INTERVIEW

At CPHI Milan this year, the pharmaceutical industry gathered in record numbers – with 62,000 pharma executives from over 100 countries, the event is widely seen as a key barometer of industry prospects. Sessions spanned a wide range of topics, including a key discussion led by Team Consulting's Alastair Willoughby on "Understanding the Problem of Decarbonisation in Drug Delivery", one of the industry's critical challenges. Looking ahead, these themes will be discussed in greater depth at Pharmapack Europe, set for January 22–23, 2025, at Paris Expo, Porte de Versailles, where industry leaders will meet specifically to advance innovations in pharmaceutical packaging and drug delivery.

ALASTAIR WILLOUGHBY,
TEAM CONSULTING

Alastair Willoughby, Head of Mechanical Engineering, is Team Consulting's lead for its cross-functional sustainability offering, where he works with his team to create robust, sustainable device designs. He is an experienced engineer with over 17 years of experience in medical device development and technical consultancy.

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Q What are the main challenges specific to decarbonising drug delivery systems?

A To start with, we need to appreciate that there are multiple delivery routes within this market, each of which presents different challenges. Team's CPHI session focused on three of these – capsules, inhalers and injectables.

When it comes to capsules, it's the upstream aspects – particularly raw materials – that are the main contributors to product carbon footprints. Therefore, players in this area have been aiming to reduce their impact by using different materials and sourcing options, as well as working closely with their suppliers.

As many people will know, with inhalers, the global warming potential of the gases used in pressurised metered dose inhalers (pMDIs) is a hot topic. In fact, it has been since the early '90s with the move away from chlorofluorocarbons to hydrofluoroalkanes, and the current focus is on securing lower global warming potential (GWP) propellants for these inhalers.

Although some inhalers are refillable, most are single use. However, it's important to remember that, in terms of environmental damage, the gases used are orders of magnitude more harmful than the fact that you're discarding a simple piece of plastic. That said, as we move to low-GWP gases, the focus will shift back to inhalers, some of which have become more complex with the addition of counters, electronics and other features, making them significantly more difficult to recycle.

For injectables, there has been significant growth in the autoinjector market, which is creating a real problem with single-use devices being discarded. We can reduce the carbon footprint of these devices by simplifying their design and using biofeedstock materials. When these are incinerated, they follow the biogenic carbon cycle, which is better than relying on fossil fuels. However, single-use products are still being discarded after each use, so we need to explore how we can minimise waste. For example, can we transition to multidose devices or create durable products with limited disposable components?

Q What role do regulatory hurdles play in the push towards decarbonisation?

A As with many new developments, the "elephant in the room" is the overarching regulatory hurdles we must navigate, whether we're making incremental improvements or implementing radical changes. Regulations can keep us in the same space for devices, rather than incentivising innovators to take revolutionary steps that could significantly reduce carbon footprints. As a result, more time is spent overcoming regulatory hurdles rather than genuinely revolutionising the industry.

Additionally, I think the industry is becoming increasingly risk averse as it becomes harder to get devices approved. Regulators need to balance the desire to reduce carbon footprint and improve patient safety with the need to avoid overly burdensome regulations that could stagnate innovation.

Q How can the industry address these challenges without compromising efficacy or patient outcomes?

A As I mentioned earlier, the regulatory framework is designed to ensure that new devices are effective and produce the desired patient outcomes. However, when it comes to innovative new designs, this can be a real challenge.

For example, even with the simplest plastic inhalers there are challenges. How do we ensure that they are still functioning correctly, such as by avoiding clogging? An effective design using features such as self-cleaning geometries and material

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to minimise deposition can, alongside analytical modelling, provide solutions to mitigate this. So, when moving to a reusable or multi-use model, the challenge is maintaining the efficacy needed to achieve the desired patient outcomes.

Q What steps should the pharmaceutical industry take to reduce emissions? Are there any low-hanging fruits or quick wins?

A The first step is improving on what we already have. This can involve using lower-carbon-footprint materials and more efficient manufacturing methods, and reducing energy use – all of which manufacturers are already working on. They may not have fully reached their destination yet, but they're heading in the right direction. In many ways, these are the low-hanging fruits. However, the bigger challenge is the continued use of single-use disposable products that are discarded after each use.

The much bigger hurdle is how to create a "circular economy" within the wider medical device industry. That's where I'd like to see progress, but it's being held back because there isn't enough of a push for people to make the radical shifts needed.

The challenge here is twofold – returning devices and then processing them. Return programmes are increasing in popularity but are still struggling to achieve mass return levels. Then, once the products are returned, there is the need to separate and process the elements. Often this results in lower quality "downcycled" products – reducing the value and properties of the polymers. While this gives the product a second life, maintaining the value of the material by recycling it into another device is the goal we need to reach. Good design for end of life and appropriate material choices, such as easily separated materials and limited colourants and additives, can all increase the potential for maintaining value through the recycling process.

Q In your view, how important is innovation in materials science to the decarbonisation of drug delivery? What advancements could be game changers in this space?

A In a word, it's vital. As I mentioned earlier, maintaining the value of materials is crucial, alongside the development of more recyclable alternatives to the high-barrier-property materials that are needed in many pharma products. Currently, manufacturers often default to using complex laminates, glass or other materials that are difficult to recycle. Finding an easily recyclable alternative material would be a clear win for sustainability in this space.

Q Can we learn anything from the increasing use of GLP-1s?

A I think there's still some uncertainty regarding which format will emerge as the winner. Most of the companies involved are focused on growth through a variety of delivery methods. Some are using dial-a-dose devices, while others are using fixed-volume, prefilled-syringe-based autoinjectors. Others are returning to vials and syringes.

Any move back to simpler products is likely driven by cost, since a vial and syringe can be significantly cheaper than a fully disposable autoinjector that is discarded after each use, which also reduces waste. However, the downside is that it may make it harder for certain patient groups to use. Therefore, patient access will likely come from a range of different platforms to support all users.

Q Given the growing focus on sustainability across industries, could contract design and manufacturing organisations (CDMOs) play a pivotal role?

A CDMOs are already playing a key role in helping to reduce both upstream and downstream carbon footprints through manufacturing. Manufacturers can gain a competitive advantage not just on cost but also on their carbon footprint, as an increasing number of companies are imposing carbon footprint requirements on their suppliers.

Collaborations are crucial and the trickle-down effect from other industries is important. As recycling becomes more efficient and new polymers are developed, we can assess how best to benefit from these advances. The challenge for the medical device industry is that it has very niche requirements that other industries do not, so there may not be many proven paths to follow. Nevertheless, we can still learn from each other about how to reduce our overall footprint, while also considering the entire ecosystem.

Q How do we balance patient access to essential medicines with sustainable practices?

A There are numerous access elements to consider, and I believe that radical sustainability solutions align well with this challenge. The industry has long been focused on more complex devices that add functionality to enhance safety or improve the user experience. While this is beneficial for certain aspects of access –

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such as enabling patients with limited dexterity to deliver their own medication – it also comes with a financial and sustainability cost.

In my view, offering a wider range of delivery options is important. For example, do you need an autoinjector to deliver the drug or would a prefilled syringe suffice? Or perhaps even a vial and syringe? These options may not only represent a lower-cost solution but also a more sustainable one.

The delivery mechanism must be appropriate for each individual. This is another example of personalised care – giving people the option that best suits their needs. Finding the right solution, of course, depends on the use scenario. For instance, single-use pen injectors may be used for a week or a month, depending on the drug. Meanwhile, reusable pen injectors may be used for three or four years. However, it's fair to say that both pen injectors and autoinjectors have larger manufacturing carbon footprints than standalone syringes.

Therefore, finding ways to reduce this footprint wherever possible, such as by exploring a wider range of drug delivery options for each patient, is an important step towards improving sustainability. Looking at revolutionary options for delivering drugs could allow us to achieve access, both financially and from a usability perspective, and sustainability goals simultaneously.

Global pharma will reconvene next year at CPHI Frankfurt from October 28–30 at the Messe Frankfurt. As the leading global community for pharmaceutical professionals, CPHI offers unmatched digital and in-person networking opportunities across the entire pharma supply chain. For more expert insights, see the CPHI Annual Report 2024, which examines the key challenges and emerging trends set to shape the industry over the next five years.

ABOUT THE COMPANY

Team Consulting is a drug delivery technology design and development partner. For over 38 years, the company has helped its clients create elegant, sustainable solutions to complex healthcare challenges. Team Consulting's multidisciplinary team of experts brings a unique blend of human-centred design, engineering, science and regulatory expertise to every project, with an unparalleled track record in drug delivery technology development. Working with organisations ranging from leading pharma companies to emerging start-ups, Team Consulting empowers its clients to create high-quality products that improve patient lives.

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