DISCUSSION PRIMER: PHARMAPACK

At Pharmapack Europe 2024, at Paris Expo Porte de Versailles (Paris, France), on January 24–25, 2024, over 5,000 attendees and more than 370 exhibitors will congregate at the heart of the pharmaceutical drug delivery and packaging industry. Key developers and innovators from companies like BD, Nemera, Aptar Pharma, West Pharmaceutical Services and many more will showcase some of their latest innovations. Ahead of this event, Pharmapack's organisers spoke with three industry experts, Alastair Willoughby, Jamie Greenwood and Chris Hurlstone, all from Team Consulting, to get their perspectives on the major trends expected to be top discussion topics at the event, and to play a significant role in the industry throughout 2024 and beyond.

PHARMAPACK By CPHI

Launched in 1997, Pharmapack is a leading European event for pharmaceutical packaging, drug delivery and medical devices and machinery. Over the past 25+ years, the event has grown from a conference with a small table-top exhibition to an event hosting over 300 exhibitors and welcoming attendees from 75 different countries.

team

Team Consulting is a world-class partner in drug delivery device design and development. For over 37 years its multidisciplinary team of experts has applied the latest approaches in design theory, engineering ingenuity and human factors to deliver products that are not only regulatory compliant but loved by end users. Working with leading pharma companies and innovative start-ups across the globe, Team Consulting thrives on helping its clients deliver the right technologies for their drug delivery needs.

OPTIONS TO CONSIDER WHEN DEVELOPING SUSTAINABLE MEDICAL DEVICES

ALASTAIR WILLOUGHBY, Head of Mechanical Engineering Group

The drive for sustainability in medical devices has continued to gain momentum as more sustainability goals are set and deadlines for carbon reduction approach. One of the key trends in this area within the drug delivery sectors, among others, is the move away from single-use devices to reusable ones, minimising the material usage and waste associated with single-use devices. This move could provide significant savings in carbon footprint, but the full impact analysis needs to consider the costs of preparing a device for reuse – whether through cleaning and re-sterilisation, reprocessing or incorporating a disposable element.

> "The cost of a reusable device, financial or in carbon footprint, may not provide a significant win, while potentially contributing to other challenges, such as transportation or more complex user interactions."

In some cases, the cost of a reusable device, financial or in carbon footprint, may not provide a significant win, while potentially contributing to other challenges, such as transportation or more complex user interactions. One example of this would be a device where the disposable element, such as a prefilled syringe, has a high financial and environmental unit cost, which, combined with a higher device cost to allow for reusability, may mean that, for a short course of treatment, a series of single-use devices may be better. As with all aspects of sustainable product design, the wider implications of design decisions must be considered.

LARGE DOSES AND ALTERNATIVE THERAPIES – THE NEED FOR RESPIRATORY DRUG DELIVERY INNOVATION

JAMIE GREENWOOD, Managing Consultant

Innovation has been relatively slow-moving in the respiratory drug delivery space in recent years. The innovation that has occurred has relied on the big players developing products for the traditional therapy areas of asthma and chronic obstructive pulmonary disease (COPD), rather than innovators developing their own devices. Meanwhile, "alternative" therapies (and whatever devices may be required to deliver them) appear to have been stuck on the backburner, with plans to advance these "at some point in the future".

However, with 2024 now upon us, the winds are shifting, and we are seeing signs of some green shoots of innovation, both in inhaled pulmonary and intranasal drug delivery. The long-promised alternative therapies for conditions other than asthma and COPD, including lung cancer, idiopathic pulmonary fibrosis, Parkinson's disease and more advanced antibiotics, also appear to be getting closer. Added to this, there are also signs that device developers are starting to mobilise and develop devices to match the particular requirements of these new therapy areas.

For example, there has been interest in intranasal drug delivery of both liquid and dry powder dose forms, targeting both central nervous system (CNS) and systemic delivery. Significantly, these intranasal treatments have been extended to treatment areas that were previously the sole preserve of injectables, such as administering lifesaving medications in one-opportunity emergency situations to reverse opioid overdose or Type 1 anaphylaxis.

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Similarly, following advances in formulation techniques for larger molecules, such as peptides and nucleic acids, there is now a new challenge for drug delivery devices to be able to handle higher dose sizes of what are often delicate formulations. This has led to a shift in the design landscape for inhaled pulmonary drug delivery devices, of which many have been developed to deliver no more than 10–15 mg of powder per use. There is now an emerging need for effective aerosol drug delivery devices that can deliver higher masses of formulations, often in excess of 25 mg. However, these requirements cannot be easily accommodated by simply re-engineering currently available products.

As such, it looks likely that this trajectory will continue in 2024; overlaid with other longer-running trends, such as improved sustainability and lower cost points, it can be expected that more drug and device developers will be scrambling to address these emerging unmet needs.

THE GROWTH OF PERSONALISED MEDICINE

CHRIS HURLSTONE, Technical Director

Recent years have seen a rapid growth in the area of "personalised" or "precision" medicine, where treatments and interventions are identified and delivered at the level of the individual, rather than as a "one-size-fits-all" solution for a population or patient group. There have been a number of drivers for this – for example, a surge in the development of new biosensor technologies, partly driven by the global response to the covid-19 pandemic, alongside the continued growth of digital and connected technologies, has resulted in a massive increase in the opportunities for diagnostics. Additionally, major advances in genetic sequencing, drug manufacturing processes and delivery device technologies have facilitated the development, approval and delivery of new personalised therapeutics.

At the level of the individual, the use of wearable sensors and at-home testing kits (e.g. for blood or saliva) has allowed individuals to proactively monitor themselves for ailments ranging from general wellness to cancers. At the national healthcare system level, advances in fields such as genetic sequencing, pharmacogenomics, scanning technologies and artificial intelligence have combined to create hugely increased opportunities for the development and deployment of screening programmes and companion diagnostics.

Companion diagnostics, which provide information on whether a therapeutic product will be both effective and safe for a specific individual, have seen ground-breaking changes. Examples of these

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include the ability to check whether a tumour has a specific gene change or biomarker that can be targeted by the proposed drug (effectiveness) and whether the impact of using a drug has had a negative impact on the patient's physiology, such as blood count (safety).

New personalised treatments exist in a number of areas, particularly cell and gene therapies (CGTs), with approved products in both the US and Europe now well into double figures. Most CGTs are in the field of oncology but there are also applications in disease areas such as cardiology, CNS disorders and metabolic conditions, such as diabetes.

The attractiveness of a therapy that can deliver a permanent cure in a single "one and done" treatment, as a replacement for ongoing weekly or monthly injections, is clear, but there are hurdles to overcome – a key example being the need for healthcare practices and systems to adapt to this new approach. Another sizeable and much talked about obstacle is the significant cost. For example, Libmeldy (atidarsagene autotemcel), developed by Orchard Therapeutics (London, UK) and approved in the UK for the treatment of rare and fatal genetic disorders in infants, costs £2.8 million per treatment, and Roctavian (valoctocogene roxaparvovec), developed by BioMarin Pharmaceutical (San Rafael, CA, US) and approved in the US for the treatment of haemophilia, costs US$2.9 million (£2.3 million) per patient.

These costs are partly driven by the highly complex processes – manufacturing, laboratory handling and surgical procedures – inherently entailed in producing and delivering these treatments. However, advances in these areas will support further growth, and this is already happening for CGTs based on messenger RNA (mRNA).

Looking specifically at mRNA research, progress was well underway long before covid-19, but the demand introduced by the pandemic supported the rapid development of mRNA vaccines. Now there is a situation whereby these learnings and pathways can potentially be applied to help secure faster approval of mRNA-based CGTs for oncology and other disease areas. In parallel, GMP manufacturing processes for lipid nanoparticles, which can form the basis of delivery mechanisms for mRNA gene therapies, are being developed and commercialised, which should help reduce costs and therefore enable increased access.

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The increase in personalised medicine is also supported by the continued development of innovative delivery devices. These are often needed to support targeted delivery of new therapies to specific parts of the body and can leverage advances in technologies such as robotics and minimally invasive surgery, imaging and monitoring, precision manufacturing and digital systems.

Pharmapack Europe 2024 will take place in Paris, France, on January 24–25, 2024. For more information, visit: *www.pharmapackeurope.com*.

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ABOUT THE AUTHORS

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.

Jamie Greenwood, Managing Consultant, is a versatile scientist with a track record spanning 20 years of technical leadership in product development, both in the medical and consumer product sectors. He has a particular interest and specialism in drug delivery and has worked on many of today's marketed dry powder inhalers.

Chris Hurlstone, Technical Director, has more than 25 years of experience in developing technologies and devices for healthcare markets, with a particular focus on drug delivery systems. A named inventor on numerous patents, Mr Hurlstone has a strong track-record in delivering innovative and robust engineering solutions.

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