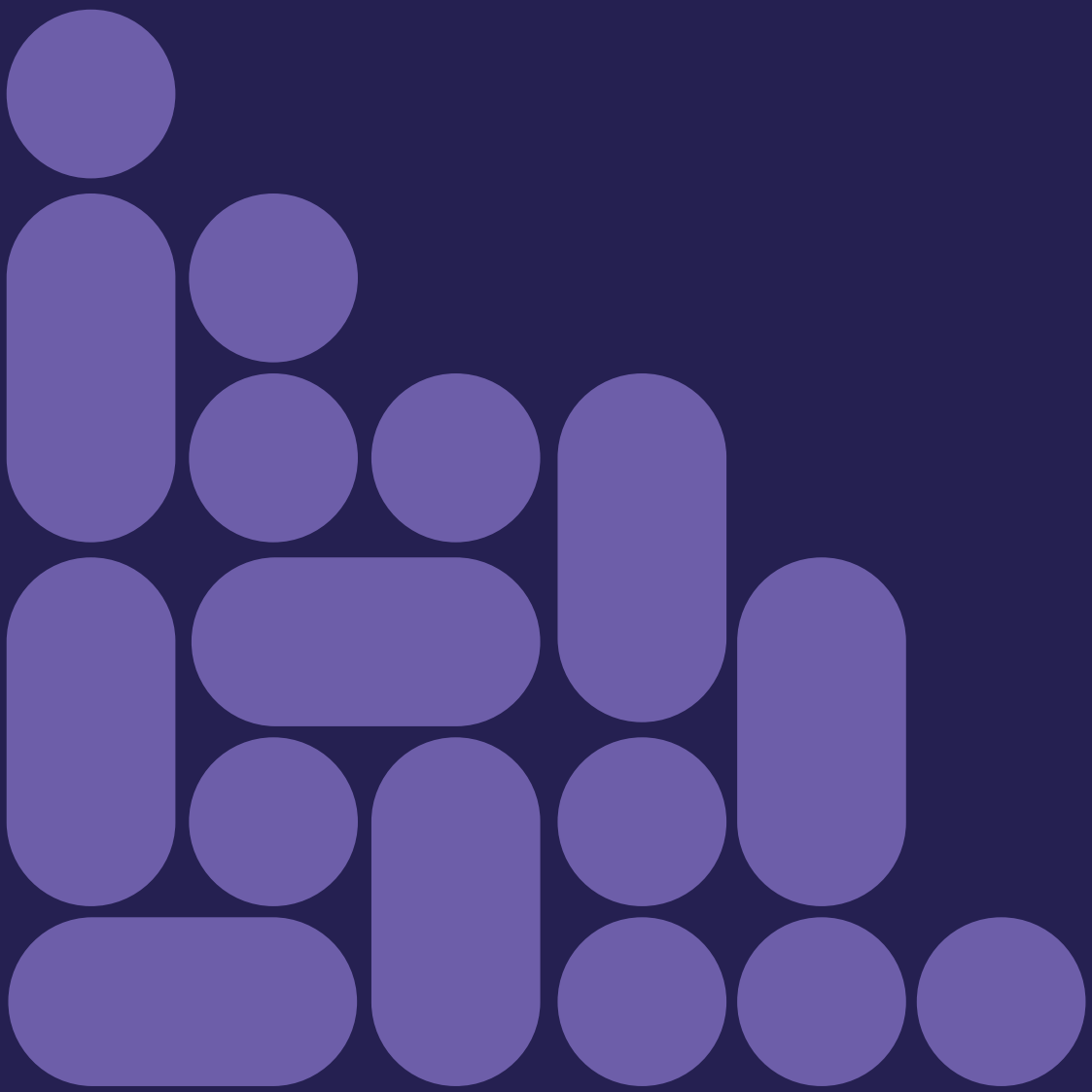
Pharmapack Survey and Annual Report 2024

PHARMAPACK
By CPHI



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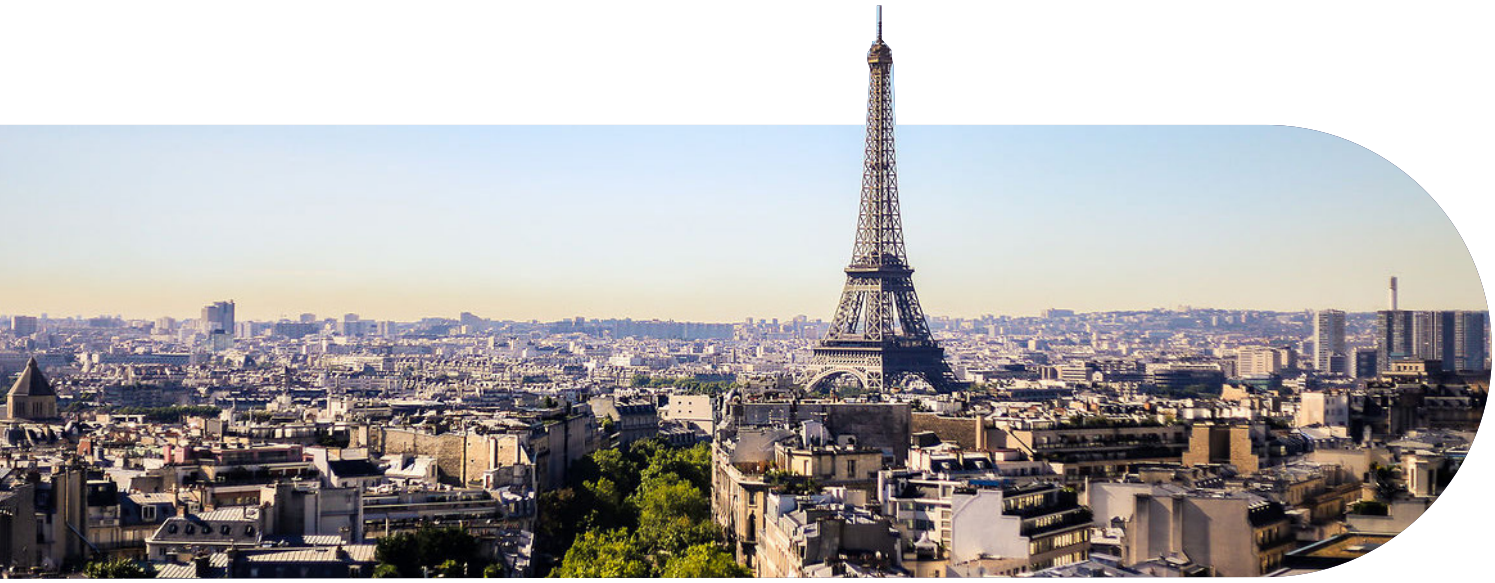
Global drug delivery innovation index hits record high with sustained growth expected in 2024



Key Highlights

Global drug delivery innovation index hits record high with sustained growth expected in 2024

France sees biggest year-on-year rise but Germany moves ahead of the USA to lead the rankings for the first time

Introduction

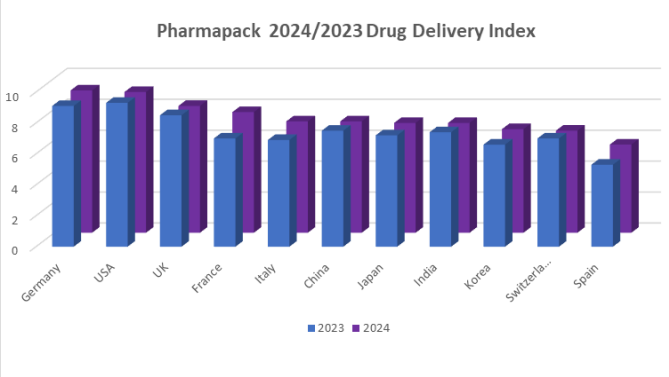
The last year has been a period when sales of covid vaccines and associated devices are—thankfully—falling. Yet rather than anticipating a sudden cliff of reduced demand and, despite a period of macro uncertainty, confidence in future growth and device innovation has quietly achieved new highs. Drug device innovation has continued to advance apace, with autoinjectors the standout performer.

In the Pharmapack Report's primary indicator – the *drug delivery innovation* index – we have seen scores rise marginally, however, dig a little below the surface of the headline metric and it's clear that this strength is not being universally felt. The other notable trend we see reported all across the sector is that the speed of device innovation itself is also unequal with certain devices seeing greater speeds of advancement. This is likely due to the patient responses observed in recent, real-world successes, as understandably device types that have had muted acceptance are seeing lesser future research demand. The final development is the ongoing duality of how to navigate and marry sustainability goals with device innovation – broadly speaking this has seen the industry shift from complex and high-tech devices to solutions that adapt existing technologies, with greater standardisation of designs now sought.

Commenting on the shifting innovation patterns we will see across the sector in 2024, and the underlying patient-based experiences behind these trends, Gregor Andersen of Pharmacentric Solutions, added: *"on-body devices, which many thought could be a panacea for the delivery of many drugs, are often proving complicated for users. They involve challenges like cleaning the skin, peeling adhesives, and wearing the device for long durations. Contrary to the envisaged benefits, these devices added complexity to the patient journey, especially in home care scenarios. In contrast, auto-injectors, which are becoming easier to use and more standardized, are therefore gaining more prominence. They offer a less risky journey which is crucial as healthcare providers navigate numerous on-body devices, each with its set of instructions."*

Pharmapack drug delivery innovation index

The *Pharmapack drug delivery innovation* index [scored out of ten] is a collateralised metric of drug delivery and device innovation across the major pharma nations. Significantly for industry prospects in 2024, **the index rose very slightly to 7.45 up from a previous record score 7.44 in 2023. Yet the majority of countries only maintained or reported slight falls** in year-on-year scores, with France easily the Index's biggest mover (+11%) rising to fourth in the rankings. In a further significant development, Germany supplanted its perennial rival, the USA, to lead the rankings in 2024. This is, in fact, the first time any country other than the USA has led the rankings and may now point to a wider shift in the location of device innovation. For example, if we look back six years to the first Pharmapack Survey we see that the gap between the top European Nations (Germany, France, the UK and Italy) and the USA is now much smaller than at any point in the survey's history. Therefore, 2024 marks a significant milestone, as these year-on-year incremental gains have seen major European nations coalesce at scores of 8 and over, with Germany narrowly surpassing the USA for the first time. The USA's score has remained extremely consistent over the last 5-years at slightly over 9 in each year – it's 2024 total of 9.1 is only narrowly below it's 2023 peak of 9.3 – however, Germany has again maintained a score of 9.2 this year, having gradually risen over the preceding five years.



The surge in France's score perhaps reflects some of the recent developments at its biggest drug device companies, with Nemera continuing to be a leading light in the industry. For example, the company announced in late 2024 it will open its third site in the United States by 20251, having already opened a site in Szczecin (Poland) earlier in the year2. This is in addition to launching new devices including the Symbioze™ platform3 – an onbody injector designed for use with large volume complex drugs (including MAbs). In a further boon for the country, Novo Nordisk – makers of the most hyped drug of 2023, Wegovy – announced it is investing €2.1 billion4 in France having already acquired French connected device maker Biocorp earlier in the year5,6.

But more widely, the French market is becoming a major hub for innovation in drug devices and medtech sectors thanks to strong government support, which is now starting to pay dividends. The new plan ["France 2030" Recovery Plan] enacted just a few years ago is set to contribute some €7.5 over the next 5-years[7].

In fact, Paris, home city of Pharmapack Europe, has seen surging numbers of health-tech companies with over one quarter of France's device makers based here – and numbers country-wide have risen fast from just over 2000 in 2020 to nearly 3000 in 2024 according to data from France Biotech. Significantly, the medtech industry already delivers in excess of €30.7 billion in revenues for France7.

We also this see evidenced directly at Pharmapack, where the Start-up Hub has remained one of the fastest growth areas

1 https://www.nemera.net/news/nemera-extends-manufacturing-capabilities-in-north-america/

2 https://www.nemera.net/news/brand-new-state-of-the-art-nemera-manufacturing-facility-inaugurated-in-poland/

3 https://www.springboard.pro/wearable-injectors-news-and-trends/

4 https://www.chemanager-online.com/en/news/novo-nordisk-invest-eu21-billion-french-production-site#:~:text=The%20Danish%20drugmaker%20announced%20to,the%20current%20Quality%20Control%20Laboratory.

5 https://www.fiercebiotech.com/medtech/novo-nordisk-offers-eu154m-negotiations-acquire-diabetes-devicemaker-biocorp

6 https://www.massdevice.com/novo-nordisk-acquires-all-shares-biocorp/

7 https://frenchhealthcare.fr/medtech-a-strategic-shift-for-france-to-develop-and-produce-the-medical-devices-of-tomorrow/

on show floor, with increasing numbers of applications from a growing range of device and technology innovators – the French market in particular is a rising focus for the event.

Another country to see a significant year-on-year rise is Italy, which has also attained its highest ever score, rising 5%, moving the country ahead of Japan, China and India. The Stevanato Group as one of the country's largest delivery companies has mirrored this success reporting 11% rise in Q3 revenues and an impressive 16% among 'high-value solutions'[8]. Further insight into the underlying trends and industry-wide strength were provided from the Group's CEO, Franco Moro in its investors press release: *"We currently see strong secular tailwinds, notably in biologics, which are creating downstream demand for high-value solutions. In response to customer demand for high-performance, integrated solutions, we are investing in growth platforms to expand our capacity for high-value solutions. The continued advancements in biologics, including mRNA applications, monoclonal antibodies, GLP-1s, and biosimilars are expected to help drive durable, long-term organic revenue growth in the range of high single-digits to low double-digits."*

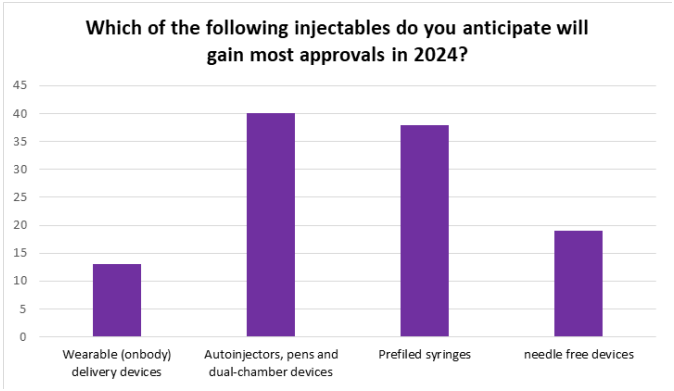
At the base of the Index both Korea and Spain reported impressive improvements in scores of 6% and 7% respectively – with the latter continuing to underline its improving reputation for innovation having also seen record rises in October's CPHI Annual Report 'drug development R&D' categories.

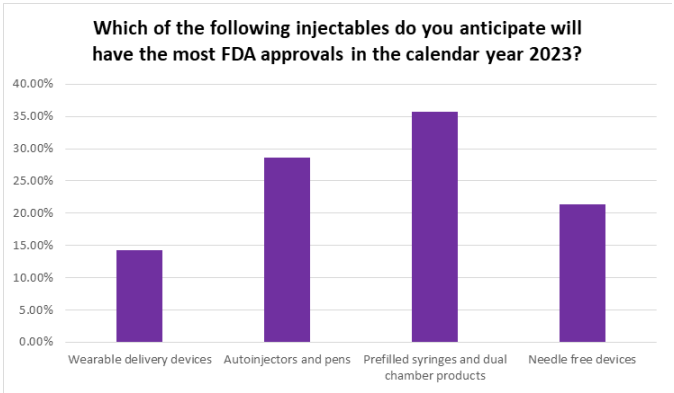
Brennan Miles, Head of Drug Delivery, Team Consulting: *"It's also great to see that drug delivery innovation and industry prospects are on the rise in the latest Pharmapack Drug Delivery Index. The index reflects the fact that Europe, the USA and the UK remain strong markets for drug delivery technology innovation, with France making notable gains in the index rankings along with Germany."*

8 https://ir.stevanatogroup.com/news-events/press-releases/detail/129/stevanato-group-reports-third-quarter-2023-financial-results

Novel Device approvals in 2024

One notable change from last year's results is that 'autoinjectors' have narrowly supplanted 'prefilled syringes' as the injectable type predicted to see the greatest number of approvals in 2024. The more complex wearable and needle free devices fell back on last year's results. In fact, our respondents predict that collectively auto-injectors and syringes will be responsible for nearly 80% of approvals this year using advanced injectables.

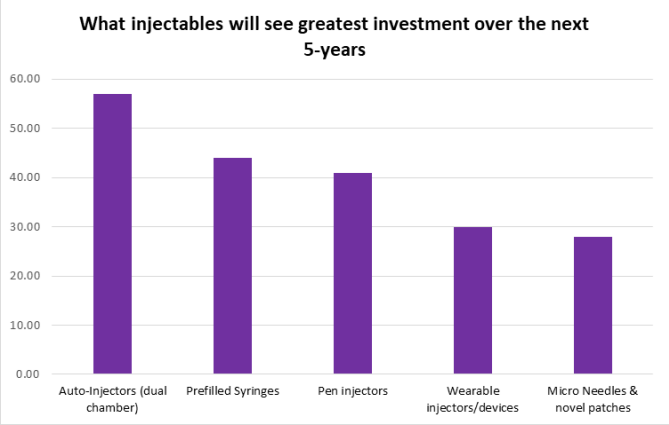




5-year injectable research outlook

When we asked respondents to look ahead five years to what types of injectors they believe will see the greatest levels of R&D investment – selecting two answers – auto-injectors (57%) emerged again as the most popular choice, closely followed by prefilled syringes (44%) and pen injectors (41%). However, more expansive wearable devices (30%) along with novel microneedles/patches (28%) were both selected by less than one third of respondents. Taken as a collective result, this perhaps points to a growing emphasis on delivery forms that minimise the time a patient interacts with device,

and toward devices with perceived simpler regulatory pathways and overall lower development costs. Our analysts reading of this situation is that while global R&D spends are recovering, the industry, as a whole, is looking at solutions it deems as less risky in terms of timelines and development costs.



Sustainability Index

Pharmapack's Sustainability Index gauges the perception of how much is being achieved by each country in terms of plastic use, waste reduction, device recycling and which therefore has the most progressed approach to sustainability. It provides a window into of how far along each country is in terms of achieving optimal sustainability of pharma devices, packaging and delivery solutions.

This year's results are incredibly encouraging and point to a renewed industry commitment to sustainability globally in 2024. Remarkably, the **overall index is up a highly impressive 8.6% year-on-year** – with every country bar India seeing an improved score. Although starting from a lower base, China's reputation has recorded a dramatic improvement in outlook, with its score improving by a massive 51% – meaning it is now much closer aligned to the lower scoring European nations, having pulled well clear of India at the foot of the table.

China has made a number of well documented efforts to reduce the waste production of its vast API manufactures within the country. More recently, the newly implemented medical devices regulations are also encouraging greener manufacturing decision within development, while the country is also now among the leaders and largest producers of green packaging[9,10] – so we expect it will continue to climb the rankings quickly, albeit having a very large distance to go to come close to the leading European nations.

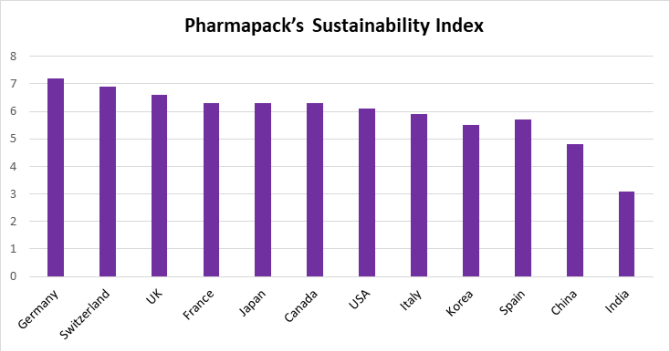
Other notable movers were Spain (up 17%), Canada (up 14%) and Korea (up 11%). At the head of the table the top three nations – Sweden, Germany and Switzerland – consolidated their positions, stretching further ahead of the UK and France. Significantly, Sweden drew level again with Germany, having briefly fallen behind in the 2023 rankings.

Country	2024 index	2023 score	% change
Sweden	7.2	6.8	6.11%
Germany	7.2	7.0	2.86%
Switzerland	6.9	6.8	1.68%
UK	6.6	6.4	3.82%
France	6.3	6.2	1.38%
Japan	6.3	5.8	8.89%
Canada	6.3	5.5	14.55%
USA	6.1	5.6	8.10%
Italy	5.9	5.5	7.27%
Korea	5.5	4.9	11.59%
Spain	5.7	4.9	17.35%
China	4.8	3.1	52.73%
India	3.1	3.2	-3.56%
All Country Index Average	5.99	5.52	8.63%

The most telling statistic is that, unlike in all other areas of CPHI and Pharmapack research (i.e. API, bio, finished dose tables), the top four European nations remain above all other countries – including the US, Canada and Japan. Therefore, the European nations are still globally perceived as the leading drivers of sustainability in pharma.

9 Dentons: Shanghai's New Incentive Policies on the Promotion of Biotech and Pharmaceutical Industry (June 2023)

10 https://www.grandviewresearch.com/industry-analysis/green-packaging-market

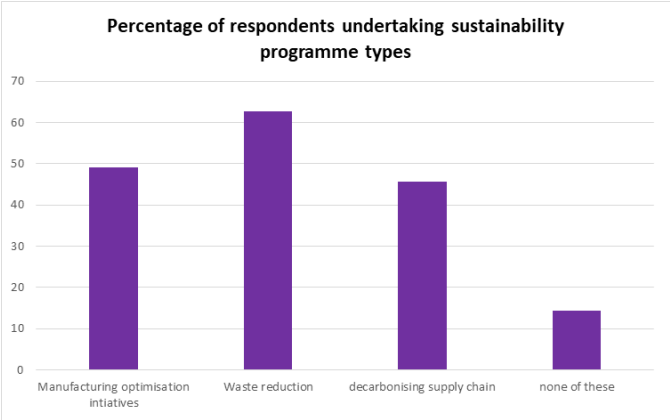


Last year the report predicted that we were potentially at the beginning of a much longer-term story of improvements in the sustainability index, so to see a record score after just one year does bode very well for global pharma's focus on this issue. The key question is can such rapid improvements be continued in the next year and over the medium-term and, will we also see a proliferation of new approaches and cross country/industry standardisation – as these are the global changes that could have the biggest real world impacts. For example, standardisation not only helps reduce costs, improve international recycling schemes as well as reusability, but also, brings about increased patient compliance – an often overlooked aspect of sustainability – through increased familiarity and reduced need for training programmes.

"The challenge of sustainability remains, however, the focus on standardized, simpler solutions is the current driving force in reshaping the landscape of drug delivery devices in 2024" Gregor Anderson, Pharmacentric Solutions Ltd

Current sustainability initiatives undertaken at company level

Emphasising the continual shift in priorities for 2024 only 14% of the industry we surveyed are not currently undertaking an environmental or sustainability programme. In fact, some 62% are investing in waste reduction programmes across manufacturing, while half are also looking to improve manufacturing optimisation – these programmes included AI and machine learning to monitor energy usage and target manufacturing improvements in production lines. Decarbonising supply chains is also an area of improvement for some 45% of the industry – with companies looking to monitor the footprints of suppliers, reduce the energy usage during transport and shorten supply chains.

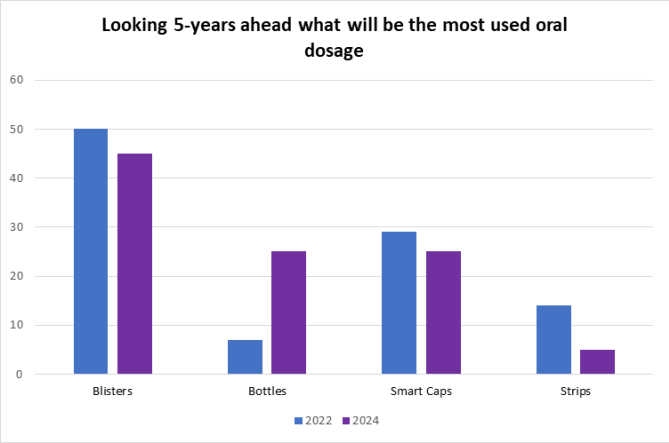


Predicting the most popular oral dosage form packaging five years ahead

The industry was asked in 2022 to look forward five years and envisage the most popular (primary) packaging solutions for industry – what is remarkable, is that when we asked this same question two years later, the answers have remained largely consistent. There is one notable exception however, bottles (PET and glass) have risen quickly in popularity taking some gains from both smart caps and blisters, but a very large component from strips – which have fallen quickly. What can be inferred from this: that potentially bottles, as a more easily recycled container, are starting to be seen as a cost-effective solution to increasing sustainability demands. We therefore envisage bottles being used as a commodity solution for many generic, high-volume drugs. Yet despite this, blister packaging remains by far the surveys dominant force and most analyst predictions foresee a quickly expanding market[11] – particularly as manufacturers find new ways to minimise or eliminate single use and non-recyclable plastics. In fact, the global blister packaging market was precited as recently as November 2023 to grow from its current 5.6bn estimated sized to 8.9bn by 2031[12].

11 https://www.transparencymarketresearch.com/blister-packaging-market-for-pharmaceutical-industry.html

12 https://www.transparencymarketresearch.com/blister-packaging-market-for-pharmaceutical-industry.html



Contract packaging prospects for

Contract packaging and contract filling is one of the newer areas of Pharmapack Europe – which itself reflects an expansion in demand – and we asked the industry to outline the industry's prospect ahead for the next 18-months into 2025. Perhaps not surprising, considering the uptick observed in other CPHI surveys and industry data points, in contract services only 6% of the industry had a 'negative outlook' for 2024. Significantly, 57% were 'moderately positive' for growth ahead in the next 18-months, while an impressive 37% were 'highly positive' about both their own and wider industry's prospects.

"I concur with the findings of the survey. 2024 will see an increasing number of manufacturers launching specialty and biologic medicines, all requiring specialist packaging solutions to help them differentiate their offerings. Moreover, this year will recognise that policy solutions are required to increase resilience, including an EU Critical Medicines Act and the WHO's draft pandemic accord. Changes to legislation seek to track supply and incentivise diversity of supply, which will need packaging services to meet this increased demand." Aurelio Arias, Director, Thought Leadership at IQVIA

Conclusion

The Pharmapack Survey Report for 2024 paints an optimistic picture for the drug delivery and packaging sector, with a convergence of positive trends in innovation, sustainability initiatives, and industry outlook. The global *drug delivery innovation index* hitting a record high indicates a trajectory of sustained growth in 2024, driven notably by the stellar performance of autoinjectors, as well as continued innovation for high value devices like on-body devices.

Germany's ascendancy over the USA in drug delivery innovation rankings signals a subtle potential reorientation of device innovation hubs [i.e. increased European prominence in a dual hegemony with the USA], while France and Italy's significant rises underscore a broader positive industry shift. The Sustainability Index, witnessing an impressive 8.6% year-on-year increase, stands as a leading indicator of innovation and future revenue streams for companies prioritizing sustainability. This upward trend is likely to persist, with expectations of further rises in the Sustainability Index's scores over the next 2-3 years.

Predictions of autoinjectors and syringes accounting for nearly 80% of new device approvals in 2024 suggests short term preference for less risky and cost-effective solutions, while the popularity of bottles as easily recyclable [low cost] solutions align with the industry's commitment to sustainability.

Contract packaging companies should also report excellent growth in the year ahead and there is a compelling case for robust growth and innovation in pharma packaging through.

Methodology

The results provide an inside track on the overall strength of the industry while also drilling down to provide insights on key areas and topical questions. With executives from around the globe – including all major pharmaceutical markets – contributing their specialist perspectives, the Pharmapack Annual Report is the *go-to* resource on the drug delivery and packaging market in 2024. The survey results were collated in late 2023 across two sperate surveys – with 200 respondents taking part.

Part 2

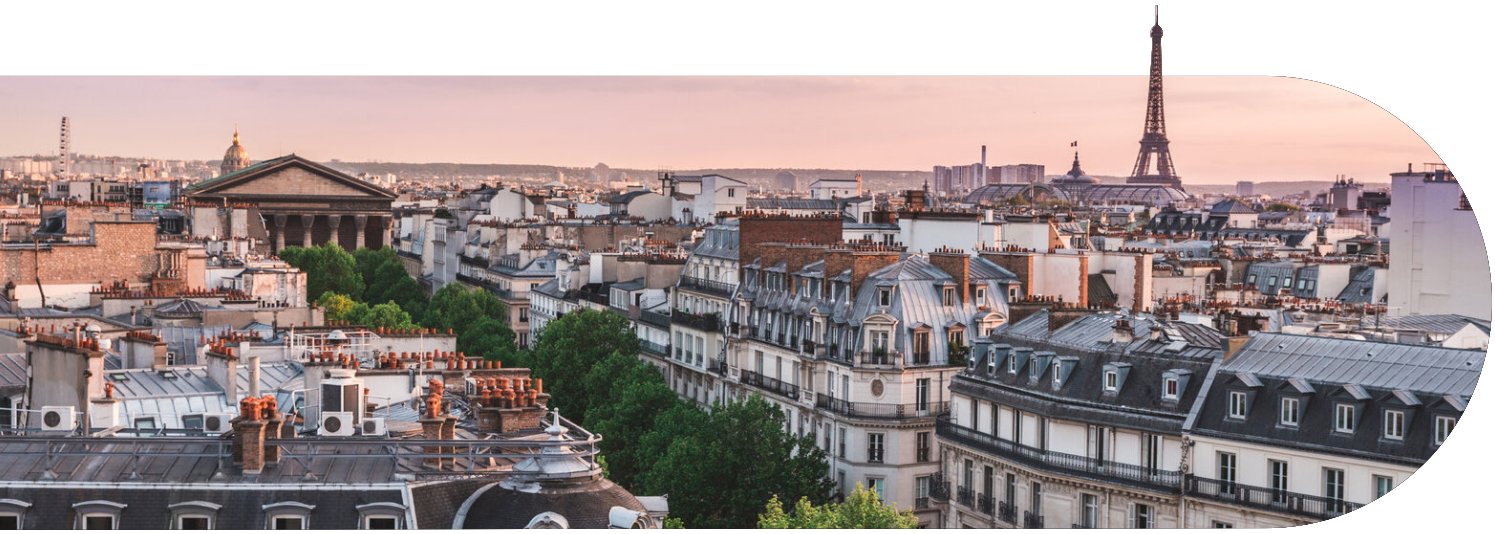
Drug Delivery Devices Roundtable With Team Consulting

Brennan Miles, Head of Drug Delivery, Team Consulting

Alastair Willoughby, Head of Mechanical Engineering, Team Consulting

Jamie Greenwood, Managing Consultant, Team Consulting

Chris Hurlstone, Technical Director, Team Consulting



Ahead of Pharmapack Europe 2024 – where over 5000 attendees are expected *at the heart of pharma's drug delivery and packaging industry* – we spoke with Team Consulting to get their perspectives on the big trends ahead in 2024 and beyond. Here is a breakdown of everything they expect:

The rise of partnership models in drug delivery device development

Brennan Miles, Head of Drug Delivery, Team Consulting

2023 has been a bumpy year with high inflation, raising costs and challenges with releasing funds for new development and innovation projects. The state of the economy has had a belt-tightening effect on private capital, and coupled with increasing financial and regulatory scrutiny, it has been harder for BioTech and MedTech companies to access equity and make progress in the way they would have liked.

These challenges have also brought new opportunities to innovate and grow in different ways. For example, partnership models supporting the entire ecosystem – from new clinical discovery to development, clinical trial and manufacturing – have replaced traditional in-house development teams. In the past few years it has almost become a cliché that a huge amount of scientific and technological innovation happens outside of the large pharma organisations.

Partnerships are now the go to way of collaborating on a joint venture, enabling companies to rapidly reach important inflection points, improve efficiency and drive down operational costs, without huge capital outlays. This is playing out in all areas of drug discovery, through to technology and device innovation.

The focus for 2024 will be continuing to build on partnership in areas like the digital space, streamlining everything in the continuum of healthcare from new molecule discovery through to clinical trials management, diagnostics, screening and patient centric treatments. Pharma's partnerships with digital and AI companies have remained steady as they are seeing strategic long-term partnerships as the ones that will pay off longer term.

Options to consider when developing sustainable medical devices

Alastair Willoughby, Head of Mechanical Engineering, Team Consulting

The drive for sustainability in medical devices continues to gain momentum as more goals are set and deadlines approach for carbon reduction. One of the key trends is the move

within drug delivery (and other sectors) away from single use devices to reuseable devices, minimising the material usage and waste associated with the 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 utilising a disposable element. In some cases, the cost, financially or in carbon footprint terms, may indicate that the move to a reusable device is simply not providing a significant win, while potentially raising 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 pre-filled syringe has a high financial and environmental unit cost, 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 your design decisions must be considered.

Large doses and alternative therapies – the need for respiratory drug delivery innovation

Jamie Greenwood, Managing Consultant, Team Consulting

Innovation has been relatively slow moving in the respiratory drug delivery space during recent years. What innovation did occur typically relied upon the products developed by 'big players' for the traditional therapy areas of asthma and COPD, rather than innovators developing their own devices. Meanwhile, 'alternative' therapies (and whatever device may be required to deliver them) appear to have been stuck on the 'back-burner', with plans to advance these 'at some point' in the future.

But 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 intra nasal 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, 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, we have seen interest in intra nasal drug delivery of both liquid and dry powder dose forms, targeting both CNS and systemic delivery. Significantly, these have been extending to treatment areas which were previously the preserve of injectables only, such as, administering lifesaving medications in one-opportunity emergency situations to reverse opioid overdose or type-1 anaphylaxis.

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, often, delicate formulations. This has led to a shift in the design landscape for inhaled pulmonary drug delivery devices, many of which 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, which can deliver higher masses of formulations (often in excess of 25 mg) – however, these cannot be easily accommodated by simply re-engineering currently available products.

It therefore looks likely that this trajectory will follow in 2024; overlaid with other longer running trends like improved sustainability and lower cost points, we can expect to see more drug and device developers scrambling to address these emerging unmet needs.

Follow-up question: Are there any particular companies or early-stage innovation hubs (regions) you are looking at closely expecting exciting developments form over the next 18-monhs?

We are working with a number of clients on exciting developments over the next 18 months, which we look forward to seeing drive new innovations in the industry. In addition to this, companies like PureIMS and Iconovo are pitching their dry powder inhaler technologies as platforms with some large doses and alternative therapies in their pipelines.

Similarly, ARS Pharma are attempting to launch their Neffy intranasal spray in the U.S.A for treatment of type-1 anaphylaxis.

The growth of personalised medicine

Chris Hurlstone, Technical Director, Team Consulting

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.

A surge in the development of new biosensor technologies, partly driven by the global response to the COVID-19 pandemic, alongside a continued growth of digital and connected technologies, has resulted in a massive increase in the opportunities for diagnostics. Meanwhile, 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 home use 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 give a hugely increased opportunity for the development and deployment of screening programmes and companion diagnostics.

The latter, which provides information on whether a therapeutic product will be both effective and safe for a specific individual, has seen ground-breaking changes. Examples of these newer companion diagnostics include the ability to check whether a tumour has a specific gene change or biomarker which will be targeted by the proposed drug (product effectiveness), or whether the impact of using a drug has had a negative impact on the patient's physiology, such as blood count (product safety).

New personalised treatments exist in a number of areas, particularly cell and gene therapy (CGT) with approved products in both the USA 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, central nervous system (CNS) and metabolic disorders such as diabetes.

The attractiveness of a therapy which can deliver a permanent cure in a single "one and done" treatment – to replace ongoing weekly or monthly injections – is clear, but there are hurdles to overcome. For example, the need for healthcare practices and systems to adapt to this new approach. Another sizable and much talked about obstacle is the significant cost of CGT: Libmeldy, which is approved in the UK for the treatment of rare and fatal genetic disorders in infants, costs £2.8M per treatment, and Roctavian, approved in the USA for the treatment of haemophilia, costs $2.9M per infusion.

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

Looking specifically at mRNA research, this was well underway long before COVID-19, however the pandemic demand supported the rapid development of vaccines. What we now have 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 diseases. In parallel, GMP manufacturing processes for lipid nanoparticles (LNPs), which can form the basis of delivery mechanisms for mRNA gene therapies, are being developed and commercialised. The outcome of this should be a reduction in costs, allowing increased access.

The increase in personalised medicine is also

supported by the continued development of innovative delivery devices. Although many emerging therapies may be suitable for delivery via existing technologies, such as PFS or infusion pumps, there is often a need for the development of new devices to support targeted delivery of new drugs and treatments to specific parts of the body. The development of these devices can leverage advances across a range of technologies such as robotic and minimally invasive surgery, imaging and monitoring, precision manufacture, digital systems and artificial intelligence.

It is very difficult to predict any specifics of not yet invented device technologies. What is clear though is that a multi-science, multi-discipline approach is required, whereby drug developers and formulators work closely and in parallel with manufacturing organisations and device developers in order to maximise the effectiveness and minimise the risk of future personalised medicines.

Part 3

What Lies Ahead for Drug Delivery and Devices

Tom Oakley, VP Design and Development at Springboard (a Sanner Group Company)

Pharmapack Report 2024: what lies ahead for drug delivery and devices

Introduction

Pharmapack Europe speaks with **Tom Oakley, VP Design and Development at Springboard (a Sanner Group Company)** ahead of his session at the event to get his perspectives on what lies ahead for the industry in 2024 and beyond.

Summary

In the evolving landscape of drug delivery and devices, sustainability and innovation converge to reshape industry practices. This article explores the critical interplay between novel materials, circular economy models, and sustainable supply chain practices. Before delving into materials and technologies, it contemplates reimagining product concepts and business models to minimize material usage, exemplified by the growing demand for reusable drug delivery devices and return-to-manufacturer schemes. As the industry grapples with the challenges of making circular models economically viable, a spotlight is cast on trends like local sourcing and manufacturing, which are expected to gain prominence in the next 18 months.

Additionally, patient-centric device development is scrutinized in light of increasing environmental considerations, exploring initiatives that align with both patient needs and sustainability goals. Looking ahead, we examine the how patient-centric innovation might evolve – highlighting weight management drugs, closed-loop delivery systems, and advancements in ophthalmic drug delivery. Finally, the dynamics of innovation are explored, with an emphasis on smaller companies driving device innovation, particularly in emerging hubs like Cambridge, Oxford, Silicon Valley, and Greater Boston, encapsulating the industry's dynamic journey toward a greener, more patient-centric future.

Sustainability

Q) In anticipating future trends, what novel materials or technologies do you foresee playing a significant role in enhancing the sustainability of drug delivery and devices industry?

TO: I shall cover novel materials and technologies shortly, but first we should consider whether we can avoid using materials altogether by changing the product concept and/or business model.

For example, on the product concept side we are seeing a renewed demand for reusable drug delivery devices so that the sheer volume of plastic and packaging from fully disposable single use devices can be reduced substantially.

In terms of business models, we are seeing

many pharma companies trialling or implementing return-to-manufacturer schemes whereby devices and packaging can be disassembled and downcycled, or in some cases recycled. In addition, there is at least one trial under way to take back used drug delivery devices from patients and distribute them to other patients.

Novel materials tend to fall into two categories:

1. Materials made from sustainable sources. These materials include thermopolymers made from crops rather than fossil fuels, or metals from recycled sources rather than primary sources. Various materials suppliers have introduced sustainably sourced options. This is a welcome development, but it will take time to validate the new materials for medical use, and they tend to be significantly more expensive than the materials they replace.

2. Biodegradable materials that could reduce the impact of landfill. These sound attractive in principle, but have drawbacks: they release carbon into the atmosphere as they degrade (sometimes in the form of methane which has a very high global warming potential); they can release harmful additives such as plasticisers and colourants; and their degradability can cause shorter shelf life and/or lower reliability.

Q) Are there specific circular economy models or strategies that you expect to gain prominence in the next 18 months?

TO: The next 18 months will be critical to the judgment within industry of whether return-to-manufacturer schemes are viable.

Examples of companies running return-to-manufacturer schemes include Novo Nordisk's PenCycle scheme[13] and Chiesi's Action for Inhaler Recycling (AIR) scheme[14]. GSK discontinued their inhaler return-to-manufacturer scheme several years ago, demonstrating that it is not easy to make such schemes worthwhile.

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The other area of prominence will be the technology and facilities needed to disassemble and recycle difficult-to-recycle devices. Most device developers now try to consider disassembly in their design, but some materials will remain difficult to recycle, and most companies are unwilling to recycle used sharps.

Q) As sustainability becomes increasingly critical, what innovations do you expect in addressing the end-of-life phase of drug delivery devices? Are there trends toward designing devices with even more sustainable disposal solutions?

TO: Perhaps the area that needs most innovation is in making reusable devices as easy to use as disposable devices. There might always remain an extra step for a reusable device, but if this can be simple and intuitive, then we would hope more devices could be reusable.

Another area for innovation is in the processes and checks that would be required to reuse a delivery device or packaging from one user to another. The quality requirements placed on devices and packaging make reuse a daunting task, but with appropriate processes it could be viable.

Design guidance for the development of environmentally sustainable products has long called for devices and packaging to be designed for simplified recycling either by enabling easy disassembly, or by using similar materials throughout. However, it seems that until recently the other requirements around safety, efficacy, usability, reliability, and cost have dominated over sustainability. Conversations and recent projects have indicated that the importance placed on sustainability has increased, which will make the innovations necessary for sustainability more likely to be incorporated into new devices and packaging.

Q) In the future, how do you foresee the drug delivery device industry building resilience and sustainability into the supply chain, especially in the face of global challenges?

TO: One of the trends we have noticed is an inclination to source materials and perform

manufacturing close to, or in, target markets. This strategy reduces material transport mileage, reduces cold chain storage and transport requirements, and can reduce geopolitical risks. However, it can require implementing supply chains, manufacturing, sterilisation, and distribution chains in multiple territories, and sometimes in territories where a given organisation does not already have such infrastructure and partners.

Patient Centricity

Q) Will patient centric device development potentially be slowed by increasing environmental considerations – how could this be mitigated?

TO: Many of the initiatives in drug delivery help both patient centricity and environmental sustainability, such as:

- The trend for formulations and devices to allow medications to be self-administered at home or work rather than needing travel to hospitals and use of all the infrastructure there.

- The trend for formulations and devices to allow less frequent dosing and therefore use of less devices, containers, and packaging. For example, GLP-1s used to be taken twice per day, then once per day, and now once per week. Longer-acting formulations may come in the future.

- The reduction in size and weight of delivery devices, which in turn reduces the size and weight of packaging and allows more devices to be transported and stored in given shipping containers.

The main tension between patient centricity and sustainability is the fact that reusable devices, which should be better for sustainability involve more user steps, which is worse for usability.

Q) Where do you think the focus on innovation will be in the next 18-months for patient centricity – are there are any particular device types or therapy areas you think will see the most advancement or the most investment?

TO: Delivery devices for weight management drugs such as GLP-1s are, unsurprisingly, attracting huge development interest and funding. Originally developed to treat type 2 diabetes, several GLP-1s have been approved for weight management and weight loss since Saxenda was approved in December 2014[1].

Table 1: Example GLP-1s and their brand names for diabetes and weight management indications.

	Dosing frequency			Brand name for each indication	
Drug	Twice daily	Daily	Weekly	Type 2 diabetes	Weight loss
Exenatide	X			Byetta	
Liraglutide		X		Victoza	Saxenda
Lixisenatide		X		Lyxumia	
Semaglutide (tablet)		X		Rybelsus	
Semaglutide			X	Ozempic	Wegovy
Tirzepatide			X	Mounjaro	Zepbound
Exenatide			X	Bydureon	
Dulaglutide			X	Trulicity	

Closed-loop drug delivery systems have now been proven in the management of diabetes. These systems use a diagnostic device, an algorithm, and a drug delivery device to manage the medication delivery automatically. There are investments in optimisation of insulin delivery systems, and the opportunity to use the technology for other therapies.

Finally, the ophthalmic drugs in development, and the new solutions that they require, has created a steady stream of device innovation over recent years and we expect that to continue or even increase in 2024.

Q) we hear smaller companies are now driving much of device innovation – are there any hubs emerging in Europe where see several promising start-ups are emerging from (or is innovation still quite spread)?

TO: The drug delivery device and packaging industry is relatively small (most people know each other!) but at the same time globally distributed. Innovations can come from anywhere in the world, and the range of people working in the industry seems to be diverse when compared to some other technical and engineering industries.

Nevertheless, there are some concentrations of talent and companies which are conducive to start-ups emerging. Well known hubs include Cambridge and Oxford in the UK, the Frankfurt area, the areas around Geneva and Zurich, Medicon Valley in Southern Sweden and Eastern Denmark, and in the US Silicon Valley, the Research Triangle in North Carolina, several clusters in the mid-West, and Greater Boston.

Author biography

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Tom leads engineering and scientific teams developing new injection devices, pumps, and inhalers. He has been the named inventor on dozens of patents throughout his 25 years' experience in the industry.

His most recent work focusses on developing robust device strategies and plans for a wide range of clients from the largest multinationals to the most dynamic start-ups.

Tom is a regular speaker at various international conferences on innovation and medical device development. He read Engineering at Cambridge University before becoming the Choate Fellow in Human Physiology and Pathology at Harvard University.

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