same drug master files (DMF) of standard virgin ELIX medical ABS formulations M203FC and M205FC. This will support an easier transition towards the use of more sustainable ABS medical materials in drug delivery devices in the coming years.

Luca Chiochia

Luca Chiochia, Business Development Manager at ELIX Polymers, graduated in Management Engineering at the Polytechnic University of Milan (Milan, Italy). Mr Chiochia has 20 years' experience in the fields of plastics, composites and devices, joining ELIX Polymers in 2017 as Business Development Manager for the healthcare strategic sector. Since 2020, he has been actively involved in the development of ELIX's E-LOOP sustainable solutions and circular innovations, including a new, broadening sustainable ABS and blends material portfolio, with chemically recycled, bio-attributed, bio-based and mechanically recycled content. Mr Chiochia has written several technical articles on behalf of ELIX about specialties and sustainable ABS for medical applications that have been published in several renowned medical and pharmaceutical magazines.

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Expert View

THE PFAS PROBLEM: IMPROVING SUSTAINABILITY WITH NONWOVEN INNOVATION

Jack Eaton of NIRI considers the current landscape for drug delivery and packaging, and how developments and research in nonwoven and fibrous materials can help businesses address the problem of per- and polyfluoroalkyl substances.

Per- and polyfluoroalkyl substances (PFAS) are widely used for their water-, oil- and stain-repellent properties. As one of the strongest single chemical bonds, the carbon-fluorine bond has nearly double the bond strength of a carbon-carbon bond. This means that these bonds resist natural, biological, chemical and microbial degradation. For chemicals containing multiple carbon-fluorine bonds, even if one bond is broken, others may persist – hence the term "forever chemicals" to describe PFAS.

Unintended leakage has led to long-term environmental accumulation, contaminating soil, ground and surface water; disrupting ecosystems; and impacting the food chain (Figure 1). PFAS are pervasive across the human population, thought to be in the blood of nearly every person worldwide.[2] The propensity of PFAS to bioaccumulate in the body has already been linked to numerous health issues and chronic diseases, including kidney, liver, bowel and thyroid diseases and cancers; reduced fertility; acute health conditions, such as high cholesterol, that increase the risk of heart attack or stroke; testicular cancer; pregnancy-induced hypertension; pre-eclampsia and small decreases in birth weight; and lower antibody response to some vaccines – which is particularly troubling with a global pandemic still in recent memory.

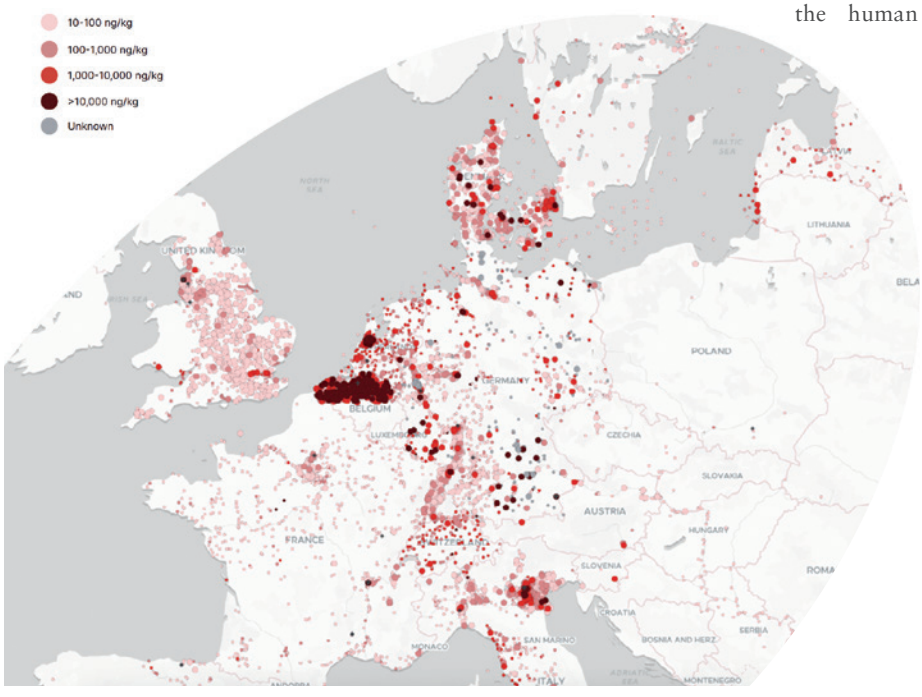

Figure 1: Distribution of PFAS contamination in Europe (adapted with permission from Le Monde and the Forever Pollution Project).[1]

"AS PUBLIC AWARENESS AND CONCERN GROWS, LEGISLATORS ARE BEGINNING TO TAKE ACTION AGAINST A SITUATION THAT IS NEITHER SUSTAINABLE NOR CONSCIONABLE – THE CLOCK IS TICKING ON PFAS REPLACEMENT."

As public awareness and concern grows, legislators are beginning to take action against a situation that is neither sustainable nor conscionable – the clock is ticking on PFAS replacement. Within the EU, the European Chemical Agency's recommendation on the restriction of PFAS will become part of REACH regulations, meaning a total ban on

"FINDING A DIRECT REPLACEMENT FOR PFAS THROUGH ALTERNATIVE CHEMISTRIES PRESENTS A RANGE OF CHALLENGES, BOTH TECHNICAL AND IN RELATION TO THE TIMESCALES OF UPCOMING PFAS LEGISLATION."

usage of many PFAS above a specified threshold quantity after the transition period. In the US, at the federal level, the Environmental Protection Agency (EPA) has proposed a nationwide ban on the manufacturing and import of certain PFAS. This includes the prevention of manufacture, processing and use of at least three hundred dormant PFAS chemicals that have not been made or used for many years without complete review and EPA risk assessment.

PFAS IN DRUG DELIVERY AND PACKAGING

A recent report from the management consultancy EPPA (Brussels, Belgium) brings the issues facing upstream suppliers into stark relief.[3] Some examples of the challenges faced by the drug delivery industry in tackling PFAS are included here.

Blister Packaging

To prevent medication degradation, many solid oral drug packaging solutions – specifically blister packaging – contain PFAS that provide the necessary moisture barrier, and are often transparent to make it easy for patients to identify the medication contained therein. The EPPA report states that "the efficacy and preservation of moisture sensitive drug API is inextricably linked to the barrier performance of immediate drug packaging."

Drug Delivery Devices

Considering just a small fraction of drug delivery devices – prefilled and reusable pen injectors – PFAS are often key to their component parts. Both types of pen injector incorporate PFAS-containing thermoplastic resins and use PFAS coatings as a dry lubricant. For accurate dosage, particularly to facilitate self-administration, prefilled pens incorporate fluoropolymers to reduce friction and prevent stickiness. Additionally, fluoropolymers are currently crucial to prefilled syringes and devices where a barrier is required between the medicine and the container walls. As the EPPA report notes,

"... PFAS are widely used in drug delivery devices ensuring quality and accuracy in the delivered dosing, as well as increasing the lifetime in multi-use devices."

Challenges and Industry Perspectives

Finding a direct replacement for PFAS through alternative chemistries presents a range of challenges, both technical and in relation to the timescales of upcoming PFAS legislation. There is a general consensus that the alternatives that are currently available do not meet all the requirements for safety and performance, and that there are environmental consequences of substitution (both known and not yet known) when investigating like-for-like alternative chemistries.

ADVANCED MATERIAL INNOVATION FOR SUSTAINABLE PFAS ALTERNATIVES

The nonwovens and textile industry is at the forefront of sustainable product development, with applications across a multitude of sectors. These are helping the medical, hygiene and pharmaceutical industries to: navigate sustainability regulations and strategies concerned with single-use plastics and circularity; upgrade product designs; increase recycled, natural and bio-based polymer content; and accelerate the implementation of new recycling technologies. Furthermore, much of this sustainable development is concerned with composite structures with various layers of textile components, coatings and surface functionalisation.

Derogations for PFAS usage in the medical sector are both limited and temporary. Therefore, given the challenges already noted, there is an urgent requirement for an innovative and commercially realistic approach. This is a space where materials innovation can play a role in R&D and product development, working towards PFAS-free alternatives.

Overperformance

Interrogating specifications may provide a solution for some current products where PFAS are routinely used, as some products may be over-specified when considering real-world usage. This is particularly pertinent to new healthcare products, whereby a circular economy approach can be incorporated into the design stage. Decoupling combined requirements for a product, at the earliest stage, may help to ensure that new developments are compatible with circular economy approaches and generate alternative solutions to PFAS. This approach was recommended by MedTech Europe in their recent PFAS position paper.[4]

3D Thinking

Changing from 2D to 3D thinking means considering the entire product system rather than an individual component or material replacement. 3D thinking is an approach that is particularly appropriate for the drug delivery sector, where PFAS are prevalent in such a large volume of components and devices. Taking a holistic, 3D approach enables different layers and materials to be combined to achieve superior performance without the reliance on PFAS.

As an example, investigating both a woven and a nonwoven PFAS-coated fabric with an oil penetration test, the oil droplet contact angle was seen to be

"3D THINKING IS AN APPROACH THAT IS PARTICULARLY APPROPRIATE FOR THE DRUG DELIVERY SECTOR, WHERE PFAS ARE PREVALENT IN SUCH A LARGE VOLUME OF COMPONENTS AND DEVICES."

>90 degrees, demonstrating hydrophobicity and avoiding any oil penetration. Focusing on the woven fabric, but with the PFAS coating removed, the oil droplet contact angle reduced from 118 degrees to 58 and then 33 degrees after five seconds. The oil penetrated the fabric sample and had poor oil repellence.

To investigate the potential for PFAS-alternative coatings and laminated structures, two different strategies were evaluated: introducing a PFAS-alternative coating and laminating the woven fabric to a nonwoven. In both of these scenarios, the oil contact angle was improved but neither option was oleophobic, and the oil started to penetrate the fabrics after five seconds. In isolation, then, these strategies did not provide an oil-repellence performance anywhere near to that of the PFAS-coated woven fabric.

However, when the two strategies were combined, evaluating two different types of PFAS-alternative coatings, in both cases the oil droplet contact angle increased and one sample became oleophobic. While the oil eventually penetrated both samples, it became clear that combining variables or strategies can enhance performance. Through additional iterative development and tailoring of the PFAS-alternative coating application parameters and the structural properties of the nonwoven, it was proven possible to develop a PFAS-free composite with comparable performance to the original PFAS-coated woven fabric (Figure 2).

In the space where like-for-like alternative chemistries are not proving suitable for the removal of PFAS from drug delivery devices and pharmaceutical packaging, a holistic, 3D approach can impact the entire product system, rather than just rethinking individual components.

Figure 2: By combining strategies and approaches, it is possible to create PFAS-free alternative materials with comparable performance.

COLLABORATION AND MEETING REGULATORY DEMANDS

The timescales for development of new PFAS-free drug delivery devices and packaging are generally significantly longer than the likely derogation periods. The EPPA report estimates that for solid dose blisters that contain a PFAS layer – assuming that a safe and appropriate alternative can be found – the timeframe is potentially between six and twelve years. The report highlights the logistical issues, where packaging-related testing capacities may well be overwhelmed, given the sheer volume of products that are impacted.

Furthermore, in-house pharmaceutical industry R&D resources are already stretched, particularly in the current volatile economic climate. As MedTech Europe's 2023 PFAS position paper notes, "Human resources that would otherwise be dedicated to treating new disease states, seeking solutions for new patient populations and solving unmet clinical needs would likely be displaced to research in PFAS-free alternatives for existing products."

Given the volume of drug delivery device and packaging products and components incorporating PFAS, collaboration with external innovation specialists can be commercially and environmentally valuable, derisking in-house R&D and speeding up new product development processes. To address the question of resource limitation – including the potential for bottlenecks – recourse to external experts can overcome these barriers to the development of PFAS-alternative materials. Where materials innovation can contribute to the removal of PFAS from drug delivery products and packaging, access to prototyping facilities and the capacity to test and refine product developments on-site can narrow the gap between concept and prototype, accelerate R&D, reduce commercial risk and help maintain downstream competitiveness (Figure 3).

"GIVEN THE VOLUME OF DRUG DELIVERY DEVICE AND PACKAGING PRODUCTS AND COMPONENTS INCORPORATING PFAS, COLLABORATION WITH EXTERNAL INNOVATION SPECIALISTS CAN BE COMMERCIALLY AND ENVIRONMENTALLY VALUABLE, DERISKING IN-HOUSE R&D AND SPEEDING UP NEW PRODUCT DEVELOPMENT PROCESSES."

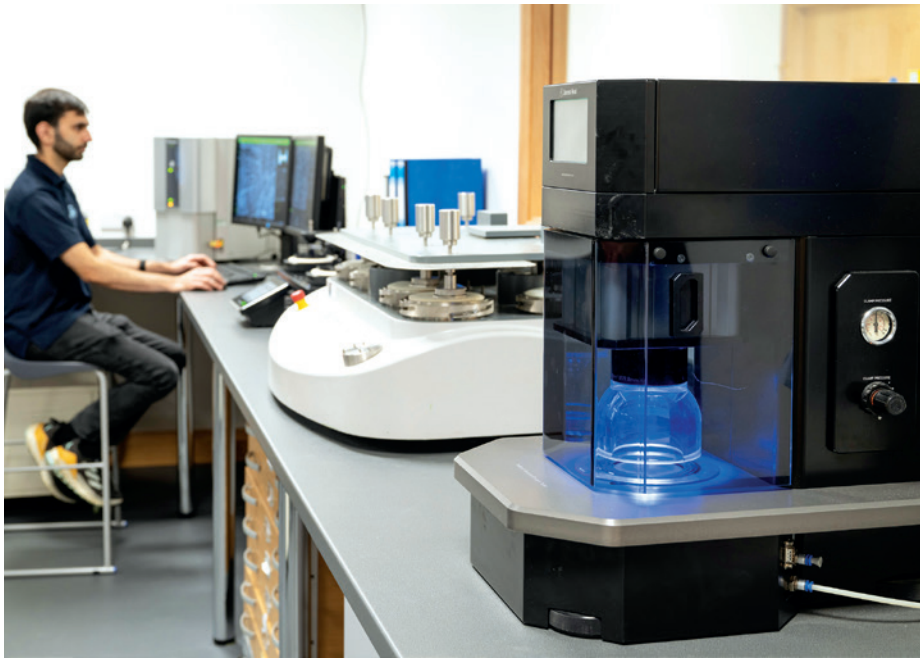

Figure 3: Partnering with a materials expert can provide access to the facilities and expertise required to prototype, test and refine PFAS-free materials.

CONCLUDING THOUGHTS

The issue of PFAS-free drug delivery devices and packaging is a current and pressing issue, regardless of whatever form of derogations and exceptions from upcoming legislation can be negotiated. However these play out, the clock is ticking on PFAS removal, and short- and long-term strategies are vital. Most companies want, and need, to address public concerns and demonstrate their commitment to environment and social governance strategies. Stringent regulations and lengthy lead-times for approvals of potential alternatives to PFAS create a great deal of uncertainty across the sector.

Whatever regulatory frameworks dictate, through 2025 and the coming years, PFAS are an issue that must be addressed globally. There are clear sector calls for derogation and exceptions, but it cannot be guaranteed that these will include a significant proportion of drug delivery devices or pharmaceutical packaging. To find alternative solutions, across this complex supply chain, collaborating with an external partner is a compelling proposition, helping to reduce commercial risk, speed up time to market with novel solutions and to achieve the ultimate – and necessary – goal of PFAS-free medication packaging and drug delivery devices.

ABOUT THE COMPANY

NIRI is an innovation consultancy specialising in product developmentfor polymers, fibres, nonwovens and advanced materials, having completed over 950 projects for more than 450 companies across the full spectrum of the supply chain. Its team of scientists, engineers and analysts have more than 400 years' combined expertise across sectors, including sustainable design, filtration, medical and healthcare, packaging, hygiene, pharmaceuticals and food and beverage. With full prototyping and analytical capability, NIRI works with clients to accelerate innovation, develop commercially viable products and identify new market opportunities.

REFERENCES

1. *Dagorn et al, "'Forever pollution': Explore the map of Europe's PFAS contamination". Le Monde, Feb 2023.*
2. *Salvidge R, Hosea L, "UK failing to match EU in fight against 'forever chemicals', say scientists". The Guardian, Jan 2025.*
3. *"SOCIO-ECONOMIC ANALYSIS Of the potential restriction of the per- and polyfluoroalkyl substances (PFAS) used in the production, packaging and delivery of human medicinal products". EPPA, Aug 2023.*
4. *"MedTech Europe Position on the Proposal for A REACH Universal PFAS Restriction". MedTech Europe, Sep 2023.*

Jack Eaton

Jack Eaton is Chief Commercial Officer of NIRI. He holds a BSc in Sports Materials Technology and an MSc in Advanced Textiles and Performance Clothing from the University of Leeds (UK) and has extensive consultancy experience at NIRI, gained over a seven-year period in various roles. He then went on to gain commercial experience in coatings, pigments and polymer processing for a diverse range of applications. In March 2025, Mr Eaton rejoined NIRI and is responsible for the commercial development of the business, combining his technical textiles knowledge and commercial experience. He oversees marketing, sales, product development and customer service activities.

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AI, DATA AND PARTNERSHIPS: THE BUILDING BLOCKS FOR MORE SUSTAINABLE CLINICAL TRIALS

Sas Maheswaran at CluePoints discusses how artificial intelligence, data and strategic partnerships can make clinical trials more sustainable – both financially and environmentally.

"ENVIRONMENTAL IMPACT IS FELT AT ALL STAGES OF PRODUCTION, FROM NATURAL RESOURCE EXTRACTION TO END-OF-LIFE, MEANING THAT THE INDUSTRY IS FACING AN INCREASING ENVIRONMENTAL IMPACT AS THE MARKET CONTINUES TO GROW."

Artificial intelligence (AI) and sustainability are hot topics in the clinical trials industry. More than 80% of current AI users, and 70% of non-users, expect AI to have a significant impact in drug discovery over the next few years.[1] At the same time, there are increasing calls for collective action to reduce the environmental impact of drug delivery devices[2] and late-stage clinical trials.[3]

Increasingly, these important areas are being discussed while AI is being recognised as a pathway towards sustainable and optimised drug development[4] and clinical trial research. This pathway is made up of three interlocking blocks – the AI technology itself, big data and strategic partnerships. All three are vital if the industry is to embrace the opportunities on offer and create a more sustainable future for clinical trials.

WHY DO WE NEED TO MAKE CLINICAL TRIALS MORE SUSTAINABLE?

The global drug delivery devices market was valued at US$42.71 billion (£33.3 billion) in 2023 and is projected to reach $63.38 billion by 2032.[5] Environmental impact is felt at all stages of production, from natural resource extraction to end-of-life, meaning that the industry is facing an increasing environmental impact as the market continues to grow.

The pharmaceutical industry generates approximately 52 megatons of CO_2 annually.[6] Around 70–80% of its carbon footprint is generated by manufacturing processes.[7] However, clinical trials also result in significant emissions, with the largest contributors including site monitoring, drug supply, study team facilities and sample lifecycles.[3]

It is vital to explore ways to make drug development and clinical trials more efficient if the industry is to meet the requirements of the Paris Agreement.

There are also ethical and business imperatives for taking action. Increasing climate change will have a huge impact on population health, driving poorer outcomes and increasing mortality and health inequality.[8] From a business perspective, streamlining processes to reduce environmental impact can also reduce costs.

The importance of sustainability is recognised industry-wide, with pharma companies coming together to highlight areas of environmental, social and corporate governance that need prioritising.[9] Regulators are also increasing pressure on pharmaceutical companies to progress their sustainability goals. For example, in Europe this includes directives on corporate sustainability due diligence[10] and industrial emissions.[11]

COMBINING AI AND DATA TO MAKE CLINICAL TRIALS MORE SUSTAINABLE

By collecting data in a way that enhances recruitment, adherence and data analysis, AI has the potential to accelerate clinical trial cycles[12] and reduce the main drivers of carbon footprint impact.

For example, the impact of a site monitor on the carbon footprint of a trial is dominated by car travel to trial sites.[3] By using AI-powered adaptive site monitoring, sponsors and contract research

"COMPREHENSIVE AI MODELS ENABLE US TO EMBRACE DATA-DRIVEN AND PERSONALISED MEDICINES AND STREAMLINE KEY STEPS OF CLINICAL TRIAL DESIGN."

organisations can improve their ability to evaluate the performance of clinical trial sites and adjust site visitation plans more effectively and efficiently.

Increasing the efficiency of clinical trials also has the potential to decrease other areas of impact. For example, by managing trial risks and accelerating resolution with AI-powered risk-based quality management (RBQM) tools, carbon hotspots – such as trial team commutes and energy use in facilities – can be reduced.

USING AI TO ENHANCE DRUG DEVELOPMENT AND REDUCE ENVIRONMENTAL BURDEN

AI algorithms can also enhance drug development because their ability to analyse complex relationships between drug properties, formulation components and physiological factors enables the prediction of drug behaviour at scale. This allows for a more comprehensive understanding of drug delivery mechanisms while aiding the design of efficient delivery systems.[13] Comprehensive AI models can enable the industry to embrace data-driven and personalised medicines, as well as streamline key steps of clinical trial design.[14] Combined, AI and big data can increase speed and efficiency, reducing the environmental burden.[15]

Machine learning (ML) can bring together large volumes of structured and unstructured data to pinpoint relevant information more quickly. This allows study teams to rapidly identify critical-to-success issues and, hopefully, reduce clinical trial failure rate. Given the time and cost it takes to design drug delivery systems, fewer failures would have a dramatic effect on the economy of drug development.

REDUCING TRIAL TIMELINES AND COSTS

The traditional data management model is struggling to cope with rapidly increasing data sources and volumes. Two-thirds of clinical data management personnel experience problems with manual data management processes,[16] which are subject to human error and may not be as effective for spotting critical issues. Source data verification is a drain on time and staff resources, yet it accounts for only 2.4% of critical data queries.[17] Average study close-out cycle time – from last patient last visit to database lock – is more than 36 days.[18]

These shortcomings significantly increase the time and cost required to bring a new product to market. On average, the journey from discovery to market takes 12 years; however, in newer areas of medicine, it can take up to 30 years.[19] New technologies provide opportunities for streamlining the data management model and making development more sustainable.

For example, an unsupervised ML model can offer up to 98% accuracy in query detection. This reduces the amount of "noise" that data managers have to review, allowing them to focus on critical-to-success queries. This, in turn, allows earlier and easier identification of any potential medical or patient safety issues with drug delivery devices.

USING AI TO CONSIDER SUSTAINABILITY

The same attributes that allow ML models to streamline data management also make them the ideal tool to help pharmaceutical companies consider sustainability throughout the drug development process. Identifying, evaluating and optimising each step in the drug discovery process requires evaluation of multiple data points from diverse sources. AI can analyse this disparate data and enable scenario modelling to unlock the potential for more sustainable design. The design principles of cost reduction, therapeutic benefit and ease of use can harmonise with lowered environmental impact.

AI can also be used to identify drugs that may be suitable for repurposing, by identifying a new therapeutic target and predicting a new therapeutic use.[20] Given the high environmental impact of developing from scratch, this, again, has the potential to increase sustainability.

ADDRESSING CONCERNS ABOUT AI EMISSIONS

While AI can be successfully used to increase sustainability in drug development and clinical trials, it is important to recognise the environmental impact of the technology itself. The data centres that house AI infrastructure are often large consumers of water and electricity, leading to increased emissions. They also rely on critical minerals and rare elements that may be mined unsustainably.[21]

The United Nations Environment Programme has made a series of recommendations to help overcome these issues.[22] They include making AI algorithms more efficient to reduce their demand for energy, recycling water and reusing components where feasible, while greening data centres by using renewable energy and offsetting carbon emissions.

WHY DO PARTNERSHIPS MATTER?

Cross-industry collaboration has been identified as a crucial action to secure a more sustainable future for the pharmaceutical industry.[23] AI is a broad discipline with almost unlimited applications. It is therefore vital that pharma companies and sponsors work with specialist partners who can help identify the right types of AI to maximise data use and streamline activities, ultimately reducing the environmental impact of research and development.

"THE DESIGN PRINCIPLES OF COST REDUCTION, THERAPEUTIC BENEFIT AND EASE OF USE CAN HARMONISE WITH DESIGNING FOR ENVIRONMENTAL IMPACT."

Given concerns about the environmental impact of AI itself, it is also vital to work with industry leaders who are developing best-in-class efficient algorithms and who promote renewable practices.

Collaboration is equally crucial when it comes to keeping a focus on sustainability, yet regulations and infrastructure to support sustainable device design, procurement and manufacturing vary globally. The industry needs to build partnerships at scale to reduce costs to individual organisations and enable it to consider the whole lifecycle of devices, as well as embedding more efficient processes throughout clinical trials.

CONCLUSION

Sustainability needs to move from being a topic that individual leaders or departments consider, to an integral part of every stage of drug development and clinical trials. This requires both cross-sector and cross-organisational collaboration.

"WE NEED TO BUILD PARTNERSHIPS AT SCALE TO REDUCE COSTS TO INDIVIDUAL ORGANISATIONS AND ENABLE US TO CONSIDER THE WHOLE LIFECYCLE OF DEVICES, AS WELL AS EMBEDDING MORE EFFICIENT PROCESSES THROUGHOUT CLINICAL TRIALS."

By creating effective strategic partnerships that combine expert knowledge with the latest technology, we can make the most of the opportunities offered by artificial intelligence and big data to secure a more sustainable future for drug discovery and the wider clinical trials industry.

ABOUT THE COMPANY

CluePoints is a risk-based quality management (RBQM) and data quality oversight software provider, harnessing the potential of artificial intelligence by using advanced statistics and machine learning to determine the quality, accuracy and integrity of clinical trial data both during and after study conduct. Aligned with guidance from the US FDA, EMA and ICH E6 (R3), CluePoints supports central and on-site monitoring, medical review and quality risk management to drive a holistic risk-based strategy in all trials. CluePoints combines the expertise of consultants and cutting-edge technology to facilitate pre-study risk assessments, identify risk controls and implement solutions. CluePoints also assists with adherence to global regulatory guidelines using RBQM technology, resulting in positive clinical development outcomes, increased operational efficiency, lower costs and reduced regulatory submission risk.

REFERENCES

1. *"Unlocking the potential of AI in drug discovery". Wellcome Trust, Jun 2023.*
2. *"Sustainability for drug delivery devices: Recommendations for industry along the value chain". BioPhorum, Jul 2024.*
3. *Mackillop N et al, "Carbon footprint of industry-sponsored late-stage clinical trials". BMJ Open, 2023, Vol 13 (8), art e072491.*

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4. *Askin S et al, "Artificial Intelligence Applied to clinical trials: opportunities and challenges". Health Technol, 2023, Vol 13 (2), pp 203–213.*
5. *"Drug Delivery Systems Market Size, Share & Industry Analysis, By Type (Inhalation, Transdermal, Injectable, and Others), By Device Type (Conventional and Advanced), By Distribution Channel (Hospital Pharmacies, Retail Pharmacies, and Others), and Regional Forecast, 2025-2032". Fortune Business Insights, Mar 2025.*
6. *Kaylor A, "Understanding the environmental impact of the pharmaceutical industry". TechTarget, Apr 2024.*
7. *"Sustainability in the pharmaceutical industry". Web Page, ABPI, accessed Apr 2025.*
8. *"Environmental Sustainability in Pharma". Article, IQVIA, accessed Apr 2025.*
9. *"Biopharma Investor ESG Communications Guidance 4.0". The Biopharma Investor ESG Communications Initiative, Mar 2022.*
10. *"Corporate sustainability due diligence". Web Page, European Commission, accessed Apr 2025.*
11. *"Directive (EU) 2024/1760 of the European Parliament and of the Council, 13 June 2024". Directive, European Parliament, 2024.*
12. *Chopra H et al, "Revolutionizing clinical trials: the role of AI in accelerating medical breakthroughs". Int J Surg, 2023, Vol 109 (12), pp 4211–4220.*
13. *Vora LK et al, "Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design". Pharmaceutics, 2023, Vol 15 (7), art 1916.*
14. *Harrer S et al, "Artificial Intelligence for Clinical Trial Design". Trends in Pharmaceutical Sciences, 2019, Vol 40 (8), pp 577–591.*
15. *Wynendaele E et al, "Sustainability in drug discovery". Medicine in Drug Discovery, 2021, Vol 12.*
16. *"Challenges And Opportunities In Clinical Data Management". Research Report, ORACLE Health Sciences, 2018.*
17. *Sheetz N et al, "Evaluating Source Data Verification as a Quality Control Measure in Clinical Trials". Ther Innov Regul Sci, 2014, Vol 48 (6), pp 671–680.*
18. *Harper B et al, "Characterizing Clinical Data Management Challenges and Their Impact". Applied Clinical Trials, 2021, Vol 30 (1-2), pp 14–16.*
19. *"Drug development – The four phases". BioSTOCK, Jan 2023.*
20. *Paul D et al, "Artificial intelligence in drug discovery and development". Drug Discov Today, 2020, Vol 26 (1), pp 80–93.*
21. *"AI has an environmental problem. Here's what the world can do about that". UN Environment Programme, Sep 2024.*
22. *"Artificial intelligence (AI) end-to-end: The environmental impact of the full AI life cycle needs to be comprehensively assessed". UN Environment Programme, Sep 2024.*
23. *Hitch J et al, "Supporting the Era of Green Pharmaceuticals in the UK". OHE, Nov 2022.*

Interview: A Sustainable Future for Self-Injection with Connected, Reusable Autoinjectors

In this exclusive interview with ONdrugDelivery's Guy Furness, **Dr Patrick Anquetil** of **Portal Instruments**, offers insight into the extensive waste involved in the self-injection market. He explains how pivoting from a model focused on fully disposable devices to reusable electromechanical autoinjectors could offer a more sustainable and cost-effective path forward for the industry. In this discussion, Dr Anquetil also introduces PRIME Nexus, Portal's adaptation of its flagship needle-free PRIME device to a scaled-down, needle-based alternative.

Q Before we delve into sustainability, could you give our readers a quick overview of Portal Instruments and its platform products?

A Portal Instruments was started about a decade ago, with a broad idea to change what it means to self-inject, as well as to change injections as a whole. Our founding principles start with Ian Hunter, a professor from the Massachusetts Institute of Technology (Cambridge, MA, US), who brought me in to lead Portal as a start-up. From the start, our approach has been to look at injections at the system level, so at heart we're an injection technology company, our flagship product being the PRIME needle-free system.

What we realised with PRIME is that, while it was advanced and preferred by patients over typical autoinjectors, it was also positioned as a premium product, making its cost potentially too high for broad adoption. So we set out to create a device that is in-between a needle-free injector and an autoinjector, but that still uses the same platform and is able to use the scaling effect that an electromechanical system can bring. This led us to simplify and miniaturise our existing needle-free platform while making it compatible with all standard primary containers used in the pharma industry, such as prefilled syringes or cartridges. That's what PRIME Nexus is – a flexible, needle-based variation of our PRIME platform (Figure 1).

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We have been working on the core electromechanical platform for a long time, so we've been able to bring all of its advantages – programmability, high precision, rapid adjustability for viscosity and volume – to a new product without having to go through a whole new, ground-up development process. All of PRIME's advantages and all the technical know-how that we've developed at Portal over the last decade easily translates to Nexus.

Q Beginning with a general question on sustainability – why is it that the pharma industry should be concerned about sustainability?

A I think the number one thing is cost. Single-use autoinjectors are amazing devices; they're produced in very high numbers with a very low failure rate. However, the one issue is that you only use them once and then you discard them. Fundamentally, this screams that there is a cost in the system that shouldn't be there.

A good analogy is the space industry. It used to take the same approach – use the rocket once and then discard it. Then SpaceX came along and said this is rubbish, we

Figure 1: Portal's PRIME Nexus reusable autoinjector.

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Patrick Anquetil, PhD, is Founder and Chief Executive Officer of Portal Instruments, leading a multidisciplinary team of engineers, scientists and business professionals dedicated to revolutionising injectable therapies with connected, reusable drug delivery solutions. His focus is on enhancing the patient experience and improving adherence to injectable therapies. With over 20 years of experience in the medtech and biotech industries, Dr Anquetil has a proven track record of innovation and strategic execution. Under his guidance, Portal has forged strategic partnerships with leading pharmaceutical companies, including Takeda, LEO Pharma and Sanofi, to integrate its cutting-edge technology into their combination products. He has successfully raised over US$60 million (£45 million) in venture capital and non-dilutive funding, propelling Portal's growth. Dr Anquetil holds a PhD in bio-instrumentation from the Massachusetts Institute of Technology (Cambridge, MA, US), an MBA from Harvard Business School (Boston, MA, US), and a master's degree from ETH Zurich (Switzerland) and the University of Tokyo (Japan). His research has been published in peer-reviewed journals and featured in prominent outlets such as MIT Technology Review, Wired, PBS and CNBC.

shouldn't do that. And now, because of that new philosophy of reusing the rockets, SpaceX is now dominating the space industry. It's a better rocket, of course, but mostly it's a cheaper rocket.

I think there's this fallacious perception that, if you make a design sustainable, it should cost more. I think that's wrong and really shows the limits of present platforms and industry thinking. In my opinion, if it's good for the environment, it shouldn't be more expensive – it should cost less.

Q Taking a broad perspective on autoinjectors, how do you rate their historical track record on sustainability?

A Fundamentally this "use once and then discard it" approach is just wrong. Historically, this was never supposed to be the standard. Originally, autoinjectors were designed for emergency use, specifically for soldiers during the first Gulf War. The US military was worried about nerve agents being deployed, so the soldiers on the ground had to be able to inject themselves quickly and reliably in an emergency. In the civilian world, that technology transformed into Meridian Medical Technologies' (Pfizer) EpiPen (adrenaline), which is another emergency-use scenario.

I don't think that when those early autoinjectors were designed, anyone believed that they would be prescribed for chronic use. For example, in the US last year, there were 6.5 million prescriptions for glucagon-like peptide 1 (GLP-1). If that's a weekly injection, that's over 300 million devices for GLP-1 alone.

To put that into perspective, imagine those devices are 10 cm long, so lined up would cover 30,000 km – for comparison, the circumference of the earth is 40,000 km. And the number of prescribed GLP-1s is predicted to grow at a 20% compound annual growth rate. This would mean that, by 2030, there will be a billion single-use devices per year being discarded just for this one therapy.

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This isn't just a cost issue – it's also an environmental one. These devices are extremely difficult to recycle due to their mix of materials, including non-recyclable hard plastics, metals and glass, some of which qualify as biohazardous waste. If you really want to recycle them, you probably have to take them apart, which is its own challenge with additional associated costs.

So, thinking at the system level, there are probably parts that we can reuse. Some parts, such as the syringe, are inherently single use, but outside the primary packaging we can reuse the mechanism. That's where there is currently space in the market that I think we should work on.

Q How does Portal balance sustainability with the requirements for device efficacy, safety and usability?

A Again, our approach starts at the system level. The first question is: if we're building a reusable device, what features are necessary to make it cost-effective? The key is to keep the disposable component as simple as possible, using materials that are easier to recycle. Once that principle is set, all the design and functionality should be concentrated in the reusable part of the device and making it intelligent.

This is where the decade of experience we've built up with electromechanical systems from working on our PRIME platform comes into play because, not only was PRIME already developed, all we needed to do was scale it back and make it more cost efficient. We were even able to reuse the same software just by adjusting it so that it's properly adapted for injection via a needle and syringe – a needle-free system needs a burst of energy to create a jet fast enough to pierce the skin, which you don't need with a needle.

Taking this approach allowed us to scale back the device by about a factor of five – Nexus is five times smaller and five times cheaper than PRIME. All the technology is still there, and the disposable part is just two pieces of plastic with some clever interlocks that enable the device to manipulate the primary container and perform the injection.

Q Connectivity, which is a key aspect of Portal's device offering, is also often associated with increased cost and increased environmental impact – do you think that assumption is fair?

A I think it's true for the current state of affairs where a significant majority of all self-injections are performed with a single-use autoinjector. With a single-use device, connectivity adds more cost and more inconvenience because the patient needs to connect anew to every device. Even with clever technologies, such as Bluetooth Low Energy, that make connecting very easy, it's still one more step that the patient needs to do.

The cynical view of course is that the industry has been talking about connectivity for a long time but no one's really figured it out. However, I think that's missing the point, in that connectivity needs to be introduced in a sustainable way to really stick, and there hasn't been a truly sustainable reusable device platform released yet. In essence, there hasn't yet been an opportunity to truly deploy connectivity in the right way.

However, there's no doubt that, once you have even the most basic data – injection time and confirmation, for example – it would be transformative. Pharmaceutical companies would know how their drugs are being used. Payers would know whether or not the drug is being administered properly. Physicians would be able to stratify their patient population by how compliant they are and identify the ones who need more guidance and assistance to get the most out of their therapies. I think there's a bright future for connectivity. Ten years from now, an autoinjector should be sustainable and connected – it should be something that's part of a patient's life.

Q Of course, sustainability goes beyond just the device – carbon footprint measurements include packaging, shipping, transport and labelling – how do you think manufacturers should be thinking about that?

A In practice, I think this is the first thing that the industry is going to tackle, which is great to see. Can we effectively use bioplastics? Can we use recycled metals? Can we find a recycling programme to process those? There's already a lot of effort being put in to address these questions. There's also the question of take-back schemes, which are an effective way to tackle CO_2, but those have proven costly because these devices are difficult to reuse or recycle.

I think connectivity has a role to play here, where it's used to track the entire life of the device and see how it's being used and to see its true end of life. How often do people lose their devices? How frequently do they get broken? With connectivity, we can get real data on this and track the entire lifecycle. If, for example, a reusable cassette has a radio-frequency identification (RFID) chip, it could theoretically be read at the recycling facility before it's processed.

The age-old adage is that if you can't measure it, you can't manage it, which is why our devices inherently include a feedback loop, enabling them to provide a very precise and very consistent injection. But there is also a critical feedback loop between the patient and the physician, and I think there is another one with the environment. It's important to track what our supply chains really look like. Where do all the components of a device come from? Answering these questions is key in moving towards more sustainable industry practices.

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Q Sustainability also extends beyond just CO_2 – companies need to have clean, non-polluting processes and products that do not damage the environment. How does Portal address non-CO_2 environmental responsibilities?

A In practice, we view it all as part of a whole. For example, think about a device that's used once and then goes to landfill. As an engineer, I need to understand how landfills work and what processes happen there, if I'm going to understand what's possible from a design perspective. I think that highlights how end-of-life considerations are genuinely challenging.

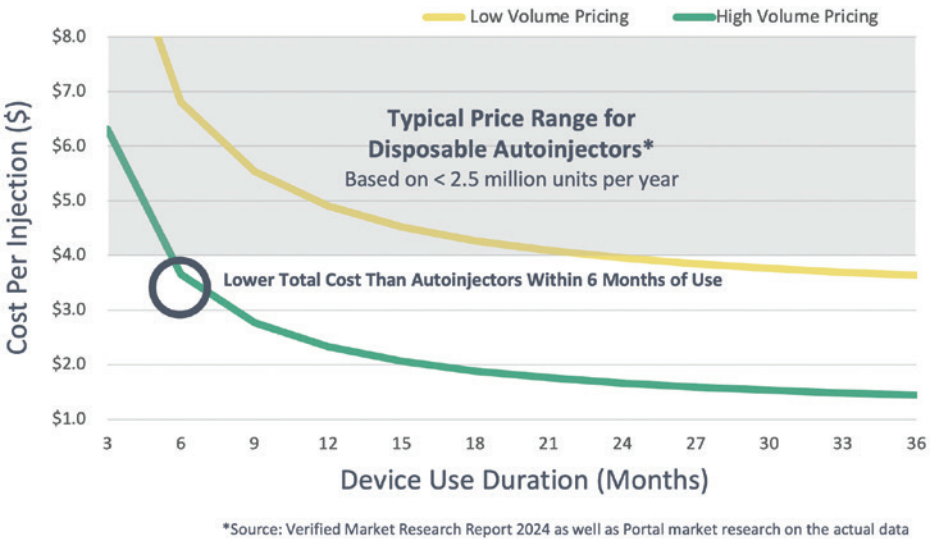

Figure 2: Price per injection over time for a reusable autoinjector.

We regularly hear from patients that they're sensitive to these concerns. The number one complaint we get is that, while the device is great and the drug is effective, patients have to throw away a whole device every time they self-administer, which is a lot of plastic going to landfill. Attempts have been made with take-back schemes, but very little has stuck or been able to be scaled up to a truly effective level.

That's why we believe that a reusable device – where the main unit is replaced every three to five years instead of after each injection – is the most effective way to significantly reduce landfill waste. This couples with our second principle: the disposable cassette should be very simple and, ideally, should use a form of bioplastic. I don't think we're going to use recycled plastics for medical devices – that tends to be frowned on in the industry – but over the last few years there's been a strong push to look at bioplastics that are more environmentally sustainable, especially as they're continually becoming more cost effective.

A I mentioned earlier, cost is the key to unlocking sustainable designs. If it isn't cost effective, it isn't going to work. I feel that a reusable, needle-based autoinjector is finally reaching the point where, after a few months of use, the device pays for itself, and that's really exciting (Figure 2).

Q Do you have any final thoughts for our readers?

A I think there's going to be a significant shift to reusable autoinjectors in the coming years, but they won't replace disposable devices entirely – I'm not under any illusions that we're going to be using only reusable devices in the next five to ten years. However, 20 years ago, the market was there for reusable pens and reusable autoinjectors, and patients were using them and getting the job done.

Then there was a shift in the market where everyone thought that making simpler, disposable devices would increase patient compliance, but the evidence suggests that it didn't pan out that way. I think right now, we're at a point where the benefits of reusable devices are becoming clear. With the innovation team we have at Portal, I think we're ideally positioned to seize this opportunity and bring more flexible, more sustainable reusable devices to market and contribute to the next step forward for the pharma industry.

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