CPHI Online

2025 Pharma Trends Outlook:

Collaborative Pharma – A New Era of Supply Chains

Welcome

Welcome

Thank you for downloading the 2025 edition of our annual CPHI Online Pharma Trends Outlook. In these reports, we take a look at the past year of pharmaceutical supply chain activities and forecast emerging trends and hot topics for the industry in the coming year.

2024 has been a bustling year for all involved in the industry. Acquisitions such as that of Catalent by Novo Holdings and potential legislation like the BIOSECURE Act, as well as global events such as the 2024 US election results and the ongoing conflicts in Gaza and Ukraine have shifted many attitudes and prospects within the pharmaceutical supply chain.

Continued focus on geographic diversification and the responsibility of sustainable practices also inform many of the trends in supply chain reconfiguration we are seeing today and potentially the future.

Welcome

The coming year will also see existing technologies being leveraged for consumer-driven demand in therapeutic areas such as oncology and chronic, degenerative diseases. Radioligands and radiopharmaceuticals are set to take the industry further than before, and continued focus on metabolic diseases will aim to meet the demand for weight-loss and diabetes drug products, particularly GLP-1 agonists and similar therapeutics. 2025 is set to become an exciting year of manufacturer and investor activity as companies scramble to find the next blockbuster drug in anticipation of the upcoming 'patent cliff'.

As part of the 2025 Pharma Trends Outlook, a roundtable discussion was held at CPHI Milan on October 9, 2024 to bring together leading pharma experts to consult on the biggest topics for pharma in 2025. We thank our many participants for their time and insight during a very busy event! As a leading event for the pharmaceutical supply chain, the Pharma Trends Outlook roundtable and report solidifies the importance of events like CPHI in generating new ideas and solutions to some of the biggest challenges facing the pharmaceutical industry.

"We at CPHI are proud to bring the biggest pharmaceutical trade show to life each year, and we hope you continue to enjoy our year-round content with reports such as this 2025 Pharma Trends Outlook report."

Vivian Xie
Editor, Pharma
Informa Markets

Patient-centric technology and Pharma 5.0

Patient-centric technology and Pharma 5.0

In last year's 2024 Pharma Trends Outlook report, we explored how Generative AI and the digitisation of the pharmaceutical supply chain would evolve. From data-oriented manufacturing, optimising all aspects of bioprocessing, transparency regarding sustainability, and active and intelligent design of drug molecules, pharmaceutical packaging, and more, Pharma 4.0 harnessed the power of AI tools and machine-learning to bolster pharmaceutical supply chain operations [1].

With the transition from Pharma 4.0, wherein AI and Deep Learning technologies prevailed, Pharma 5.0 brings with it a shift in mindset regarding the digitisation of the pharmaceutical industry. Namely, a focus on human-centred and patient-centric uses for these technologies are taking centre-stage [2]. The personalisation of products is especially important for the field of pharmaceuticals [3]. This new age of industrial revolution will usher in a new way of working with digitised manufacturing – humans and machines working together [3].

Pharma 5.0 will explore not only how AI can bolster pharmaceutical workflows but also how to extend these benefits to healthcare practitioners and ultimately to patients.

> **"One aspect that we are observing is not only focused on making technology more patient-centric, but also on improving the efficiency of communication between patients, doctors, and pharmaceutical companies,"**
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> 
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> **Enzo Troncone**
> Founder and CEO of Butterfly Decisions

"Key points here include understanding the major advantages of using AI today, evaluating the reliability of these technologies, and recognising that implementing such advancements requires significant investment.

Without the right resources, developing the technology needed for a patient-centric system to effectively support healthcare becomes challenging."

And the industry is responding in kind. Global spending on drug products is expected to increase by 3–6% in the next 5 years, amounting to a whopping USD$1.9 trillion [4]. More and more companies are incorporating AI and machine-learning technologies into their drug product operations – the US FDA has seen a surge in applications for biologics and drug products that utilise some form of AI in their processes [4]. In total the market for AI use in drug discovery is projected to grow to USD$7.94 billion by 2030 [4].

"The European Union, for example, have invested in a recovery plan post-COVID called PNRR," explains Troncone. "More than EUR200 billion was invested in the Italian economy, and a large portion of that money will go towards healthcare systems – around 15 to 20 billion. This aspect is important – if you don't have the right resources, you will not develop the right technology to have more effective, patient-centric healthcare systems."

However, challenges continue to surround the applications and validation of AI applications, especially in a highly scrutinised industry such as pharmaceuticals [5]. For drug manufacturers, delivering the needed healthcare results to patients as part of Pharma 5.0 will require a strategic approach to the implementation of AI in processes [6]. A one-size-fits-all approach will not serve an industry looking to tailor their manufacturing evolution [6]. The alignment of AI and machine-learning technologies with clearly defined needs and goals will maximise the capabilities offered by Pharma 5.0 [6].

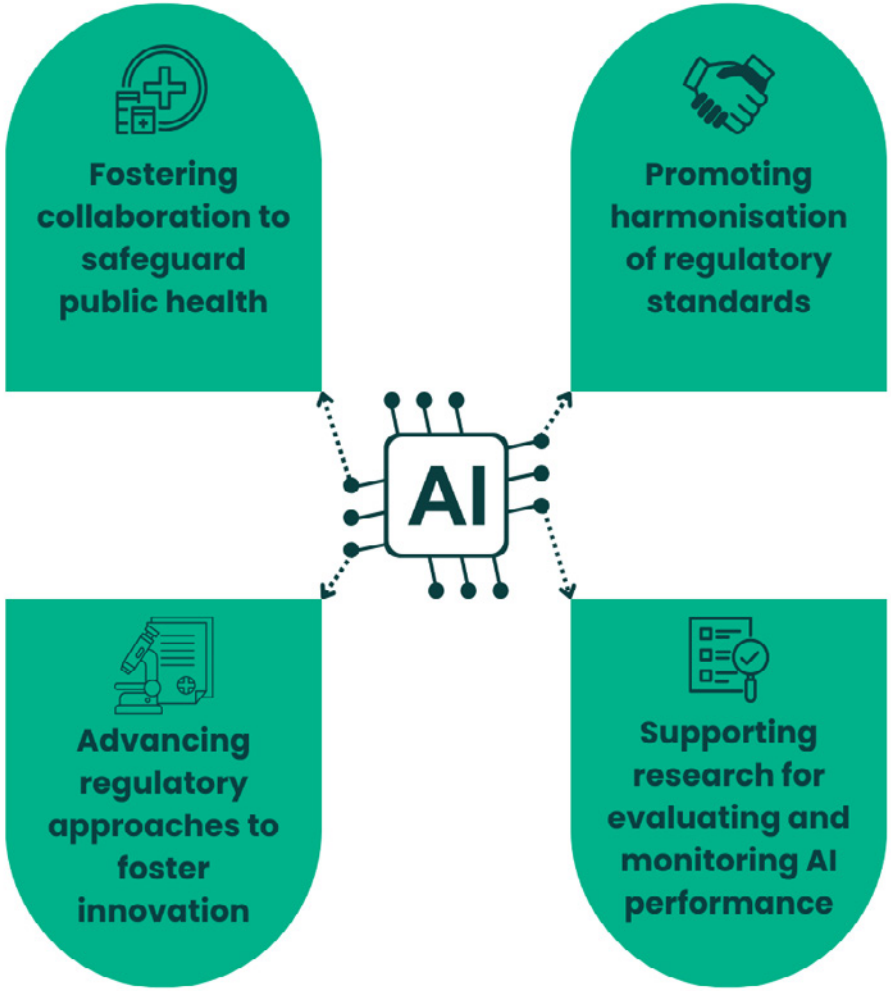
"In order to have an AI strategy, ask yourself this question: what do you want AI to solve for you?" adds **Catarina Abreu, Head of Nutraceuticals at PIPA LLC.** "If we really want to implement a robust AI strategy, while considering ethics – especially while we are talking about patient centricity – for the transformative capacity of these technologies, we must not only analyse trends in the patient as a consumer, but also the shift in their behaviours. This is where we need to start."

Concerns are also being raised regarding the regulation of AI and Deep Learning technologies used during the drug development and manufacturing process. From molecule discovery to pre-clinial and clinical trial

conduction to commercialisation of safe drug products, the pharmaceutical industry remains a highly vigilant sector of healthcare. This tension comes as Pharma 5.0 wrestles with the making digital technologies work for humans rather than at the cost of [7]. In response to the challenges of AI implementation in the pharmaceutical industry, which include maintenance and optimisation of the supply chain, balancing improved patient outcomes with financial investments and profits, the implementation of generative AI models and large language models (LLMs) responding to human-generated data, and the ethical concerns of accountability and harmonising regulations, among others, several national health agencies have begun to implement some means of oversight on AI use in pharma [8].

For example, the use of LLMs in supporting regulatory tasks and processes have exposed certain risks around data security and inaccurate answers [8]. Report generation and summarisation of clinical and safety data, while meant to expedite decision-making, can hinder the whole operation if inaccurate [8]. The EMA have since issued several recommendations for

Regulatory focuses for AI in pharma



regulatory authorities seeking to ensure the safety of both data input and output regarding LLMs [8].

In October 2024, US FDA published an article in JAMA with a detailed perspective on regulating AI in healthcare, including pharmaceutical product development and manufacturing [9]. In the article, FDA medical product centres described four key areas of focus for the future of AI use and development in medicinal products: fostering collaboration to safeguard public health, promoting harmonisation of regulatory standards, guidelines, tools, and best practices, advancing regulatory approaches that support innovation, and supporting research related to the evaluation and monitoring of AI performance [9]. The bottom line amongst these areas of focus is the balance between fostering innovation within healthcare industries and supporting the needs of those who need it most – the patients [9].

"In today's market, where patient-centred and consumer-centred approaches are increasingly important, companies need to ensure their AI strategies consider both ethics and data quality," comments Abreu. "For example, consumer expectations have evolved dramatically. Years ago, companies would ask doctors

what treatments to prescribe. Now, consumers are actively researching and demanding products based on their health benefits, safety, clean labels etc. Since I entered the industry over 15 years ago, clean label products have always been a topic of discussion, but consumers today are more informed than ever. There are now apps that allow consumers to scan product labels, whether it is for pharmaceuticals, nutraceuticals, or food supplements, and instantly assess the safety or compliance with standards like Generally Recognized as Safe (GRAS) status in the US."

Abreu relates this to the importance of pharmaceutical professionals and experts in the implementation of AI strategies: "Humans are essential for validation and play a critical role in the process. This is a cyclical process – we create the algorithms, but we also ensure they are properly validated... It's not just about creating the algorithms or machine-learning models; it's also about ensuring that they function correctly. The system's understanding and growing intelligence require continuous human input to make sure everything is working as intended."

Establishing a pharmaceutical data boundary

Establishing a pharmaceutical data boundary

Data generation, processing, and analysis in particular is a topic of great interest and concern for the pharmaceutical industry regarding the implementation of AI strategies in workplaces.

"The thing to emphasise is that to develop a successful AI strategy, you must first have the right data," explains Abreu. "From our experience working with companies seeking AI strategies, one common issue is the lack of data. Many organisations aren't collecting the data they need, or when they do, it's often incomplete or unstructured. It's also important to recognise that 'bad' data is just as valuable as 'good' data. Bad data, such as when a lab test doesn't yield the expected results, can be critical in process optimisations. Understanding why something didn't work is just as important as knowing what does work. This data helps optimise processes,

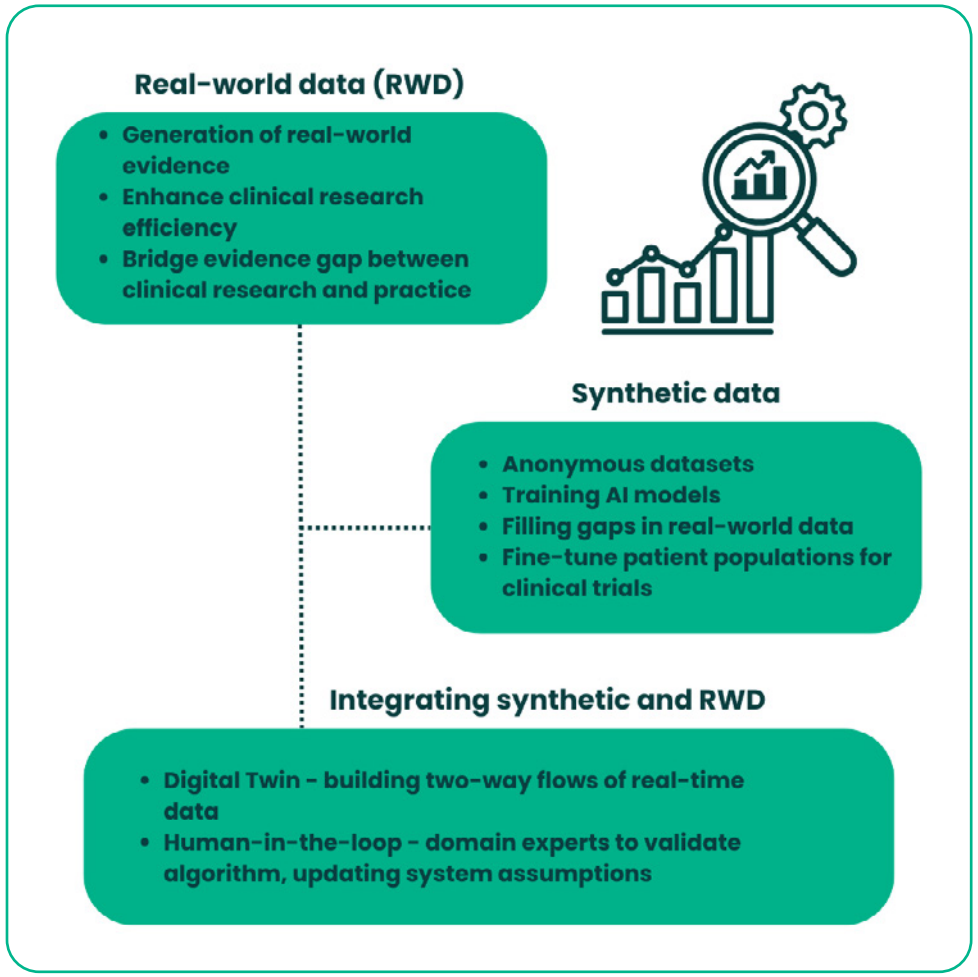
improve supply chains, and reduce costs. It could even lead to better energy management, resource allocation, and time efficiency."

Using AI and Deep Learning technologies in the pharmaceutical supply chain for data acquisition and analysis is nothing new – our 2024 Pharma Trends Outlook discussed two pillars of generative AI use in the pharmaceutical supply chain, one of which was Big Data Analytics [1]. In targeting specific patient populations during sourcing to bottleneck and efficiency improvements during manufacturing, Big Data Analytics has a lot to offer the pharma supply chain – if used properly [1].

"A clear data boundary is essential," comments **Purna Thakker, Founder and CEO of ADPT Solutions.** "This refers to the specific data you choose to work with and analyse. In my company's case, the data is always generated internally within the company. However, I've noticed that as AI becomes more accessible, people may turn to tools like OpenAI's Copilot without fully understanding the implications. I tested Copilot by asking it to generate a quality manual. It provided a list of items to include, but if you examine the details, you would find that the data it uses is collected from various companies and reflects their interpretations rather than regulatory standards. This highlights an important point: to create reliable AI systems, you first need a deep understanding of the data and the regulations that govern it. Only then can you build AI models that are accurate and easy to validate."

However, some disagree as to the potential of AI in generating said data. "When I talk to a number of CEOs right now with the ambition to digitise, there's a definite rhetoric of whether it is possible to remove the human in the process of creating data in the first place," mentions **Neil Kelly, CEO of Vector.** "The question is whether the appetite is there for removing the 'human' as a barrier to be successful in digital."

The field of synthetic data continues to develop, with the potential in the healthcare sector to benefit screening and healthcare policies, clinical interventions, fine-tuning patient populations for clinical trials, and more [10]. Some studies have already investigated the use of synthetic data in healthcare, such as using such data as a proxy for real-world data obtained from large-scale health surveys [10]. However, these studies continue to use partially synthetic data, and concerns remain regarding



inherent bias in generative models, lack of transparency in synthetic data, accuracy and interpretability trade-offs, and necessary and robust auditing methods [10].

Abreu responds that "This is a cyclic move, meaning that we as humans create the algorithms, but we also ensure that we have a team to validate the process. This team can include scientists, bioinformatics, data analysts, and others. It's not just creating an algorithm or machine learning – it's also making sure that these technologies function properly and the system is understanding and growing that intelligence, which needs to have human input."

Troncone, however, disagrees. "I believe it's possible to generate data by integrating human-generated data with synthetic data," he states. "This creates a model that simulates the behaviour of a system, and those systems can generate data for you – this is a well-known technique not just used in healthcare but also in energy and other fields. The best approach is to integrate in a process we call 'human-in-the-loop', with someone validating the algorithm, that is the assumption behind the system that is simulating the data. I agree that the first step is asking the right question, but this does not come from a data scientist, it should come from domain experts."

The future of strategic pharmaceutical collaborations

The future of strategic pharmaceutical collaborations

2024 brought with it a major shake-up for the pharmaceutical outsourcing sector. In early February, Novo Holdings announced their acquisition of pharma and biotech CDMO Catalent for US$16.5 billion, setting in motion questions regarding the fate of the wider pharmaceutical supply chain [11]. Mergers and acquisitions within the pharmaceutical industry are nothing new – however, this may be the first time in a long time that a pureplay outsourcing company has been snapped up by a drugmaker to meet unprecedented patient demand for Novo Nordisk's blockbuster GLP-1 drugs in aiding weight loss [12].

The complexity of the pharmaceutical supply chain

was made evermore clear during the COVID-19 pandemic, and Catalent's acquisition has exposed other potential roadblocks to supply chain transparency [12]. Those already in contract with Catalent were left in a partnership quandary – what would this mean for their existing projects with Catalent? Though it took a few months, an open letter published in October 2024 detailed Catalent's position: "[Catalent's] commitments to you will not change, your products will remain our focus and your proprietary information will be protected" [13]. Even so, some drugmakers such as AstraZeneca and Abbvie have questioned and posited the importance of developing one's own independent supply chain and in-house manufacturing capacity over outsourcing partnerships [11].

Moreover, such acquisitions could signal issues for certain types of therapeutics. As one of the top gene therapy CDMOs in the world, there exists the potential (though this remains to be seen) for future unavailability of CGT manufacturing capabilities should Catalent be restricted from its outsourcing partnerships [12]. However, that is not to dismiss the capabilities of other contract firms anticipating what the industry will need as Catalent's acquisition develops. Whether drugmakers will choose to invest in their own in-house manufacturing or seek other partners remains to be seen.

Other pharmaceutical partnership disruptors include the recent BIOSECURE Act, which has passed through the US House of Representatives and, if signed into legislation, will prevent US pharmaceutical and biotechnology companies from contracting and partnering with certain Chinese CDMOs, namely WuXi [14]. While the industry has already begun to make moves in response to the Senate's pending decision – Hong Kong shares of WuXi AppTec and WuXi Biologics have already slumped by 11% in September – there are differing opinions on what precisely the Act means for the contract pharmaceuticals sector.

"It's important to remember that WuXi and its subsidiaries are an exception among Chinese CDMOs," explains **Claudia Lin, Executive VP at Pharmatech Associates, a USP Company.** "WuXi has successfully expanded its business rapidly, particularly in the US and EU, but this level of success is not common. WuXi's success was a result of the right circumstances, visionary leadership, and significant investment.

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When considering whether other companies or regions can replace WuXi's capacity, it's essential to understand that replicating their success isn't as simple as building more facilities. Operating at WuXi's level of technical expertise, quality, and compliance takes time and significant effort. This reality applies to all companies, even some American ones, who might see opportunities arising from the challenges Chinese CDMOs face under the BIOSECURE Act. To take advantage of these shifts, companies need more than just capacity – they must be able to operate with the same level of technical excellence and regulatory compliance that WuXi has demonstrated. This point cannot be overstated: success in this space is about much more than just scaling up operations."

Unmesh Lal, Global Research Director at Frost & Sullivan, is more optimistic about long-term opportunities in the face of short-term uncertainties: "The BIOSECURE Act will impact Chinese CDMOs & CROs that have been at the forefront of innovation and the transition towards a CRDMO business model; the near-term uncertainty shall lead to geographical diversification, divestitures, and corporate restructuring along with the reconfiguration of supply chains in the mid-term. This in turn shall create long-term growth opportunities for South Korea, India, and other Southeast Asian markets, wherein we are witnessing investments in capabilities, talent, and capacity expansion by contract pharma service providers, particularly as we've seen an increase in IPOs for Indian CDMOs."

However, there is some disagreement as to the impact on specific sectors such as CGTs. While Lal mentions that existing CDMOs have excess capacity for the CGT market, and may be well-positioned to serve this area, Lin is cautious on the ability of these existing CDMOs to begin investing in scaled production of CGTs, which is not necessarily a result of the BIOSECURE Act itself. "CGTs and new biologics are inherently more variable than traditional biologics. Scaling up for monoclonal antibodies can work because they require large-scale production and multiple sites. But you cannot apply the same strategy to CGTs. Even WuXi was unable to accomplish this by just building massive facilities. They shut their Shanghai facility down within 3 years because it just wasn't viable. Companies need flexibility and variety rather than scale numbers."

Regardless of the reason why drugmakers choose to partner or not partner with contract organisations, collaborations are becoming evermore strategic and competitive. The pharmaceutical contract organisation sector will see the next year become a decisive time to optimally position themselves to meet the increased demands of an everchanging industry dynamic.

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Global pharmaceutical supply chain reconfigurations

Global pharmaceutical supply chain reconfigurations

The BIOSECURE Act may not just impact Chinese CDMOs, but the entire global supply chain for the pharmaceutical industry, along with existing supply chain disruptions. Experts point to a potential complete reconfiguration of the entire pharmaceutical supply chain.

Aurelio Arias, Director at IQVIA, states that, "It's fascinating to consider the supply chain reconfiguration aspect of this situation. The first-order effect is the potential drying up of the supply into the US as a result of the ongoing decoupling efforts with China. Europe hasn't been as aggressive in this decoupling process – they seem more focused on risk reduction than full disengagement. However, the demand gap in the US

remains significant, and it will need to be filled by other countries. This presents a valuable opportunity for Indian, Southeast Asian, and European manufacturers to step. The second-order effect is that WuXi Biologics and other Chinese manufacturers won't disappear; instead, they'll redirect their excess capacity to other markets. This oversupply could drive prices down in regions that hadn't anticipated this influx. Europe is an obvious target to absorb some of this capacity given its large market size, and similarly, other Asian markets could become focal points for Chinese manufacturers. However, this shift could create unintended consequences for European manufacturers. While they might find opportunities in the US market, they could face increased competition domestically as Chinese supply enters Europe. This would force European manufacturers to navigate both opportunities abroad and challenges at home. Ultimately, this reconfiguration of supply chains raises an important question; do policies like these truly reduce reliance on a single country, or do they merely reshuffle dependencies? The supply chain may become less efficient overall, but China isn't going anywhere. It will remain a key player in the global market."

"I think there is clearly a high barrier to entry space, even when considering expansion. What WuXi Biologics has built over time is a comprehensive, end-to-end continuum of capabilities, spanning discovery, development, and large-scale manufacturing," adds **Pushpa Vijayaraghavan, Director and Practice Lead – Healthcare at Sathguru Management Consultants**. "Their business model is deeply integrated and this seamless continuum is a challenge to replicate, particularly from a customer perspective, as bridging the gap between capabilities takes significant effort and time. CROs and CDMOs across regions like the US, Europe, India, South Korea, and Japan are well-positioned to capitalise on the opportunities presented, however much will depend on the pace of execution, particularly in capacity expansion and preparing to meet market demands. The next 12-18 months will be critical. This period will determine how global CROs and CDMOs step up to address the supply gaps and ensure these gaps do not become obstacles to the industry's growth. The risk of supply shortages is a looming concern that could impact the sector's trajectory if not managed effectively."

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Building supply chain resiliency remains a mainstay topic for the entire pharmaceutical industry, whether this be through nearshoring efforts or other strategies.

"FDA budget allocation for supply chain is incredibly necessary to improving the FDA's data infrastructure and their ability to respond to shortages more efficiently," comments **Molly Bowman, Head of Strategy for Pharmaceutical Supply Chain Management at Clarivate.** "However, the consensus seems to be that the agency will likely require much more funding to build long-term supply chain monitoring and mitigation systems to ensure a robust US drug supply chain."

Additionally, the increased interest in certain drug products, such as GLP-1 agonists, will have certain effects on how the supply chain will need to adapt. "The increasing popularity of GLP-1 agonists like Wegovy, Ozempic, and Zepbound have significant implications for the pharmaceutical supply chain," Bowman adds. "Increasing demand for these treatments strains manufacturing capacity and distribution channels as well as requiring increased production. These synthetic peptides require specialised production facilities and temperature-controlled logistics, which adds complexity and cost to the supply chain. As more companies develop GLP-1 agonists and as competition increases companies will need to improve their supply chain efficiency to stay competitive."

As the industry watches with bated breath on how the supply chain will fare under these new conditions, experts unilaterally agree that preparing for the worst by considering all aspects of scaling capacity AND technical expertise will be critical in the coming months. Concurrently, drugmakers will have to carefully plan and prioritise the kinds of partnerships they need, as well as where.

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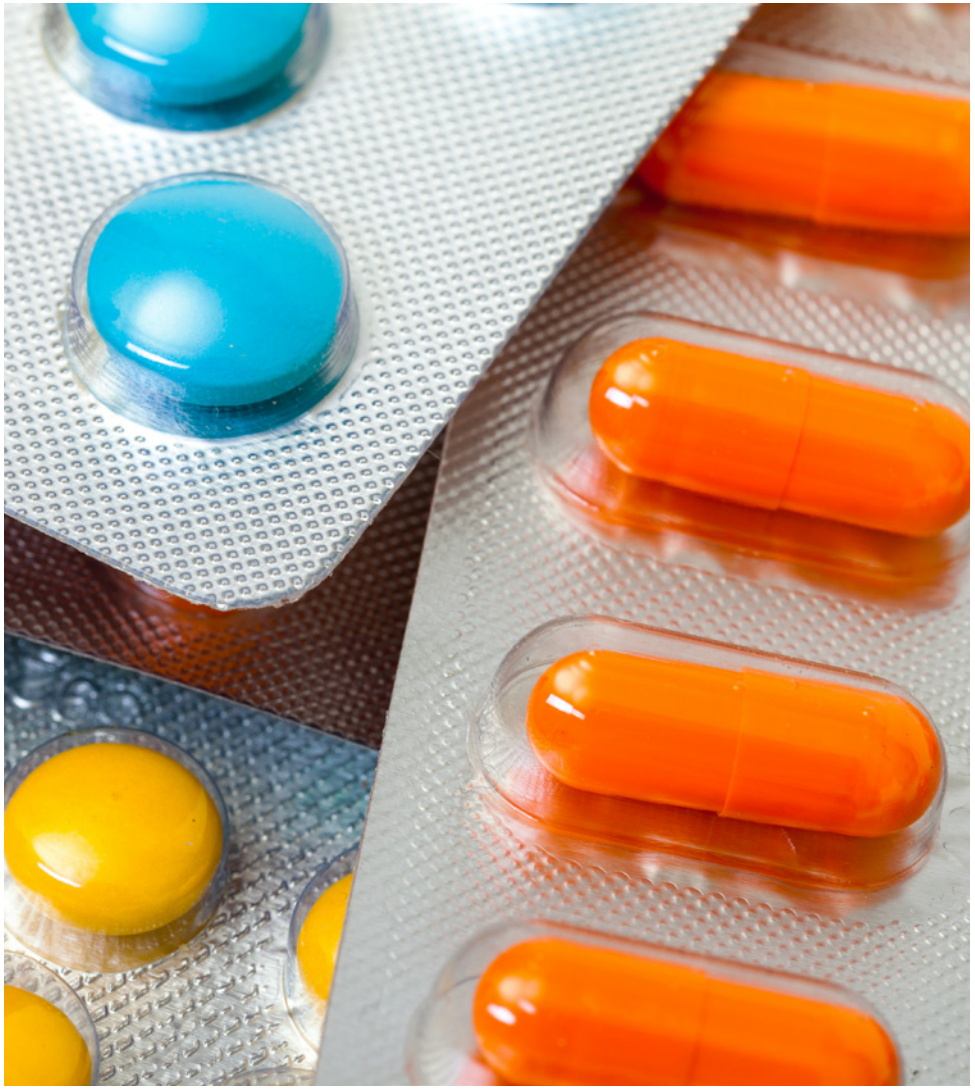
An eye on India's pharmaceutical manufacturing

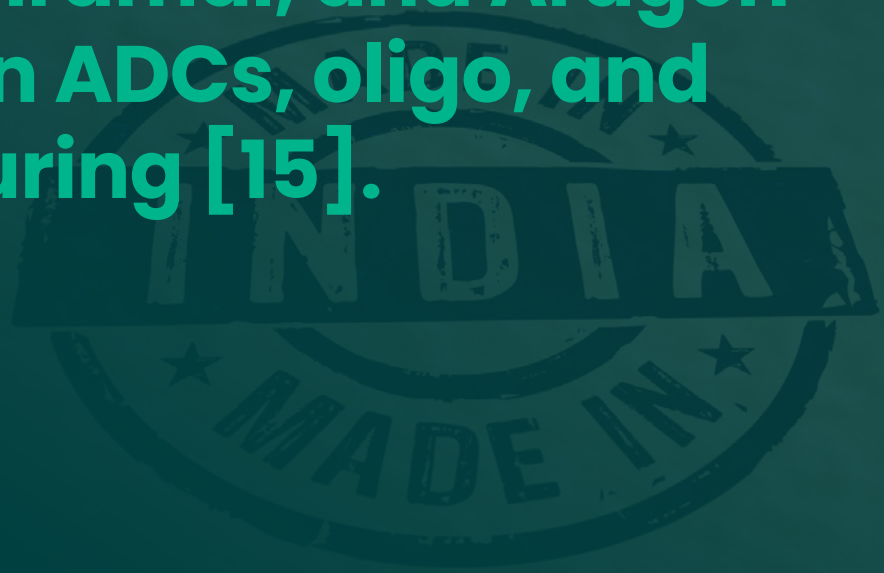
An eye on India’s pharmaceutical manufacturing

One region that may see an increase in activity and partnerships is the Indian manufacturing sector. With a major market out of play with the BIOSECURE Act, as well as increasing demand for capabilities in areas such as CGTs and novel modalities and technologies, the market is poised for another regional manufacturing superpower (despite the industry’s calls for regional diversification).

The Indian CRDMO industry currently holds around 2-3% of the global market share but many anticipate significant growth for the sector [15]. It has led the way in expertise for areas such as generic API and formulations manufacturing, and with small molecules contributing around 60% to the global CRDMO industry, India’s contract manufacturing sector is set to make strides in advanced manufacturing capabilities like antibody–drug conjugates [15].



India also boasts the most USFDA-approved sites outside of the US [15]. Along with biologics and biosimilars, Indian companies are also looking to address a gap in the small molecule CDMO space, with top Indian CDMOs such as Syngene, Piramal, and Aragen building capacity in ADCs, oligo, and peptide manufacturing [15].



"India is poised to play a pivotal role in the biosimilar space, as many Indian companies are deeply committed to the development of biosimilars," comments **Sudarshan Jain, Secretary General and Committee Member at the Indian Pharmaceutical Alliance and IGBA.**

Nikhil Chopra, CEO of JB Chemical and Pharmaceutical, agrees. "What India has shown in the last decade is that they have the capabilities to deliver high-quality drugs at affordable prices," he states. "Affordability remains a critical issue in [India], where 90% of healthcare expenses are paid out-of-pocket given the low penetration of health insurance. This reality places immense pressure on ensuring that essential medicines are accessible to patients. Nevertheless, India's progress in the pharmaceutical sector has made a significant different both nationally and globally."

India also boasts the most USFDA-approved sites outside of the US [15]. Along with biologics and biosimilars, Indian companies are also looking to address a gap in the small molecule CDMO space, with top Indian CDMOs such as Syngene, Piramal, and Aragen building capacity in ADCs, oligo, and peptide manufacturing [15]. Specialised formulations are also expected to see the rise of Indian manufacturers proliferating the market [15]. The Indian biopharmaceutical CDMO sector is already valued at US$15.6 billion as of 2023, and is expected to reach almost US$27 billion by 2028 [16]. The past decade has seen a growth in technological infrastructure for the biomanufacturing sector, and the development of a skilled workforce with the required expertise [16]. With similarly lower labour costs, infrastructure, and skilled workers as China, many expect India to serve those looking to mitigate current and future risks in their supply chains [17].

Chopra adds that, "10 years ago, [India] was largely known as a volume-driven generics producer. Today, Indian companies have shown remarkable capabilities in delivering high-quality drugs at affordable prices. India's progress in the pharmaceutical sector – delivery affordable, quality medications – has made a significant difference. In the long run, this will benefit the country and provide much-needed relief to all patients."

Whether the rise of India-based pharmaceutical contract organisations is a direct result of the BIOSECURE Act is still up for debate – what is almost unanimously agreed is that India's biopharmaceutical sector is one to watch in the coming years.

Biologics patent cliff: A turning point for new modalities

Biologics patent cliff: A turning point for new modalities

2025 will also be a turning point for many drugmakers as some of the biggest blockbuster drugs come off of patent [18]. Between 2023 and 2030, 18 of the world's largest pharmaceutical companies, from Abbvie to Johnson & Johnson, are bracing for a potential decline in revenue once the patents for leading branded products expire [19].

The patent cliff might not spell all doom and gloom, however. This is not the first time the pharmaceutical industry has faced such expirations, and a few key trends are emerging as the industry prepares for another wave of patent expiries [18].

"As we approach the biologics patent cliff around 2030 – particularly with checkpoint inhibitors like PD-L1 therapies coming off patent – we're seeing interesting trends," comments Arias. "For example, while drugs like Keytruda have been highly impactful, they appear to be reaching their efficacy ceiling, and some competitors are now producing therapies with greater effectiveness."

Perhaps the biggest question the patent cliff poses to the pharmaceutical industry is not one of profit, but one of innovation. "One key concern is that the biologics patent cliff isn't being adequately addressed with biosimilar alternatives," Arias adds. "Developing biosimilars is simply too costly, which leaves many biologics coming off patent without suitable replacements. [IQVIA's] analysis shows that nearly 70% of biologics losing patent protection between now and the end of the decade will not have biosimilars ready. The pipeline focus tends to prioritise oncology or immunology biologics with billion-dollar revenues, leaving smaller, orphan, or more complex biologics without alternatives."

Such concerns beg the question regarding balance between patient access to life-saving drug products and where the industry should prioritise innovation. "This raises a societal question: Should we aim to develop biosimilar alternatives for smaller and more complex

biologics, or are we content with addressing only the high-revenue monoclonal antibodies?" questions Arias. "The savings from biosimilar development do not currently justify the growing investment required for new technologies, especially as modalities evolve. For instance, ADCs are gaining significant investment but are incredibly challenging to replicate. Similarly, bispecific and multispecific antibodies are complex, and few companies are confident about replicating these. Many companies are reluctant to engage with these areas, which could lead to a situation where innovator companies develop 'off-patent-proof' medicines that remain prohibitively expensive."

Jain adds that "The critical question is this: while many biosimilars are expected to enter the market, the cost of developing them remains high – from a patient's perspective, however, biosimilars offer hope as potential solutions for many previously untreatable diseases. There are two key developments like to shape this landscape. The first is that the regulatory environment will need to evolve to align more closely with patient needs. The second is that biologics companies are increasingly using patent strategies to extend the lifecycles of

their drugs. Humira has leveraged over 250 patents to prolong its exclusivity. This raises an ongoing debate: are patient rights more important than patent rights? This question will only grow more prominent over time. For the healthcare and pharmaceutical industries, there is a clear responsibility to strike a balance. While innovation is undeniably vital, it must not come at the cost of accessibility."

Vijayaraghavan, however, sees more opportunity for the industry and for patients in the years to come. “There are two key themes worth highlighting. First is the critical issue of low- and middle-income countries (LMIC), and the second is lifecycle management, which encompasses both technology innovation and delivery advancements,” she states. “CGTs remain a major global priority for innovation. While monoclonal antibodies

are well-established and the ‘immune checkpoint inhibitor cliff’ looms, cell and gene therapy represents the strongest growth area in the global pipeline. What’s particularly noteworthy is the emergence of LMIC-originated cell and gene therapies. We are now seeing pipelines developed in LMICs, with strategies focused on achieving regulatory approval and market access in their home countries first – for example, India-originated cell and gene therapies being approved in India or China-originated therapies being approved in China.

This marks a significant shift toward LMIC-developed innovations serving LMIC patients directly, running parallel to Big Pharma pipelines advancing through FDA and European regulatory pathways. 5 years ago, this trend was far less pronounced, but it has intensified in response to the pressing access challenges posed by the high pricing of current cell and gene therapies, often exceeding half a million dollars per treatment. Meanwhile, biosimilars and biologic follow-ons remain a complex space. Innovators are focusing heavily on antibody-drug conjugates (ADCs), such as trastuzumab ADCs, as well as on delivery innovations like reduced infusion times and patient self-administration. These advancements

offer clear benefits for patients, but they also create challenges for biosimilar companies, potentially delaying biosimilar launches. However, biosimilar manufacturers are also embracing delivery innovation to remain competitive. These dynamics will continue to evolve, but the emphasis on life cycle management – through both delivery innovation and next-generation modalities like ADCs – remains a focal point. For me, the dual trends of LMIC-originated cell and gene therapy pipelines and the evolution of biosimilar regulations are particularly exciting and transformative for the industry."

Alternatively, there may be a continued trend of further mergers and acquisition activity throughout the supply chain as companies look to strengthen their growth strategies and minimise the impact of patent expiries [18]. Regardless of the strategy taken, both drugmakers and contract organisations alike will need to band together to continue driving innovation while bringing accessible, lifesaving medications to patients [18].

Biomanufacturing and bioproduction for a sustainable industry

Biomanufacturing and bioproduction for a sustainable industry

Sustainability is not a new topic within the pharmaceutical industry, but the industry is buzzing with innovative technologies and strategies to tackle the issue of sustainability. One such emerging trend is the use of biomanufacturing and bioproduction within the industry, utilising biological systems to manufacture and produce commercial drug products [20]. Although not a new technology, biomanufacturing is continuing to evolve to meet challenges relating to sustainability and increasing the efficiency while minimising waste from pharmaceutical manufacturing processes [20].

"There's a lot of exciting innovation happening in synthesis right now," comments **Christina Smolke, CEO and Co-**

Founder of Antheia Inc. "Many countries are placing a strong emphasis on biomanufacturing and biotechnology. We're seeing tremendous advancements in areas like biocatalysis and cell engineering, where engineered cells and enzymatic routes are being used to produce complex ingredients, including intricate small molecules and large molecules. These innovations have the potential to transform how we produce critical pharmaceutical molecules to be significantly more sustainable, leveraging renewable feedstocks, reducing the use of harmful solvents and toxic chemicals, and minimising waste streams. Not only are these new processes more sustainable, but they are also more efficient and cost-effective. This shift is no longer theoretical – biomanufacturing is successfully producing pharmaceutical products at commercial scale and the market is receptive and eager for this innovation, as it adds resiliency and surety to these vital supply chains."

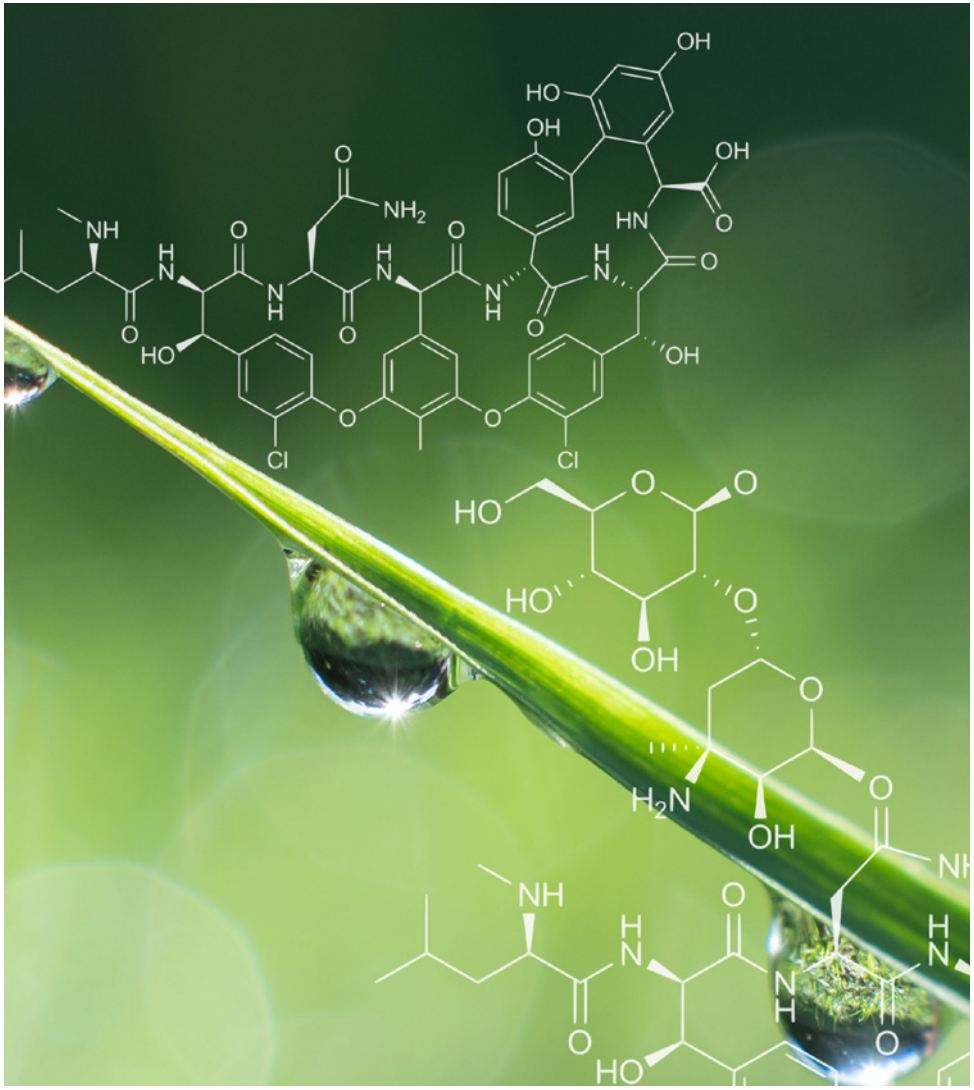
Interestingly, flow chemistry technologies are another established technology being brought to the forefront of sustainable innovation [21]. Offering such benefits as improved heat control, mass transfer, minimal impurity generation, and improved yields, flow manufacturing can also help pharmaceutical manufacturers to implement Green Chemistry principles into their workflows [21].

However, Smolke heed the importance of choosing the right manufacturing process for the intended molecule and product.

"When we talk about advanced manufacturing technologies continuous flow chemistry and manufacturing stand out," she says. "However, we also see biomanufacturing and biotechnology as complementary approaches. As someone who develops these processes, I firmly believe that these technologies work in harmony. Specifically, when dealing with complex molecules – whether large molecules or highly intricate small molecules – flow chemistry often lacks efficiency. This is where biomanufacturing shines."

> **Using enzymes as catalysts, we can carry out precise reactions under aqueous conditions to build molecular complexity in a highly efficient and sustainable manner. This creates a significant opportunity to expand biotechnology as a true complement to synthetic and flow chemistry."**

Christina Smolke
CEO and Co-Founder of Antheia Inc



"Going forward, there will be two clear paths: for certain ingredients, flow chemistry will continue to be the optimal approach; for a broader set of complex ingredients, biotechnology will enable the development of sustainable, cost-efficient processes."

Jing Li, Senior VP of Process Chemistry at PharmaBlock, agrees, adding, "While it may not be the best fit for certain modalities, like biologics, it has a significant impact when applied to small molecules. For companies like ours, where the core business is focused upstream – such as intermediates and raw materials – flow manufacturing has proven to be transformative. In upstream chemical transformations, many processes involve hazardous or dangerous reactions.

Flow chemistry offers a safer and more efficient alternative in these cases. That's why it has become a core technology in the pharma block space, where we are pioneering many advancements, including incorporating biocatalysis. I completely agree that flow chemistry might not be ideal for biologics or other areas, but for small molecules, it has substantial potential to enhance sustainability and operational efficiency. There's still a long way to go, but the impact is undeniable."

Sustainability collaborations become strategic

Sustainability collaborations become strategic

On collaborative strategies, an increasing trend towards partnerships that prioritise sustainability goals and implementing sustainable initiatives is affecting the kinds of collaborations seen throughout the pharmaceutical supply chain. **Managing Director of AllocNow Daniel Bochnitschek** comments, "It's a global challenge, especially Scope 3 emissions given the complexity of the supply chain. One of the prerequisites for achieving these sustainability goals is to have standards for sustainability accounting. You cannot be sure that your partners have calculated their metrics in a way that you can reliably use. This is a big challenge for the industry where metrics can be very heterogeneous and difficult to identify."

"With the EU Carbon Reporting directives, there is increasing pressure for transparency in pharmaceutical and biotech companies regarding their emissions across

Scopes 1, 2, and 3," adds Arias. "Looking at the data, there are clear trends. Scope 3 emissions – particularly those related to manufacturing – account for roughly 90% of a company's total emissions. This analysis focuses solely on emissions, not considering other environmental factors like plastic usage or toxicity. The upstream supply chain is receiving greater attention across all industries, including pharmaceuticals. However, if we examine the trajectory, it becomes evident that the pharmaceutical sector is far off-track to meet its Net Zero or even carbon neutrality targets. Companies are unlikely to achieve these goals by 2030, 2040, or even 2050 unless significant action is taken."

Arias points out that certain regions such as Europe have led the vanguard on tackling sustainability from a policy standpoint, while progress in the US has been slower. However, during the roundtable, he questions the impact of India as a manufacturing powerhouse and its stance on the question of sustainability. "Here in Europe, there is a cultural and corporate acknowledgement that change is necessary, and companies are increasingly committed to reducing emissions. However, given India's central role as the engine of global pharmaceutical production, collaboration and alignment with these efforts are essential. How is the conversation around sustainability evolving domestically within the Indian pharmaceutical sector?

Jain responds that, "Sustainability is indeed a high priority for India, and I can also speak from my role with the International Generic and Biosimilar Association. As far as the pharmaceutical industry is concerned, we need to develop a clear and comprehensive policy regarding the usage of plastics. The industry's reliance on plastics is significant, yet there is currently no robust plastic policy. Another critical area of focus is toxic antibiotic leakage, which poses significant environmental challenge. Addressing this issue requires global collaboration among pharmaceutical companies to mitigate its impact. While sustainability is a top priority for India, it is also a global concern that demands a collective effort."

Chopra adds that, "The challenge with Scope 3 emissions is the dependency on the supply chain and vendor compliance. Monitoring and ensuring adherence across the supply chain remains a significant hurdle." However, some optimism finds its way into the conversation. "The increasing awareness around sustainability is

encouraging," Chopra states. "Sustainability is now a central theme in many industry conferences in India, and the government continues to push initiatives such as waste management, water harvesting, and solar energy adoption. However, a more focused and collaborative effort is needed to address the complexities of Scope 3 emissions effectively. Looking ahead, as India sees a rise in healthcare infrastructure, particularly in tier-2 and tier-3 towns, new challenges will emerge. Balancing the delivery of quality healthcare with sustainability will be critical. This dual focus – improving healthcare access while ensuring environmental responsibility – will require strategic planning and collective action."

Elvire Regnier, Founder of Regenerative-Advisory, speaks to the actions companies can take, particularly in the procurement and sourcing steps of their supply chains, as well the tools and technologies available to help tackle the complex machine that is the pharmaceutical supply chain. "To implement such practices effectively, companies must dive deep into their supply chains, which can be incredibly complex," she acknowledges. "Managing this manually can be near impossible. Advancements in AI are now providing powerful tools to monitor and manage these supply chains. AI platforms can help identify risks in the supply chain. These tools track global activities, such as deforestation or unethical labour practices, by monitoring news reports, lawsuits, and other signals. When a potential issue arises, the system flags it and alerts the Chief Procurement Officer, and can then decide whether to take action such as engaging with the supplier or cutting ties. The crucial point is that these tools now exist and are more accessible than ever. 5 years ago, such comprehensive tracking was much harder to achieve. Today, companies have little excuse not to leverage these technologies to ensure sustainability, ethical practices, and compliance across their supply chains."

“AI platforms can help identify risks in the supply chain. These tools track global activities, such as deforestation or unethical labour practices, by monitoring news reports, lawsuits, and other signals.”

Elvire Regnier,
Founder of Regenerative-Advisor

On opportunities to both ensure and display sustainability credibility, Li offers some insight. “Many companies are now adopting science-based targets (SBTs) to objectively demonstrate their progress towards sustainability goals. As a supplier in the pharmaceutical industry, we are part of a larger ecosystem, and for us to meet our SBT commitments, we need our suppliers to share and commit to these same goals. At the same time, there is immense pressure within the pharmaceutical sector to prioritise cost efficiency and reduce expenses. Balancing this pressure with the need to adhere to stringent sustainability criteria is particularly challenging. However, our company is committed to this dual responsibility, and we are actively working with our supply chain partners to align on these objectives. This is an area that requires collective effort from the broader community, including forums like CPHI and others, to establish sustainability as a shared value. It’s important to recognise that sustainability doesn’t always mean choosing the cheapest option; sometimes, it requires investing in more sustainable practices, even if they come at a slightly higher cost. Pharmaceutical companies must understand that paying a little more for sustainability is an investment in a better future.”

Adding to the call for global collaboration, Vijayaragjavan says, “On one end, areas like packaging have seen considerable progress – such as the introduction of digital labels where regulations permit, replacing traditional inserts. Similarly, energy-related solutions are somewhat easier to address since they apply broadly to manufacturing operations, with transferable knowledge and best practices readily available. The more complex challenge lies upstream, particularly in transforming manufacturing value chains to meet scope one sustainability goals.

This will require significant innovation, especially in areas like biotransformation. While this opportunity is just beginning to gain traction, some regions are making strides – the US, for example, has initiatives like NIIMBL, and India now has a biomanufacturing policy, which BioE3 helped craft for the government. However, from an industry perspective, implementing these changes is daunting. For example, transitioning to enzymatic biocatalysis within large-scale chemistry reactions requires companies to develop entirely new capabilities. Today, most manufacturers lack the tools to identify the right enzymes for specific processes, test their

effectiveness at a biotech-chemistry interface, and scale them up from medium to large-scale production.

What's clear is that we need an infrastructure ecosystem to enable these upstream transformations at scale. This means bridging the gap between innovative biotech capabilities and large-scale manufacturers. Establishing cross-border collaboration platforms, similar to NIIMBL, can help drive this transformation. Cost pressures are real, but there's a significant opportunity to integrate enzymatic biocatalysis into API reactions.

Currently, only 0.1% of this potential is being utilised. Global collaboration is essential to unlocking this opportunity. The upstream transformation of API manufacturing represents the industry's biggest chance to create a positive sustainability impact over the next decade."

Future collaborations may even need to be less than favourable for the companies involved, as Regnier mentions: "Competitors can collaborate to create a shared framework – a common language and unified set of requests for the supply chain. While this practice isn't something I've seen yet in the pharmaceutical industry, it could be worth considering as a way to support progress in ESG initiatives. However, this effort must be done in collaboration with suppliers. Collaboration is essential because implementing ESG initiatives is challenging, and suppliers can be valuable partners in driving meaningful change."

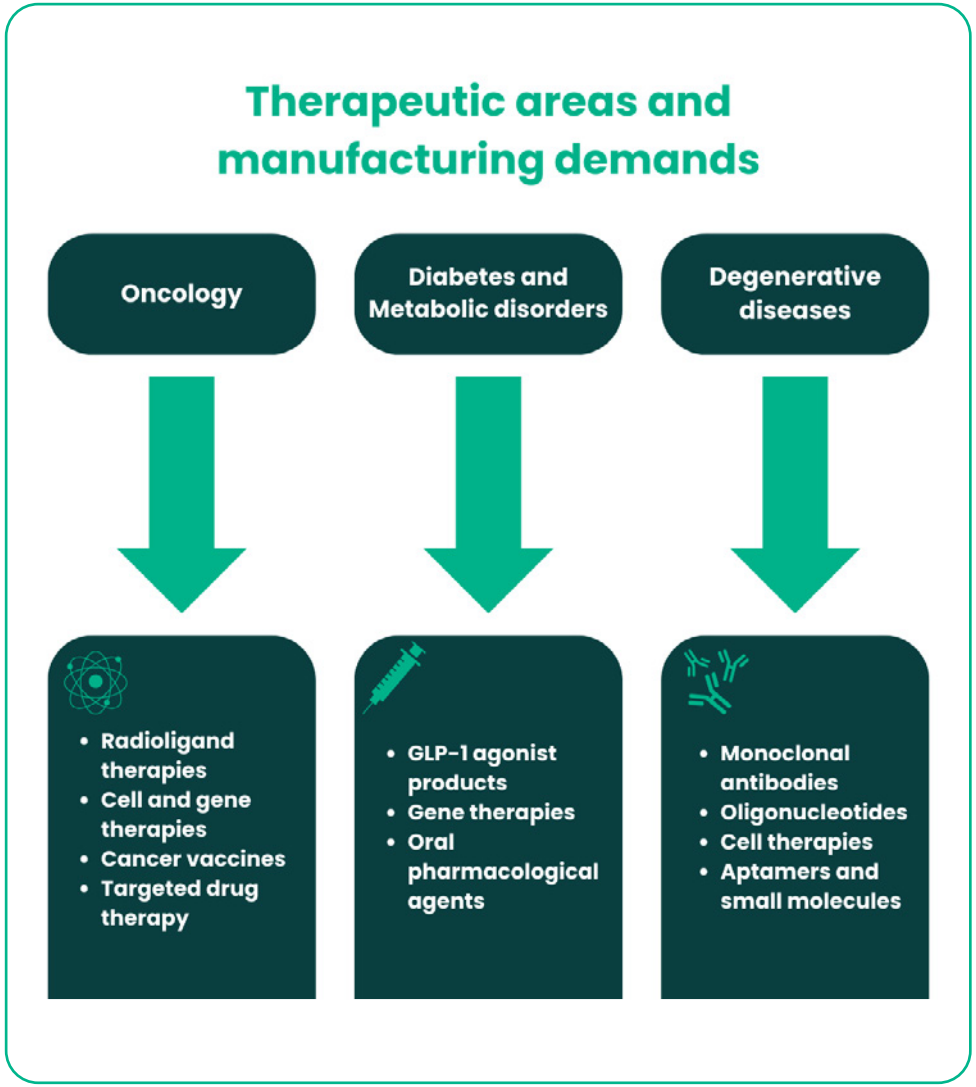
Top therapeutic areas of focus

Top therapeutic areas of focus

As we do each year, CPHI Online publishes an article on drug approvals to uncover the products that have been approved so far during the year [22]. Seeing what comes down the drug approval pipeline shines a light on where drugmakers and their partners are finding opportunities and challenges in the continued development of novel drugs [22]. These therapeutic areas, in turn, drive much of the R&D and manufacturing we see in such modalities as CGTs, peptides, mAbs, radioligand therapies, and mRNA treatments.

As of June 2024, 18 drugs across oncology, immunology, cardiovascular, and more have been approved by the US FDA [22]. This does not come as a surprise, according to experts.

"There's a noticeable shift happening in chronic therapy areas like cardiology, diabetes, obesity, and oncology," comments Jain. "These therapeutic areas have been



undergoing significant changes, especially as the industry moves from small molecules to larger molecules. Biologics in particular are becoming increasingly important, with biosimilars poised to create significant opportunities in this space."

Treatments for cancer and oncology clinical trials are expected value up to US$300 billion by the end of 2025. As one of the highest-tested therapies in clinical trials in the US (constituting 15.4% of trials analysed in a study by Definitive Healthcare), this volume is only expected to grow. Yet, following oncology is endocrinology and metabolic disease, perhaps attributable to the rise in demand for GLP-1 drug products in recent years [23]. Out of all the novel drugs approved by the US FDA in 2024, Immunology and Infectious Diseases and Oncology topped the charts [22]. And this trend is not US-exclusive.

"We're witnessing a significant shift from treatment of acute to chronic conditions, and within chronic conditions there's an especially keen focus on degenerative diseases such as rheumatology, oncology, and obesity-related conditions," states Chopra. "From the Indian perspective, as a developing nation, the emphasis is increasingly on early diagnosis and management of lifestyle diseases. This approach not only helps patients achieve better health outcomes but also improves their quality of life, especially as more drugs go off-patent and become accessible. This trend is particularly pronounced in lifestyle-related diseases, where early intervention can make a substantial difference. At the same time, there is rapid innovation in drug delivery platforms that combine therapies with advanced delivery mechanisms. These advancements are proving to be highly beneficial for patients, particularly in areas like glaucoma, obesity, and heart failure. Heart failure, in fact, is projected to become a major health challenge in the coming decade in India, given the current disease burden. To highlight the scale of the issue, consider some statistics: over 100 million people in India suffer from hypertension, and another 100 million are affected by metabolic disorders. Obesity is also emerging as a significant concern. The sheer magnitude of these conditions underscores the importance of early diagnosis, the availability of off-patent drugs, and innovative drug delivery platforms in addressing this growing burden. These advancements will play a critical role in improving patient outcomes and helping them lead better-quality lives in the future."

Consumer demand driving manufacturing investments

Consumer demand driving manufacturing investments

In a similar vein, there may be a trend towards certain manufacturing investments as a result of patient demands for certain medications. The star example of this trend is the boom in investment for Novo Nordisk's GLP-1 drug products, including semaglutide and liraglutide. In June 2024, Novo Nordisk announced plans to build a US$4.1 billion filling site exclusively for Wegovy injection pens [24]. Wegovy also made headlines when it was granted approval in the Chinese market, where obesity is on the rise with 540 million adults expected to be overweight by 2030 [24].

Other drugmakers such as Eli Lilly are also moving forward with their own diabetes and weight-loss drug products, scrambling to meet the demand [24]. With such visibility

and headline-making results, it's little wonder that drug manufacturers are beginning to take note of where it may be best to put their time and investments.

In addition, the great demand for oncology therapies and interventions, especially given the rise in colorectal cancer as the second-leading cause of cancer-related deaths [25] has created a surge of interest in radiopharmaceuticals [26]. While nuclear imaging has long been used in diagnostics, the pharmaceutical industry is now realising the possibilities of offering potential standalone interventions [26]. In fact, radiopharmaceuticals are expected to create up to US$27 billion in investments by 2031, providing a prime opportunity for manufacturers to provide services and capabilities in radiotherapeutics [26]. Some companies are already taking advantage – Europe's first industrial-scale facility dedicated to the manufacturing of lead-212-based radioligand therapies was opened in February 2024 by Orano Med [27] and Novartis announced in September 2024 the construction of two of their own radioligand therapy facilities in the US [28].

"It's important to consider where the demand is evolving and where investments are being made," Vijayaraghavan agrees. "It's clear that demand is shifting, especially in areas like cell and gene therapy. In the context of low- and middle-income countries (LMICs), chronic conditions such as diabetes are becoming a major focus. For example, semaglutide and peptides, which were not expected to grow significantly in volume, have suddenly exploded in demand. This shift in demand is impacting the technology platforms used, with recombinant DNA becoming more attractive in the peptide space, particularly for diabetes, due to its larger patient base compared to previous small-volume applications. So, we're seeing high demand in areas like peptides, chronic therapies, and cell and gene therapies. On the investment side, this is driving a response to meet that demand. However, in the cell and gene space, there are already reports of overinvestment in certain modalities. Incremental investments in these areas will require careful thought, particularly in determining where the next wave of investment should go. Additionally, there's a growing need for a geographical rebalancing of supply. As demand shifts globally, we're likely to see increased investment in supply chains in regions like India, the US, and Europe. This geographical rebalancing of supply will lead to further investments in infrastructure and capacity in the coming years"

Patient-driven pharmaceutical packaging and drug delivery

Patient-driven pharmaceutical packaging and drug delivery

Pharmaceutical packaging continues to be a mainstay topic for the industry as focus turns towards changing patient demographics and consumer demands [29]. As many countries face a rapidly aging population, the implications for the healthcare industry extend to pharmaceutical packaging and challenges related to non-adherence of lifesaving medication or taking multiple medications [29]. As a majorly overlooked part of the product design (given the more inspired focus on drug development and manufacturing), pharmaceutical packaging remains an opportunity for the industry to respond to increased calls for patient-centred pharmaceutical products and responding to consumer needs [30].

Challenges related to patient-centricity within the packaging sector relate mainly to designing purpose-led experiences regarding treatment while maintaining product safety and efficacy [30]. The individual patient experience using a particular drug product relies on such aspects as safe transportation and delivery of the product to patients and healthcare providers, packaging and components such as labelling and leaflets with clear information for self-care and self-administration, storage stability, and more [30]. Additionally, pharmaceutical packaging is often developed and manufactured once the drug formulation and finished dosage form are finalised [30]. Pharmaceutical packaging is also tightly regulated to ensure medication integrity while protecting patients themselves – for example, child-resistant packaging [30]. Safety and security of pharmaceuticals will remain one of, if not the, top priority for the industry [31].

In an **exclusive Pharmapack digital workshop,** Mark Tunkel, Global Category Director, Services at Nemera, could not overstate the increasing challenges of drug delivery devices and combination packaging products. "[These challenges] include significant growth in the drug

development pipeline, the need for more complex delivery devices to address targeted applications, and drug attributes, and increased migration of care from clinical environments to self-administration and home settings," he states. "This is coupled with a crowded competitive landscape across all segments in which multiple players may be pursuing the same applications. Our pharma partners are under increased pressure to drive patient centricity as well as create value for patients and other stakeholders beyond the molecule. This is especially true when we consider the potential impacts of connectivity."

However, many business cases exist to pursue innovations in patient-centred packaging – can child-resistant packaging still be used by senior citizens or those with muscular dysfunction? With a trend toward decentralised clinical trials and self-administered treatments, it is becoming evermore apparent that patients must be taken into consideration when it comes to pharmaceutical packaging. Patient-centricity is no longer a 'nice-to-have' but can be the difference in a company's profit margins. In a review of multiple case studies on patient-centred packaging development in mid- and large-sized pharmaceutical companies, one study had a user

state they felt "stupid" for being unable to open their own medication [30]. In all cases studied, pharmaceutical packaging that took into account all stakeholder values, including patients, also increased their market share and visibility, advocating a shift from traditional reliance on existing and cost-effective packaging options [30].

Furthermore, increased patient awareness of their own sustainability footprint is impacting the way they use daily elements, including their medication [31]. Not only do patients require the right medication, they expect companies to provide the right packaging for a sustainable lifestyle for both themselves and the planet [31]. Again, this consumer-led demand presents more opportunities for packaging innovation focusing on the values of all stakeholders involved – reducing weight, optimising product circularity, and reducing the amount of packaging not only serves a company's own sustainability initiatives, but also positions them as leaders in packaging innovation and sustainability [31].

And the pharmaceutical packaging sector is already responding in kind to the need for patient-centred drug delivery technologies. "[We] start with the foundation of patient needs," Tunkel states in his presentation. "This is

best achieved through mapping the patient journey to develop an intimate understanding so that the entire journey and process is considered through the earliest stages of development. Comprehensive understanding of the user enables teams to determine how those needs can be effectively addressed, whether through the device, the integration of connectivity, or other assets. This helps ensure that developed technologies are meeting market needs in an optimal way. We use interviews and in-context observations of practices, processes, and experiences within the patient's home or natural-use environment."

This holistic approach synthesizes all inputs from all stakeholders to yield robust outcomes, addressing patient experience pain points or for those involved in clinical trials. Characterising patient needs also informs how connected solutions can be improved and provide opportunities to establish the selection of technologies, complementary drug device and packaging, and more. All these aspects can place a company at the forefront of innovation in pharmaceutical packaging and drug delivery – this past Pharmapack 2024, the **Patient-Centric Design Award** credited Dr Ferrer BioPharma for their innovations in fluid dynamics to enhance patient comfort and compliance while taking nasal sprays.

Biotech IPOs and corporate pharma dealmaking

Biotech IPOs and corporate pharma dealmaking

When the COVID-19 pandemic halted many industries, the pharmaceutical and biotechnology landscape saw an explosion of activity [32]. The demand for vaccine technology and pharmaceutical innovation resulted in increased investments in preclinical biotechs throughout 2021 and 2022 [33]. However, as the world emerged from the pandemic in 2023, the industry had to contend with the rapidity of its growth, witnessing some of the lowest indices by October 2023 [32].

2025 is expected to be the year where IPOs for biotechs and corporate dealmaking will see an increase in activity as the industry shakes off the sluggishness of the past few years [34]. The Jeffries Annual Healthcare Temperature Check surveyed senior leaders and investors across the biotechnology and global healthcare industries, and found less urgency with regards to

raising capital for biotechs, though this does not necessarily mean the worry is no longer existent [35]. This tentative optimism is further bolstered by two-thirds of respondents expecting the FTSE 100 indices to be higher by the end of 2025, a number that is even higher regarding the MSCI World Healthcare Index [35]. In fact, as of mid-September 2024, the US alone has reported 18 biotech IPO's raising US$3 billion, which is almost the total amount for the whole of 2023 [32].

This confidence may be attributed to attitudes towards geopolitical tensions overriding funding challenges as the biggest risk to healthcare and pharmaceuticals [34]. Continued M&A activity are also driving much of the ramp-up in IPO listings, with private biotechs receiving increased attention from public pharmaceutical companies [36]. Pressure from the aforementioned patent cliff and strong incentives to find the next blockbuster drug product is shaping much of the start-up listing landscape [36]. With the slow IPO terrain of the last few years, a number of private biotechs are waiting for the right time to go public [36].

However, there are certain aspects for a biotech to increase the likelihood of successfully going public – good management, robust clinical data, significant existing capital raised, and clear mission and company journeys are some of the most valuable assets for those looking for investors [32].

Investor preference has shifted from preclinical biotechs to those at the clinical stage, with a favourable market for those at Phase II studies [32]. Such companies offer a well-rounded and differentiated clinical package offering innovative products with the data to back it up [32].

Might there be other options for biotechs looking to raise capital? That depends on where biotechs are looking. Venture capital remains a possibility, with investments in biotechs reaching GBP£6.96 billion by Q3 of 2024, a 90.2% increase from 2023 [37]. Private financing, while it remains slightly more difficult, shows some hope – as of August 2024, total funding almost reached the full annual total of 2023 at US$15.1 billion [32].

Ultimately, 2025 is set to continue the increasing pace of public funding for biotech companies looking to list, with growing opportunities in both private and public investments – if the company knows when and where to look.

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References

References 1/3

[1] 2024 Pharma Industry Trends Outlook: Collaboration, Market Maturity, and Digital Futures [Accessed November 1, 2024]
https://www.cphi-online.com/2024-pharma-industry-trends-outlook-collaboration-news123403.html

[2] Pharma 4.0 and 5.0: Digital Pharma Manufacturing Innovations [Accessed October 29, 2024]
https://www.uk-cpi.com/pharma/digital-pharma-manufacturing

[3] What is Industry 5.0 [Accessed October 29, 2024]
https://www.innopharmatechnology.com/news/what-is-industry-5-0

[4] Embracing Pharma 5.0 for a patient-centred future [Accessed November 4, 2024]
https://www.pfizercentreone.com/insights-resources/articles/embracing-pharma-50-patient-centered-future

[5] Beyond pharma 4.0: pharma manufacturing and Industry 5.0 [Accessed November 4, 2024]
https://manufacturingchemist.com/beyond-pharma-4-0-pharma-manufacturing-and-industry-5-0-207433

[6] How Industry 5.0 Might Benefit Pharma Manufacturing [Accessed November 5, 2024]
https://www.contractpharma.com/contents/view_experts-opinion/2023-03-17/how-industry-50-might-benefit-pharmaceutical-manufacturing/

[7] FDA lists top 10 artificial intelligence regulatory concerns [Accessed November 6, 2024]
https://www.hoganlovells.com/en/publications/fda-lists-top-10-artificial-intelligence-regulatory-concerns

[8] Analysis: European Medicines Agency issues guidance on AI use in pharma regulatory science [Accessed November 6, 2024]
https://www.htworld.co.uk/news/analysis-european-medicines-agency-issues-guidance-on-ai-use-in-pharma-regulatory-science-osborne24/#:~:text=Variability%20in%20results%2C%20potential%20%E2%80%9Challucinations,are%20among%20the%20potential%20risks.

[9] FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine
[Accessed November 7, 2024] https://jamanetwork.com/journals/jama/fullarticle/2825146

[10] Harnessing the power of synthetic data in healthcare: innovation, application, and privacy
[Accessed November 12, 2024] https://www.nature.com/articles/s41746-023-00927-3

[11] What the Novo Holdings and Catalent deal means for pharma outsourcing
[Accessed November 13, 2024] https://www.cphi-online.com/what-the-novo-holdings-and-catalent-deal-means-news123724.html

[12] Catalent Acquisition by Novo Holdings: Evolution of the Industry
[Accessed November 13, 2024] https://www.contractpharma.com/issues/2024-03-01/view_features/catalent-acquisition-by-novo-nordisk-evolution-of-the-industry/

[13] Catalent Issues Open Letter to Customers Regarding Pending Acquisition by Novo Holdings
[Accessed November 18, 2024] https://www.catalent.com/catalent-news/catalent-issues-open-letter-to-customers-regarding-pending-acquisition-by-novo-holdings/

References 2/3

[14] The BIOSECURE Act: implications for the pharma supply chain [Accessed November 18, 2024]
https://www.cphi-online.com/the-biosecure-act-implications-for-the-pharma-news125446.html

[15] Next Big Pill: India's Pharma Outsourcing Power Play [Accessed November 20, 2024]
https://www.avendus.com/india/avendus-eye/the-next-big-pill-india-s-pharma-outsourcing-power-play

[16] Can India Leverage US Biosecure Act to Strengthen CRDMOs? [Accessed November 25, 2024]
https://www.biospectrumindia.com/features/97/25309/can-india-leverage-us-biosecure-act-to-strengthen-crdmos.html

[17] India seeks a seat at the drug services table [Accessed November 25, 2024]
https://cen.acs.org/business/outsourcing/India-seeks-seat-drug-services/102/i25

[18] Drug Patent Expiries: a steep cliff or opportunity for innovation? [Accessed November 26, 2024]
https://www.cphi-online.com/drug-patent-expiries-a-steep-cliff-or-opportunity-news124320.html

[19] The Looming Patent Cliff: Big Pharma Giants Brace for Fall [Accessed November 26, 2024]
https://thehealthcaretechnologyreport.com/the-looming-patent-cliff-big-pharma-giants-brace-for-fall/

[20] Biomanufacturing: an overview [Accessed November 29, 2024
https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/biomanufacturing

[21] CPHI Online Trend Report: How can flow chemistry help businesses achieve their sustainability goals? [Accessed November 29, 2024]
https://www.cphi-online.com/cphi-online-trend-report-how-can-flow-chemistry-news125250.html

[22] Seeking new opportunities: Novel drug approvals of 2024 infographic [Accessed December 2, 2024]
https://www.cphi-online.com/seeking-new-opportunities-novel-drug-approvals-of-news124739.html

[23] Most common clinical trial therapy areas [Accessed December 2, 2024]
https://www.definitivehc.com/blog/most-common-clinical-trials-by-therapy-area

[24] This week in GLP-1 drug headlines: Manufacturing investment and new market launches [Accessed December 3, 2024]
https://www.cphi-online.com/this-week-in-glp-1-drug-headlines-manufacturing-news124765.html

[25] Colorectal cancer [Accessed December 5, 2024]
https://www.who.int/news-room/fact-sheets/detail/colorectal-cancer#:~:text=Colon%20cancer%20is%20the%20second,and%20mortality%20rates%20were%20observed.

[26] What's hot in 2025: Radiopharmaceuticals [Accessed December 5, 2024]
https://www.criver.com/eureka/whats-hot-2025-radiopharmaceuticals

[27] The future of targeted alpha therapy development and manufacture [Accessed December 5, 2024]
https://www.europeanpharmaceuticalreview.com/article/217962/the-future-of-targeted-alpha-therapy-development-and-manufacture/

References 3/3

[28] Novartis begins construction of two new radioligand therapy facilities in the US, expanding its world-class RLT manufacturing and supply network [Accessed December 5, 2024]
https://www.novartis.com/us-en/news/media-releases/novartis-begins-construction-two-new-radioligand-therapy-facilities-us-expanding-its-world-class-rlt-manufacturing-and-supply-network

[29] Patient-Centric Pharmaceutical Packaging Design [Accessed December 10, 2024]
https://www.roechling.com/fileadmin/downloads/Roechling_Medical/Brochures/EN/Roechling-Medical-Patient-Centric-Design-Whitepaper.pdf

[30] Exploring How and Why to Develop Patient-Centered Packaging: A Multiple-Case Study with Pharmaceutical Companies [Accessed December 10, 2024]
https://pmc.ncbi.nlm.nih.gov/articles/PMC8688390/#:~:text=Developing%20patient%2Dcentered%20packaging%20means,with%20the%20illnesses%20%5B10%5D

[31] The packaging trends shaping the future of pharma [Accessed December 11, 2024]
https://packagingscotland.com/2024/04/the-packaging-trends-shaping-the-future-of-pharma/

[32] IPOs on course for recovery but does biotech need public funding anymore? [Accessed December 11, 2024]
https://www.bioxconomy.com/investment/ipos-on-course-for-recovery-but-does-biotech-need-public-funding-anymore-

[33] As biotech recovers, venture firms' preferences appear to shift [Accessed December 12, 2024]
https://www.biopharmadive.com/news/bio-2024-venture-funding-biotech-ipos/718119/

[34] Healthcare executives expect more IPOs and corporate dealmaking in 2025 [Accessed December 12, 2024]
https://health.economictimes.indiatimes.com/news/industry/healthcare-executives-expect-more-ipos-and-corporate-dealmaking-in-2025/115473001#:~:text=Frankfrut%3A%20Healthcare%20executives%20and%20investors,healthcare%20report%20showed%20on%20Tuesday.

[35] Jefferies Healthcare Temperature Check 2024 [Accessed December 10, 2024]
https://www.jefferies.com/about/conferences-events/london-healthcare/2024-temperature-check/

[36] Private biotech M&A surges amid difficult IPO market [Accessed December 12, 2024]
https://www.biopharmadive.com/news/biotech-startup-private-acquisitions-pharma-2024/721981/

[37] UK biotech defies global market pressures, secures £808 million in Q3, reports BIA [Accessed December 12, 2024]
https://www.bioindustry.org/resource/uk-biotech-defies-global-market-pressures-secures-808-million-in-q3-reports-bia.html#:~:text=Venture%20capital%20investment%20in%20biotech,%C2%A3221%20million%20and%20Switzerland

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