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## DRUG DELIVERY & ENVIRONMENTAL SUSTAINABILITY

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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Owen Mumford
Pharmaceutical Services

Owen Mumford
Pharmaceutical Services

# SUSTAINABILITY IN DRUG DELIVERY – THE STATE OF PLAY IN 2023

Here, Isobel Filipova, Design Engineer – Sustainability Lead Product Development at Owen Mumford, explains where the healthcare industry stands on current environmental objectives, identifies obstacles to achieving sustainability in drug delivery and looks at how the sector can make progress to meet its objectives.

Once a relatively niche concern, sustainability and environmental protection is now a mainstream requirement in society – and in the medical device market. Traditionally, drug delivery devices have relied heavily on single-use plastics to ensure safe, effective administration to the user. However, given increasing pressure from regulators and consumers alike, medical device manufacturers are making environmental concerns a greater priority. There is an industry consensus that sustainability must be addressed – and urgently – to reach the ambitious objectives set by international standards, such as net zero by 2050 (Figure 1).

## WHERE DO WE STAND TODAY?

It is widely accepted that the healthcare industry is a major polluter. According to a 2019 report, which remains the most recent study available, health systems produce 4%–5% of national greenhouse gas (GHG) emissions – meaning that if the healthcare industry was a country, it would be the fifth largest emitter of greenhouse gases in the world.[1] Although current literature on GHG emissions in the pharmaceutical industry is limited, studies published to date indicate a significant contribution to climate change.[2]


Figure 1: There is an industry consensus that sustainability must be addressed – and urgently – to reach the ambitious objectives set by international standards such as net zero by 2050.

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"The purchasing power of healthcare systems is being used to encourage suppliers to consider environmental impacts more carefully."

Until now, the healthcare industry has been somewhat sheltered from scrutiny surrounding its sustainability practices, with current European legislation on sustainable manufacturing practices, end-of-life management and packaging often containing exemptions for medical devices, and strict regulatory requirements demanding single use for many invasive medical devices. However, several directives, including the Waste Electrical and Electronic Equipment (WEEE) and Restriction on Hazardous Substances (RoHS) directives, are in the process of being reviewed and could be applicable in future. One area in which progress is essential is packaging; under the revised Packaging and Packaging Waste Directive, all packaging placed on the EU market will need to be "reusable or recyclable in an economically feasible way" by 2030, with minimal exceptions for the healthcare industry.[3]

With the increasingly strict regulatory requirements surrounding environmental reporting, and the regular inclusion of environmental credentials in medical device tenders, companies who do not act now risk losing access to markets around the world.[4] There is already evidence that the purchasing power of healthcare systems is being used to encourage suppliers to consider environmental impacts more carefully. For example, in the US, group purchasing organisations are appointing Senior Directors of Environmentally Preferred Sourcing and, in the UK, the NHS's "*Delivering a 'Net Zero' National Health Service*" report sets out sustainability targets and the interventions required to achieve them, including steps to decarbonise the supply chain by no longer working with suppliers who do not meet its net zero commitments by the end of the decade.[5]

While international treaties, legislation and corporate social responsibilities to investors and wider society have led companies in all sectors to set sustainability targets, measure climate change impacts and report GHG emissions, a high level of fragmentation remains in how this is done in the medical device and pharmaceutical industry. Multiple methodologies, impact measures and data sets are used, and national regulations for both practices and reporting vary. Additionally, even where companies apply the same methodologies, there are inconsistencies in reporting, particularly regarding Scope 3 reporting,[2] resulting in a lack of comparable data across the industry.

## WHAT SHOULD WE BE MEASURING AND HOW?

To appreciate the full environmental impact of drug delivery devices, it is vital that sustainability is not reduced to product manufacturing or disposal alone. The corporate footprint as a whole, including Scopes 1, 2 and 3, must be taken into account.

When examining the products themselves, lifecycle assessment offers a holistic methodology for fully understanding environmental impact at every stage and allowing immediate changes to be made to products already on the market, rather than starting from scratch and creating entirely new products. While ISO standards 14040[6] and 14044[7] provide a framework and guidelines for lifecycle assessment, they do not specify the methodologies or impact measures to be used, contributing to the fragmentation and differences in reporting across the industry. This, in turn, limits the ability to effectively compare products in terms of their environmental impact.

Consequently, it is vital that industry-wide standards and best practices are established if ambitious targets are to be met. This will require medical device manufacturers to collaborate and pool knowledge and resources if true progress is to be made.

## WHAT IS HOLDING US BACK?

### Safety Concerns

While sustainability in the healthcare system is an important objective that must not be neglected, the safety of patients and users remains the critical priority. The risks associated with hazardous medical waste and biological contamination, in addition to cost considerations associated with sterilisation and reprocessing, have meant that manufacturers have been hesitant to move away from their usual practices. In addition, the reprocessing and reuse of single-use devices is discouraged in both Europe and the UK[8] – unlike in the US, where reprocessing has been more widely accepted since the 1970s[9] – and the US FDA is currently working to advance the science of reprocessing.[10] Moving forward, it is likely that invasive devices will continue to require some disposable components to meet regulatory requirements surrounding safety and hygiene.

Packaging is another area where safety concerns can obstruct sustainability efforts. Medical device packaging must play several roles – protecting the contents of the packaging, protecting people (including children) and preventing counterfeiting. This often requires a combination of materials, complicating waste management.

### Legislative Barriers

Strict regulatory requirements, driven by legitimate safety concerns surrounding medical waste, limit the reprocessing and reuse of medical devices to limit healthcare-associated infections. Under the European Medical Device Regulation, recycled devices are subject to the same level of scrutiny as new devices, with full responsibility for the device being placed on the reprocessor.[11] The complexity of compliance with these rules may discourage manufacturers from taking this approach.

Differing national legislation on separating hospital waste, and even differing definitions of hospital waste itself, further contribute to the complexity of the issue. The use of disposable personal protective equipment during the covid-19 crisis highlighted issues with healthcare waste management, with data from 2019 (the latest available) indicating that 30% of healthcare facilities are unequipped to handle the amount of waste they produce, even outside of the pandemic.[12] As a result, most hospital waste ends up in mixed waste due to lack of user training and risk aversion, and thus loses its value.[13] Even where materials are properly sorted and recycled, the inclusion of recycled materials in medical and pharmaceutical packaging is particularly difficult, as packaging legislation currently does not take into account advanced recycling techniques.

Although current legislation presents a range of obstacles to implementing greener solutions, widespread acceptance of the need to prioritise sustainability means shifts are likely in the near future, particularly as we move towards the deadlines set out in the European Green Deal.[14]

### Commercial Viability

Affordability and cost are major concerns for manufacturers, particularly in today's financial climate. Given the high proportion of many manufacturers' revenues that come from disposable, single-use devices, which are responsible for 1.4% of supply chain emissions in the NHS alone,[15] it is essential that any steps towards sustainability are commercially viable. The cost of certain processes, such as sterilisation, is a factor that may be discouraging their wider adoption.

Commercial concerns, in particular the competitive mindset, also foster a secretive climate where many manufacturers are hesitant to collaborate with competitors and share their solutions. This contributes to the multiplication of approaches and measures, reduces efficiency and impedes far-reaching industry-wide change.

## WHERE CAN WE MAKE IMPROVEMENTS?

### Sustainability by Design

Device design already takes into account a number of factors around the whole lifecycle of a product, from development and material selection to scalability and end-of-life disposal. However, the current focus on user-centricity and profitability must be extended to include environmental and social impacts at an early stage.

Device design considerations are essential. Many small steps are already being taken at every stage of the product lifecycle to streamline the use of resources, optimise manufacturing processes and reduce waste. Even where products must retain a disposable element for safety and hygiene reasons, there are myriad opportunities for improvement, including assessing the impact of raw products to select the most environmentally friendly materials, optimising device size and decreasing packaging volume. Producing a minimum disposable unit within a reliably reusable "shell" is also a realistic ambition.

Manufacturing processes also present opportunities for reducing environmental impact. From optimising logistics to reducing water use and increasing energy efficiency, greener initiatives not only offer a sustainability benefit but also reduce operating costs. Additionally, new technologies play a role in reducing waste, through streamlined manufacturing processes.

### Behavioural Change

To meet ambitious sustainability targets, both within and beyond the industry, systemic change is necessary, which must consider not only how the product is manufactured, but also the whole system. New business models must focus on circularity instead of the current linear approach, for example, reducing the number of materials used per product to facilitate recycling, thus enabling waste management companies to provide a high-quality supply of recycled products for use in subsequent manufacturing.

User information is crucial to prevent undermining efforts to produce more reusable or recyclable materials. Healthcare facilities alone generate an estimated one million tonnes of clean, non-infectious healthcare plastic waste per year.[16] Providing healthcare professionals with training on how to properly sort and dispose of this waste would considerably increase the amount available for reprocessing and reuse. UK legislation requiring hospitals to become more sustainable may encourage NHS trusts to provide such training.

Finally, cross-industry collaboration must be encouraged to drive standardisation and allow the whole industry to benefit from procedural and technological advances. It is vital that manufacturers work with regulatory bodies to review and revise current legislation, creating an environment in which the necessary changes can be made, allowing for greater sustainability while maintaining the highest standards of safety and hygiene.

"User information is crucial to prevent undermining efforts to produce more reusable or recyclable materials."

## CONCLUSION

Despite the challenges that adopting sustainable practices will present for the device industry, many stakeholders have begun to realise that greener practices contribute to revenue growth and improved customer relationships,[17] providing a strong business case for environmental progress.

This recognition means that innovation will play an important role in the endeavour to meet ambitious sustainability targets, but a holistic approach to product design – based on industry-defined lifecycle assessment methodologies and cross-industry collaboration – will be the essential components in achieving far-reaching progress.

## ABOUT THE COMPANY

Owen Mumford is a medical device manufacturer with a global presence across the UK, Europe, the US and Asia, pioneering the advancement of medical technology for 70 years. The company manufactures its own brand of medical products and is a trusted partner to many of the world's largest pharmaceutical and diagnostic companies. Its leading medication administration, blood-sampling and testing solutions are designed and manufactured for the comfort, safety and dignity of patients, healthcare professionals and caregivers as a priority. Driven by its purpose to do business in the right way, Owen Mumford is one of the first medical device companies in the world to achieve B Corp certification and has set science-based targets to achieve net zero by 2045, as part of its long-established and continually evolving sustainability agenda.

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## ABOUT THE AUTHOR

**Isobel Filipova** holds the role of Design Engineer – Sustainability Lead Product Development at Owen Mumford, bringing expansive knowledge on corporate social responsibility and on implementing sustainable practices for businesses. Ms Filipova is responsible for establishing and maintaining the sustainability strategy across Owen Mumford's research and development division. Since joining the company in early 2021, Ms Filipova has accelerated Owen Mumford's sustainable product design approach by using a holistic approach incorporating systemic research, rationalised concept development and a clear understanding of user experience and needs to present innovations that meet customer needs and enable a circular economy. Ms Filipova believes in a holistic approach to sustainability that reviews the entire ecosystem to identify opportunities for positive change, reduced environmental impact and truly innovative solutions.

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# SUSTAINABILITY UNLEASHED: DRIVING POSITIVE IMPACT IN THE PHARMA INDUSTRY

In this article, Justin Schroeder, Global Vice-President of Technical Services, Ann Cartwright, Global Strategic Sourcing Director, and Gigi Bat-Erdene, Global ESG Program Manager, all at PCI Pharma Services, discuss the unique challenges facing the pharmaceutical industry in adopting environmental, social and governance principles, and present a way forward to achieve the necessary goal of improving sustainability within the industry.

## INTRODUCTION

As worldwide regulatory bodies and governments start placing stricter environmental regulations and guidelines on the pharmaceutical industry, nearly every major pharmaceutical manufacturer has pledged to work toward net zero. For example, in 2006, the Pharmaceutical Supply Chain Initiative created five principles "to articulate what the industry expects from the supply chain", including ethics, labour, health and safety, environment and management systems.

The industry has generated tremendous momentum towards sustainability since environmental, social and governance (ESG) principles have become a main focus, but there is still more progress to be made. The environmental component specifically has proven challenging for the pharma industry. As of 2019, for example, the carbon footprint of the pharmaceutical industry was 55% higher than that of the automotive industry.[1] Organisations are beginning to understand that an ESG plan must extend beyond their own internal processes and take the efforts and impact of the greater supply chain into consideration, including their partners and contractors.

ESG-related challenges will not be overcome overnight. In fact, it's a continuous journey with no end point. ESG principles must become part of the fabric of an organisation to achieve long term and meaningful results, from hiring to sourcing raw materials to packaging to transport. This may sound daunting, but this article will provide expert insights into developing and building a successful ESG programme that makes a difference.

## UNDERSTANDING THE LANDSCAPE

The pharmaceutical industry approaches ESG considerations from a distinct standpoint. The landscape is heavily regulated and has encountered numerous challenges in recent years, such as the covid-19 pandemic, which significantly impacted the industry's operational model and raw material supply chain.

> "ESG-related challenges will not be overcome overnight. In fact, it's a continuous journey with no end point."

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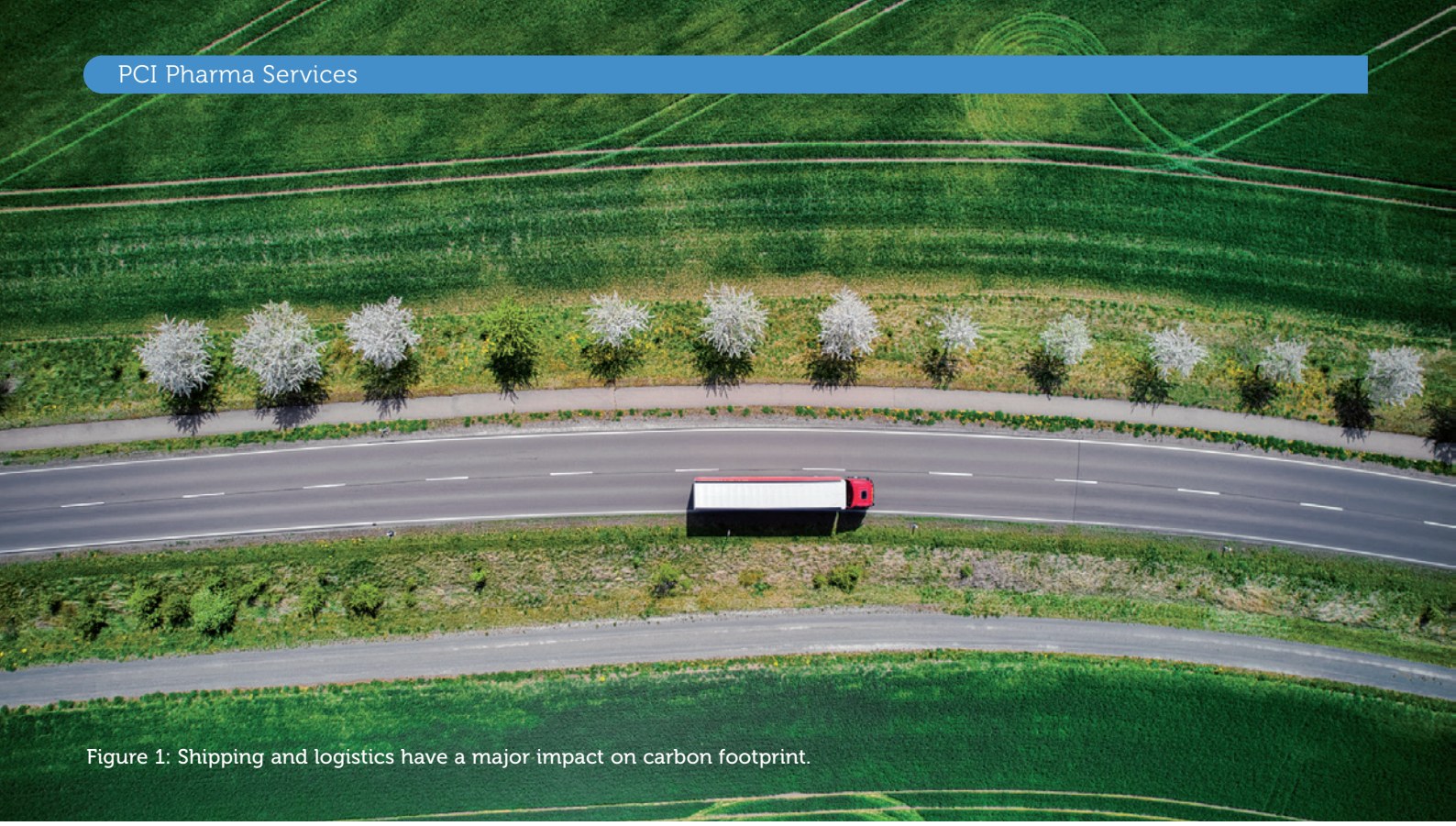

Figure 1: Shipping and logistics have a major impact on carbon footprint.

In response, pharmaceutical companies have had to seek materials from more distant sources and order smaller quantities. Unfortunately, this shift has had adverse environmental implications, primarily in terms of transportation and carbon footprint (Figure 1).

The industry also faces heightened pressure to expedite the introduction of new drugs to the market. Consequently, there is less time available for thorough formulation development. This equates to new medicines potentially being less shelf stable, putting a greater burden on packaging materials.

This means that you need high barrier materials to help protect the product and make sure that you don't sacrifice any shelf life or sterility. However, these materials often are not sustainable or eco-friendly, in large part because they frequently require layering to enhance protective properties. Whether it's for moisture, light or degradant gases like oxygen, these protective measures can clash with the established recycling and recovery infrastructure and guidelines.

Simultaneously, a sharp increase in overall product development costs, as well as high inflation, have pushed the priorities of ESG and profitability against each other. Couple this with evolving ESG standards and regulations, and it's not surprising that most pharmaceutical companies have to work hard to keep up with the regulations and market demands, typically with limited resources.

"The question is – how do you measure success? From an environmental perspective, you've got to have a starting point to be able to gauge what impact you're having."

Consumer opinion, new legislation and global frameworks are demanding that companies step up their ESG efforts. Some organisations are focused more on the social aspects of ESG rather than the environmental side, according to PwC. A recent study by the consulting firm found that, over the past 16 months, 77% of pharmaceutical ESG efforts were social, 12% were environmental and 11% governance. However, some companies are taking a more holistic approach, focusing on all three disciplines – environmental, social and governance.[2]

## IDENTIFYING A STARTING POINT

In August 2022, a multinational pharmaceutical and healthcare firm published a 30-page document titled "ESG Key Performance Indicators". Grounded in Global Reporting Initiative standards, this guide provided a thorough account of its ESG achievements spanning the past three years. The company's performance figures were impressive, which was consistent with its ongoing commitment to sustainability. Earlier in the year, Standard & Poor's Global Ratings had already acknowledged this company as one of the leading proponents of sustainability. Not long after this recognition, the pharmaceutical giant reported robust sales growth in its earnings statement.

A US$123 billion (£101 billion) market cap may make it easier for a company of this size to create and execute on an ESG plan, but this is still achievable by any pharmaceutical company willing to put in the work. The question is – how do you measure success? From an environmental perspective, you've got to have a starting point to be able to gauge what impact you're having. ESG being such a broad topic, it can mean a lot of different things to a lot of different people, so having a defined framework and methods of measurement enables people to align in terms of priorities, short-term and long-term goals and what success looks like in a tangible way.

Companies may start with a materiality assessment, including engaging key stakeholders (both internal and external), to pinpoint and understand the factors that have the greatest impact on the organisation's long-term success. Part of this process could involve supply-chain mapping to evaluate the ESG performance of suppliers and partners to ensure that they are aligned with the company's vision

and values. Another practice is to compile a greenhouse gas inventory, known as "emissions mapping", to define a baseline of where the company currently stands, which is key for monitoring progress on emission-reduction efforts.

As PwC points out, the best ESG assessments incorporate a multi-pronged approach, a method that PCI Pharma Services has adopted and encourages its clients and vendor partners to consider. To comprehensively assess environmental impact and sustainability efforts, it is essential to disaggregate total energy consumption by fuel types, account for the total refrigerants used within the organisation and record the overall fuel consumption of company vehicles. PCI's assessment and annual sustainability report also encompasses the monitoring of water usage, greenhouse gas emissions, waste water discharge and waste and hazardous materials released into the environment.

By adhering to these guidelines, a company can effectively oversee its entire manufacturing supply chain. This entails tracing the origins and practices associated with API sourcing, monitoring energy providers and energy usage across the entire supply chain and addressing every facet from research to shipping. This comprehensive approach includes employee use of electricity, resources and transportation, as well as the company's packaging, recycling and waste generation.

## MAINTAINING STEADY PROGRESS

After establishing a baseline assessment of their ESG performance, organisations can readily initiate incremental changes that can accumulate substantial benefits. In fact, there's often common, low-hanging fruit that can be addressed right away. As an illustrative example, another pharmaceutical giant has been actively pursuing a variety of simple, quick-to-implement processes and changes. According to this company's 2021 Enhancing Environmental Sustainability report, it achieved its goal of eliminating 17 types of single-use plastics at 132 US-based workplaces by substituting all single-use plastic bottles in vending machines with recyclable aluminium, glass or biodegradable alternatives (Figure 2).

"After establishing a baseline assessment of their ESG performance, organisations can readily initiate incremental changes that can accumulate substantial benefits."

Figure 2: Recycling is an easy step to take towards bettering our planet.

The company identified another straightforward opportunity by scrutinising its vendor selection procedures. In September 2021, it introduced an updated set of criteria for all its suppliers, aiming to minimise its overall carbon footprint. The company requires its suppliers to adhere to specific ESG objectives, thereby contributing to the reduction of Scope 3 emissions and the overall reduction of its emissions output.

PCI has adopted similar practices when selecting vendor partners to advance its ESG goals. This approach not only benefits PCI's clients, but also enables them to make significant progress. PCI is already assisting some of its clients in conducting ESG pilot initiatives, yielding positive outcomes. Customers can leverage PCI for exploratory joint development projects and unique collaborations to test the water and determine if those changes work for them, potentially using those iterations as a catalyst for broader change. This has helped PCI discover what its suppliers do and understand their supply chains on a new level.

There are many benefits to these types of projects. For example, collaborations across the supply chain have the potential to benefit all parties – not just the company implementing the changes. Partners can see improvements in their sustainability metrics, as well as other key ESG principles such as diversity and inclusion and fair labour practices.

## CONCLUSION

Every company across the globe faces the heavy burden and critical mission of reducing its carbon footprint. Pharmaceutical companies have the added challenges of a restrictive regulatory environment and a lack of cohesive ESG strategies. However, it is both possible and necessary to overcome these challenges.

There is a step change in terms of the energy and resources being poured in from the supply side into research and development around more sustainable materials, whereas, in the past, this was probably seen as a cost burden and there was little incentive to pursue it. Now it feels like there's such a groundswell of consciousness around ESG that there is that energy being poured into it, which can be seen in some of the recent innovations publicised within the industry.

Internally, companies should assemble a team that focuses on ESG and start with projects that have measurable outcomes, such as installing energy-saving lighting, movement sensors and water-saving

features. Companies can also work with their local municipalities to get clear, consistent recommendations for recycling. Externally, organisations will make massive strides if they embrace collaboration with their partners and customers to implement real changes. The good news is that the industry is embracing the necessary changes and coming up with solutions that will truly make a difference.

## ABOUT THE COMPANY

PCI Pharma Services is a leading global CDMO, providing integrated end-to-end drug development, manufacturing and packaging solutions to increase product speed to market and opportunities for commercial success. PCI brings the proven experience that comes with more than 90 successful product launches each year and over five decades in the delivery of supply-chain healthcare services. With 30 sites across Australia, Canada, North America, the UK and Europe and over 5,250 dedicated employees, the company's mission is to bring life-changing therapies to patients. Leading technology and continued investment enable PCI to deliver development to commercialisation solutions throughout the product lifecycle, collaborating with its clients to improve the lives of patients globally.

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## ABOUT THE AUTHORS

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

**Ann Cartwright** is the Global Strategic Sourcing 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 Sustainable Procurement Lead with a team of buyers, working toward specific goals and targets aligned with the sustainable procurement ESG pillar. These include setting key performance indicators with PCI's supply partners on topics such as Scope 3 emissions, waste generation, diversity and sustainable innovations.

**Gigi Bat-Erdene** is Global ESG Program Manager at PCI. Ms Bat-Erdene is passionate about empowering individuals and businesses to play a bigger role in creating a more inclusive future for all. She joined PCI shortly after completing her undergraduate programme at Columbia University (NY, US) as a Sustainable Development major, and is now leading the buildout of PCI's ESG programme, driving enhancements across impact and reporting strategy, including activities related to climate change; human rights; diversity, equity and inclusion; and sustainable procurement.

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# HOW LIFECYCLE ASSESSMENT SUPPORTS INSIGHT-DRIVEN SUSTAINABLE DESIGN

Here, Paramesh Natarajan, Principal Engineer, Shadi Bavar, Mechatronics and Integrated Systems Engineer, and Charlie Dean, Head of Sustainable Medical Technology, all at Cambridge Consultants, present the case for using screening lifecycle assessments to lead into more detailed targeted and comprehensive lifecycle assessments focused on the areas of greatest environmental impact, using a screening lifecycle assessment of a hypothetical body-worn injector as an example.

Drug delivery devices will play a pivotal role in achieving the UN's sustainable development goal of good health and wellbeing for all. This is true for body-worn injectors, which ensure consistent and accurate dosing of essential medicines over long periods of time while granting patients the freedom to conduct their usual daily activities. However, despite their benefits, they can have a high environmental impact due to their complex and short-use-life componentry. At a time when climate change is a top priority, is it possible to develop safe and effective drug delivery devices, including body-worn injectors, with a reduced burden on the environment?

When considering the environmental impact mitigation of a drug combination product, the first requirement usually focuses on maintaining or improving clinical efficacy and patient safety. The second is often around achieving equivalent or lower cost. At first glance, these two requirements can seem to prohibit sustainable initiatives. Whilst challenging, sustainable device innovation is more likely to succeed with a rigorous and insight-driven approach. Lifecycle assessment (LCA) is a methodology that has been developed to achieve just that.

LCAs are a comprehensive, data-driven and systematic approach to uncover the greatest opportunities to reduce environmental impact, which can often be counterintuitive. This article outlines a screening LCA on a conceptual body-worn injector to identify hotspots and opportunities for mitigation. It also aims to uncover different levels of LCA and when best to use them.

## TYPES OF LCA

Conducting an LCA is often considered a burdensome and costly exercise. When assessing the full lifecycle, numerous data sources, and thus data owners, are required. In most cases, the types of data required are not even typically measured or reported. Commissioning an assessment for the first time with the expectation that it will be fully comprehensive for public marketing claims will likely result in a long, drawn-out process, as engaging with every stakeholder for the first time to request relevant data will be prohibitively time consuming. Fortunately, the LCA framework can be adapted to suit different levels of investment and commitment for different applications (Figure 1). Understanding how to scale LCA rigour is key to making the most out of the initiative to target ambitious sustainability goals.

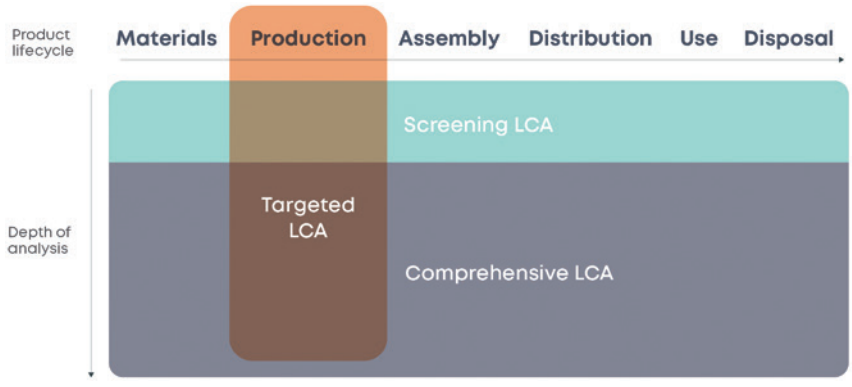


Figure 1: Types of LCA.

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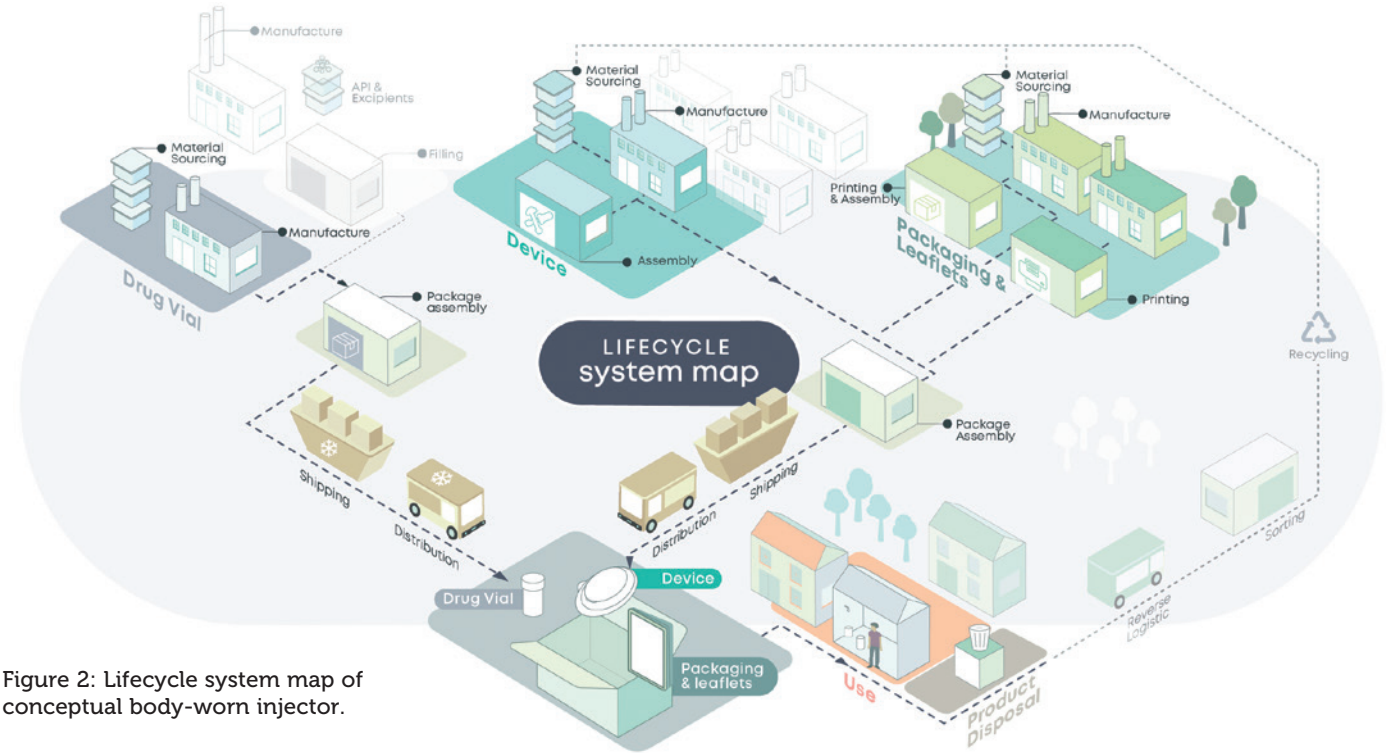


Figure 2: Lifecycle system map of conceptual body-worn injector.

> "The goal of a screening LCA is to identify the biggest environmental impacts in a product's lifecycle and use them to inform strategic decisions early in the design process."

## SCREENING

The goal of a screening LCA is to identify the biggest environmental impacts in a product's lifecycle and use them to inform strategic decisions early in the design process. As such, the approach should be a top-level sweep of a full lifecycle, focusing on relevant impact categories, such as global warming, water usage and ozone depletion. Given this high-level approach, when populating the lifecycle inventory (LCI), the analyst will need to make broad assumptions about processes and components. This may include using existing devices as a template for material choices, material quantities, assembly locations, etc. This may also include use of market average data from existing databases, such as EcoInvent, rather than primary data specific to the product in focus.

The benefit here is a quick turnaround on getting results and a low reliance on data fidelity, but great care must be taken when interpreting results, given the level of uncertainty around the inputs. The output of a screening LCA can provide valuable and timely insight to guide system architecture but should not be used to make competitive market claims.

## TARGETED

During the development process, the screening LCA is just the first step towards quantifying impacts. It is important to refine the model further and improve confidence in the screening LCA's results. The goal of the targeted LCA is to make focused optimisations to the product's design by taking a detailed approach to a particularly impactful area identified by the screening LCA. As such, the scope is limited to perhaps a single component or module, or maybe a particular process, such as the transport impacts from one site to another. Targeted analyses should be conducted in close collaboration with the relevant stakeholder to ensure efficient knowledge and data sharing; for example, with the product design and engineering team for gathering data on materials and manufacturing processes.

## COMPREHENSIVE

When progressing through the design process, targeted analyses should be conducted on differing areas to increase confidence in areas of high impact, shed light on unknown areas of impact and further optimise the design. Naturally, what started as a screening LCA starts to look increasingly comprehensive through these targeted analyses. By the point a comprehensive LCA has been done, it is likely that only fine-tuning optimisation can be carried out. As such, the goal of a comprehensive LCA is often to get an accurate impact assessment that can be reviewed and published externally. As with the screening LCA, the scope is broad, but at a vastly increased level of detail and fidelity, where the LCI could be the combination of preceding targeted LCAs.

## SCREENING LCA OF CONCEPTUAL BODY-WORN INJECTOR

### Goals

1. Illustrate the merits and accessibility of the screening LCA, while also highlighting the limitations
2. Identify environmental burden hotspots and propose recommendations for well-targeted mitigations.

### Scope

High-level impact assessment of a conceptual disposable body-worn injector, from raw material extraction through to disposal (cradle to grave). The whole system map shows the breadth of the lifecycle in scope, as well as an approximation of the level of fidelity included in this screening LCA (Figure 2). High-level assumptions were made to give an indication of the

impact associated with every relevant process throughout the product's lifecycle. Mapping in this way can enable easy visualisation of the supply chain.

### Lifecycle Inventory

The product system includes mechanical componentry, casings, electronic systems, wiring, batteries, the drug primary container, needles, syringes, packaging and instructions for use (Figure 3). Notable exclusions include the drug formulation, at-home drug refrigeration, consumables associated with site preparation and a companion smartphone or similar device. The drug product was excluded due to variability in formulation and therapeutic area, and the monitoring devices were excluded due to variability in product embodiment and classed as an accessory to a broader product system. Given that the LCA is at a screening level on a conceptual device, market average lifecycle inventory data from the EcoInvent 3.9 database was used for the processes, materials and components used.

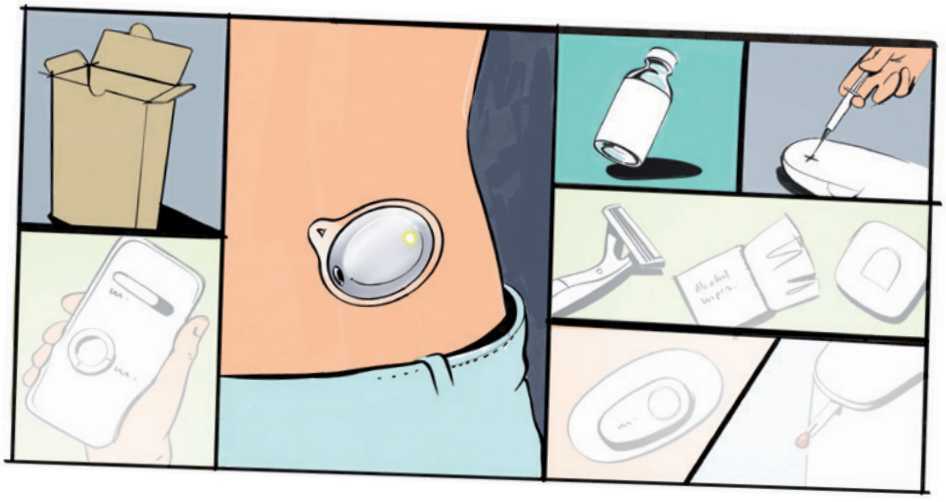

Figure 3: Product system inventory, with out-of-scope items greyed out.

## IMPACT ASSESSMENT

The results of the screening LCA are calculated for over 20 impact categories quantifying environmental impact in a variety of specific sectors, from which the most relevant can be focused on in greater detail. Each category aggregates contributions toward a specific impact and quantifies them using a single unit; for example, global warming is reported in mass of $CO_2$ equivalent and represents not only direct carbon emissions, but also other sources of global warming, such as methane and nitrous oxide. Other impact categories include fine particulate matter formation, soil acidification, waterway eutrophication, human toxicity, land use, water use and energy use.

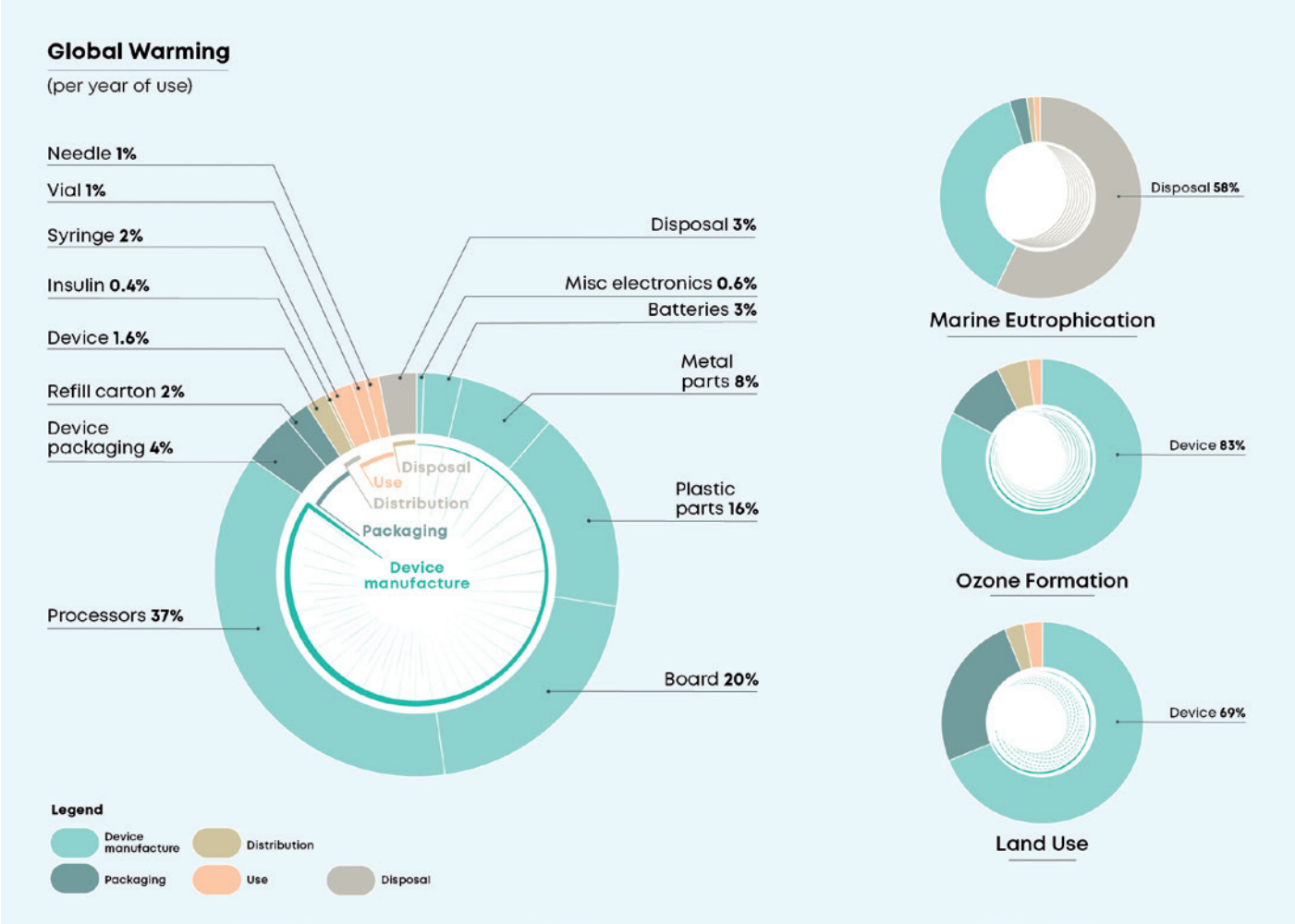


Figure 4: Screening LCA results of conceptual body-worn injector.

The results of an LCA are versatile and can offer insights beyond the relative contribution of each element of the device or lifecycle to an impact category. The components of the device can be grouped as needed to compare the impact of functional submodules, types of materials, lifecycle stages or even manufacturing processes.

## INTERPRETATION

Due to the nature of a screening LCA, the absolute values are not reported to prevent any comparison to published comprehensive analyses conducted at a deeper level. However, key insights may still be drawn from the distribution of impacts.

The results revealed that device manufacture represents 75–95% of the environmental impact across all categories but one (Figure 4). Taking global warming as a representative example, two thirds of device impact are due to the printed circuit board and integrated circuit chips, which have a high demand for electricity during manufacture and extraction of raw materials.

The remaining stages of the lifecycle – packaging, distribution, use and disposal – have remarkable impacts in only one or two categories each. The most significant contribution of packaging is in land use and ozone depletion, where it makes up approximately 25% of the lifecycle impact in those categories. The land use is primarily caused by manufacture of integrated circuit chips, boxboard shipping cartons, printed circuit boards and metal components. Distribution has relatively low impact across all categories but makes the most significant contribution towards ozone formation (10%) – the impact comes from container ship transport, not only of the final product, but also of the copper and gold used in the printed circuit board assembly manufacture. There was no significant contribution from use in any category.

Finally, product disposal has a high contribution to marine and freshwater eutrophication (60% and 40%). It is possible that this is due to municipal solid waste disposal, notably treatments of waste plastic mixture.[1] This observation highlights the limitation of relying on market average LCI data, in this case EcoInvent, as it is not known if this deviation from the trend is accurate. Further investigation into plastic waste processing for landfill would be advisable in follow-up targeted analyses.

## STUDY SUMMARY

The printed circuit board assembly emerged as the most influential component across the range of impact categories, making it a prime candidate for mitigating environmental impact. The results indicate that implementing ways to reuse the electronics has the potential to significantly reduce the impact of device manufacture.

It is important to rely on data-driven analysis, rather than gut-feel assumptions, to identify targets for design change. This concept is underscored by some unexpected results of this LCA – the batteries did not appear as significant contributors, perhaps counterintuitively, despite their large mass and rare metal components. Distribution, including refrigerated cold-chain storage of the drug product, also had lower impact across a range of categories than expected.

Lastly, when leveraging the results of a screening LCA to drive decisions or engage with stakeholders, it is key to offer sufficient context around the limitations and assumptions made. In this case, this LCA was used for educational purposes on a conceptual device and may not accurately reflect results for products on the market.

## CONCLUSION

Despite its limitations, conducting a screening LCA is a valid and valuable exercise to begin strategising on sustainable drug delivery device transformation. The alternative approach of committing significant investment based on opinions or trends in sustainability is far less likely to lead to successful sustainable device development. The LCA framework is flexible enough to allow for scaling the level of analytical rigour to suit the application. Starting early in development with a screening LCA will ensure that development teams are more aware of sustainability objectives, more likely to measure and report relevant data, and prime partners throughout the supply chain to engage with the process to pave the way for targeted and comprehensive analyses to follow.

## ABOUT THE COMPANY

Cambridge Consultants develops breakthrough products, services and intellectual property, and provides business consultancy in technology-critical issues for clients worldwide. For more than 60 years, the company has been helping its clients turn business opportunities into commercial successes, whether launching first-to-market products, entering new markets or expanding existing markets through the introduction of new technologies. With a team of more than 800 members, including engineers, scientists, mathematicians and designers, with offices in Cambridge (UK), Boston (USA), Tokyo (Japan) and Singapore, Cambridge Consultants offers solutions across a diverse range of industries, including medical technology, industrial and consumer products, digital health, energy and wireless communications.

## REFERENCE

1. *Vlasopoulos A et al, "Life cycle assessment of plastic waste and energy recovery". Energy, 2023, Vol 227, Article 127576.*

## ABOUT THE AUTHORS

**Paramesh Natarajan** is a Principal Engineer with five years' experience in multidisciplinary systems in the medical and biotech sectors. He is particularly interested in balancing varying stakeholder needs through well-planned system architecture.

**Shadi Bavar** is a Mechatronics and Integrated Systems Engineer specialising in the development of medical technologies. She has a passion for multidisciplinary work and excels in applying analytical skills and methodologies to tackle exciting design challenges.

**Charlie Dean** is the Head of Sustainable Medical Technology at Cambridge Consultants, specialising in integrating sustainable principles into novel medical device development. Mr Dean has experience across a broad range of drug delivery device products, combining analytical and design mechanical engineering expertise to optimise devices for high-volume production.

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| January | Prefilled Syringes & Injection Devices | Dec 14, 2023 |
| February | Skin Drug Delivery: Dermal, Transdermal & Microneedles | Jan 4, 2024 |
| March | Ophthalmic Drug Delivery | Feb 1, 2024 |
| April | Pulmonary & Nasal Drug Delivery | Mar 7, 2024 |
| Apr/May | Drug Delivery & Environmental Sustainability | Mar 21, 2024 |
| May | Delivering Injectables: Devices & Formulations | Apr 4, 2024 |
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# GREEN THINKING: HOW TO BECOME A MORE SUSTAINABLE ORGANISATION

Here, André Jansen, Technical Sales Manager and Ron Cisliek is Director of Business Development – USA, both of IGS GeboJagema, describe how the high-precision mould maker is fostering a culture of "green thinking" and making sustainability a core part of its business.

In recent years, many organisations have moved from a passive stance to active engagement on sustainability issues. But, to truly lead in this area, companies must graduate from one-off sustainable initiatives and cultivate a mindset. We all need to create a culture of "green thinking" that questions, challenges and innovates the way we do business at every turn.

So, what exactly is green thinking? For IGS GeboJagema, it is an approach that allows organisations to constantly do better and improve. Green thinking is about challenging your thinking in everything you do, facilitating innovation and always keeping an eye on the bigger picture.

> "In the quest to become a truly sustainable organisation, it is critical to question every part of your daily operation."

## CHALLENGE EVERYTHING

As organisations strive to reach their strategic goals, questioning business processes that function well is rarely a priority. It is easy to overlook how we can improve on the way we usually do things. But, in the quest to become a truly sustainable organisation, it is critical to question every part of your daily operation. The covid-19 pandemic managed to trigger the creative thinking required to improve "business as usual".

For example, a few months after the pandemic started in 2020, IGS GeboJagema introduced remote validation (Figure 1).

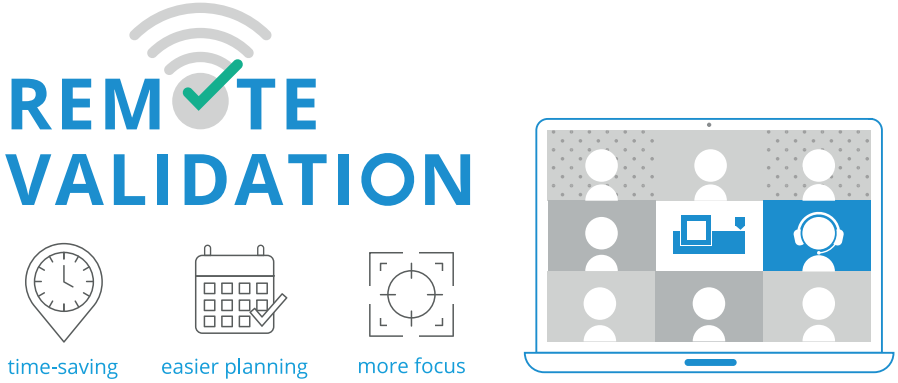


Figure 1: Remote validation reduces travel and associated carbon emissions.

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Whereas customers usually travelled to its facilities in Eindhoven for the validation process of their mould, the IGS GeboJagema team designed a solution to follow the process online. By removing the need for air travel, taxis and hotels, this not only saves clients a lot of time but also prevents a significant amount of carbon emissions.

Following the success of remote validation, IGS GeboJagema also introduced remote support. This service enables the company's engineers to assist customers in optimising their production process using an augmented reality headset. One option is to ship a Microsoft HoloLens to customers within 24 hours, allowing for faster support with lower carbon emissions than on-site engineer visits. However, IGS GeboJagema encourages customers to consider acquiring their own HoloLens. Many companies, after using the technology for the first time, choose to invest in their own devices, which allows for both the fastest and the greenest support (Figure 2).

IGS GeboJagema is also investigating the possibility of specialised shipping packaging for moulds. Redesigning the packaging to be more compact saves space, which ultimately reduces the number of freight containers needed for shipping. This might seem like a small detail but, with multiple shipments leaving the company's facilities every day, even a small change can lead to significant reductions in carbon emissions.

In short, green thinking means challenging ourselves in every little thing we do. We must examine all our activities, including mundane day-to-day tasks that seem far removed from our core business and ask: how can we do better?

Figure 2: An IGS GeboJagema operator joins the call through a headset during remote validation.

## CULTIVATE INNOVATION

Innovation is rarely easy. It requires focus, follow-up and dedication to find better ways of doing things and, possibly even more challenging, implementing them. IGS GeboJagema's solution has been to establish dedicated innovation teams. Meeting bi-weekly, a team is composed of various roles, including the Chief Innovation Officer, a Process Engineer, a Technical Sales Specialist and the Chief Sales Officer. This allows the team to explore ideas springing from different sources: market developments, new technologies or upcoming laws and regulations. With an understanding of both client needs and technical possibilities, solutions can be brainstormed. When a promising idea is found, a project is created to explore its potential and feasibility. Crucially, the innovation team has an independent budget to realise these projects, which prevents bureaucracy and ensures the team can move quickly. The outcome of such a project can range from a PowerPoint presentation to a proof-of-concept mould – and everything in between.

An example of this approach to innovation was a project IGS GeboJagema realised in the ophthalmic market. For the production of an optical product, small disposable plastic parts are used. These parts remain functional in the production process for about 30 minutes before being recycled. IGS GeboJagema's initiative was simple but effective: to reduce the wall thickness of these parts by 15%. The implications were far-reaching. The reduced wall thickness resulted in a faster cycle time, allowing for greater output with the same energy consumption. Additionally, there was less waste material that needed to be recycled, further reducing the carbon footprint of the product (Figure 3).

This innovation may seem like "low-hanging fruit". But even an idea that might look straightforward in hindsight is not easy to implement. The change took almost four years. Clients need to have a suitable project where the innovation can first be implemented – and they require a degree of confidence that a new idea will work. It requires frontrunners to be patient, diligent but persistent in rolling out their innovative solutions.

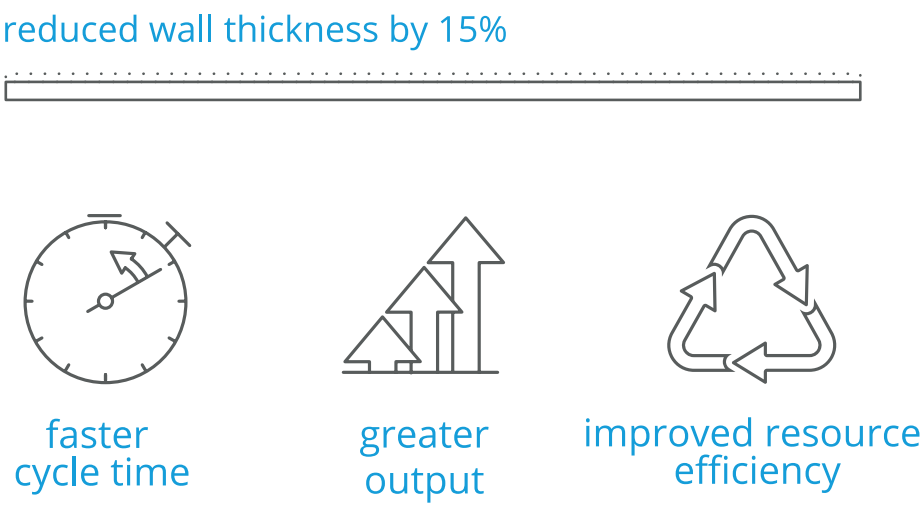


Figure 3: Small improvements can have a significant impact.

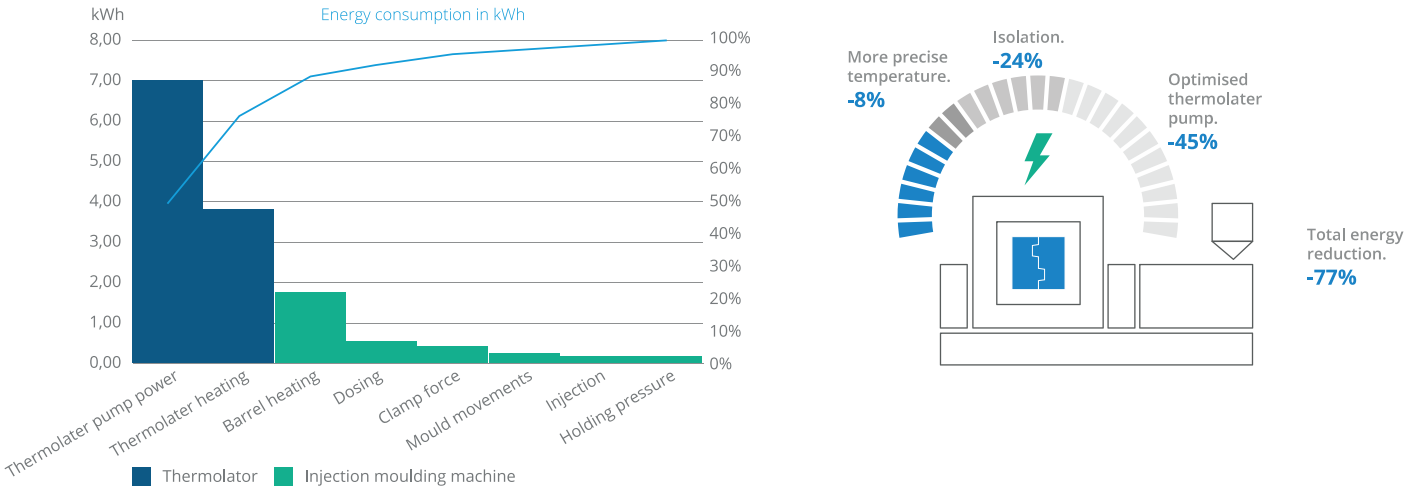


Figure 4: An optimised thermolator significantly reduces energy consumption.

## FOCUS ON THE BIGGER PICTURE

A production line is a patchwork of expertise, with many specialised suppliers contributing their piece of the puzzle. But each supplier excelling in their own domain is not enough. IGS GeboJagema believes it is critical to examine the entire production process. By understanding how everything works together, it is possible to find more effective and sustainable solutions (Figure 4).

> "It is critical to examine the entire production process. By understanding how everything works together, it is possible to find more effective and sustainable solutions."

One example is the thermolators (cooling pumps) used in the moulding process. From an engineering perspective, the primary concern is whether a cooling pump is powerful enough. So, once the pump performs as expected, it is easy to overlook the sustainability aspect and ask whether the pump might be more powerful than necessary. But this question can often massively improve energy efficiency. IGS GeboJagema applies a more precise approach and calculates the specific needs using the Reynolds number: a measure used in physics to understand fluid movement. It makes it possible to select a less powerful, yet equally effective pump. This simple switch can maintain product quality while reducing energy consumption by up to 80%. The energy saved may appear minimal at only a few kilowatts per day but, because most production lines operate around the clock and use multiple thermolators, it becomes a substantial annual reduction (Figure 5).

In the same way, IGS GeboJagema makes recommendations for other components, such as hot runners or robot systems, that can either reduce cycle time or are simply more energy efficient. The challenge often lies in persuading clients to reconsider a component that has been working well for years. Choosing a familiar, yet potentially suboptimal, component is safe. Choosing an unknown but potentially superior option is perceived as risky. IGS GeboJagema tries to make it easier for clients to make the better, greener choice through detailed case studies with compelling data.

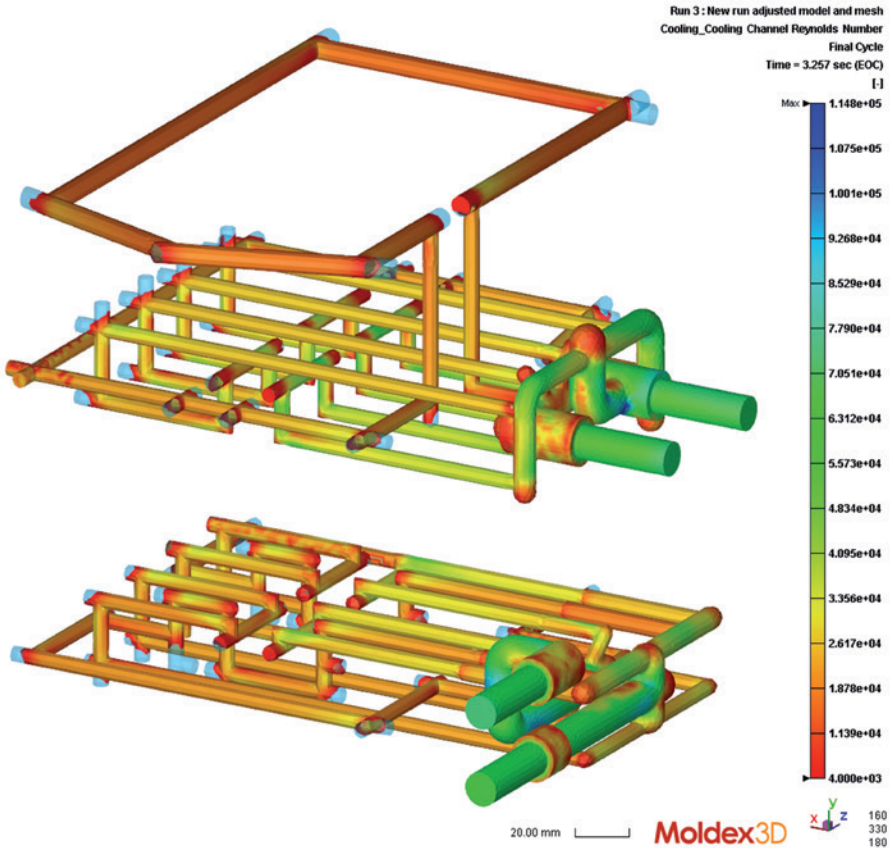


Figure 5: IGS GeboJagema calculates the required cooling power using the Reynolds number.

## CONCLUSION: A CHANGING MARKET

The market landscape is evolving. The incentive to embrace sustainability is growing stronger every day. Whereas a few years ago sustainability was often seen as a means of cost cutting, it has now gained intrinsic value, appealing to a broad range of stakeholders including clients, consumers and employees. Crucially, more and more organisations are requiring their suppliers to achieve a certain "sustainability score", as determined by tools like Eco Vadis, in an effort to establish a green supply chain. In short, sustainability has changed from an optional corporate social responsibility activity to an integrated part of business strategy.

IGS GeboJagema believes that green thinking should be woven into the very fabric of an organisation, from questioning day-to-day activities, to developing sustainable innovations and keeping an eye on the bigger picture to help partners make their operations greener. Businesses that fail to integrate sustainable action into their organisations risk being left behind, while truly green companies thrive.

## ABOUT THE COMPANY

IGS GeboJagema is a high-precision mould maker that designs, manufactures, validates and maintains moulds for products where extreme precision is vital, from glasses and contact lenses to asthma inhalers, insulin pens and blood diagnostic devices. The company specialises in collaborating with medical OEMs early in the product lifecycle, allowing its engineering team to develop innovative moulding solutions.

## ABOUT THE AUTHORS

**André Jansen** is Technical Sales Manager at IGS GeboJagema, responsible for the commercial relationship with healthcare ophthalmic customers, with a focus on long-term partnership and added value by innovative improvements on the customer side. He has more than 30 years of experience in technical sales in the injection moulding and manufacturing industry and has worked for IGS GeboJagema since 2011.

**Ron Cisliek** is Director of Business Development – USA at IGS GeboJagema, responsible for the commercial development and sustaining relationships with healthcare customers. He has a keen focus on attention to detail using his profound understanding of what it takes to design, construct, and operate effective part solutions for global healthcare OEMs and CMOs. He has more than 35 years of international experience in the injection-moulding industry and has worked for IGS GeboJagema since 2022.

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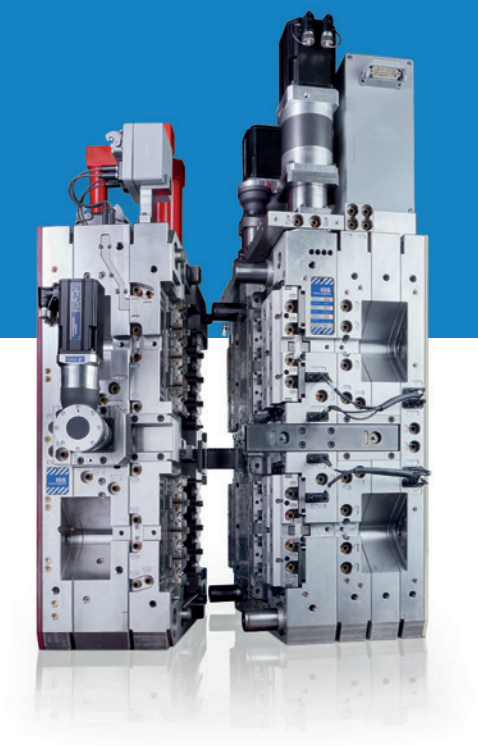

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H&T PRESSPART

# DRIVING SUSTAINABLE DRUG DELIVERY DEVICES WITH CONTINUOUS IMPROVEMENT PROCESSES

**In this article, Marc Severin, Sustainability Program Manager at H&T Presspart, discusses the company's H&T Excellence programme and how it has been expanded to include methods and training to help H&T Presspart identify environmental impact at a product group level and take co-ordinated action to reduce carbon emissions across the organisation.**

H&T Presspart's products reach millions of patients every day, giving the company the responsibility and the opportunity to drive ecological and social transformation. Resources are finite, and the boundaries of the planet have already been partly exceeded. The scenarios of climate science show the drastic impacts of a rising global temperature on life on Earth. The 1.5°C target from the Paris Climate Conference in 2015 leads the way to preventing the most severe scenarios and is a model for all kinds of organisations to transform their businesses to contribute to this ambitious goal.

Patients, societies, people and politics are becoming increasingly aware and have a greater sense of urgency to become active in the push towards environmental sustainability. Guidelines, regulations and standards like the Sustainable Development Goals (SDGs), the Corporate Sustainability Reporting Directive (CSRD) and the emissions reporting standard Greenhouse Gas Protocol provide organisations with multiple challenges and the potential to become more sustainable, contributing to a world that operates within the planetary boundaries. H&T Presspart is working with different kinds of standards to create sustainable pathways and is aligning them with legal, supply chain and customer requirements.

H&T Presspart has set ambitious targets for the transformation of its value chains. For example, it aims to achieve a greenhouse gas (GHG) emissions reduction of 80% in operations by 2033 and achieve net zero emissions across the value chain by 2050. To pursue these ambitions, the company has set further operational targets for different areas in strategic action fields.

Whilst seeking growth, industry needs to identify new ways of designing and manufacturing products, and a focus on the value stream is essential for responsible business practices. Reducing the input of resources, waste and linear streams requires a completely new mindset. Thinking circularly enables companies to drive positive change. Thinking circularly is the way to a world that respects planetary boundaries.

## DRIVING TO PERFECTION

H&T Presspart, as part of the Heitkamp and Thumann Group, embarked on the implementation of H&T Excellence, an operational excellence management programme, over 10 years ago. Since then, operational excellence has been embedded into the organisation and is now an integral part of its organisational culture.

Joel Willerding, H&T Excellence Manager, explains, "The focus of H&T Excellence is on eliminating or reducing waste by creating a culture of continuous improvement. Such a culture can only be developed within the company if each employee experiences the benefits of the

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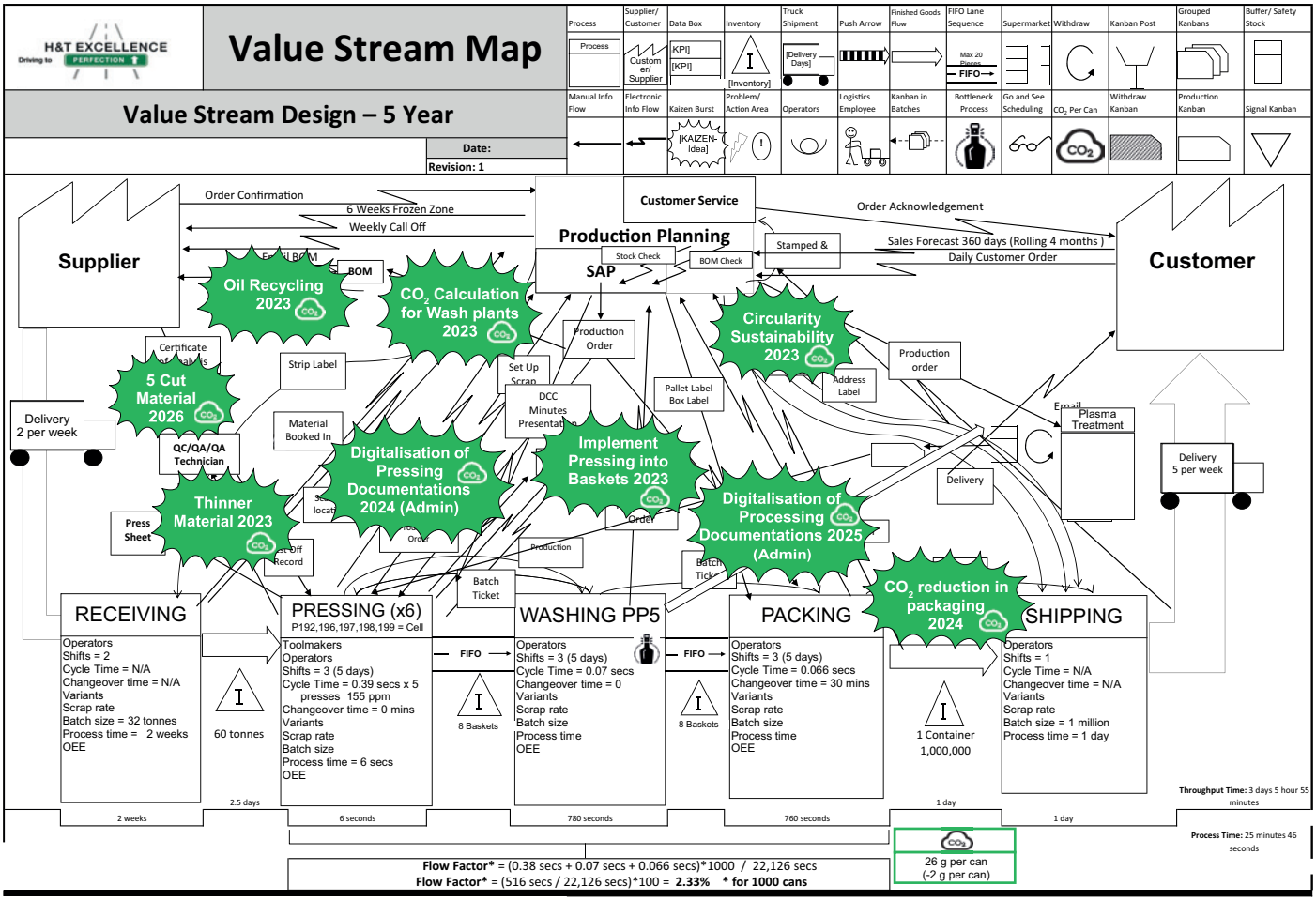


Figure 1: An example of a value stream mapping with all steps, with a focus on improvement areas.

> "During workshops and training sessions, which form part of the H&T Excellence programme, H&T Presspart encourages its employees to embrace continuous improvement culture and the benefits of lean principles, and to apply them to their own processes."

lean principles in their own workplace. On the one hand, we need a long-term strategy to show us the overall direction we need to take and the path to achieving our objectives. On the other hand, all employees must be included in the improvement process and the targets must be broken down, from senior management to shop floor employees."

During workshops and training sessions, which form part of the H&T Excellence programme, H&T Presspart encourages its employees to embrace continuous improvement culture and the benefits of lean principles, and to apply them to their own processes. Generating a positive attitude towards change amongst employees, as well as sharing best-practice solutions and enabling the constant exchange of information across the organisation, is a key approach to continuous improvement within the Heitkamp and Thumann Group.

As part of the H&T Excellence programme, H&T Presspart has adopted value stream analysis (VSA) as one of the central tools for the identification of improvement potential. This is a powerful methodology used to visualise and analyse the flow of materials, information and processes within an organisation (Figure 1).

## MAPPING THE VALUE STREAM TO INCLUDE CARBON EMISSIONS

A major milestone for the sustainable business transformation at H&T Presspart has been the integration of sustainability into the H&T Excellence programme and the identification of carbon emissions at each point in the value stream, from goods and materials receipts to the takeover of final goods by the customer.

In the first step, the current state of the value stream is mapped from the extraction of raw materials through manufacturing, distribution and use, all the way to disposal. In addition to operational data, environmental data, such as GHG emissions, is now also collected at each stage of the value stream to help identify inefficiencies, sustainability hotspots and related improvement potentials in operational processes. H&T Presspart's tools can help prioritise measures to reduce its environmental impact and carbon footprint, such as the optimisation of the transportation routes, energy efficiency or waste generation.

Next to concrete optimisation ideas, the results of VSA led the way for H&T Presspart's product footprint calculator, which can assess the environmental impact of product groups from raw material extraction to delivery to customers. The

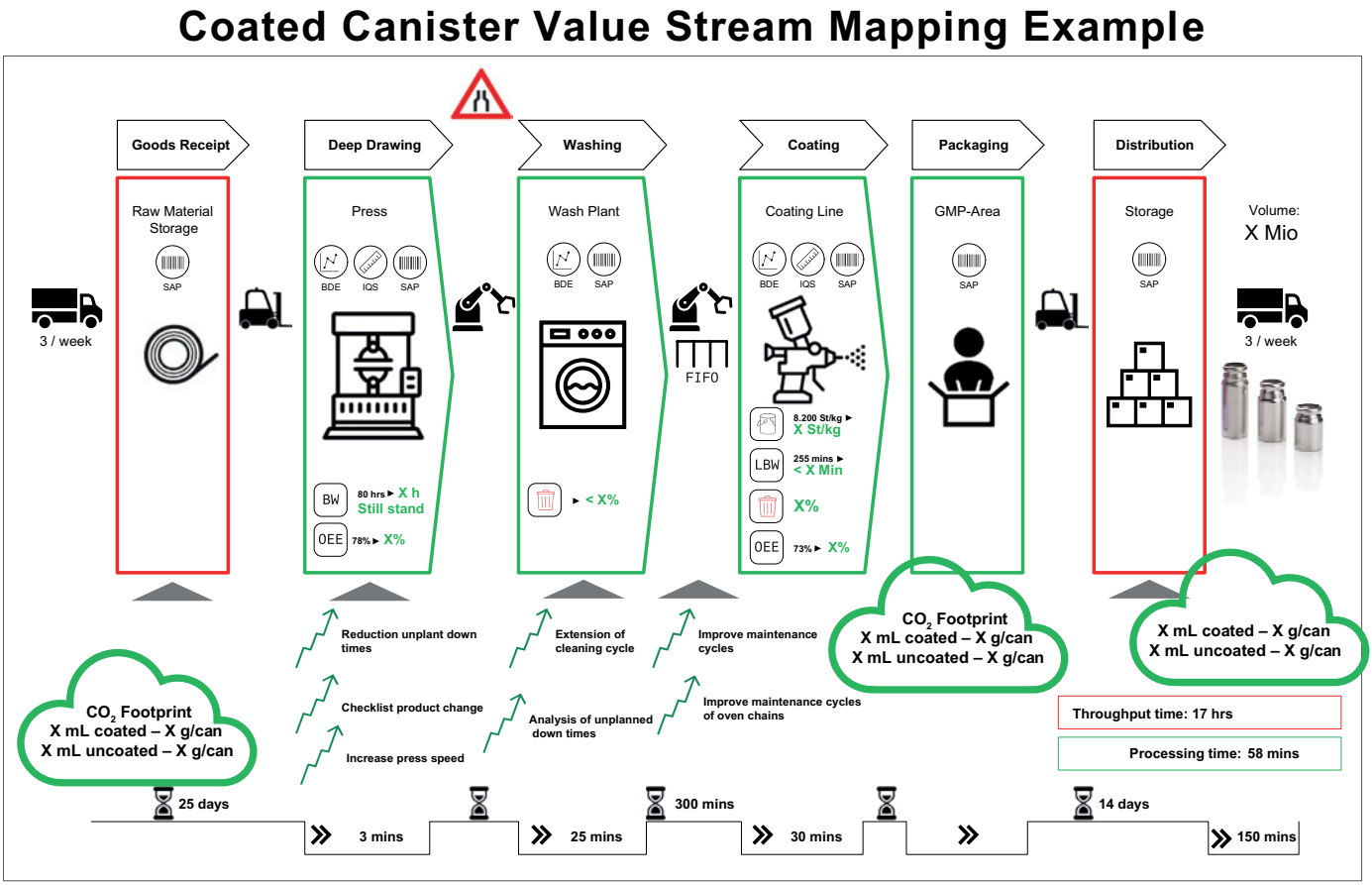


Figure 2: Process design after the implementation of all *kaizen* measurements.

tool has been individualised for the specific needs and value streams of different product groups at each of the company's sites. Each site can tailor its data input, such as for throughput times, materials and consumables, or electricity or energy use, to obtain information about which step of a particular value stream comes with the highest carbon footprint or potential for improvement. These potentials for positive change or improvement (*kaizen*) are then mapped in a *kaizen* diagram, which also shows the intended state after implementation of all actions or improvements (Figure 2).

The product footprint calculator gives H&T Presspart a tool to map the pathways for a more sustainable product. Striving for this, the company differentiates between ideas it can implement itself and those that need strong co-operation and transparency along the supply chain. H&T Presspart works with suppliers and customers in partnership to evaluate alternative materials, product designs or production processes and analyses the potentials and benefits in co-operation with them.

> "The product footprint calculator gives H&T Presspart a tool to map the pathways for a more sustainable product."

## CONTINUOUS IDENTIFICATION OF IMPROVEMENTS

The product footprint calculator gives H&T Presspart the chance to identify key drivers and large levers at a product group level. The company has identified that raw material has by far the highest share of a product's carbon footprint, with more than 80% for a metered dose inhaler (MDI) canister and 65% for an MDI actuator. In contrast to this, energy consumption is comparatively low. This is mainly due to the fact that the electricity requirement to run a press or a coating line is high in general, but only a fraction of that applies on a single product basis. If a deep drawing press consumes 1.5 kWh per 1,000 parts, the electricity requirement to produce a single canister is only 1.5 Wh.

The same can be observed in terms of coating. While a canister weighs around 8 g, the lacquer weight per can is less than 1 g, so that >7 g is purely aluminium. When considering that aluminium has a carbon footprint more than 20 times higher than conventional electricity, it is possible to directly derive priorities and action from that analysis.

> "Going deep into the data, it is possible to understand the impact of various measures for improving material scrap, waste generation or packaging."

Going deep into the data, it is possible to understand the impact of various measures for improving material scrap, waste generation or packaging. Those measures often have a low impact on the total carbon footprint when looked at in isolation. However, working on a series of these improvements leads to significant improvements over time. For example, by implementing a series of energy consumption improvements and optimisations in H&T Presspart's cold

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air and water supply management, the company was able to realise an estimated carbon footprint reduction of about 35 Tn, in addition to significant cost reductions.

There are multiple tools in addition to VSA that can help identify potentials to avoid waste, reduce energy or material consumption or improve production and material efficiency. These tools have been embedded into H&T Presspart's operational excellence culture and can now be used not just to identify cost savings, but also to identify potentials for GHG emission reductions. With Total Productive Maintenance (TPM) programmes and training, H&T Presspart is constantly reducing unplanned downtime or increasing the lifespan of equipment. With frequent Single Minute Exchange of Die (SMED) initiatives, workshops and training, the organisation identifies and realises measures to reduce the planned downtime of machinery and complete production lines.

## SUSTAINABLE DRUG DELIVERY FOR TOMORROW

The H&T Presspart operational excellence programme was embedded in the organisation more than 10 years ago. The evolution to integrate sustainability into the programme, its tools and training has given H&T Presspart a structured approach to identifying improvement areas and quantifying potential ways to reduce the company's carbon footprint and to help create a pathway to more sustainable drug delivery devices. The development of a product footprint calculator through VSA is one method that has enabled the organisation to not only measure the environmental impact at product group level, but also identify and act upon opportunities for sustainability improvements. By bringing together a cross-functional team, leveraging data-driven insights, and integrating sustainability into its decision-making processes, the company is well equipped to navigate the challenges and opportunities of a more sustainable future.

## ABOUT THE COMPANY

H&T Presspart is a market-leading manufacturer of drug delivery devices and components with more than 50 years' experience and enjoys a worldwide reputation for competence, quality and innovation in the pharmaceutical market. H&T Presspart's Technology Center supports its customers' new product developments and strategic initiatives. H&T Presspart has four European manufacturing sites in Germany, Spain, Switzerland and the UK and also has sales representation in China, India, the US and Uruguay.

## ABOUT THE AUTHOR

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# TRANSFORMING PHARMACEUTICAL MANUFACTURING TO DRIVE SUSTAINABILITY AND COST EFFICIENCY

In this article, Michael Astle, Executive Director of Legal Affairs and Head of ESG, Gareth Jenkins, PhD, Vice-President of Science and Technology, and Edward Mayo, Engineering Project Manager, all at Quotient Sciences, explore current strategies to reduce carbon emissions and drive cost efficiency throughout the healthcare industry.

Transforming the healthcare industry's current manufacturing practices into more energy-efficient alternatives is a task of paramount importance. The industry, including pharmaceuticals, produces approximately 5% of global carbon emissions and must do its part to meet carbon reduction targets in line with the Paris Agreement.[1,2] Across the pharmaceutical industry, manufacturers are changing their operational strategies to help limit global warming to a temperature increase of 1.5°C above pre-industrial levels.[2] By reducing carbon outputs through energy-saving methods, these modifications are also helping to drive cost efficiency for manufacturing lines, which has become increasingly necessary as energy prices rise.

Maintaining regulatory compliance when altering current operating systems to meet sustainability demands can be a complex task. The industry is highly regulated and must meet GMP guidelines to ensure that its products are safe for patients. Any changes to drug substance (DS) or drug product (DP) manufacture must be strictly monitored, ensuring that there is no impact on quality as a result, and that the process remains compliant and the product safe.

## OVERCOMING CHALLENGES TO SUSTAINABLE SOLUTIONS

The pharmaceutical industry prioritises patient safety, and GMP guidelines define stringent safety standards that all products intended for patients must meet. Implementing the changes required to meet sustainability targets without compromising regulatory compliance can be challenging. To help overcome these barriers, an effective strategy is essential, taking into consideration any possible implications that could occur as a result.

> "Completing extensive risk assessments to pre-empt the potential effects of any alterations allows for mitigative measures to be implemented, de-risking sustainable practices for a smooth transition."

Completing extensive risk assessments to pre-empt the potential effects of any alterations allows for mitigative measures to be implemented, de-risking sustainable practices for a smooth transition. This, coupled with an effective electronic monitoring system and a robust quality control (QC) testing programme, offers assurance that any changes made will have minimal to no impact on product quality. As revalidation will be required, an opportunity to improve GMP compliance also arises, implementing techniques to further improve DS and DP safety and efficacy while reaching sustainability targets. Effective partnering with colleagues in quality assurance is vital to delivering improvements in sustainability while maintaining elevated quality standards.

## TRANSITIONING TO SUSTAINABLE MANUFACTURING

Many changes can be made to current operations to improve environmental sustainability and reduce operational expenditure, some of which are discussed here.

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### Optimising Current Operations

Examining current manufacturing processes and operating procedures can help to identify inefficient methods that could be optimised to reduce carbon emissions and make processes more cost efficient. This could include:

- **Process optimisation:** Analysis of current processes to identify suboptimal practices that could be improved to minimise resource usage and waste, as well as further streamline reactions.
- **Supply chain sustainability:** Ensuring that sustainability objectives are shared across the entire supply network contributing to a company's greenhouse gas emissions.
- **Personnel training:** Educating employees on sustainable practices and offering guidance on how they can help reach sustainability targets.

Through this evaluation, small changes can be made that can have large impacts on helping to reach sustainable solutions.

### Modifying HVAC Systems

Heating, ventilation and air conditioning (HVAC) systems in particular have high energy consumption, accounting for 60–90% of cleanroom energy usage.[3] As a core component of cleanroom systems, the use of HVAC systems is vital to ensure that the environmental conditions of the cleanroom meet those required for sterility and stability. However, with such high energy costs, HVAC systems offer a prime opportunity for introducing more energy-efficient methods to meet sustainability targets.

The use of HVAC systems can be enhanced by adjusting the settings to meet DP needs while consuming the minimum energy possible. With an in-depth understanding of DS and DP, the manufacturing process and the regulatory requirements, a compromise can be made to meet the needs of both.

> "With such high energy costs, HVAC systems offer a prime opportunity for introducing more energy-efficient methods to meet sustainability targets."

A recent innovation has led to an advancement in HVAC systems, forming reactive airflow systems. These HVACs induce a variable, demand-based airflow supply. Instead of working at fixed airflow rates, these modified HVAC appliances use a robust environmental monitoring system to respond to changes in the environment. For example, a shift in particulate concentration would "switch on" the airflow system to ensure the environment remains within acceptable levels. This reactive feature circumvents the need for fixed airflow rates.[4]

As an example of the impact that implementing newer HVAC technologies can have, in a real-life example three obsolete rooftop HVAC units were replaced with brand new units at a pharma development facility. The existing obsolete units all had a seasonal energy efficiency ratio (SEER) rating of 10.8 or less, while the new units all had an SEER of 14. This equates to the new units using 21% less energy per year while maintaining equivalent or better temperature and humidity control in critical processing areas.

Aside from energy consumption, much of the potential environmental impact of HVAC equipment can come from refrigerant leaks. Effective preventative maintenance and intelligent operation of HVAC equipment are key elements of reducing the total environmental impact. As it is a large contributor to carbon emissions, optimising HVAC usage significantly reduces energy consumption, helping the move toward sustainability.

### Harnessing Technological Advancements to Enhance Manufacturing

Technological advancements have had a significant impact on sustainable manufacturing capabilities to streamline production. Through more efficient working practices, such as building automated workflows, the time and cost associated with drug development, scale-up and manufacture can be significantly reduced.

One example is the use of continuous manufacturing. Although an understanding of the chemical reaction is required, with continuous flow chemistry, reaction components are seamlessly transferred into, and products removed from, a reactor. This leads to a highly efficient and scalable process, which removes the need to produce large quantities of unneeded material and reduces the timelines for scale-up. With this accelerated approach, costs are reduced and energy consumption is minimised, all while quickly and reliably delivering increasing quantities of DS. Integration of automation into earlier drug development stages can help to further accelerate production and reduce carbon emissions.

With the increased availability of online analytics and accessible process data modelling, robust approaches for developing new sustainable chemical processes can be adopted. A recent example is the optimisation of a catalyst system to work in environmentally benign solvents, scoring 77 out of 100 using the GreenMetric assessment against the 12 Principles of Green Chemistry.[5]

> "To help implement manufacturing changes to reach sustainability goals, a partner with technical knowledge, experience and a proven track record can help to provide solutions for decarbonisation and improving cost efficiency while maintaining regulatory compliance."

## A PARTNERSHIP TO DRIVE SUSTAINABLE SOLUTIONS

To help implement manufacturing changes to reach sustainability goals, a partner with technical knowledge, experience and a proven track record can help to provide solutions for decarbonisation and improving cost efficiency while maintaining regulatory compliance. When deciding on a partner, it is essential to ensure that sustainability goals align. Choosing partners with a commitment to sustainable practices and the appropriate expertise will be vital for businesses in meeting their sustainability targets.

## ABOUT THE COMPANY

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programmes and tailored services

across the entire development pathway. Cutting through silos across a range of drug development capabilities, Quotient saves precious time and money in getting drugs to patients. Everything Quotient does for its customers is driven by an unswerving belief that ideas need to become solutions, and molecules need to become cures, fast, because humanity needs solutions, fast.

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## ABOUT THE AUTHORS

**Michael Astle** is the Executive Director of Legal Affairs and Head of Environment, Social and Governance (ESG) at Quotient Sciences, with over seven years of experience in the pharmaceutical industry. In this role, he oversees both the organisation's legal team and its ESG activities. As well as being a qualified lawyer, Mr Astle studied Business Sustainability Management at the University of Cambridge's Institute for Sustainability Leadership (UK). He is passionate about partnering with others to find solutions for business and the environment.

**Dr Gareth Jenkins**, PhD, is the Vice-President of Science and Technology at Quotient Sciences, with over 25 years of experience in the pharmaceutical services industry spanning drug discovery, drug development and drug product manufacture. Dr Jenkins brings a passion for science and innovation built on a broad and deep knowledge of medicinal chemistry, process development, industrial biotechnology, synthetic biology, continuous manufacturing, process analytical technology and process engineering. He uses this experience to guide drug development roadmaps from candidate selection, through pre-clinical and across clinical development phases. Dr Jenkins holds a degree and PhD in Organic Chemistry from Imperial College London (UK) and an MBA in Entrepreneurship from Manchester Business School (UK). He is also a Fellow of the Royal Society of Chemistry.

**Ed Mayo**, is the Director of Site Engineering at Quotient Sciences, with over 10 years of experience in pharmaceutical manufacturing. Mr Mayo's background as a manufacturing engineer and consulting process engineer gives him a unique perspective in understanding the needs of both internal and external customers. He is responsible for the leadership of the site engineering team and facilitates capital projects. He brings with him a strong focus on data driven continuous improvement and organisational discipline.

# THE EVOLUTION OF THE PHARMA ECOSYSTEM: PRODUCT PERFORMANCE NOW MEETS SUSTAINABILITY

**Here, Bettine Boltres, PhD, Director Scientific Affairs and Technical Solutions, Glass Systems at West Pharma, and Shivani Polasani, Product Development Manager at Corning, discuss how the pharma industry can progress towards a more sustainable future and consider the role that the Corning/West collaboration can play in supporting pharma's sustainability goals.**

In an industry where compassion and empathy for humankind are deeply rooted and values widely subscribed to, it should come as no surprise that the pharma industry is making significant efforts to address the sustainability conundrum. Whether as a pharmaceutical manufacturer or drug containment provider, the industry's primary role is to enhance and help save the lives of patients, ensuring that the safety and efficacy of the drugs used are safeguarded without compromise. That said, there is now an equally vital imperative – to support the global impetus to reduce carbon dioxide equivalent ($CO_2e$) emissions and help to create a more sustainable planet.

The question is therefore not if, but how, we can work towards a more sustainable future while protecting the interests of the patients we serve. The answer, specifically in injectables, has unequivocally been answered by the work undertaken by the West Pharmaceutical Services and Corning Incorporated collaboration.

## THE SIZE OF THE CHALLENGE SHOULD NOT BE UNDERESTIMATED

According to Deloitte, the global greenhouse gas emissions directly generated by the pharma industry are estimated to be around 52 megatonnes of $CO_2e$ per year.[1] This figure does not include indirect energy-related emissions through the entire supply chain, such as transportation, cold chain, etc, which contribute further to the final figure.

Another report estimates that the industry generates about 48.55 tonnes of $CO_2e$ per US$1 million (£821,000) in revenue generated, which is 55% higher than the emission intensity estimated for the automotive industry, i.e. 31.4 tonnes of $CO_2e$ per $1 million generated.[2]

If we take the injectables segment, Corning estimates that over 150,000 tonnes of Type 1 borosilicate glass is used annually in the global production of pharmaceutical vials. Due to complex regulations, most

> "The simple reality is that pharma and its supply chain partners must continue to do more work together to achieve greater sustainability heights while ensuring that the safety and efficacy of the drugs manufactured is maintained."

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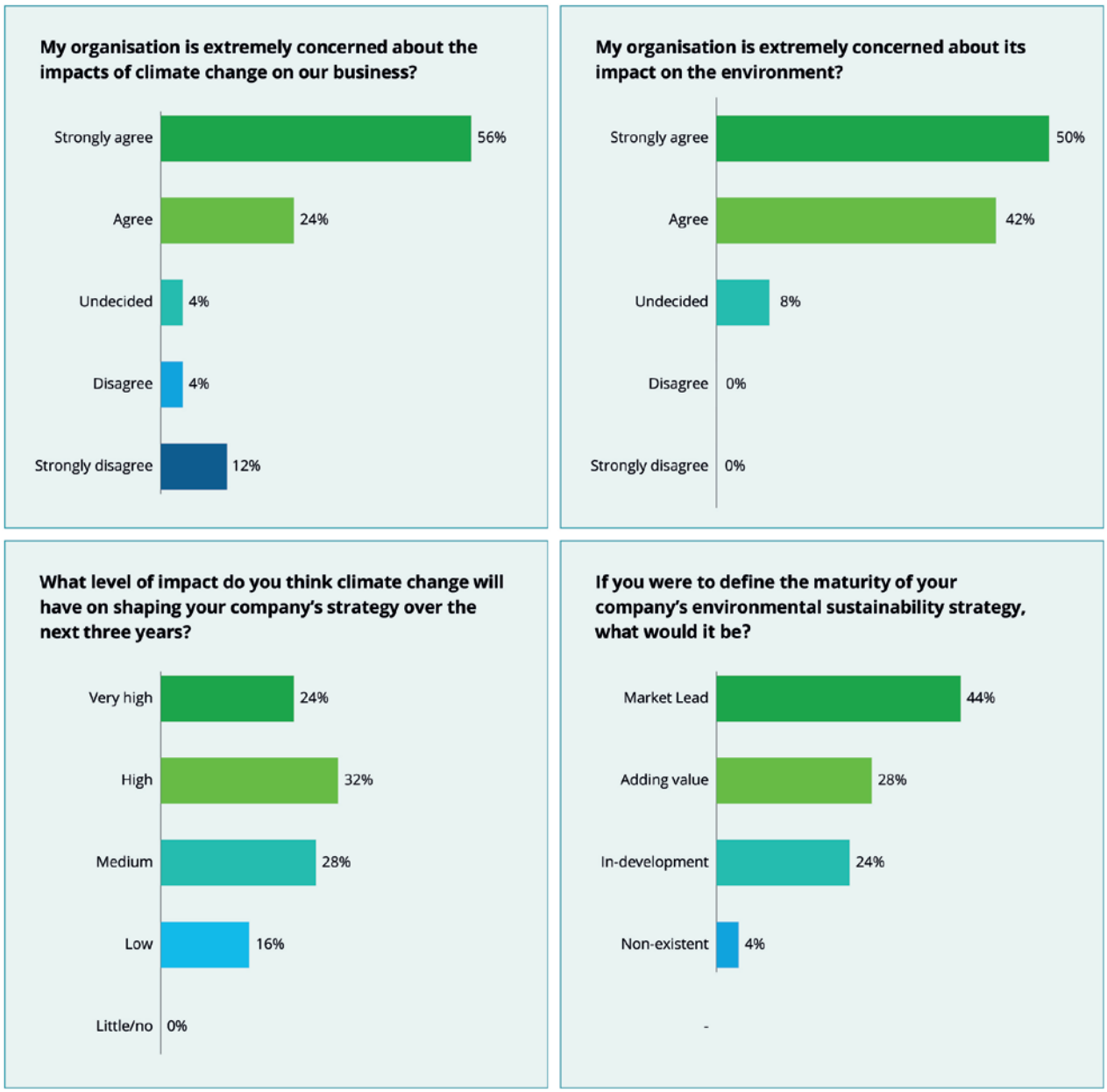



Figure 1: Pharma's attitudes towards sustainability.[4]

of this glass is discarded as medical waste each year, filling landfills across the world, according to internal estimates based on Corning Type 1 glass tubing production and awareness of industry capacity.

The simple reality is that pharma and its supply chain partners must continue to do more work together to achieve greater sustainability heights while ensuring that the safety and efficacy of the drugs manufactured is maintained. West believes that sustainability should be considered an integral component along with safety, efficacy and the manufacturability of pharmaceutical drugs.

In response to this imperative, many pharma companies have adopted ambitious plans with measurable goals; however, such a transformative change does not happen overnight and, for some, bridging the gap between high aspirations and meaningful, measurable action can be challenging.

## THE HEAT IS ON

A greater number of consumers and investors are paying real attention to a brand's sustainability track record and overall values when it comes to company reputation and ethics. Beyond product performance, more and more are now actively discerning which brands to purchase or invest in based on criteria such as sustainable packaging, reduced waste in manufacturing, a commitment to ethical manufacturing standards and reducing overall global warming potential (GWP).[3]

This attitude is not lost on pharma executives. Indeed, in one report, 80% of sustainability leaders in pharma said that they "strongly agreed" or "agreed" that their organisation was extremely concerned about the impact of climate change on their business, with 92% reporting that they were concerned about their organisation's impact on the environment.[4]

As global warming continues to threaten the planet, there is therefore no question that the heat is on to address the GWP of all manufacturing operations, including pharmaceuticals. There is, of course, another important dynamic to this imperative – how to ensure any improvements made in terms of sustainability do not compromise the safety, efficacy and operational efficiency embedded in the manufacturing of pharmaceutical products (Figure 1).

## PERFORMANCE MUST MEET SUSTAINABILITY

Building on the recent collaboration with West and Corning, which brings together more than 200 years of experience, the team is now taking on this challenge and is excited to bring Corning® Viridian™ vials to the market, directly addressing the thorny challenge of meeting performance and sustainability together in a system-level containment solution. The exclusive supply and technology agreement provides pharma partners with access to some of the most innovative products in parenteral drug delivery.

Corning® Viridian™ Vials are a transformative innovation that reduce glass waste and manufacturing emissions without compromising manufacturing efficiency. Indeed, data demonstrate that Viridian™ Vials reduce material waste by 20%, while reducing $CO_2e$ emissions by up to 30%.* Additionally, filling-line data with Optima (a leading manufacturer of fill-finish equipment based in Schwaebisch Hall, Germany) demonstrates the ability of Viridian™ Vials to increase fill-finish efficiency by up to 50%.** It can also reduce cosmetic rejects and lower glass particle generation by up to 96% (Figure 2).

As a design that included sustainability from first principles, the Viridian™ Vial is a market first. The metrics have been achieved by reducing the wall thickness of the vial, reducing the overall mass from the conventional 2R that weighs 4.4 g. There is another added sustainability advantage too – a thinner wall creates additional capacity in the vial itself, enabling the use of potentially fewer vials to meet demand.

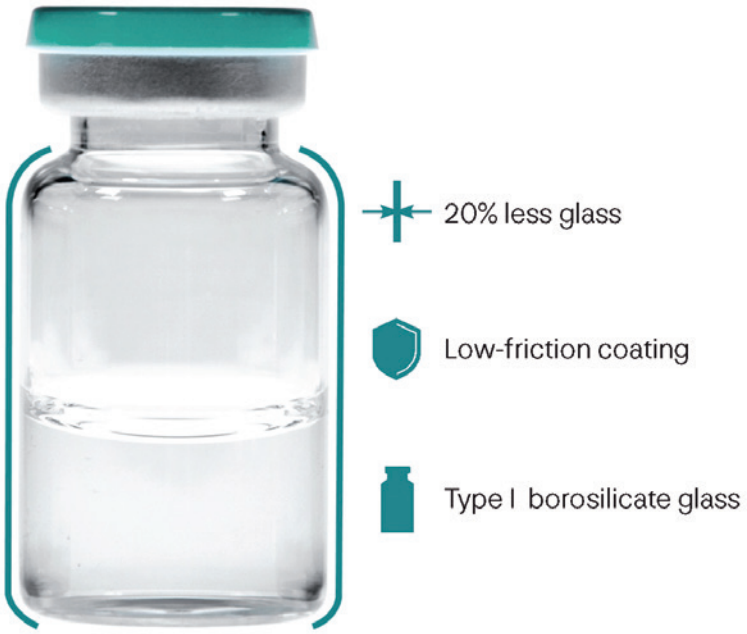
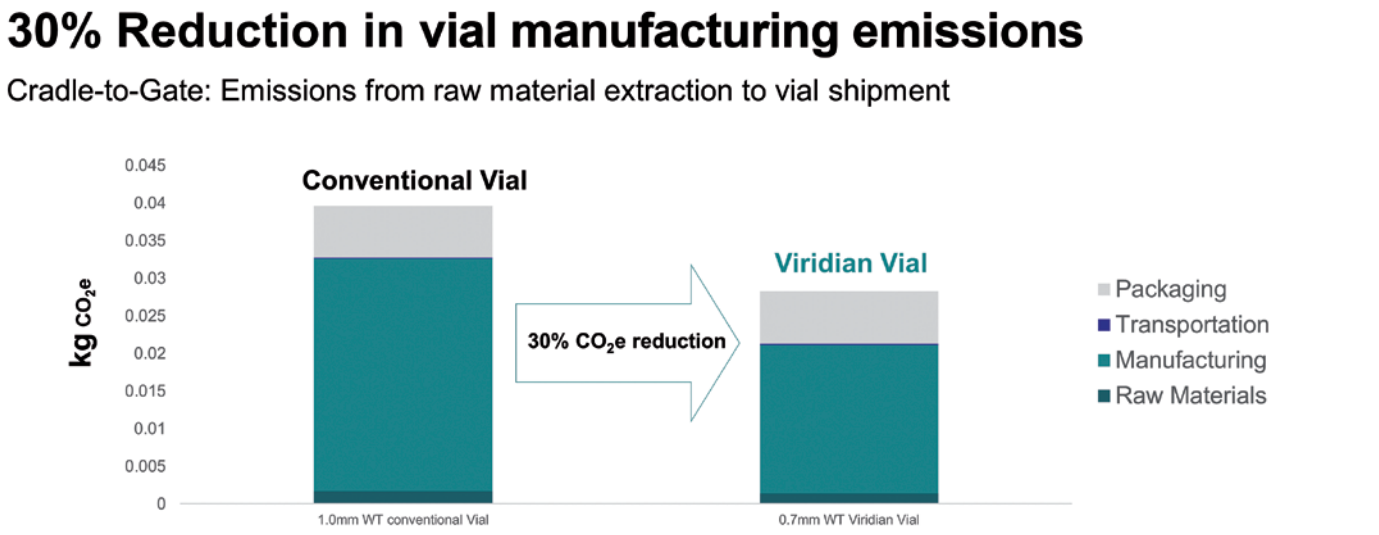



Figure 2: Viridian Vials' protective external coating can reduce damage that leads to cracks, breaks and cosmetic rejects.

Taking the additional step to substantiate emission reduction claims, Corning worked with Sphera, a leading provider of Environmental, Social and Governance performance and risk management software, to conduct a cradle-to-gate, third-party lifecycle assessment (LCA), which compared Corning® Viridian™ vials with conventional borosilicate vials. The report discusses how Viridian™ Vials can reduce $CO_2e$ emissions by up to 30%. Furthermore, the report additionally shows that even compared with conventional vials manufactured with 100% renewable electricity, Viridian™ Vials can reduce




| Format | Wall Thickness | Raw Materials g $CO_2e$ per vial | Transportation g $CO_2e$ per vial | Manufacturing g $CO_2e$ per vial | Packaging g $CO_2e$ per vial | Total g $CO_2e$ per vial |
|---|---|---|---|---|---|---|
| 1.0 mm conventional Vial | 1.0 | 1.7 | 0.17 | 30.9 | 7.0 | 40 |
| 0.7 mm Viridian Vial | 0.7 | 1.4 | 0.15 | 19.7 | 7.0 | 28 |
| | **Reduction** | **18%** | **11%** | **36%** | **0%** | **30%** |

CORNING • Assumes use of **Non-renewable electricity for production of 1.0mm** wall thickness conventional vials

Figure 3: Third-party LCA of 2R standard conventional vials with 1.0 mm thickness vs Viridian Vials with 0.7 mm wall thickness.

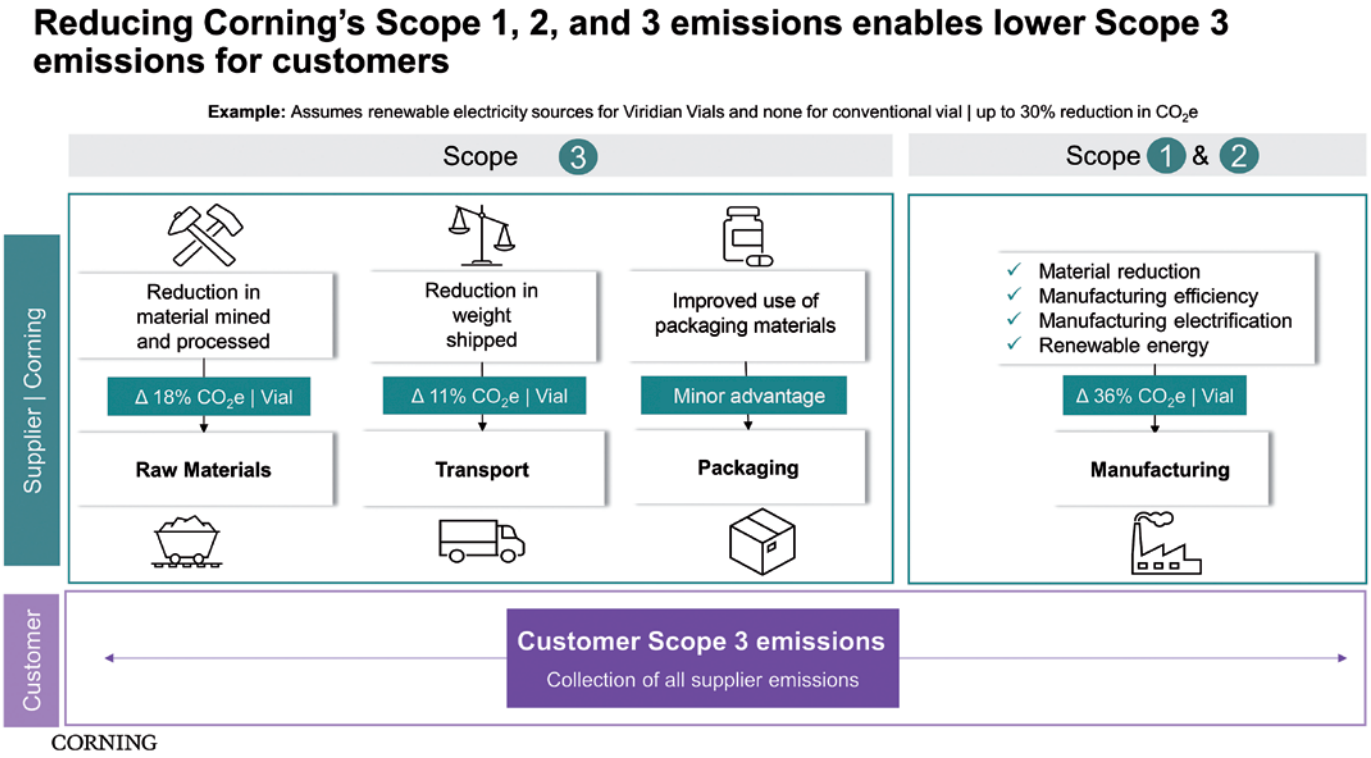



Figure 4: Reducing Corning's scope 1, 2 and 3 emissions enables lower scope 3 emissions.

emissions by up to 15%. The LCA is currently undergoing independent peer review to further validate the claims.

## LOWER GWP, SAME SPECIFICATION, NO COMPROMISE

Breaking down the per-vial $CO_2e$ improvement by category, the LCA shows a reduction of 0.3 g of $CO_2e$ from raw material extraction, 11.2 g of $CO_2e$ from manufacturing (tube forming, converting and coating) and 0.03 g of $CO_2e$ from tube and vial transportation. If these data were extrapolated to 10 million vials, Viridian™ Vials could save up to 114,000 kg of $CO_2e$, which is equal to consuming more than 12,900 gallons of fuel, and eliminate around nine tonnes of glass from landfill waste (Figure 3).[5]

Additionally, Viridian™ Vials, being borosilicate glass, are compliant with USP <660> Type I hydrolytic resistance testing and Ph. Eur. 3.2.1. They also meet ISO standards regarding outer and neck dimensions to mitigate the need for change parts on customer filling lines that already use ISO standard borosilicate vials (Figure 4).

## A PRODUCT IS NO GOOD IF YOU CAN'T HANDLE IT

In the development of Viridian™ Vials, it was essential that vial performance was not impacted by the product design. To this end, Viridian™ Vials can be seamlessly integrated into current fill-finish production facilities without the need for change parts on filling-line equipment and with equivalent or better vial breakage rates. The important point here, as the Optima data demonstrate, is that a thin-wall vial will have a high breakage rate and will not maintain performance rates without Corning's protective coating.

Viridian™ Vials are equipped with Corning's proprietary exterior coating that ensures the vial has a low coefficient of friction and maintains glass strength through fill-finish processing and transportation. This provides the basis for improved throughput and reduces the likelihood of vial damage, rejects and glass particles. Indeed, the external coating used on Corning® Valor® Vials and Viridian™ Vials can improve filling-line efficiency by 20% to 50%,[6] with a reduction in the likelihood of damage that leads to cracks and breaks and a 96% reduction in glass particles.[7] Improved efficiency also supports a reduction in pharmaceutical production costs.

## PROVING PERFORMANCE

In collaboration with Optima, two vial types were tested; a standard uncoated 2R borosilicate vial (4.4 g) and a 2 mL Viridian™ Vial (3.5 g). The vials were run at 450 vials per minute and recirculated >120 times, simulating >200,000 vials processed for each group. The trial resulted in no breakages being observed in washing, depyrogenation, accumulation, singulation or while at the star wheels. The Viridian™ Vials demonstrated a lower tip over rate compared with conventional vials. There were no functional issues with washing or depyrogenation and no need for modification of fill-finish processes not additional change parts required.

## THE PHARMA SUPPLY CHAIN HAS AN OBLIGATION TO DO MORE

When reporting emission data, the international standard is to classify energy usage and emissions into three categories, scope 1, 2 and 3. The three scopes are a way of categorising the different kinds of emissions that a company creates in its own operations (scope 1 and 2) and in its wider value chain (scope 3). The Greenhouse Gas Protocol defines it as "Developing a full [greenhouse gas] emissions inventory – incorporating scope 1, scope 2 and scope 3 emissions – enables companies to understand their full value chain emissions and focus their efforts on the greatest reduction opportunities".[8]

While scope 1 covers emissions that an organisation owns or directly controls, scope 2 emissions are those that a company indirectly causes and come from the energy it purchases. Scope 3 encompasses emissions that an organisation is indirectly responsible for, up and down its value chain. Pharmaceutical companies are looking for suppliers to develop innovative solutions to support scope 3 emission reductions. Recently, much of the narrative at industry events has been about engaging the supply chain in helping pharma manage its scope 3 commitments.

Of course, in this setting, innovation needs to be "feasible", meaning a drop-in solution that is accessible and balanced with pragmatism – the time/cost/risk paradigm is a paramount consideration for pharma. This is where Viridian™ Vials really deliver true value – they deliver demonstrable benefits with careful consideration to maintaining specification and operational efficiency. But this is just the beginning; the Corning/West collaboration will continue to innovate and further improve to support pharma's sustainability efforts.

## CONCLUSION

The supply chain has responsibility to work in partnership with pharma to better support its scope 3 commitments. There are, of course, many ways to achieve that goal, such as to improve operational efficiencies to increase the speed of manufacturing and reduce energy consumption, or invest in renewable energy, among others. To change the game regarding sustainability, there needs to be a measured and innovative approach. The first-of-its-kind Viridian™ Vial was created not only from a product perspective but from a wider ecosystem standpoint, delivering real gains in sustainability while positively impacting the overall sustainability credentials of the manufacturing environment. Hence, designing for sustainability does not need to cost the earth or compromise on traditional key performance indicators. The heat is on, but there is now a tangible opportunity to contribute to dialling down the temperature and delivering on those scope 3 sustainability aspirations.

** Corning in-house data – independent LCA by Sphera.*
*** Corning in-house data.*

## ABOUT THE COMPANIES

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## ABOUT THE AUTHORS


**Bettine Boltres**, PhD is Director Scientific Affairs and Technical Solutions, Glass Systems, supporting the scientific exchange between West and the pharmaceutical industry. This complements her work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging and wrote the book *When Glass Meets Pharma*. Since January 2019, she has been a member of the PDA Board of Directors. Since 2015, Dr Boltres has been an active member of the USP Packaging and Distribution Expert Committee, as well as the European Pharmacopoeia Commission Group of Experts 16 (elastomers), and the GLS Working Party (glass) and convenor of the ISO TC76/WG 4 on elastomers and member of the WG 2 on rigid containers.

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# TIPS AND TRICKS FOR IMPLEMENTING SUSTAINABILITY INITIATIVES

**In this article, Henryk Badack, Senior Vice-President Technical Service and Internal Project Management at Vetter, outlines the company's efforts to establish sustainable business practices.**

Achieving sustainable business practices in the pharmaceutical and biotech industry is no easy feat. Through trials across its 70+ year history in the industry, Vetter has established proven processes to activate meaningful and authentic sustainability initiatives and projects.

Vetter's 2022 Sustainability Report outlines the company's commitment to integrating sustainability into its growth worldwide. This is proven through the steps the company takes to make lasting and vital change in line with the needs of the world and society. For example, Vetter joined more than 300 other pharma companies in signing the UN Global Compact – a pledge to align itself with the UN Sustainable Development Goals through sustainable and responsible corporate governance.

> "Companies must go beyond minimising their carbon footprint... they must also seek to find a balance between the three pillars of ecological, economic and social impact."

To adequately achieve a steady dedication to acting sustainably, companies must go beyond minimising their carbon footprint, although this remains important. They must also seek to find a balance between the three pillars of ecological, economic and social impact. Only then can organisations truly achieve sustainable business practices that support their growth, the success of their customers and the betterment of society as a whole.

As a contract development and manufacturing organisation (CDMO), Vetter serves as a partner to pharma and biotech companies of all sizes and scopes. As such, the organisation wants to lead by example and set the standard for what it hopes all others in the industry can achieve with regards to a daily commitment to sustainability.

## THE "WHY" BEHIND THE EFFORT

To integrate sustainability wholeheartedly into everyday business practices, it must be done as a core foundation of an organisation. There are those who follow the regulations and requirements of sustainable practices, but there are also those who truly want to lead in the space because it aligns with their own company values. With the incorporation of its environment,

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health and safety management system and the documented transparency of its successes and hurdles, Vetter established steps early on to guide its growth in sustainability. European companies are also obligated to observe the "Green Deal" initiated by the EU, which sets a goal to be the world's first climate-neutral continent by 2050. This will be achieved by reducing greenhouse gas emissions by more than half by 2030, and the industry must make changes to contribute to this goal successfully.

Since biopharma companies cannot expect to emit no $CO_2$ due to strictly binding regulatory requirements, Vetter chose to put in effort in other ways to offset this unavoidable emission.

When sustainability is woven into everything a company does, it has its own strategic benefits. For example, the past three years since the start of the global pandemic have highlighted how fragile the supply chain can be. When new bottlenecks arise along the supply chain, it can have negative implications on patients in need receiving the medications they so desperately rely on. Vetter took steps to incorporate sustainability despite other external challenges that it faced and, as a result, has built a capacity for resilience to disruptions along the supply chain.

As customer demands increase and patient needs remain high, it is the company's responsibility to find solutions to overcome outside obstacles and continue to meet the timelines it has outlined with its customers. By finding solutions to avoid dependency on one supply chain partner, Vetter has grown through the challenges and come out on the other side stronger.

## FROM CONCEPT TO REALITY

Vetter has been conceptualising and putting into practise an environment, health and safety management system for over a decade. One result has been carbon neutrality across all Vetter sites since 2021. However, this did not happen overnight. Rather, it took an extensive and fully integrated commitment to enhance efficiency through technological adjustments, offsetting where needed, and shifting the company-wide mindset to one led with sustainability in mind. The real challenge comes when trying to measure success and make changes based on lessons learned.

Vetter published its first ever sustainability report in 2022, guided by the requirements of the German Sustainability Code and the Sustainability Report Standards of the Global Reporting Initiative. The report not only acknowledges the company's progress and successes but holds it accountable to achieving its goals. With these outward-facing commitments made in writing, Vetter is holding its feet to the fire to reach its sustainable goals in the timelines it has proposed. As a family-owned company, this is not just to improve the outputs for customers and patients, but to leave a legacy the organisation can be proud of for many generations to come.

In an industry with particularly high carbon emissions, how did Vetter become a leader in sustainable growth?

The company established an independent sustainability management system that supports, tracks and measures all related projects. By documenting its progress, the company can accurately identify areas of success and areas for improvement

> "Through years of investment, Vetter has optimised its existing systems, built new, energy-efficient construction and focused on the generation of renewable energy."

to constantly evolve its practices for the greatest impact. This is a top-down commitment with a clear trickle-down effect as the owner family and managing directors recognise the great importance of sustainability and fully support the strategies as driving forces behind the overall business strategy.

In addition, Vetter established a sustainability core team to keep a finger on the pulse related to industry-wide trends, and to keep the organisation on track to achieving the goals expressed in its annual sustainability update.

## HONING A PATH FORWARD

As a highly technical pharma service provider, Vetter requires special production conditions and must adhere to strict regulatory requirements from various authorities. However, that does not make it impossible for the company to find ways to make its production sites more environmentally friendly. Instead of changing extremely precise processes, it focused on adjusting its technical infrastructure outside of its pharma production zones.

Figure 1: The photovoltaic systems on Vetter production facilities.

Through years of investment, Vetter has optimised its existing systems, built new, energy-efficient construction and focused on the generation of renewable energy. One area of success has been its water-for-injection recirculation system, which has allowed it to save 47,196 kWh of electricity, 13,452 kWh of gas and 1,562.5 $m^3$ of water each year. By using direct current electric motors in its ventilation systems, it can replace the alternating current electric motors with a more energy-efficient alternative. This has saved 1,720 kWh per motor per year, all without jeopardising the quality and control of the cleanroom processes.

Another way Vetter has made strides in its sustainable practices has been through the expansion of photovoltaic systems on the roofs and facades of its production sites (Figure 1), as well as through the use of geothermal energy. This allows it to cover its energy requirements through partially self-generated renewable energy. These, and several other sustainability efforts, have spanned an investment of over €7.8 million (£6.8 million) in more than 125 individual projects.

Beyond what many consider the traditional sustainable initiatives, Vetter has also taken a creative approach to achieving sustainability through unique employee programmes, such as its bike-leasing programme, charging stations for electric bikes and cars (Figure 2), enabling remote work to avoid unnecessary commuting and covering the costs of local train tickets for commuters. These efforts are easy to implement and offer high rewards – and can be implemented by any company committed to acting sustainably.

## IMPLEMENTING SUSTAINABLE PRACTICES

Establishing sustainable practices for a pharma or biotech company goes far beyond the idea. It must extend into how it is put into practice, measured and reported on and, eventually, improved. By collecting past and current efforts and outcomes and aligning them with strategic goals for the future, companies can create a comprehensive sustainability report to serve as a guide for years to come. Success comes down to the collection and analysis of data and the way this information is used to drive future sustainability commitments.

This will not come without its challenges – many of which Vetter has faced. The production of critical life-saving medications is resource intensive, and manufacturing requires significant energy-intensive production infrastructure. While none of this can be jeopardised, there can be workarounds and innovative solutions to help meet sustainability goals without harming the end product – life-saving medications for patients.

Keeping an eye on new opportunities for sustainable growth will keep your company at the forefront of this ever-evolving landscape. As you find new technologies to serve in capacities to reduce fossil fuel resources or other environmentally taxing issues, you can achieve measurable success in sustainability that can be built upon for decades.

The industry's strength is in numbers – the biopharma sector should combine forces to find new solutions for growth, from sustainable packaging to new technology tools, to maximise flexibility and sustainability while never compromising its work.

The most important element to remember when deciding how to incorporate sustainable business practices into your organisation is that sustainability does not always need to be high tech. Every company must define its own route to sustainable success and must put one foot in front of the other every single day to truly see the impact needed. Sustainable business is a lifetime commitment that must be adhered to without an end date in mind.

Figure 2: Vetter has on-site bike parks for all employees.

## ABOUT THE COMPANY

Vetter is a leading CDMO with headquarters in Ravensburg, Germany, and production facilities in Germany, Austria and the US. As a global player, the pharma service provider also has its own sales locations in the Asia-Pacific markets of Japan, China, South Korea and Singapore. Around the world, small and large renowned pharma and biotech companies rely on the decades of experience, high quality, modern technologies, reliability and commitment of more than 6,000 Vetter employees. In close partnership with its customers, the Vetter team supplies patients all over the world with medicines, many of which are vital. The CDMO provides support from drug product development through clinical and commercial filling to a wide range of assembly and packaging services for vials, syringes and cartridges. With innovative solutions, Vetter develops prefilled drug-delivery systems, together with its customers, to continuously improve patient safety, comfort and compliance. The company is a pioneer in the industry when it comes to sustainability, and acts as a socially and ethically responsible corporate citizen.

## ABOUT THE AUTHOR

**Henryk Badack** is Senior Vice-President Technical Services and Internal Project Management. In this role, he is responsible for the company's internal, technical and infrastructure projects as well as for plant and site development, environmental health safety and Vetter optimisation systems. Mr Badack has 20 years of experience in the pharma industry, having joined Vetter in 2003 as a Project Manager for validation and qualification projects. He later held positions of increasing importance at Sandoz in 2007–2008, before returning to Vetter in 2009.

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# MAKING LOW-CARBON-EMISSION SINGLE-USE MEDICAL DEVICES A REALITY

**Here, Veluska Bruce, PhD, ESG Project Manager at SHL Medical, discusses the design and development of single-use autoinjectors in the context of sustainable development.**

Sustainability is a vast topic that could well be contextualised through the United Nation's (UN's) efforts on sustainable development over the decades. In 1987, the UN Brundtland Commission defined sustainability as "meeting the needs of the present without compromising the ability of future generations to meet their own needs". Then, in 2015, the UN General Assembly agreed on the Sustainable Development Goals (SDGs), a normative concept that many countries embrace to achieve a sustainable future for humankind and the planet. Today, sustainability is a shared responsibility with multiple facets, which merits discussion and transformative action in the pharma and medical device industries.[1]

In light of this, it should be acknowledged that the development of the autoinjector helped set the standard for home-based parenteral treatments. In many ways, it manifests sustainable development focusing on healthcare. As a medical device that delivers precious drugs and biologics to patients with chronic diseases, the autoinjector has re-envisioned patient autonomy, particularly in parenteral therapy. SHL Medical is proud to be a significant part of the evolution of autoinjectors, and the company is committed to challenging, rethinking and embodying what it means to enable patient independence. SHL plans to expand its portfolio of innovative drug delivery devices by 2030, in turn helping more than eight million patients to be independent.

> "Disposable medical devices, which include autoinjector products, must carefully balance materials, cost, performance, reliability, shelf life and end of life."

## SUSTAINABILITY BEYOND A LOW-CARBON-EMISSION PRODUCT

The promotion of health and wellbeing is a crucial piece of the UN SDGs. SHL uses its technical device expertise to help its pharma partners accelerate patient access to medical devices worldwide. Cognisant that these medical devices are essential to millions of patients suffering from chronic diseases, SHL believes that autoinjector products as a convenient treatment modality will stay. At the same time, advances in the medical device industry have led to the realisation of the urgent importance of product lifecycle management that supersedes current ideals. Thus, disposable medical devices, which include autoinjector products, must carefully balance materials, cost, performance, reliability, shelf life and end of life.

Time is of the essence when it comes to global sustainability. Current attempts by businesses across many industries to introduce eco-friendly and zero-impact products are laudable. Perhaps, resorting to introducing new products that claim to be eco-friendly may be the only solution. In any case, reality dictates that a persisting challenge remains to drive sustainability in existing products. For SHL, sustainability requires a dynamic, two-pronged approach: addressing what's already existing while shaping the path toward a better sustainable future.

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Figure 1: SHL Medical's sustainable design principles.

It remains a fact that the autoinjector embodies the improvement of lives in its DNA. While arguably metaphorical, this reflects the recognition that autoinjector products will remain integral to the limited options for delivering necessary parenteral treatment within modern medicine. As autoinjector products continue to proliferate now and in the future, sustainability should come from as early as product conceptualisation – embedded in the product's DNA. At the same time, SHL acknowledges the need to intercalate sustainable designs into the identity of existing products and their processes. The company is calling on the rest of the industry to act upon this pressing challenge.

Upholding the established importance of autoinjectors, SHL is investing efforts towards sustainable design thinking. It is reshaping the lifecycle of its solutions and their processes – driving impact and improving the quality of life for patients – without draining the planet's resources further and respecting its limits. To this end, the SHL sustainable design principles (Figure 1) were developed – the company's guiding compass to think and act sustainably beyond the confines of introducing a purported eco-friendly product. Going beyond impact neutrality, SHL focuses on driving regenerative thinking, design and innovation.

The application of the sustainable design principles implies following a systematic approach that strives to achieve products with the lowest possible environmental impact throughout the product lifecycle without compromising performance, patient safety, functionality or quality. SHL uses these principles as a foundation to design products following a circular approach.

## EMBRACING A CIRCULAR DESIGN APPROACH

From the perspective of a single-use medical device manufacturer, it might seem that the ultimate goal is to reduce the device's footprint. Indeed, this is true, but to fully acquire a circular mindset, one must think beyond any conventions and innovate products to maintain the starting material in the loop.

Product design is a crucial element in enabling circularity. It has been shown that up to 80% of the product emissions, from material usage to end-of-life product waste, can be tailored during the design phase. Particularly for autoinjectors, the intricate design of every component can affect the device's circularity. To preserve resources, it is therefore vital to include circular inputs that have a low footprint, can be recycled or regenerate naturally.

SHL's sustainable design principles are based on eco-design and circular design theory.[2] Following a circular approach (Figure 2) in the device design allows recovery after usage. Circularity in the context of single-use devices includes designing and producing products that can be recovered and reused after usage. Another would be reshaping operations to minimise consumption and eliminate waste by turning them into new resources.

## DESIGN FOR REUSE AND REFURBISHMENT: A MATTER OF TRUE SUSTAINABILITY

In the context of circularity, recovery is a broad term that encompasses the process of recycling and reusing. It describes the recovery process ways in which a valued raw material can be used in other products and describes the implementation of reuse. Specifically, direct reuse may be defined as "any operation by which products or components that are not waste are used again for the same purpose".[3] To be able to reuse products or core parts of the products (e.g. refilling the drug in the same


Figure 2: SHL's sustainable design principles follow a circular design approach.

> "Having a data-driven approach is essential for identifying areas for prioritisation and understanding the real environmental impact of products and processes."

autoinjector), the result must be as good as the new product and comply with the functional requirements. Usually, the direct reuse strategy involves the collection of by-products from the waste stream of the already-used products, which entails cleaning, sorting and quality testing processes. Thus, before deploying the idea of refiling and re-dispensing a drug in the same autoinjector, SHL urges its fellows in the industry to bidirectionally quantify all the processes involved to identify the best option.

Further, autoinjectors, as healthcare products, are subject to the laws and regulations of the market where they are used. If the product is considered waste after usage, additional steps need to be considered for it to be reintroduced onto the market. At present, one must ask: "How does the regulatory landscape look when it comes to combining new and reused parts?" Recovery and refill mechanisms are promising options and need joint industry efforts to find the conditions for a successful deployment. SHL believes that careful planning is of utmost importance prior to setting foot into uncertainties. In the end, the decision to explore novel recovery programmes all boils down to the true essence of sustainability. Figure 3 shows SHL's reflections when designing for circularity.

## DATA-DRIVEN DECISION MAKING

For SHL's sustainable design principles, design for circularity aims to uphold an innovative product design process that would result in the lowest environmental footprint across a product's lifetime, supported by data-driven decisions.

One may then ask: "How do you generate an insightful amount of quantitative data to support the decision-making process to enable product circularity?" Here, lifecycle assessment (LCA) is critical to providing a framework for measuring the environmental footprint during the lifecycle of a product. Further, having a data-driven approach is essential for identifying areas for prioritisation and understanding the real environmental impact of products and processes.[4]

Through LCA, it is possible to analyse a product's environmental impact across the entire lifecycle. This includes when raw materials are first produced or extracted and when the product is manufactured, used, disposed of and/or recycled. A quantitative compilation of energy, materials and waste for the product and the impacts of these are then evaluated and interpreted. Scientific results and findings are behind each standard environmental impact assessment method. The ecological impacts are sorted into several categories, including particulate formation, climate change (or carbon footprint), water depletion, etc.

To this end, SHL has conducted ISO 14040/14044 compliant LCAs to quantify environmental impact. While

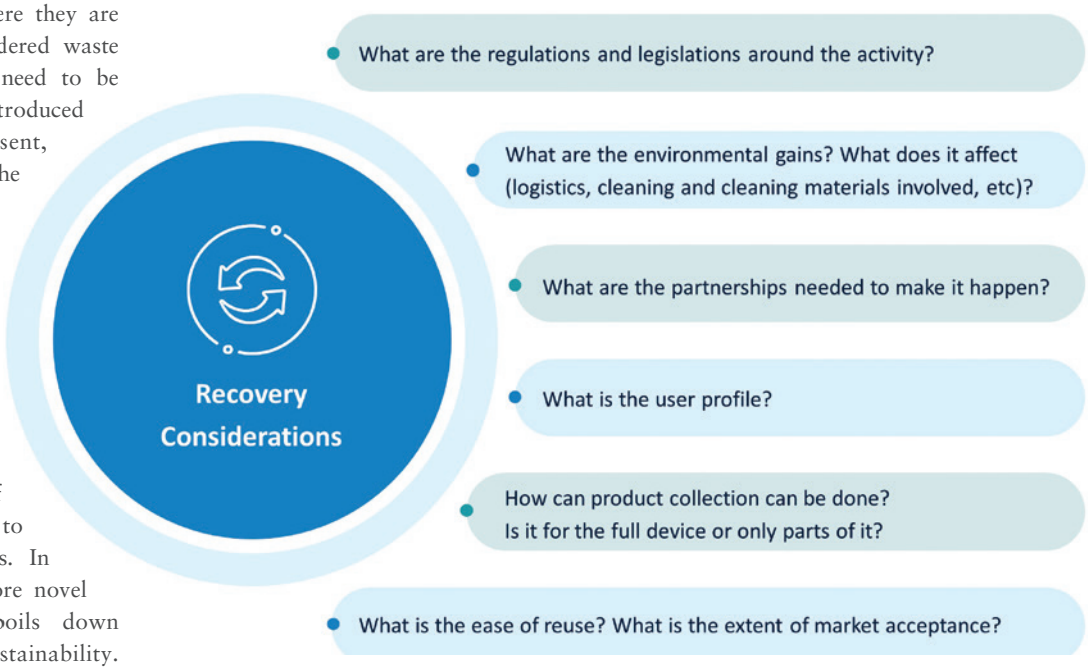


Figure 3: A main idea web showing SHL's considerations regarding recent industry discussions on autoinjector recovery and refill mechanisms.

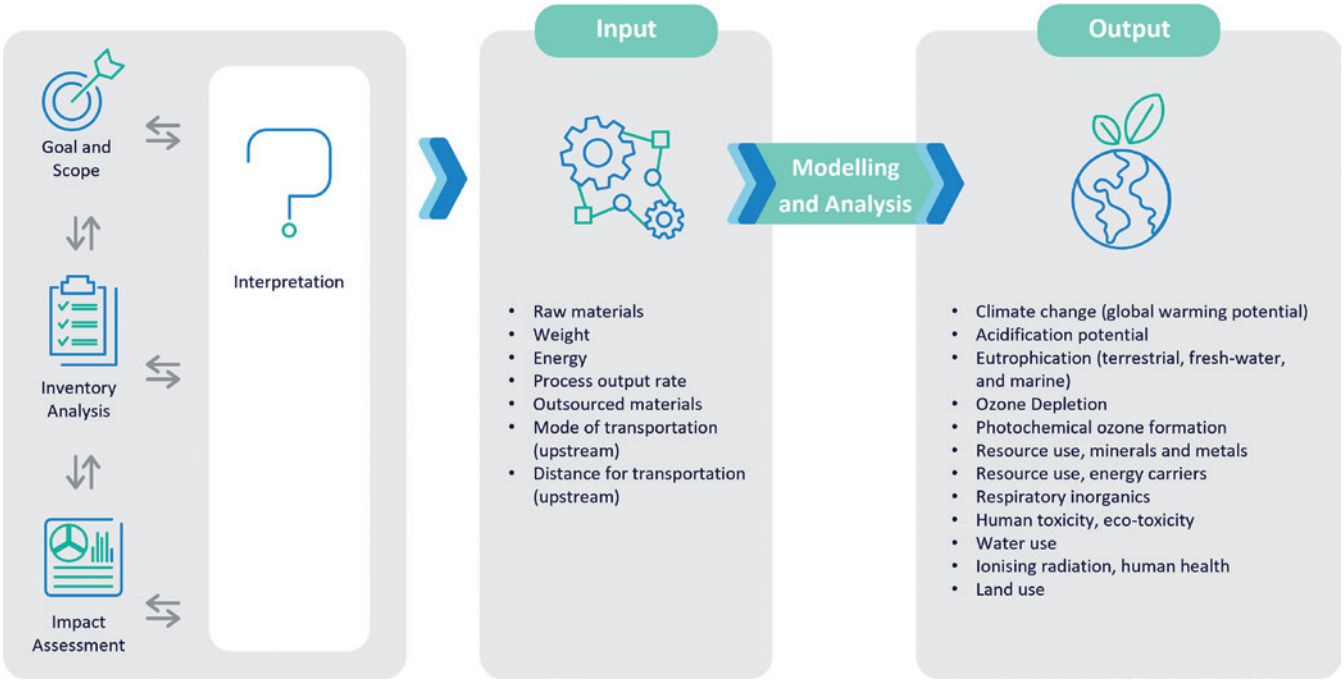


Figure 4: SHL's environmental impact assessment process and its applications.

there are several LCA environmental impact assessment methods to choose from, Environmental Footprint v3.0 is selected for the analysis shown in Figure 4. Furthermore, the usage of LCA is expanded for the following:

- Analyse the current product's environmental footprint and leverage the results as input for new developments
- Analyse the footprint of internal processes to find improvement opportunities
- Analyse the frequency of the (potential) treatment and discuss the most sustainable solution.

Generally, LCA focuses on the lifecycle of a product, containing detailed data on each of the phases during its entire lifecycle. Thus, it can be very technical and extensive and usually focuses on only one autoinjector device.[2] To design devices with the lowest environmental impact, it is necessary to understand the footprint beyond one product to go towards an entire portfolio (Figure 5).

SHL has developed a flexible parametric model that monitors emissions during the device lifecycle by adjusting the process building blocks. The emissions data are then reflected throughout the cycle according to set logic, making it possible to iterate LCAs of different device products quickly.

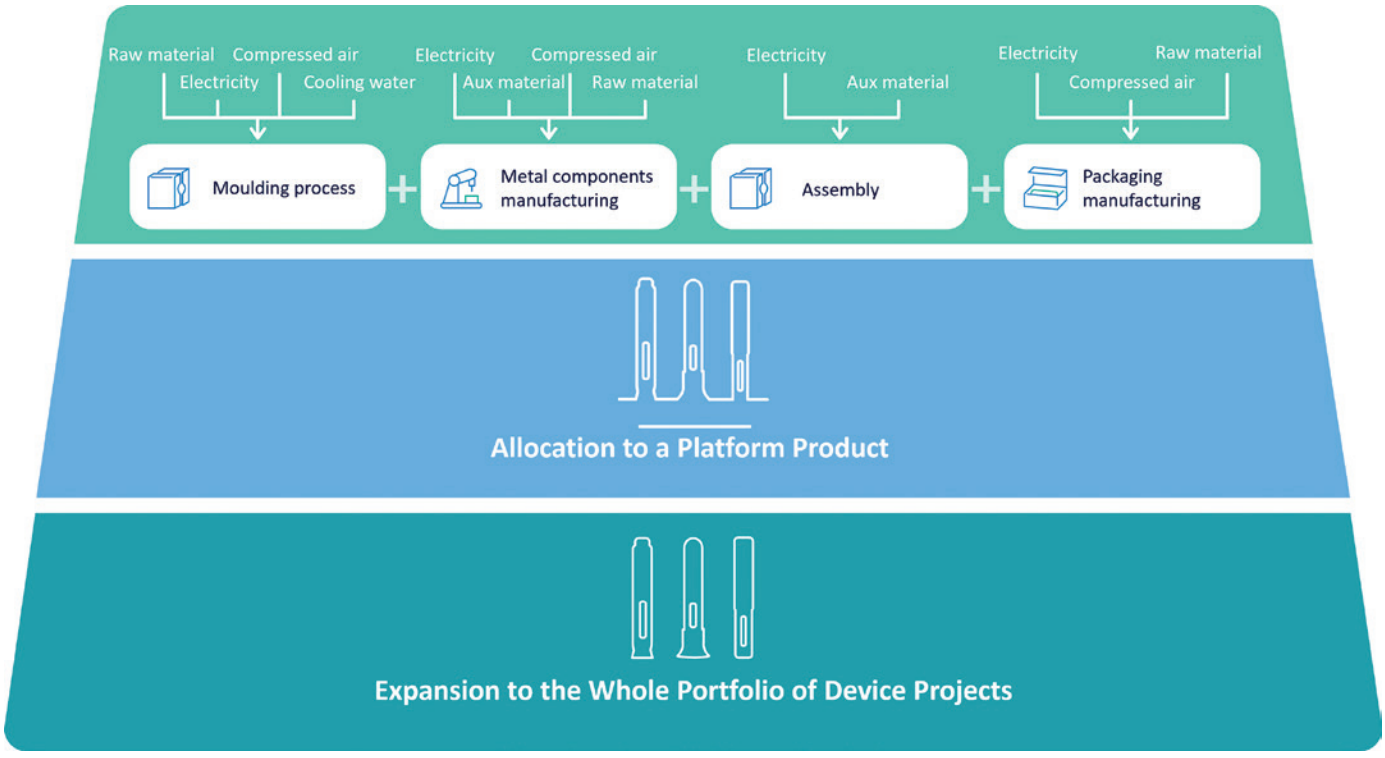


Figure 5: A diagram exhibiting the top-down approach for LCAs at SHL.

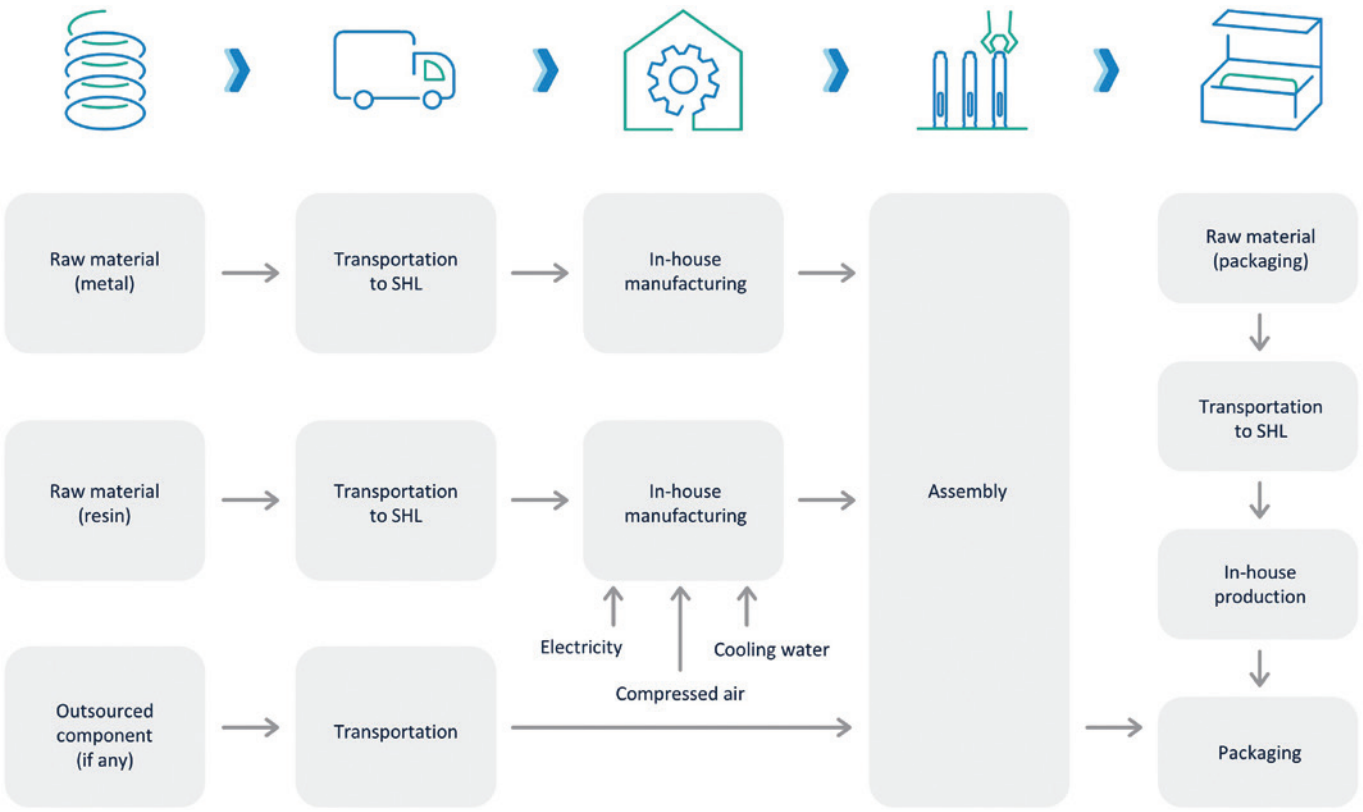


Figure 6: SHL's parametrised LCA model with a cradle-to-gate approach for autoinjector manufacturing.

The SHL model assigns material and energy usage that reflect the respective production processes. In turn, such material and energy usage data are associated with the respective output from production. In this sense, we have the footprint of the activities and, subsequently, the product based on specific process activities following a top-down approach.

SHL has set a cradle-to-gate boundary for its LCAs, assessing the product lifecycle until it leaves the factory gates and before it is transported to the consumer. This boundary strategy can significantly reduce the complexity of the analysis and create faster insights into internal processes (Figure 6).

SHL's ultimate vision is to go beyond its gates and work with its customers to achieve and analyse its products cradle-to-cradle. This approach supports circular design since, in contrast to a cradle-to-grave boundary where the analysis reaches up to the disposal of the product, it exchanges the waste stage with a recycling process by "closing the loop". The combination of circular design with LCA methodologies allows the measurement of the environmental performance of various products, comparison of circular strategies, and the definition of targets to measure and foster circularity over time.

Additionally, quantifying the benefits of circular efforts is of great importance to carefully evaluate potential burden shifting and trade-offs between the applicability of the different principles. This highlights how scenario analysis becomes critical to applying other levers during the circular design.

## UNDERSTANDING THE NATURE OF THE MATERIALS AND PROCESSES

How could material choices be reconsidered to lessen the product's impact without affecting performance? As part of SHL's circular design approach, design for sustainable materials usage aims to employ low environmental impact materials that are equivalent in performance to the conventional raw materials used in the company's processes. These materials could have renewable attributes, such as bio-based or recycled materials.

Raw materials are one of the highest contributors to emissions in autoinjector devices, taking up around 35% of a device's total carbon footprint – plastics being the largest contributor in this category. For the plastics used, the high emissions are because these materials are typically taken from finite sources. Therefore, SHL is in the process of incorporating bio-based resins into its devices and recycled plastics for the packaging to minimise the emissions related to materials. This allows the company to reduce the environmental footprint, meet its design requirements and comply with regulatory standards (Figure 7).

SHL's approach to circular design focuses on addressing the root causes of waste and pollution. For example, burning fossil fuels to generate energy can never be circular. Hence, using renewable energy plays an important role in the circular design approach. For a single-use device, SHL has found that this implies around a 90% reduction in the emissions related to electricity.

Aside from raw materials, waste management is also a pressing challenge in addressing product circularity. SHL's design for zero waste aims to create products that can be more easily disassembled and raw materials returned into a circular economy (i.e. suitable for recycling, avoiding scrap and designing out waste from processes). For SHL, designing out waste means using the scrap from moulding or just designing the parts so that no scrap is obtained.

Furthermore, SHL upholds design with less material input (less weight), fewer material types, less volume and a smaller number of parts – following the "reduce

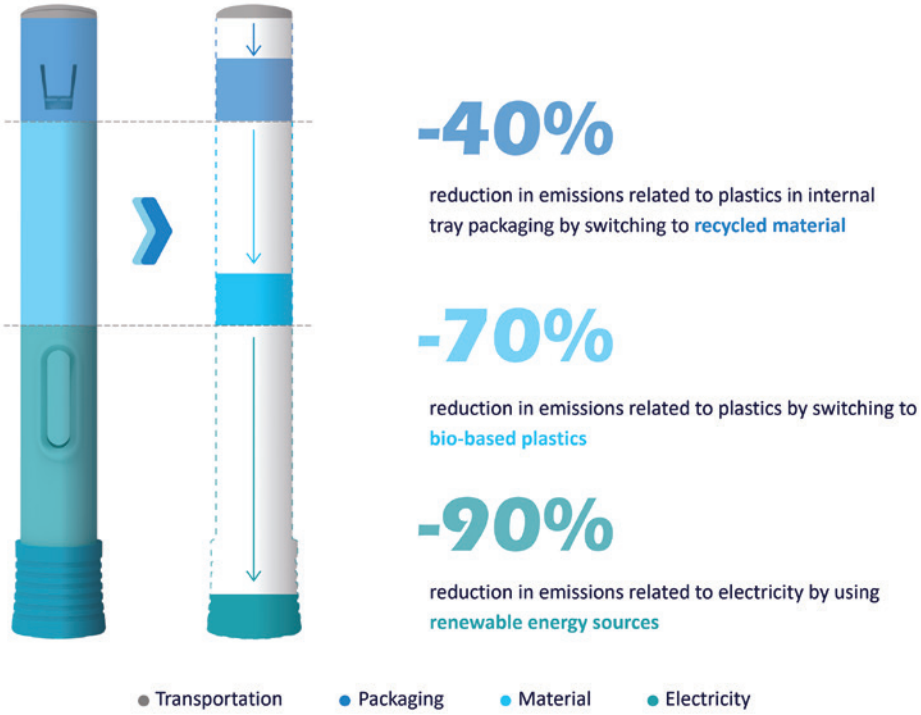


Figure 7: LCA of a single-use device.*

by design" approach by focusing on being less resource intensive. One example involves eliminating the tray packaging for internal logistics. SHL has studied different scenarios whereby innovating the process and having a "no tray" approach could reduce emissions related to packaging for internal logistics by half.

## CONCLUDING REMARKS

No matter the type of medical device, rethinking how SHL sources materials, manufactures products and reduces waste is one way towards its sustainability commitments to reduce its footprint and accelerate the transition to a circular economy.

In the last few years, SHL has found opportunities to decrease its single-use device footprint significantly. SHL recognises that every drug delivery device development process has its carbon mark, and it is committed to lowering it. The idea is for its existing device offerings to evolve into the most eco-friendly versions possible, without saying they are "eco-friendly/zero waste" products.

SHL is committed to following a decarbonisation path in alignment with the science-based targets initiative in the race to battle climate change. As the company pursues the true essence of sustainability, it is committed to reducing the environmental impact of its devices to as much as 30% by upholding eco-design principles. SHL is on course for a transformative journey of using fully renewable energy by 2030. The company's progress motivates it to play its part and build a more sustainable future for all, and SHL is calling on other industry players to join it in this challenge.

## ABOUT THE COMPANY

SHL Medical is a solutions provider in the design, development and manufacturing of advanced drug delivery devices, such as autoinjectors and pen injectors. The company also provides final assembly, labelling and packaging services for leading pharmaceutical and biotech companies across the globe. With locations in Switzerland, Taiwan, Sweden and the US, SHL Medical has successfully built a strong international team of experts that develops breakthrough drug delivery solutions for pharma and biotech customers. These include advanced reusable and disposable injection systems that can accommodate large-volume and high viscosity formulations – and connected device technologies for next-generation healthcare.

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** LCA of a single-use autoinjector. Calculations were derived from an ISO-compliant LCA study. The study was peer reviewed in 2023 using the Sphera LCA for Experts software (formerly known as GaBi) 2022 database. The external critical review of the report was conducted according to ISO 14044. Calculations depend on assumptions and methodologies used, as well as the recentness of the data. Comparison of these numbers to in-kind, non-SHL alternatives may not provide a direct comparison. This information may be subject to revision if assumptions change, or as modelling data becomes more current.*

## ABOUT THE AUTHOR

**Veluska Bruce**, PhD, is Environmental, Social and Governance (ESG) Project Manager at SHL Medical. She plays a key role in implementing SHL Medical's sustainability programme, supporting initiatives that encompass the company's overall sustainability ambitions and strategies. Dr Bruce holds a PhD in Fibre and Polymer Science from the KTH Royal Institute of Technology (Stockholm, Sweden), where her research focused on the design of degradable polyester-based materials. She has worked in the medical industry for over seven years, focusing on product development and sustainability initiatives. Dr Bruce joined SHL Medical in 2018, where she has worked leading testing activities on primary packaging and devices for various customer projects, innovation research activities and, most recently, driving innovations for ESG initiatives and ensuring that the global ESG strategic targets are achieved.

# SHAPING A SUSTAINABLE BIOPHARMA INDUSTRY

In this article, Jimin Han, Director of Sustainability at Samsung Biologics, delves into the intricate landscape of sustainability challenges within the biopharma industry and explores the innovative solutions that are steering drug development toward a greener future.

The biopharma industry plays a pivotal role in global health, but its operations come with distinct sustainability challenges. The industry's carbon footprint is a pressing concern, prompting a shift towards more sustainable practices.

## THE SUSTAINABILITY ISSUES OF THE HEALTHCARE SECTOR

Greenhouse gas (GHG) emissions are one of the leading threats to global health, with extensive social and environmental consequences. As these emissions have a direct influence on the trajectory of climate change, the need to identify and mitigate their underlying drivers has never been more urgent.[1]

The energy-intensive processes that underpin drug development and manufacturing are major contributors to the healthcare industry's considerable carbon footprint, to which the biopharma industry contributes significantly. The healthcare sector was accountable for contributing 4.6% of global GHG emissions,[2,3] which would rise further without essential countermeasures. This carbon footprint is predominantly attributed to manufacturing, raw materials and logistics networks within the field. Notably, supply chains emerge as the primary cause of emissions within the healthcare sector, wielding a significant influence that contributes to over 50% of total emissions.[4]

> "Supply chains emerge as the primary cause of emissions within the healthcare sector, wielding a significant influence that contributes to over 50% of total emissions."

New ways of working must be introduced to help reduce the biopharma industry's contribution to global carbon emissions. Companies must adopt renewable energy sources and optimise manufacturing processes to actively reduce GHG emissions without compromising quality.

Within the biopharma sector, there are intricate and interconnected sustainability challenges that require urgent attention. By implementing a net zero GHG strategy, opportunities arise for the biopharma industry to emerge as a pioneer of sustainable practices.

## BARRIERS TO A SUSTAINABLE BIOPHARMA INDUSTRY

Meeting net zero GHG ambitions requires the successful navigation of challenging adaptations across the healthcare industry within various core aspects of the industry's operations. A successful transition to a sustainable future in the biopharma sector requires strategic solutions to the following key considerations.

### Navigating Strict Regulatory Requirements

The biopharma sector operates within a stringent regulatory landscape, which can present a significant challenge to meeting sustainability goals. Balancing compliance with evolving emissions standards while driving innovation forward demands meticulous planning, co-ordination and proactive strategies. In particular, adapting manufacturing and production processes to reduce emissions requires validation testing to ensure that there is minimal impact on the drug's safety and efficacy.

### Achieving Net Zero Emissions Across Supply Chains

To attain genuine net zero status, a company must address emissions not only within its own operations, but also within its supply chain from first, second and other

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"Transitioning to net zero emissions often means adopting sustainable alternatives to existing practices and technologies, which may incur higher initial costs."

tier vendors. The complexity of supply means influence over the entire chain is unlikely, limiting control over reducing GHG emissions of the supply chain.

### Calculating Emission Factors for Raw Materials in a Complex Network

Network complexity also results in difficulties when calculating the emissions factor of raw materials. Unlike industries with well-established emissions data, the emission factors for raw materials, particularly within the biopharma sector, have not been calculated. Ensuring alignment of sustainable practices and emissions reduction strategies throughout these intricate networks requires diligent oversight by each contributor at each stage of supply.

### Addressing the Cost of Sustainable Alternatives

Transitioning to net zero emissions often means adopting sustainable alternatives to existing practices and technologies, which may incur higher initial costs. These expenses can include investments in new technologies, materials and infrastructure, and may even result in companies buying carbon offsets or paying carbon taxes. Considering the rising costs of carbon, offsetting is not a long-term solution. Ultimately, balancing eco-friendly practices with economic viability demands meticulous financial planning and strategic decision making.

### Overcoming Geographic Limitations

The global nature of the biopharma industry introduces geographic constraints that influence the feasibility of emission reduction strategies. Differing regulations, resource availability and infrastructure limitations in various regions pose challenges to implementing uniform net zero initiatives. For example, the low availability of sustainable systems in key geographies, such as limited access to renewable electricity in the Asia-Pacific region, results in decarbonisation challenges.[4] Adaptable strategies are essential to accommodate these geographic nuances effectively.

## RESPONDING WITH SUSTAINABLE SOLUTIONS

Although there are challenges, the biopharma industry also has the opportunity to address the need for sustainable practices with proactive initiatives that reshape the drug development landscape.

One such initiative is the Sustainable Markets Initiative (SMI), which is a collaborative health systems task force that aims to accelerate the transition to net zero healthcare. The SMI's primary focus lies in mobilising governments, businesses and organisations to collaboratively shape market systems that drive positive social, economic and environmental outcomes. By fostering co-operation between healthcare providers, policymakers and industry leaders, this initiative seeks to drive systemic change towards sustainable healthcare practices.

The SMI has a particular focus on the following areas:

- **Decarbonising supply chains:** Embracing collaboration across the supply chain to introduce systems that advance decarbonisation, such as renewable energy, responsible sourcing, clean heat and green transportation logistics, is pivotal to reducing the industry's environmental footprint.[4,5]
- **Rethinking patient care pathways:** Incorporating sustainable practices into patient care pathways not only benefits the environment but also fosters improved patient outcomes and experiences. Driving a reduction in emissions across patient care contributes to lower disease progression and allows for the identification of opportunities for decarbonisation while also improving patient care.[5,6]
- **Digital innovation in clinical research:** Harnessing digital technologies and data analytics in clinical research can streamline processes, reduce waste and enhance efficiency. This accelerates drug development while minimising environmental impact. Leveraging digital transformation across the biopharma industry supports and accelerates technological progress, which can assist in achieving net zero transitions.[5,7]

These SMI measures aim to overcome sustainability challenges and reshape patient care, creating a healthcare landscape that is medically advanced and environmentally responsible.

## OPPORTUNITIES FOR SUSTAINABLE SUPPLY CHAINS

As the largest driver of emissions within the healthcare sector, supply chains offer a critical opportunity for transformative change. Aside from the efforts being made by the SMI, there are other ways to integrate sustainable approaches within supply chain operations that can yield far-reaching benefits. These approaches can range from reducing emissions and waste to enhancing overall efficiency and resilience.

The path to achieving net zero emissions within supply chains requires a multifaceted approach. Companies can evaluate sourcing practices, prioritising suppliers committed to sustainable practices and reduced emissions. In addition, implementing innovative logistics solutions, such as increasing manufacturing efficiency and integrating renewable energy sources, optimised routing and alternative transportation modes, can drastically minimise carbon-intensive activities.[4,6,7] Moreover, collaboration across the supply chain, sharing best practices and fostering transparent communication is crucial to the industry's collective impact on GHG emissions.

Strategic investments in technology and data analytics can also play a pivotal role. Advanced supply chain management systems enable real-time tracking, helping companies identify emissions hotspots and areas for improvement. More efficient manufacturing operations can also streamline production and decrease costs, striving for sustainability while overcoming economic barriers to sustainable healthcare.

Aside from improving processes, an alternative approach to address validation challenges in biologics manufacturing is transitioning to 100% renewable energy sources. This can be achieved through various

"The path to achieving net zero emissions within supply chains requires a multifaceted approach."

strategies, such as adopting zero-emissions energy technologies, including power purchase agreements, renewable energy certificates and eco-friendly transportation options. Collaborative efforts with suppliers to decarbonise the supply chain also offer significant potential for mitigating GHG emissions.

## REDEFINING HEALTHCARE FOR A SUSTAINABLE FUTURE

As the biopharma industry navigates the landscape of sustainability challenges and possibilities, redefining the future of healthcare as environmentally conscious and medically advanced, the industry can set a powerful precedent for other sectors. Translating key insights into solutions is crucial for achieving significant sustainability changes, with collaboration and partnership across the healthcare sector vital to reducing GHG emissions. Ultimately, the establishment and disclosure of goals and progress, aligned with set timeframes and specific actions, are key to solidifying a transformation towards sustainable healthcare.

## ABOUT THE COMPANY

Samsung Biologics is a fully integrated contract development and manufacturing organisation offering state-of-the-art contract development, manufacturing and laboratory testing services. With proven regulatory approvals, the largest capacity and the fastest throughput, Samsung Biologics is an award-winning partner of choice and is uniquely able to support the development and manufacturing of biologic products at every stage of the process while meeting the evolving needs of biopharmaceutical companies worldwide.

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# ENVIRONMENTAL DRIVERS FOR CHANGE IN DRUG DELIVERY DEVICES

In this article, Will Morris, Senior Design Engineer at Haughton Design, discusses the positive changes that have occurred when it comes to environmental sustainability in the medical industry, in the context of examining what more can be done.

When designing medical devices, it is important to focus on the positive impact that they have on people's health, but not to ignore the negative impact that they can have on the environment. It is a sobering experience to visualise the quantity of devices that are being designed, the scale at which they will be manufactured, and the resultant magnitude of carbon dioxide equivalent ($CO_2e$) emissions and non-recyclable plastic produced.

Globally, healthcare is responsible for two gigatonnes of $CO_2e$ annually – 4.4% of global emissions. This is not an insignificant amount; it is equivalent to the $CO_2e$ emissions produced in powering every single home in the US with electricity for one year. So, it is important not to "greenwash" the industry. However, it is worthwhile reflecting on the positive changes that have occurred when it comes to environmental sustainability in the medical industry, in the context of examining what more can be done.

## SYSTEM CHANGE

### UN Sustainability Goals

In 2015, all United Nations (UN) member states adopted the 2030 Agenda for Sustainable Development. This ambitious programme consists of 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries and organisations. There are a number of goals directly relating to environmental impact. The SDG 2030 agenda encourages all countries to take concrete actions and adopt policies that align with the SDGs to promote a more sustainable and prosperous world for all.

### EU Circular Economy

Europe is committed to its vision for a circular economy and its plans to achieve climate neutrality by 2050. The European Union's (EU's) Circular Economy Action Plan details initiatives to make sustainable products the norm in the EU, empower consumers, ensure less waste and make circularity work for people, regions and cities. This is arguably one of the biggest experiments towards achieving a sustainable and prosperous economy.

"With nearly half a tonne of municipal waste being produced per person, the EU is aiming to introduce new waste output measures for both prevention and reduction."

The circular economy will have an impact on a variety of medical devices, either directly or indirectly. Electrical and electronic equipment is one of the fastest growing waste streams in the EU. Electronic products that are to be placed on the EU market will be designed for longevity, reuse, repair, update and, ultimately, recycle. This will have an impact on connected healthcare products, wearables, diagnostic devices and electronic drug delivery products.

Single-use non-recyclable plastic products will be phased out wherever possible. By 2050, plastics could account for 20% of oil consumption and 15% of greenhouse gas emissions – and there could be more plastic in our oceans than fish! That is why eco-design will be prioritised, striving for devices to last longer and/or be easily recyclable.

With nearly half a tonne of municipal waste being produced per person, the EU is aiming to introduce new waste output measures for both prevention and reduction. Appropriate medical waste disposal is complex, and it will be interesting to see what future legislation various markets will adopt to cater for potentially hazardous contaminated medical waste.

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### The NHS Impact

The UK NHS has committed to reaching net zero by 2040 for the emissions it directly controls – and by 2045 for the emissions it influences. Since the publication of its "Delivering a Net Zero NHS" report, the NHS England board has approved a road map to help suppliers align with its net zero ambitions between now and 2030:

- **April 2022:** All NHS procurements will include a minimum 10% net zero and social value weighting.
- **April 2023:** For all contracts above £5 million per annum, the NHS will require suppliers to publish a carbon reduction plan (CRP) for their UK Scope 1 and 2 emissions and a subset of their Scope 3 emissions as a minimum.
- **April 2024:** The NHS will extend the requirement for a CRP to cover all procurements.
- **April 2027:** All suppliers will be required to publicly report targets and emissions, and publish a CRP for global emissions aligned to the NHS net zero target, for all their Scope 1, 2 and 3 emissions.
- **April 2028:** Carbon footprinting will be required for individual products supplied to the NHS. Exact scope and methodology to be decided.
- **~2030:** Access to NHS contracts will only be available to those who demonstrate their progress through published progress reports and continued carbon emissions reporting through the Evergreen sustainable supplier assessment.

### Legislation

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS); Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); and the Waste Electrical and Electronic Equipment (WEEE) Directive are significant EU regulations that have been implemented to address environmental and health concerns related to hazardous substances in products and chemicals, and to set rules for the proper collection, recycling and treatment of WEEE. Additionally, the introduction of ISO 14040:2006 enables the industry to better understand and address the environmental impacts of products (Figure 1).

One of the most notable environmental actions regarding hazardous substances was taken in the late 1980s with the Montreal Protocol. At an international level, it was recognised that chlorofluorocarbons (CFCs), a propellant commonly used in pressurised metered dose inhalers (pMDIs), contained ozone-depleting substances. As such, timelines were set to phase out CFC-based inhalers, which are now being switched to hydrofluoroalkane (HFA)-based inhalers.

Even more positive change is beginning within the inhalation sector, where MDI propellants are again changing to HFC 152a or HFO 1234ze(E), propellants that have lower global warming potential (GWP) than their currently used counterparts. In the UK, there is also a stronger push towards dry powder inhalers (DPIs), a format of drug delivery that has a GWP an order of magnitude lower than pMDIs. However, pMDIs are still required as an option, as DPIs cannot typically be used by all patients. It is clear, however, that there is accelerating positive change in this sector, which is likely to affect the trajectory of other types of drug delivery devices as well.

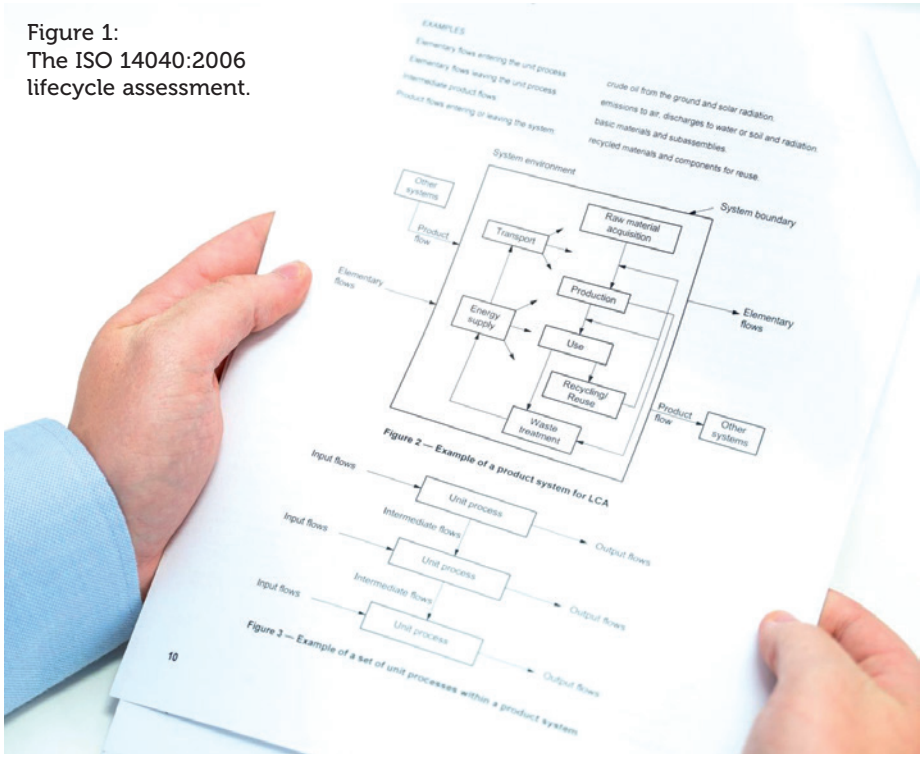


Figure 1: The ISO 14040:2006 lifecycle assessment.

## MANUFACTURER CHANGE

Many organisations are working hard to reduce their environmental impact. Some companies have publicised their alignment with their priority SDGs, while others have published their own sustainability initiatives.

In the inhalation sector, many organisations are working hard to achieve not only the SDGs but also their own sustainability initiatives (some actually coming online before the 2015 SDG programme). Some organisations have released new devices and schemes to combat factors such as polluting propellants, excessive material use, modular electronic add-ons and end-of-life device management.

> "Some organisations have released new devices and schemes to combat factors such as polluting propellants, excessive material use, modular electronic add-ons and end-of-life device management."

The industry is also seeing more modular and reusable electronic devices, such as Nemera's (Lyon, France) Symbioze on-body injector and Owen Mumford's (see this issue, page 6) UniSafe reusable autoinjector. The ability to segregate a device's mechanical elements from the drug pathway and/or bodily fluid contact has enormous potential for a lot of existing combination products. The key aspect is ensuring that additional complex user steps are not required for preparation of the device during and after use.

The way in which devices are designed has a significant impact on their carbon footprint. YpsoMed (Burgdorf, Switzerland) has developed the YpsoMate Zero, the world's first zero-carbon-emission autoinjector. Many other organisations are looking to take this further and are developing drug delivery devices that eliminate polluting plastics, reduce their plastic use or are made from a mono-material solution.

There are also device platforms for pharmaceutical companies to select from, rather than designing their own bespoke device. Furthermore, there's even collaboration between multiple contract development and manufacturing organisations to produce the same components and devices to further improve economies of scale, and potentially lower environmental impact.

There are several end-of-life device management programmes. GSK's Complete the Cycle programme (2012) resulted in the recovery and recycling of two million inhalers, saving an estimated equivalent of 8,665 cars' emissions in one year. Chiesi's Take AIR recycling programme (2021) enabled any inhaler brand and type to be recycled by post. And Novo Nordisk's PenCycle programme allowed users to recycle their empty drug delivery pens via selected stores, community pharmacies and at-home collection services.

The success of these initiatives has been mixed, as it depends on a variety of complex factors. The environmental efficacy of a scheme needs to be regularly evaluated to ensure that it has a net positive impact regarding the act of recycling and the infrastructure/logistics required versus disposal and incineration. As seen by some of the early pilot studies, these initiatives require thorough planning, complex logistics and – the most difficult challenge – a change in human behaviour.

## PEOPLE CHANGE

Medical device users play a crucial role in driving positive change for medical devices to be more environmentally friendly. In the consumer sector, almost every product has promotional marketing regarding the product's "green" credentials – whether a shampoo bottle is made with post-consumer recycled plastic or shoes are delivered with plastic-free packaging. This marketing is there to drive eco-conscious people to make informed purchasing decisions. In the healthcare sector, the hope is that consumers will opt for medical devices that are designed with environmental considerations in mind, providing it doesn't make their personal health management more painful, costly or complex.

"Medical device users play a crucial role in driving positive change for medical devices to be more environmentally friendly."

Healthcare professionals (HCPs) are now being asked by their patients, "Which of these devices is most sustainable?" This question would have been impossible to answer years ago, but now decision aids

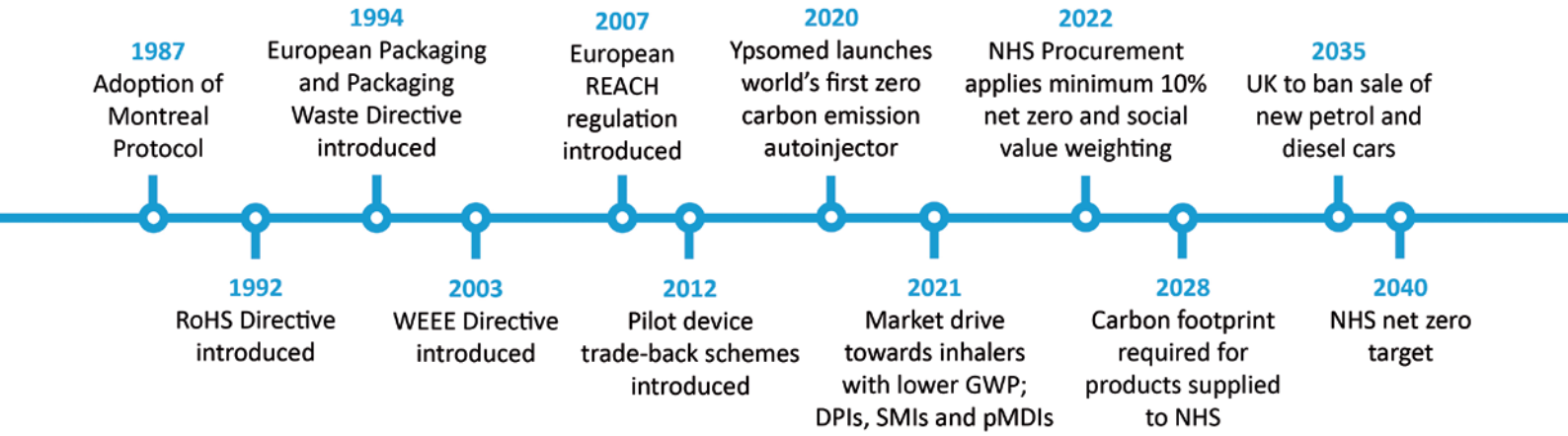


Figure 2: A timeline of sustainability progress since the adoption of the Montreal Protocol.

are being produced that enable GPs to discuss complex matters with their patients, such as which inhaler has the lowest carbon footprint, often with comparable equivalents, such as a journey in a petrol car or the $CO_2e$ of baking a loaf of bread.

Increased at-home care will play a significant role in driving more sustainable drug delivery solutions. Users will naturally try to maximise the use of their devices to save on the cost of buying a new device or the effort of travelling to their local pharmacy. Patients will start to realise and voice their concerns regarding the wastefulness of their drug delivery devices. There will be recognition that the syringe is the only important element to dispose of responsibly – the complex mechanism to deliver the drug could be reloaded and used again if allowed by the device's design, or at least could be separated into a recyclable waste stream.

All these factors will also be driven from the complexity of appropriate disposal. In the inhalation sector, many people who use pMDIs are shocked to hear that they are not allowed to separate the plastic body from the canister and place them into recycling. Disposal of medical waste can be confusing, therefore, expect to see developments in clarity of appropriate waste disposal instructions, techniques to limit wasteful disposal and strategies to eliminate disposal.

## CONCLUSION

In the 30-plus years since the adoption of the Montreal Protocol, there has been significant positive change regarding making drug delivery devices more environmentally friendly (Figure 2). However, there is still so much more opportunity for improvement. It is clear that it's not just a single-sided argument; legislators telling manufacturers what to do, and then forcing people to only use certain types of drug delivery devices. Rather, it is a complex three-way discussion that is now being informed by real-world data and both bottom-up and top-down information exchange.

Development of a truly sustainable drug delivery device is a complex challenge. However, with each sustainable innovation, the sector will move closer to responsible development of medical devices to benefit both people and the planet.

## ABOUT THE COMPANY

Haughton Design is a UK-based design consultancy that specialises in providing medical device design, development and engineering services for global healthcare, medtech and pharmaceutical clients. The company's mission is to accelerate its clients' medical device development programmes by developing devices that are grounded in robust engineering, manufacturability, usability and sustainability. Haughton Design's clients in the drug delivery space value its innovative approach, technical expertise, fresh ideas and improved time to market. The company's services are designed to make the medical device design and development process easier for its clients and their teams.

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**Will Morris** is a Senior Design Engineer and Business Development Manager at Haughton Design. He has 10 years' experience in the medical and engineering sectors, having supported the development of a variety of injection and inhalation drug delivery devices, as well as other medtech devices, surgical equipment, healthcare products and scientific instrumentation. Mr Morris is Haughton Design's Sustainability Champion and believes there is great potential for a positive impact within the medical sector, for both people and the planet. He believes regulatory constraint is not always the limiting factor to achieving sustainability – but, rather, engineering creativity.

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