RETHINKING DRUG DELIVERY DEVICES FOR SUSTAINABILITY AND INNOVATION

In this article, Sergio Malorni, Senior Consultant, and George Bostock, Senior Consultant Engineer, both at Cambridge Design Partnership, discuss the issue of designing for sustainability, including going beyond "Reduce, Reuse, Recycle" to "Rethink" and looking to adjacent and consumer industries for inspiration on innovations the drug delivery industry can adopt with a view to reducing its environmental impact.

The drug delivery industry is putting ever increasing efforts into the pursuit of both measuring and reducing its impact on the environment. While a large portion of this effort has been focused on improving operational efficiency in drug, device, product packaging and distribution areas, attention is now starting to turn towards their product development processes, using "design for sustainability" methodologies, as seen recently with AstraZeneca's[1] product environmental stewardship and Novo Nordisk's Circular for Zero[2] initiatives.

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Efforts vary in ambition, such as having greener propellant ingredients in pressurised metered dose inhalers[3] or sophisticated take-back schemes that enable closed loop recycling. But most of the efforts have tended to be directed towards a focus on material substitution and reduction. This approach is perfectly valid and often justified by its associated cost savings.

However, these incremental steps tend to be too limited in scope to push forward the significant changes needed to shift the needle towards the greater sustainability goals that the industry is likely to be asked, if not required, to meet in the future. In this article, we will share a variety of additional "design for sustainability" approaches that our engineers and designers at CDP have applied to drug delivery device development projects. These have not only resulted in significant improvements in sustainability and reduction in cost – but also are a means of driving product and service innovation.

SYSTEM-LEVEL INNOVATION FOR SUSTAINABILITY

As a rule of thumb, the first port of call when considering how to make a drug delivery device more environmentally sustainable is to apply the first R in the "Reduce, Reuse, Recycle" mantra, specifically looking towards material content reduction. Whilst rules of thumb are useful, they may lead you to bark up the wrong tree. For example, the main environmental culprits of a delivery device design may be its energy-intensive production process and high part count requiring transport-intensive sourcing. In this case, exploring less intensive production methods through shape or material changes, reduced part count and simplified sourcing may yield much higher sustainability gains than simple material reduction.

Lifecycle assessment (LCA) can help identify a design's "hotspots" through a systematic cradle-to-grave calculation of several environmental impact metrics, such as greenhouse gases (GHG), water usage and waste tonnage. If appropriately done in line with the ISO 14000 series of standards, and with the right assumptions and boundaries, LCAs can guide a product development team to focus on the real design changes that count for sustainability.

However, despite this cradle-to-grave viewpoint, this approach still may not be holistic enough to find more significant opportunities. The analysis can sometimes be too focused on the drug delivery device and/or packaging. Zooming out from the product and exploring the broader therapy eco-system with Systems Thinking can help find impactful opportunities to improve the

Sergio Malorni
Senior Consultant
T: +44 1223 264428
E: Sergio.Malorni@cambridge-design.com

George Bostock
Senior Consultant Engineer
T: +44 1223 264428
E: George.Bostock@cambridge-design.com

Cambridge Design Partnership
Church Road
Toft
Cambridgeshire
CB23 2RF
United Kingdom

www.cambridge-design.com

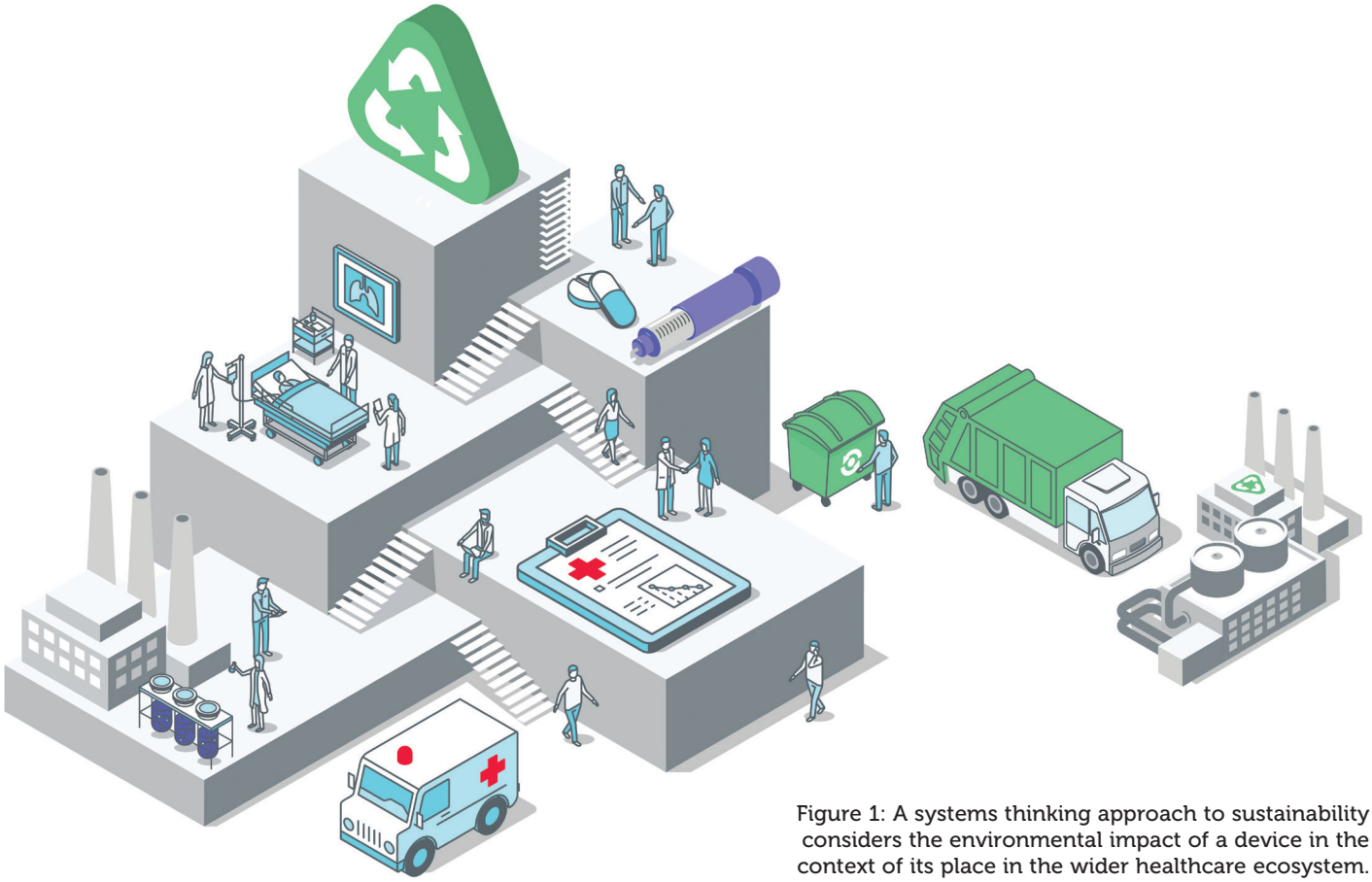

Figure 1: A systems thinking approach to sustainability considers the environmental impact of a device in the context of its place in the wider healthcare ecosystem.

sustainability of the drug delivery device. Essentially this approach asks, "how can we reimagine delivering the same benefit more sustainably?" – but at a higher level.

Systems thinking starts with mapping out the interrelationships between drug, delivery device, diagnostic system and a patient's visits and communications with their healthcare provider. It even includes other medical interventions that may result in low efficacy or poor adherence to medication. Although it might seem to be a significant endeavour, it can be scaled using simple approximations that will ultimately help to identify other potential routes of exploration. Data on care pathways is becoming richer and more transparent, and it can be complemented by primary research, mapping the ecosystem components and their relationships. Systems thinking tools and techniques such as functional modelling, "Rapid LCAs" and design sprints can then be used to help create unique configurations, evaluate trade-offs and sense-check their potential viability.

This type of systems thinking approach can drive strategies such as reducing the number of different devices through consolidation, replacing products with services and setting a focus around reducing the need for patients to visit clinical settings or stay in hospital. In short, it considers not just the device itself, but the device as part of the larger healthcare ecosystem (Figure 1).

Systems thinking can also help justify less intuitive approaches. For instance, connected devices are not typically viewed as green compared with unconnected versions. However, the environmental impacts of their disposable electronics and batteries might be counterbalanced by a reduction in patient journeys to clinics, avoidance of complications and earlier interventions, all of which come with environmental impacts. Diabetes is a good example, where poor disease management can lead to difficulties in later life that create additional hospital visits that come with significant GHG emissions impacts.[4]

Similarly, some single-use wearable injectors might appear less "green" than the intravenous infusion therapies they replace. However, the increased cradle-to-grave environmental footprint might be offset by the footprint savings from a reduced number of injection devices, reduced drug waste, improved adherence and, as seen with the aims of Neulasta® Onpro® injector,[5] to reduce hospital stays.

Essentially, systems thinking has the ability to manage the tension between the desire to reduce product material for the environment, versus the desire to create more complex products to deliver more patient-centric care. If performed credibly, LCA analyses could show that, on balance, more complex products could be better for the environment, by offsetting the preventable wider impacts of less effective treatments.

However, the more exciting scenarios are when systems thinking allows you to create new pathways, products and services in areas where few have ventured, fuelling innovation.

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SUSTAINABILITY-DRIVEN TECHNOLOGY INNOVATION

Following on from the higher system-level perspective, we can now zoom inwards to the device and packaging design to find further design for sustainability opportunities.

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This focused approach starts with identifying sustainability-themed insights from the therapy journey that can drive product development. These can be gained concurrently during primary and secondary research to define the unmet needs of stakeholders. Do stakeholders and users care more about a perceived reduction in waste or GHG emissions? Will patients separate different recycling materials? Is there a demand for such materials in the material recovery market?

Armed with such insights, the second step is to understand the main environmental culprits of the device, packaging or service using an LCA analysis. With hotspots identified, one can increase the opportunities for innovation by looking beyond "Reduce, Reuse, Recycle" – to Rethink!

Platform drug delivery device solutions can provide ample opportunity to illustrate the Rethink approach. Take the case of a platform single-use electromechanical wearable injector. Applying a Reuse approach to improve sustainability, one can change the architecture to a part-reusable (electromechanical power unit) and part-disposable (pump mechanism and primary container) provided patients accept the extra steps, and if additional risks are avoided. However, one can go further with a Rethink strategy by exploring non-optimal generalised solutions that might be present in platform designs.

In this example, the non-optimal solution may be found in the core pumping technology. As these platforms may ask the pump to serve many injection volumes, viscosities, flowrates and accuracy requirements, certain implementations may not be optimal as the core technology is too general – and carry over design elements may not be required.

For therapies like insulin delivery, where flowrate is critical, sensors and electromechanical systems are the go-to solution. However, if flowrate accuracy isn't crucial, as is the case with a good-sized portion of the market for subcutaneous biologics injections, there is an opportunity for Rethink. Instead of motors, complex mechanisms and batteries, could we make use of expanding materials or hydrogels that push against a flexible drug container? Or perhaps old-fashioned mechanical clockwork escapements might be a solution? The Rethink strategy, underpinned by a drive for sustainability, provides a methodology for challenging conventional thinking.

INSPIRATION FROM ADJACENT MARKETS

Drawing inspiration from other markets and sectors can also move you towards more interesting approaches. As an example, the reprocessing of single-use surgical devices (SUDs) is notable; hospitals realise that it not only reduces total waste but also net cost. Surgical drills, electrophysiology catheters, endotracheal tubes and balloon angioplasty catheters are all examples of SUDs suitable for reprocessing. While much of this reprocessing is done by hospitals themselves, there is still a market to be found, with new companies being created to fill this need in a service sector estimated to reach nearly US$1.7 billion (£1.3 billion) by 2022.[6] Likewise, this impetus has been further facilitated with the EU MDR Article 17 that allows SUD reprocessing if it is also permitted under national law.

Therefore, we can draw inspiration for potentially reducing environmental impact in hospitals by surveying which drug delivery devices are ripe for reprocessing. This may require further product development, such as having more resilient components and developing in-process functional testing. However, if cost savings are possible and the LCA analysis indicates a net environmental benefit, this can open new markets for the drug delivery device sector.

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INSPIRATION FROM CONSUMER MARKETS

Drug delivery device manufacturers are coming to realise that patients are also consumers. This influences expectations on the usability and aesthetics of devices, apps and packaging. It would also be reasonable to expect that green initiatives and expectations seen in the consumer sector could also cross over into the drug delivery sector.

We should look at how consumer brands are evolving, with an increasing number of pledges to improve their sustainability position by leading companies, such as Nestle (Vevey, Switzerland) and Unilever (London, UK), aiming to achieve net zero emissions within a decade. With a strong emphasis on packaging recycling, systemic challenges have been encountered in this area, with material recovery facilities not processing a good portion of what they receive from consumers' recycling bins due to, for example, poor economics or technical feasibility in sorting and separating materials such as paper from multi-layer beverage cartons.

As a result, significant industries have banded together to create their own materials recovery routes and recovery technologies on a local and global scale, such as TerraCycle (Trenton, NJ, US) for popular consumer packaging, or beverage carton manufacturers like Tetra Pak (Pully, Switzerland).[7] Major consumer brands have also invested in the development of unique recyclable materials, such as Pulpex paper bottles.[8] Likewise, there is the potential for the uptake of specialist recycling methods aimed at the consumer sector, such as chemical reprocessing involving the conversion of polymers back into their raw monomers or other chemical substances ready for repolymerisation.[9] Such methods, paired with a renewable energy source, could be an interesting future solution for the medical industry. Lastly, consumers are increasingly willing to take that extra step of separating materials and binning them according to recycling needs, for both domestic and speciality waste streams.

We, in the drug delivery industry, can take inspiration from these consumer sector trends. Yes, it may take some time for consumer container technologies to evolve into medical ones, or for pharma and device companies to band together to create specialist recycling waste streams. However, in the interim, devices and packaging can evolve to leverage consumer recycling infrastructure and patients' willingness to take the extra steps for sustainability.

SUMMARY

Design for sustainability for drug delivery devices can often be viewed as an "add-on process" to reduce their environmental impact, employing the conventional Reduce, Reuse, Recycle mantra. However, there are other powerful methods beyond this, such as Rethink – considering how to deliver the therapy benefit more sustainably through systems thinking. Coupled with inspiration from other markets in terms of recycling and reuse, design for sustainability is not simply an add-on process to drug delivery development projects, but also the source of innovation for the future.

ABOUT THE COMPANY

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

ABOUT THE AUTHORS

Sergio Malorni is a Senior Consultant at Cambridge Design Partnership. He specialises in leading multidisciplinary development programmes for drug delivery devices from early-stage user and stakeholder research, strategy, concept creation, engineering and production transfer. Holding a Mechanical Engineering degree from McGill University in Montreal, Canada, and being a named inventor on numerous patents, his 30-year career includes development of a variety of mechanical and electromechanical devices including wearable injectors, prefilled syringes, pen injectors, dry powder inhalers, sublingual spray and patient-controlled analgesia pumps – many of which incorporated design for sustainability.

George Bostock is a Senior Consultant Engineer at Cambridge Design Partnership. During his time at CDP he has had experience across a wide range of projects, from consumer goods through to performance-critical drug delivery devices. He was a named Red Dot Design Award winner for CDP's First Response Monitor, a wearable connected medical device. Having previously worked in the aerospace industry as a systems-design and integration engineer, Mr Bostock has a keen interest in systems thinking, tools and techniques. He now co-leads CDP's sustainability cross-sector team, where he believes that the consideration of the wider system and product context is critical to ensuring long-term impactful solutions.

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