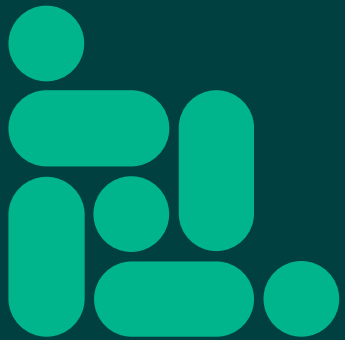




2024 Pharma Trends Outlook:

Collaboration, Market Maturity, and Digital Futures



In Partnership
with





2024 Pharma Trends in Focus

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Contributors



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Introduction

The [2023 CPHI Online Pharma Trends Report](#) delved into critical issues, from reshoring drug production to manufacturing reimaged through Pharma 4.0, exploring how the industry grappled with challenges like supply chain disruption, security, and escalating drug manufacturing costs. Amidst these hurdles, 2023 provided a chance for the pharmaceutical supply chain to proactively address issues, marking a shift towards resilience and quality management.

Learning from the past, the industry is embracing a proactive mindset, propelling it into a new era of supply chain robustness. Protecting consumers from supply shortages, adulteration, and counterfeit products remains a top

priority for the industry. Cross-industry collaboration for sustainability initiatives, the US FDA's Quality Management Maturity program, and patient-centric packaging designs are leading the pharmaceutical industry into the future. Underpinning these strategies is the increased digitisation of the supply chain with generative AI and machine-learning technologies.

[Arvato CSDB](#) is a leading example of the digitisation of the industry – a software providing proven serialisation solutions to over 80 pharmaceutical companies, ensuring seamless implementation of legal requirements against counterfeit medicines. This positive shift is anticipated to extend into 2024, with initiatives and guidance fostering industry investment and collaboration. The goal is clear:

enhance efficiency in delivering medicines to patients securely and on time.

The CPHI Online 2024 Pharma Trends Report, sponsored by Arvato Systems, dissects emerging trends. From the impact of generative AI on the supply chain to mature quality management plans for biomanufacturers, excipient market growth, biologics outsourcing, and more, these expert insights provide a valuable outlook for those navigating the global supply chain in 2024.

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Data and AI in the Pharmaceutical Industry

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1

Generative AI and supply chain digitisation

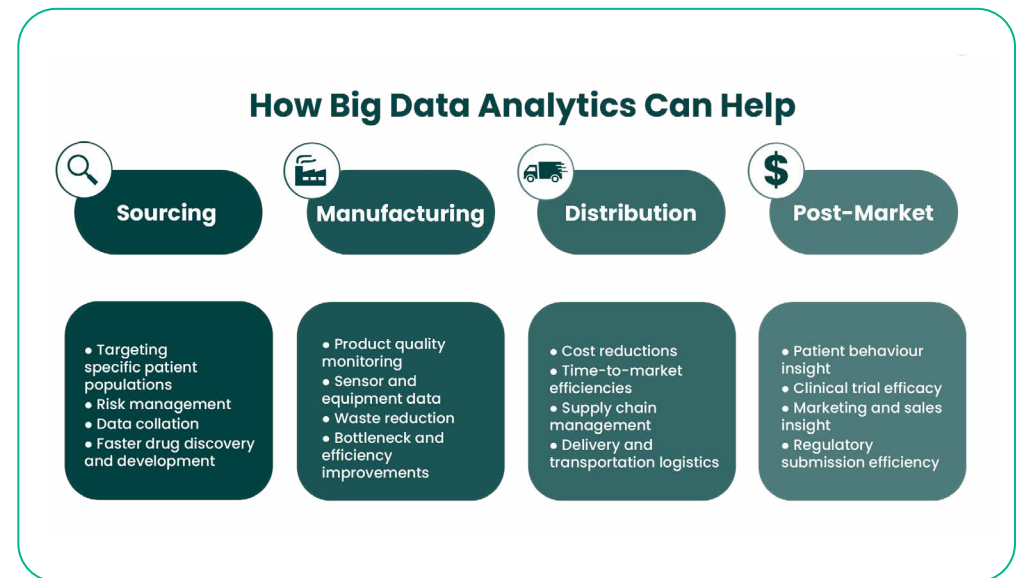


Generative AI and supply chain digitisation

2024 will see the evolution of digital technologies for supply chain management, according to **Stefan Moch, VP Health of Arvato Systems**, who sees this manifesting in two major ways. "One of the two topics is Big Data Analytics in the pharmaceutical industry," he states. "Big Data Analytics is revolutionising pharmaceutical manufacturing, with a significant impact on quality control and regulatory compliance. Manufacturers employ data analytics to monitor and control product quality by analysing data from various sensors and equipment. Additionally, production processes are optimised through the identification of bottlenecks, waste reduction, and efficiency improvements. Data analysis is integral to supply chain management,

enabling better inventory management and minimising risks of shortages or excess inventory."

Big Data Analytics was one of our 2023 Pharma Trends Report predictions. Many expect it to continue pushing the industry towards digitalisation in efforts to reduce product lead times and manufacturing costs [1].





Data-oriented manufacturing for pharmaceuticals has been acknowledged by regulatory bodies as a means of not only reducing costs and time-to-market, but also ensuring quality and efficiency of processes. With many steps in the pharmaceutical manufacturing process generating large amounts of data from numerous sensors and equipment, the ability to gather, sort, store, and analyse all this information will differentiate leading manufacturers from the rest.

“In biopharma specifically, it has been challenging to balance demand and supply post-COVID,” comments **Nicola Coles, Phorum Director at BioPhorum**. “During the pandemic, healthcare purchasers and governments stocked up on medicine and licence holders stocked up on manufacturing technology and ingredients. Then, demand fell off a cliff. This has had a huge impact on the pharmaceutical supply chain.” Though Coles acknowledges these difficulties in supply, AI technologies will be the way forward for a resilient supply chain: “I would like to see AI harnessed to accelerate the flow of information across

the supply chain – transparency is a critical element for sustainability and resiliency, and frankly, we are not moving fast enough or with sufficient purpose. Too much data with no data architecture will impede the industry’s progress.”

Moch also cites cybersecurity as a leading trend for the digitalisation of the pharmaceutical supply chain. “A ‘taboo subject’, it is one that should be the focus of every company, especially in an industry with such sensitive data,” he states. “In a time where not only criminals but also governments use cyber-crime for their purposes, cybersecurity plays a critical role in the pharmaceutical sector, ensuring the protection of sensitive data such as patient records, research findings, and valuable intellectual property.”

Bikash Chatterjee, President and Chief Scientific Officer at Pharmatech Associates, agrees: “Applying machine learning and artificial intelligence can optimise and accelerate all aspects of bioprocessing, from cell culture and upstream processing to downstream processing with chromatography and filtration. PAT sensor technology



and sophisticated chemometric modelling all continue to improve in terms of accuracy, thanks to the maturation of support vector machine quantum computing software and analytical tools.”

Digitalisation is not restricted to the manufacturing of the drug product itself – pharmaceutical packaging is seeing an uptick in active and intelligent design, with the market expected to grow at a compound annual growth rate (CAGR) of 9% by 2025 [2]. Active pharmaceutical packaging refers to packaging design engineered to respond to changes in atmospheric conditions inside and outside the package itself [2]. This is in contrast to the standard inert packaging solutions well-known to the industry. With more complex therapeutics entering the market, pharmaceutical packaging must keep pace with changing industry demands. “The use of smart packaging, such as intelligent labels and RFID tags, enables real-time monitoring of medication usage, temperature control, and expiration dates,” **Peter Schmitt, Co-Founder and Managing Director at Montesino**, states. “This technology





ensures medication safety and enhances patient adherence.” Moch warns that inadequate digitisation of certain parts of the supply chain may result in internal disruptions by “hindering the tracking and management of raw materials and finished drugs, contributing to supply chain vulnerabilities. This ultimately leads to shortages of medicines around the globe.” He emphasises the value in stakeholder communication: “Effective communication among stakeholders is pivotal for managing shortages, and poor digitisation can impede this exchange, making it difficult to coordinate responses effectively.

For example, Generative AI and advanced digital technologies are playing increasingly central roles in alleviating drug shortages in the pharmaceutical industry. These technologies can optimise the pharmaceutical supply chain by forecasting demand, identifying potential bottlenecks, and improving inventory management... these technologies facilitate seamless communication and collaboration among stakeholders in the pharmaceutical ecosystem, ensuring efficient coordination during potential

shortage scenarios. Moreover, generative AI expedites drug development, potentially offering alternatives to critical drugs in short supply. By embracing these digital tools, pharmaceutical companies can better predict, manage, and mitigate the impact of drug shortages, ensuring reliable access to essential medications for patients.”

“The use of smart packaging, such as intelligent labels and RFID tags, enables real-time monitoring of medication usage, temperature control, and expiration date. This technology ensures medication safety and enhances patient adherence.”

Peter Schmitt

Co-Founder and Managing Director, Montesino



2

Consumer driven packaging innovations



Consumer driven packaging innovations

2023 saw the rise of the Contract Packaging Organisation (CPO) and an increase of outsourcing activities in the packaging sector; the global pharmaceutical contract packaging market size is projected to grow 7.43% from 2023 to 2030 [3]. Advancements in technology and changing industry needs are constantly pushing the pharmaceutical packaging sector to evolve, and 2024 is poised to be a transformative year with incoming regulations around sustainability and safety.

Globally, the pharmaceutical packaging market is predicted to reach a value of USD \$90 billion by 2030 [4], with some estimates predicting up to USD \$1 trillion [5].

With such figures, **Berta Mota, Circular Economy Director at Anthesis Group**, emphasises that pharmaceutical packaging must be more than an afterthought.

“Many pharma companies have been working on improving their pharmaceutical packaging, and analysing which part of their operations relates to packaging better understand the magnitude of these processes,” Mota states. “Although changes of packaging in pharma can be more complicated and restricted than in other sectors, there is room for improvement – it is a question of identifying where we can create change either in the short term or long term. This also helps the whole company and all departments involved understand which direction to follow and set up internal policies to make pharmaceutical packaging operations be more sustainable and circular.”

Patient-centric packaging is top of the priority list for pharmaceutical packaging experts. Schmitt comments that “As personalised medicine becomes more prevalent, pharmaceutical packaging will also become tailored to individual patients. Customised dosing instructions,



patient information leaflets, and packaging design will cater to specific patient needs.” User-centric design can range from child-resistant packaging and senior-friendly containers through to intelligent packaging to increase patient adherence [2]. Smart packaging can enhance user experience: increased health literacy with QR-enabled packaging, RFID tags to identify and monitor side effects in real-time, and wearable drug delivery devices exemplify the potential of smart packaging to improve health outcomes and trusted interactions between patients and the wider pharmaceutical industry [2].

By 2025, the market for active and intelligent packaging is expected to grow at a CAGR of 9% [2]. The potential for smart packaging reaches beyond just the patient – supply chain logistics are also reaping the benefits first-hand. Real-time tracking of cold chain transportation provides rapid identification of potential risks, proactively responding with corrective measures to ensure product safety and quality [6]. Additionally, such technologies can protect against costly reactive actions – in 2020, nearly 30% of

the USD \$1.75 billion spent on pharmaceutical cold chain logistics was spent on pharmaceutical packaging [6]. Continued advancements in pharmaceutical packaging will also be spurred by the development and approval of biologic drugs and complex therapeutics.

“The rise of biologic drugs, which require specialised storage and transportation conditions, will drive the development of new packaging solutions,” Schmitt states. Temperature-controlled packaging and advanced cold-chain logistics will be the frontrunners for such solutions.

Innovations in pharmaceutical packaging will also force the industry to evolve their operations, with much movement towards outsourcing partners for packaging. “There are two separate trends here,” Schmitt explains. “The move to outsource pharmaceutical packaging is driven by cost and operational efficiency, lower capital requirements, flexibility and scalability. Mature oral solid dosages will continue to lead this trend from in-house to outsourced. The move to personalised medicine and biologics and corresponding decrease in Minimum Order Quantity MoQ will drive a trend



toward in-house packaging. Here, Regulatory and Quality Control concerns, IP protection, and strategic flexibility are key. These trends highlight the ongoing evolution of pharmaceutical packaging to meet the needs of patients, healthcare providers, and regulators. By embracing innovation and sustainability, the trend continues to enhance medication safety, improve patient experience, and reduce environmental impact.”

Coles also states the need for standard guidance in areas of sustainability for packaging. “Shifting to recycled content for packaging and devices requirements is a classic example of a change that is encouraged through one set of regulations, but this requires alignment of CMC Regulatory to implement at scale. We need to discuss co-validation wherever possible – a product licenced today could be on the market unchanged for 30+ years. We need to create regulatory environments that encourage flexibility and rewards innovation rather than stifling it.”

In the nearer future, sustainable manufacturing practices and a total mindset shift will be at the centre of ESG

“The rise of biologic drugs, which require specialised storage and transportation conditions, will drive the development of new packaging solutions.”

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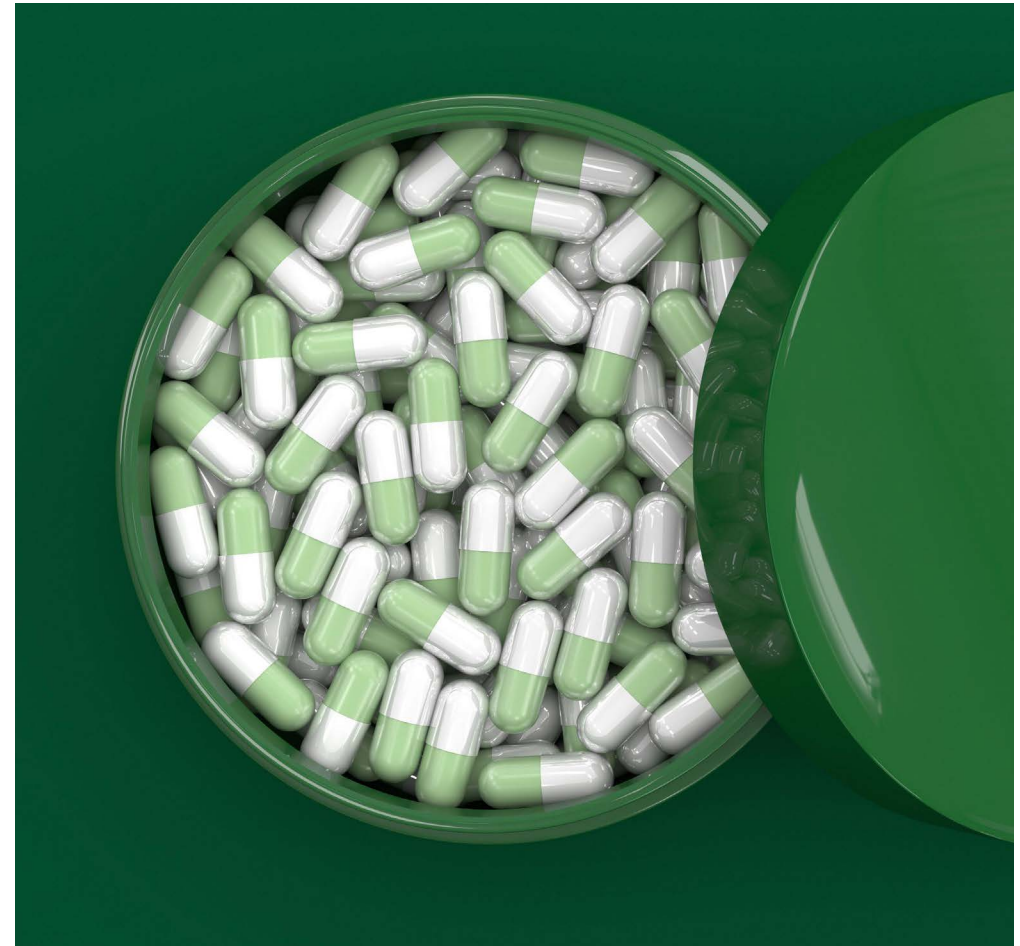
initiatives, with a particular focus on pharmaceutical packaging. The production and transportation of pharmaceutical products contributes the most significant impact to the pharmaceutical industry’s carbon footprint [7]. Alternative materials, manufacturing processes, and transportation methods are all at the frontiers of sustainable innovation.

However, Mota emphasises the need to go beyond “replacing materials with alternatives. This can help to



create more circular and less impactful products but there is room for improvement on strategies like re-use where applicable, including take-back systems. The material we are replacing with an alternative might not be needed, and we could probably create a packaging that is half the weight (a monomaterial), one that can even be included in a take-back system. My colleague Ellen Struther recently presented at Pharmapack about 'Designing and Implementing Successful Take Back Schemes for Used Devices and Packaging'."

Despite the combined efforts of the supply chain, there is still a long way to go for Mota. "Many countries now have well-developed recycling systems for standard formats of packaging materials, but pharma materials can sit outside the 'normal' formats because there are multiple materials, product residues, non-standard shapes etc. Implementing take-back schemes can be part of the solution while ensuring that they are ethically operated and legally compliant."





3

Mature quality management and control



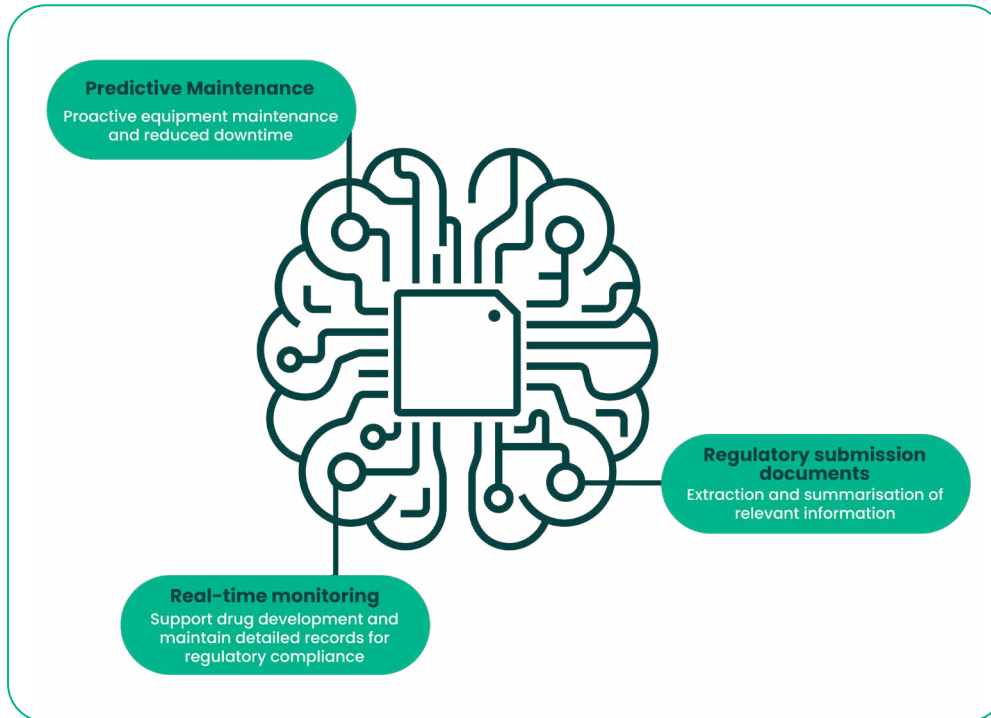
Mature quality management and control

Last year saw increasing demands for nearshoring and re-shoring efforts to build supply chain resiliency. Ongoing global instability, including conflicts in Ukraine and Gaza, continue to disrupt delicate supply chains. The US FDA reported that while the number of new drug shortages had fallen significantly from a high of 250 in 2011 to just 49 in 2022, the US FDA emphasises that continued shortages pose a real threat to public health [8]. The EMA have also released a guidance on shortage preparedness for Autumn/Winter 2023–2024, citing shortages in critical treatments such as amoxicillin [8]. In 2019, the Federal Drug Shortage Task Force reported that 62% of drugs that went into shortage between 2013 and 2017 were linked

to manufacturing or product quality issues, such as substandard manufacturing facilities and quality defects in finished products [9].

Up to now, this preparedness has focused on actions to be taken after such disruptions occur. Many within the industry are now calling for proactive, front-end quality assurances, regardless of supply chain continuity (or discontinuity). Designing quality assurance into operations and processes upfront can help organisations better position themselves en-route to market [10].

For Moch, Big Data Analytics will be an integral part of this preparedness: “Predictive maintenance is another key application, allowing for proactive equipment maintenance and reduced downtime. Real-time monitoring, support for drug development, and maintaining detailed records for regulatory compliance are all facets of how Big Data Analytics enhances pharmaceutical manufacturing.” He is also optimistic about the use of generative AI in the standardisation of quality control and data extraction for decision-making: “Generative AI can create regulatory



submission documents by extracting and summarising relevant information from extensive text data sources. This aids in expediting the approval process and ensures

compliance with regulatory requirements. It can also produce detailed quality control reports by extracting data from sensors and manufacturing equipment. This ensures the consistency and quality of pharmaceutical products throughout the manufacturing process.”

The continued digitalisation of the pharmaceutical supply chain may very well extend through to active quality control for manufacturers and pharmaceutical companies. Yet, in a highly regulated industry, it is important to place precision and predictability at the centre of business and operational decisions. This makes the implementation of generative AI in the pharma supply chain a challenge due to the “inherent probabilistic nature of AI outcomes”, as Moch states. “Sovereign AI, deployed in controlled environments, offers a promising solution that harmonises these seemingly opposing requirements. Sovereign AI refers to the application of large language models like Chat GPT within secure, managed clouds, private cloud environments, or even on-premises by using quantised models. This deployment flexibility provides



pharmaceutical businesses with a range of options to achieve the level of control and predictability needed to meet regulatory demands. AI models can be deployed on high-performance cloud computing infrastructure, private clouds, and on-premises setups, all fully adhering to data regulations and compliance standards. Importantly, these servers and environments can be strategically located in the same jurisdiction as the pharmaceutical business, ensuring alignment with regional legal terms and providing regulatory certainty. Within this framework, adhering to the pharmaceutical industry regulations is facilitated. The sovereign AI model is inherently designed to function within these frameworks, reducing the friction that often occurs when integrating AI into regulated processes.”

Regulatory authorities have also recognised the importance for drug manufacturers and developers to implement a quality culture mindset. In August 2023, the FDA’s Center for Drug Evaluation and Research launched the Quality Management Maturity Program, aimed at encouraging drug manufacturers to implement ‘mature

quality management practices’ [11]. These practices include both tangible solutions and cultural mindset shifts concerning quality management [11].

Sireesha Yadlapalli, CEO of Pharmatech Associates, discussed the importance of such programmes in her presentation at [CPHI Barcelona in October 2023](#): “Over the last few years, there’s been significant focus on regulatory oversight and regulatory actions. Issues such as product recalls and drug shortages all continue to point to the importance of focusing on quality...now, we cannot just address quality at the backend by checking whether somebody is complying – we need to start at the front end and ask what can be proactively put in place to ensure quality. QMM is a great initiative that looks at culture approaches, fostering a mindset of continual improvement that we hope will result in fewer backend issues that require correction actions, at a huge cost for all involved.”

Such mindset changes and their evaluation are still being prototyped, but companies are already involved with the US FDA’s QMM programme – a positive shift towards mature



quality management throughout the industry. In 2023, the EMA also updated the ICH Q9 with similar guidance on preemptively mitigating quality issues in risk management plans [12].

Additionally, the rise in complex therapeutics, biologics, and biosimilar manufacturing brings their own set of challenges [11]. With patents expiring on established drugs, many pharmaceutical companies must contend with the quality measures required for commercial production of these products. Designing with quality assurances into each process and aligning these considerations can reduce disruptions in the manufacturing and commercialisation process, ultimately getting a drug product to market faster at less cost [11].

Stephanie Gaulding, CQA, CPGP Managing Director of Pharmatech Associates also points to a rise in technologies and digital transformations that empower employees to demonstrate a company's mature quality management. "There is a trend driving our industry towards competency-based learning, so there will be a big change in many of

the familiar LMS or training platforms and tools serving the pharma industry," she states. "Over the years, these tools have evolved to support our compliance-based view of training (e.g. reading procedures and completing training). What we see emerging during health authority inspections in recent years is stronger interest in a company's ability to demonstrate that employees are qualified to perform a function or activity, and the inspectors are astute enough to understand that reading a procedure is not enough. Combine this external pressure with the ever-increasing needs of our industry to respond and deliver at faster speeds, and you end up needing different learning systems that are at their core adaptive, learner-centric, and support competency-based learning. What's more, the days of "death by PowerPoint" as a training method are over as learners' demand and expect content in their preferred learning style and the ability to learn through collaboration with others. Our learning experiences going forward will look more like pathways for employees to navigate and consume at their own pace, coupled with collaborative spaces like those that exist in Slack or MS Teams."



Relegating quality control to an afterthought and not at the forefront of innovation risks inefficiency and slower time to commercial markets. “Regulatory challenges are amplified by inefficient digital systems, resulting in slower regulatory processes and inspections, ultimately causing production interruptions and drug shortages,” Moch comments.

“The lack of transparency within the supply chain is a well-documented issue, with modern digital systems capable of greatly enhancing transparency. Poor digitisation obstructs

the sharing of critical information among stakeholders, hampering efforts to predict and address shortages...these technologies streamline regulatory compliance through automated data analysis and document management, accelerating approvals and minimising production disruptions. Real-time monitoring and transparency are enhanced through generative AI, allowing for quick issue identification and response. Data-driven decision-making supported by AI insights helps allocate resources efficiently and adapt to market changes.”





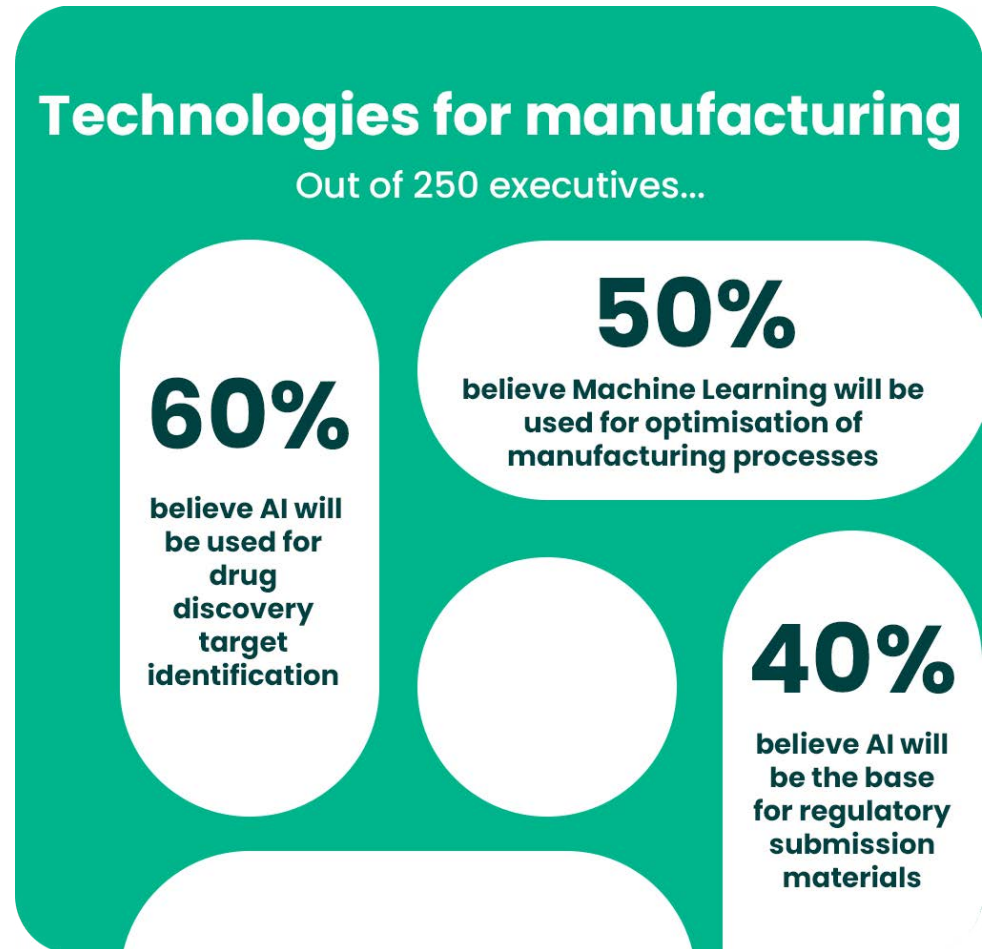
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Biotech and R&D outsourcing practices: investing and acquiring



Biotech and R&D outsourcing practices: investing and acquiring

Our [2023 CPHI Annual Report](#), which compiles results from the CPHI Annual Survey of over 250 pharma executives along with expert analysis of the industry, anticipates a rise in biotech funding and growth within the pharmaceutical contract services sector [13]. Additionally, a survey conducted by Scorpius Biomanufacturing revealed that, out of 100 respondents, more than half believed their





Outsourcing behaviour

Out of 100 respondents...

50%

believe
outsourcing
activity levels
will increase
from
2024–2026

37%

believe
outsourcing
activity
levels will
remain the
same

companies' outsourcing activities would increase from 2024–2026 [14].

Another 37% expected their outsourcing activity levels to remain the same [15]. As more and more complex therapeutics move from R&D to clinical trials and eventually the commercial market, pharmaceutical companies and biotechs are rethinking their biomanufacturing studies for 2024 and beyond. The market for biologics has grown rapidly, despite the biotech slowdown of recent years [15]. With estimated CAGRs of between 4% and 9.24% by 2030, the market is estimated to reach USD \$500 billion [15]. Biologics are estimated to make up 55% of all innovative drug product sales by 2027 [14].

With a number of biologics losing exclusivity as patents expire, the market is primed for biosimilar development and commercialisation [16]. However, **Dan Stanton, Managing Editor at BioProcess International**, states this may be more difficult to achieve with advanced therapeutics: "Over the past few years, the contract development and manufacturing organization (CDMO) sector has seen



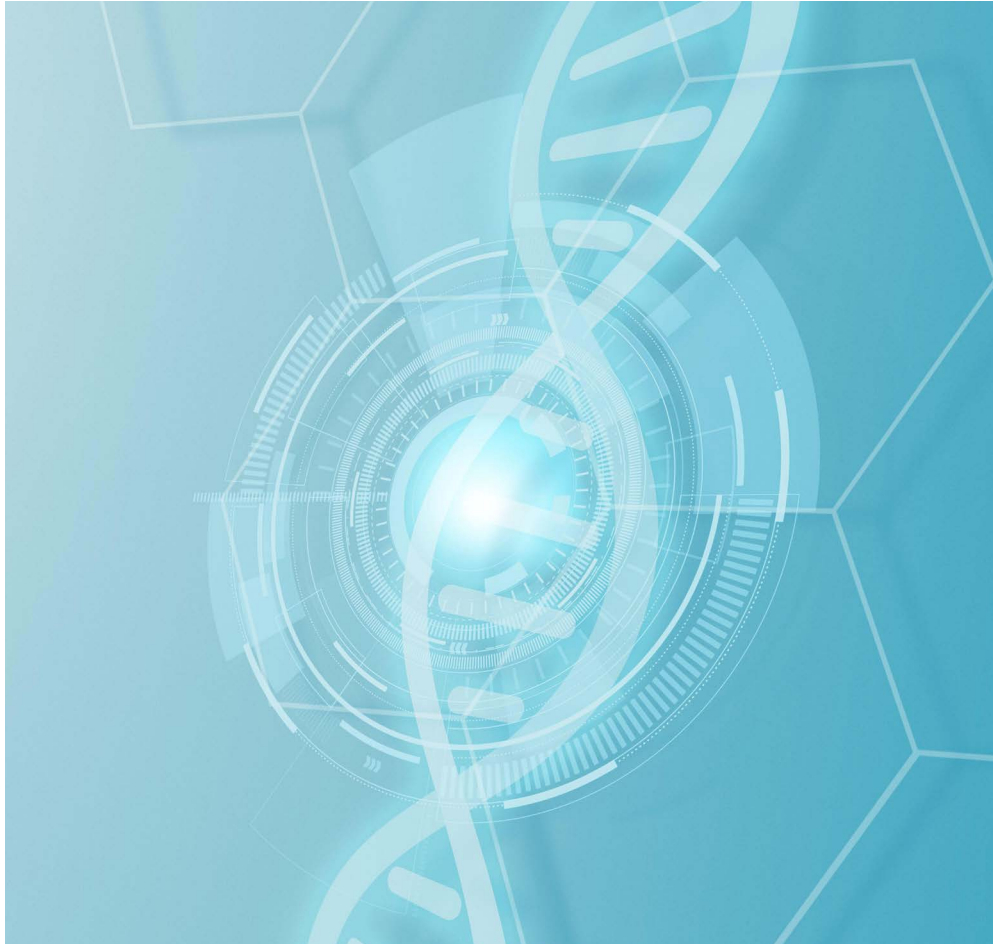
dozens of new entrants, driven by the complexities and technological needs of cell and gene therapies, and intensified through the COVID-19-driven gold rush. But advanced therapies have somewhat stalled in reaching their commercial potential and the post-pandemic landscape has resulted in overcapacity. Combined with the difficult investment biotech backdrop, it must be asked whether demand can sustain the current number of start-up CDMOs?”

The demand for R&D occurring in the biologics arena will require companies to make critical decisions regarding resource management and outsourcing activities for successful and timely delivery of therapeutics [15]. “We’ve already seen some firms move away from the CDMO space – [Emergent BioSolutions’ ‘de-emphasis’ on the business](#), [Baxter’s exit from the sector](#), PE-backed AcuraBio [shutting up shop](#), for example – and this trend is likely to continue, or even intensify over the coming period,” Stanton states. Yet, 71% of the CPHI Annual Survey respondents state that the drive towards increased outsourcing is being fuelled by

the biologics R&D boom [15]. So where does that leave the CDMO space and its players?

Stanton explains: “As with all good ‘boom and bust’ cycles, there are those ready to pick up the pieces, whether they are large players looking to pick up tech and expertise, or ambitious mid-sized manufacturers hoping to grow by acquisition to challenge the likes of Lonza, Fujifilm Diosynth, and Samsung Biologics. We’re already seeing the latter happen through deals such as [Ajinomoto’s merger with Forge Biologics.](#)”

Additionally, the biotech slowdown of 2019–2022 may be nearing a shift. Research from the CPHI Annual Report 2023 suggests biotech funding may also be a key driver in increased contract services trends [13]. Total funding for the biotech sector sat at USD \$30.2 billion in July 2023, with the full year trading ahead of 2022 [13]. Though funding for biotechs is still half the levels of 2020, the tides may change for R&D pipelines, and consequently CDMO activities, in the near future [13]. This change might already be in the air – Cromatic, a full-stack digital platform for outsourcing



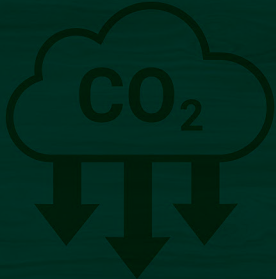
life sciences research, announced in November 2023 their closure of USD \$5.3 million in funding from venture capital (VC) [17]. With the goal of matching biotechs to relevant CROs across the industry, investment into platforms such as Cromatic may be spelling out an increase in outsourcing activity for the pharmaceutical industry like never before.

“Furthermore, it’s likely new players will see an opportunity to move into the space and leverage their core life sciences services to drive synergies in the CDMO space,” Stanton states. “Bioprocess vendor Danaher, for example, could make good on rumours it wanted to add a Catalent-sized CDMO to its offering. Meanwhile, players from India including [Aurobindo](#) and [Aragen](#), perhaps buoyed by the rapid growth of WuXi Biologics and Korean CDMOs, are signalling their intentions to become global players in the space. And with the CDMO environment described above, acquiring rather than building would make the most sense.”



5

Collaborative sustainability by all, for all





Collaborative sustainability by all, for all

Environmental, social, and corporate governance (ESG) are a continuing point of discussion for the pharmaceutical industry in 2024. This year we published our [CPHI Sustainability Report 2023](#), we explored how the pharmaceutical industry produces 55% more emissions than the automotive industry. This makes it one of the largest global contributors to greenhouse gas emissions [18]. For **Enric Bosch Radó, Global Third-Party Chemicals Manager/Human Pharma Supply Chain at Boehringer Ingelheim**, future sustainability hurdles for the pharmaceutical industry involve “water scarcity and pharmaceuticals in the environment/antimicrobial resistance.” One of the most problematic issues for the

pharmaceutical industry, at present, are scope 3 emissions and overall decarbonisation of the supply chain, which occur throughout the supply chain and are difficult to quantify from indirect third-party contributors [18].

This way, collaboration among industry players is the best approach to set up and standardise expectations. “The Pharmaceutical Supply Chain Initiative (PSCI) is the Pharmaceutical and Healthcare industry group leading this collaborative approach,” states Radó.

Yet, such considerations and collaborations across the entire supply chain are exactly what the pharmaceutical industry must face together, Mota states: “Strengthening ties with upstream and downstream players is key. Because scope 3 emissions are not directly controlled by companies despite being responsible for the biggest portion of impact within companies, it is unreasonable to assume a company alone can reach ambitious decarbonisation goals. Not only can partnerships help to establish more realistic and transparent objectives, but they also balance efforts. This is not a one-year job – it will take time and needs to move



forward steadily without time for a pause.”

Mota cites Ferrer Pharma’s presentation at CPHI Barcelona, focused on their Sustainable Packaging Model, created with the support of Anthesis. It is a part of Ferrer’s objective “to lead change towards more sustainable production by adopting criteria and commitments that minimise the environmental footprint of its containers and packaging,” Mota explains. “Of course, this is not done in a month, but it is an iterative and long-term process, which involves the collaboration of different departments as well as key players such as providers.”

Additionally, initiatives like the PSCI or [Together for Sustainability](#) are committed to the dissemination of information amongst its members. Supplier audits and assessments, once completed, are shared with all members, saving time and energy in conducting industry-wide audits and creates more transparency.

Coles also sees the impact of licence holders as essential. “Programs such as Energize and Activate are essential – with licence holders, communicating clearly what their

requirements are enables suppliers to gear up,” she states. “Suppliers need strong signals from licence holders so that they can direct resources to sustainable alternatives. The more coherent licence holders can be, the faster this ship will turn. That coherence is coming from carbon SBTi commitments – a strong commitment and signal for the need to reduce emissions. But I do not see that clarity for circularity and without it, we cannot hope to achieve our stated emission targets.”

Aurelio Arias, Director, Thought Leadership at IQVIA, also comments on the impact of scope 3 emissions for the pharmaceutical industry: “Pharmaceutical companies, realising the urgency of environmental stewardship, are reporting commitments to curtail greenhouse gas emissions in their ESG reports. Aggregating the results of companies with extensive audits shows that scope 3 (indirect emissions throughout the supply chain makes up 95% of a company’s average emissions, as shown in Figure 1. The complexities of scope 3 emissions mean that precise reporting is challenging, but we do know that raw material



extraction, manufacturing, and the use of medicines are the largest components in scope 3 emissions,” Arias explains. “In 2022, there were sharp rises across Scope 3 for major companies as shown in Figure 2. This is due to various factors including COVID-19 vaccine distribution, changes :

Figure 1: Average Reported Emissions (n = 15, CO2e, 2022)

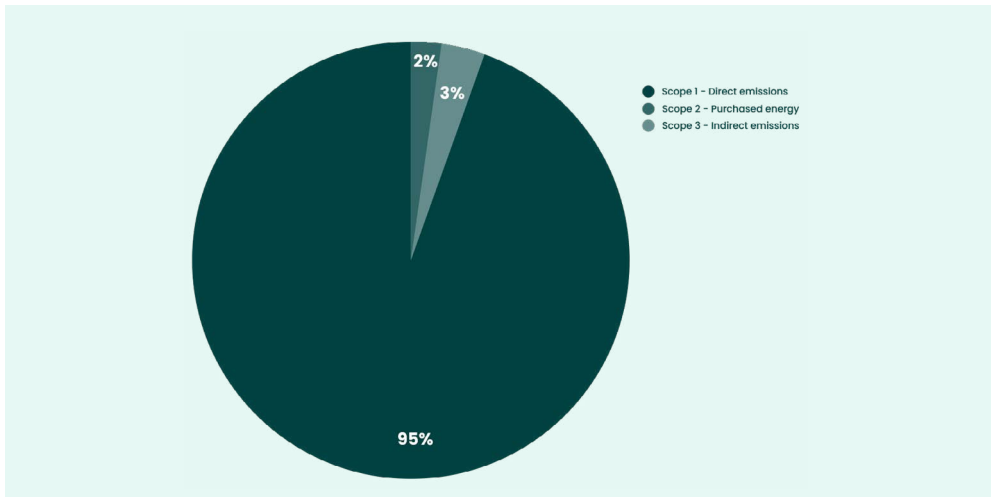


Figure 2: Average Pharma emissions reduction (Percent of company-reported baseline, CO2e)



in transportation modes from sea to air, and increased business travel as restrictions eased. For Arias, collaboration will also be a key component of coordinating ESG efforts in 2024. He states: “Tackling these indirect emissions requires coordination and buyer



pressure from healthcare systems, and 2024 will be the year when commitments are set. As part of an international initiative attempting to achieve this stewardship, the WHO launched their Operational Framework for Sustainable Healthcare Systems [19] on the run up to COP28. The key objectives of the framework are to guide and support them in strengthening their climate-related initiatives. So far, 74 countries (since COP28) have committed to sustainable low-carbon healthcare systems [20], with 28 having gone a step further and pledged to achieve net zero. Every year, more and more countries pledge their commitments and with a model to follow, this will give further clarity in 2024 and beyond.” Radó also states that while sustainability may be an achievable goal, it will be “beyond 2024, as it will not be achieved in the short term but rather as a long-term goal.”

Coles is less optimistic about the future of sustainability, but still emphasises the importance of collaboration. “The majority of the industry has not yet developed clear plans to reduce carbon emissions, which I see as base camp in terms of the transition to a more sustainable industry.

To be blunt – even as an industry full of scientists we have yet to fully experience our Enlightenment period. If we did, we might also consider sustainable pharma in the context of sustainable society – truly tackling health inequalities. We have a key role in shifting the agenda from cure to prevention, which would make us sustainable. We have a key role in demonstrating how to manufacture sustainably – not just in terms of carbon, but land use, water use, material sourcing. Sadly, I think there is a lifetime of work before we can consider sustainability achievable. But there are great minds working on this in every corner of the industry – the trick is to connect them through collaboration such as BioPhorum – to connect, collaborate, and accelerate.”

For scope 3 emissions in particular, organisations such as Energize conduct Scope 3 Peer Groups. These cross-industry groups approach suppliers from the pharmaceutical and chemical industries to report on scope 3 emissions. Meeting on a monthly basis, these groups provide transparency throughout the industry supply chains.



6

Making excipients great again





Making excipients great again

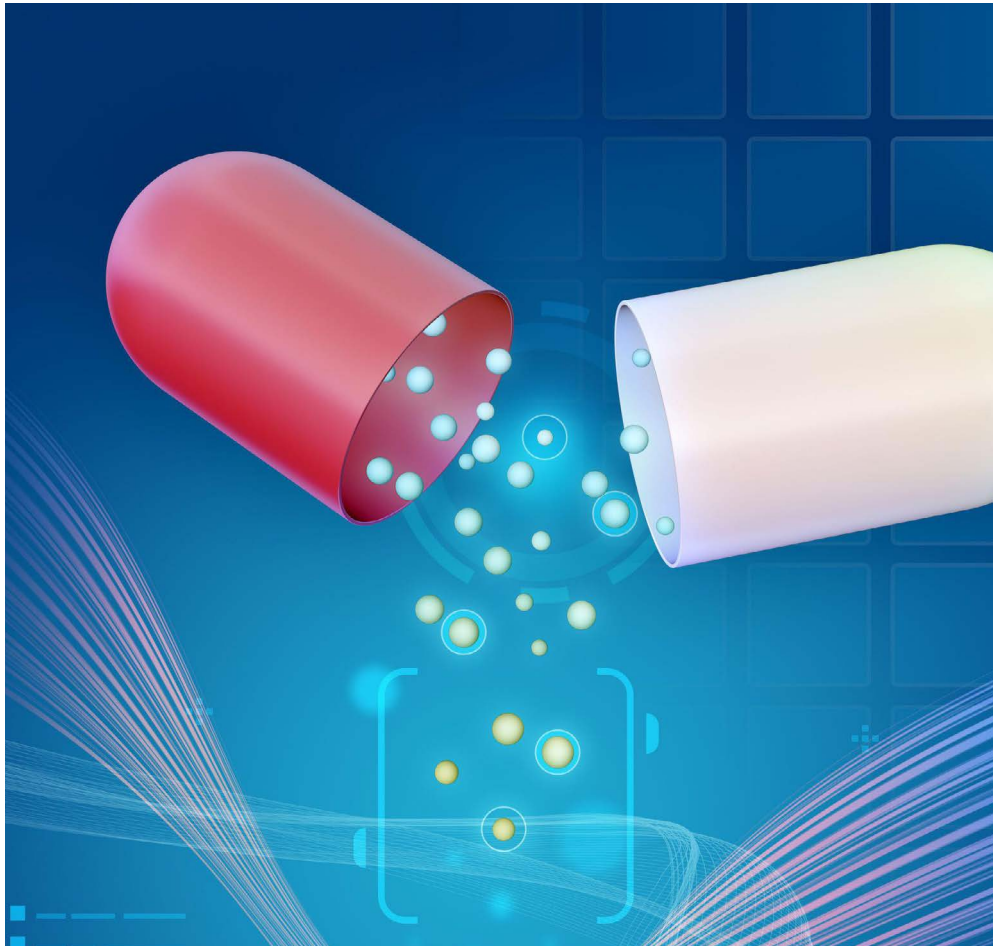
In last year's [CPHI Online 2023 Pharma Trends Report](#), we took a look at how excipients may incentivise biotechnological innovation [21]. The COVID-19 pandemic saw the use of two novel lipid excipients in mRNA vaccines. This bolstered existing interest in excipients – in 2021, the US FDA launched the Novel Excipients Pilot Program to further incentivise research and manufacturing of novel excipients [21].

In a [CPHI Online Feature Article](#), **Iain Moore of IPEC Europe** discussed the awakening of regulatory authorities to the importance of excipient development and manufacturing: "I think the FDA are very enlightened – they did some surveys and got back some hard messages about drug products failing to make it to market because the excipients weren't effective enough in delivering the API.

That's a worrying statement. After all that investment and time to meet a therapeutic need, and then it fails because there isn't an appropriate excipient."

Market research projects a CAGR of 6.1% from 2022–2027 for pharmaceutical excipients, while nutraceutical excipients are also projected at a growth rate CAGR of 6%. By 2029, it is expected that the global market for pharmaceutical excipients will reach upwards of USD \$12 billion [22]. With a relatively stable market that is expected to only increase in its rate of growth to 2027, it's little wonder CPHI Barcelona saw an explosion of excipient developers and service providers on the show floor this past year. Exhibitors such as Roquette, Clariant, and IFF showcased such excipient innovations as moisture-sensitivity and low nitrite solutions, while the inaugural CPHI start-up market welcomed excipient manufacturers like Galvita AG [23].

This boom in excipient R&D and manufacturing is being driven by several factors. An increasing demand for generics, where close to 9 out of 10 prescriptions administered in the US were for generics in 2023, is



leading to an increased need for their excipients [22]. With governments in developing countries boosting local manufacturing of generics to improve healthcare systems and cost burdens, the rise of generic drugs is pushing the global demand for excipients [22]. Advancements in personalised medicine, multifunctional ingredients, and nanotechnology are also enhancing drug delivery solutions, leading to the investigation of other excipient forms and applications [24].

Excipient markets to watch for growth are led by the Asia Pacific pharmaceutical excipient region. This market is expected to grow to nearly USD \$2 billion by 2028 [25]. China and India, similar to APIs, are leading the APAC pharmaceutical hubs in manufacturing excipients for the region [25]. Existing markets in North America and Europe have also demonstrated strong growth, with the US dominating the North American region and Germany to lead the pharmaceutical excipients market in Europe to meet the rise in production of novel drug medications and the development of customised therapies.



7

Pricing, costs, and patients – balancing the pharma trinity



Pricing, costs, and patients – balancing the pharma trinity

Patient-centricity is now less of a trend and more a necessity for the pharmaceutical industry. Now, pharmaceutical companies and contract services must finally contend with the delicate balance to be made between business and patient. Now, pharmaceutical companies and service providers alike are contending with the balance between rising costs and getting the right drugs to the right patients.

Supply chain shortages are nothing new for the pharmaceutical industry. However, new challenges are

putting the resiliency of the pharma supply chain to the test. Recent GLP-1 supply chain shortages are just one such example – ongoing supply issues with Ozempic (semaglutide) and Trulicity (dulaglutide) began in September 2022 [26]. As of July 2023, all GLP-1 analogues have been affected by these continuing supply chain shortages [26]. “The off-label use of GLP-1 for weight loss has driven worldwide drug shortages and left patients scrambling to find alternative supplies,” Chatterjee explains. “Big Pharma companies are committing funds to build capacity for both API and drug products while contract manufacturers struggle to keep pace with demand. Realistically, intermittent shortages of GLP-1 receptor agonists will be the norm through 2024, and potentially 2025 for some programs, as Big Pharma looks to bring new capacity online.”

Despite increased manufacturing for generics, pricing challenges are putting pressure on drug manufacturers and their businesses, particularly in North American markets: “The US domestic market is in untested waters



Supply chain shortages are nothing new for the pharmaceutical industry. However, new challenges are putting the resiliency of the pharma supply chain to the test.

regarding generic drug pricing,” Chatterjee states. “Between 2022 and 2023, more than 46% of drugs on the market saw prices increases above the inflation rate. The passage of the Inflation Reduction Act would penalise drug manufacturers for price increases above the inflation rate for any drugs sold to Medicare, and since Medicare makes up approximately 18.7% of the US population today, its impact on bottom line profitability is tangible. As inflation cools, so will the ability to raise prices significantly.”

Inflationary pressures are not limited to generics – with accelerated approvals for new cell and gene therapies,

inflation in pharmaceutical pricing is expected to soar into the double digits in 2024 [27]. “New modalities such as cell and gene therapy and mRNA vaccine technology have increased from 11% to 21% of the drug development pipeline,” Moch states. “This change is likely to bring more fragmentation of technology, new supply chains, and unique product life cycles. For instance, CAR T-cell therapy is a type of treatment in which a patient’s T cells are genetically engineered to express a chimeric antigen receptor that targets a specific tumour antigen.” Continuing to invest in innovation and R&D will rely on the willingness of drug manufacturers to balance patient access to therapeutics [27].

However, there may be some relief on the horizon for both manufacturers and patients – the rise of biosimilars thanks to patent expirations can have a substantial effect on managing rising drug costs [27]. “I would look for the larger generic drug manufacturers entering the US market to pivot toward biologic drugs and biosimilars that enjoy higher margins compared to small molecule drug therapies, to



better withstand downward pricing pressures,” Chatterjee advises. Though the maturity of the biosimilar market is still nascent, 2024 will prove to be a pivotal year for the industry to test the 2023 launches of biosimilars to therapeutics such as Humira.

Moch also sees the role of digitalisation throughout the supply chain as essential but warns of the challenges: “The pressure to digitise in the pharmaceutical industry is high. Companies want to be competitive, minimise costs, and streamline processes – with the help of digital solutions. Informing, deciding, implementing all of that with the acceptance of the employees is a big challenge. Effective change management strategies are critical to successful implementation,” Moch explains.



8

Evidence-based herbal medicines



Evidence-based herbal medicines

Interest in nutraceuticals and natural extracts continues to gather momentum; the nutraceuticals market grew to USD \$291.33 billion in 2022, with an expected CAGR of 9.4% between 2023 and 2030 [28]. **Nigel Pollard, Chair of the Board of Directors for Empowered by Evidence**, states that “as some consumers become more informed through better access to evidence, there will be more incentives for companies to serve these consumers better with tangible, product-specific evidence of safety and efficacy.”

The coming year is set to bring an increase in interest of evidence-based traditional remedies and natural ingredients for use in modern pharmaceuticals and nutraceuticals.

Consumer demand for natural health products, driven

in part by an interest in customised healthcare and integrative medicinal practices, is paving the way for industry investment in research and manufacturing for natural ingredients and products [29].

While interest in natural ingredients for therapeutic use is nothing new, science-based evidence for their efficacy and safety is on the rise, as demonstrated in the [CPHI Online Trend Report Pharma’s Next Big Opportunity: Exploring the Potential of Herbal Medicines in Modern Healthcare](#).

Consumers are not only scrutinising established and experimental pharmaceutical treatment options – they are critically analysing the science in support of nutraceuticals and natural ingredients. Ingredients that will see a surge in interest from pharmaceutical companies might include Ashwagandha, CBD, and psychedelics.

Regulatory incentives will also play a role. “Organic certification from the United States Department of Agriculture’s Strengthening Organic Enforcement rules and Empowered by Evidence independent certification



of reproducibility and specific clinical evidence are new initiatives this year,” Pollard explains. “Also, regulators continue to attempt to address issues of products that are outside of clear regulatory pathways, such as the Australian Therapeutic Goods Administration looking at medicinal mushroom products. The responsible industry, which is increasingly global in nature, has little guidance on recognised international standards. This is an impediment to patient and evidence-based innovation.” Increased regulatory guidance and incentives in the coming year will help push the research required for science-based evidence for natural products.

Trending areas in the natural products market, according to Pollard, include brain health and e-gaming performance, with companies across the globe “seeking new innovative product formulations and building the evidence base for their products in this area.”



9

The future of B2B pharma marketing



The future of B2B pharma marketing

The power of in-person interactions cannot be understated – as the events industry recovers from the COVID-19 pandemic, the appetite for a return to face-to-face meeting and events may be even larger than pre-pandemic. However, the rise of digital B2B marketing for the pharmaceutical industry during the pandemic years is set to continue in tandem with a return to in-person connections [30].

Traditional channels of brand visibility and marketing saw a leap towards digital and hybrid solutions during the pandemic, but pharma seemed to lag behind. “Part of the challenge for pharma marketing teams at the minute, particularly for CDMOs, CROs, or equipment manufacturers, is that they don’t have sophisticated CRMs and marketing automation systems that would expect from a tech

company or consumer brand,” **Raman Sehgal, Global President and Founder of ramarketing, states.** “We’re on that journey but for us it’s about getting visibility about someone at a certain point of their customer funnel, handing over some data, and eventually converting them into a client.”

More than 60% of healthcare providers state they use digital media for professional purposes, and close to 70% of patients are using digital solutions for healthcare monitoring [31]. The successful pharmaceutical service provider will also make the shift towards digital solutions to engage their business and customer base.

B2B pharmaceutical marketing must contend with a changing customer landscape. Healthcare marketers are shifting towards a digital mindset to continue delivering to their consumers [32]. The rise of digital therapeutics, precision medicine, and customised clinical trials and therapeutics are leading to a digital marketing revolution focused on delivering personalised customer experiences [32].



“Precision medicine refers to the creation of tailored treatment plans for individual patients,” Moch states. “In practice, this is increasingly being done with technology and data. Precision medicine takes into account differences between individual patients and seeks to take advantage of them with the aim to find the right drug for the right patient at the right time.” This precision in treatment plans must be mirrored in the marketing practices of pharmaceutical vendors as it will be an expectation by customers in 2024 for such digital solutions, including digital engagement, telehealth, e-detailing, and direct-to-consumer approaches [32].

According to IQVIA, evolving digital capabilities will lead to greater interconnections between pharmaceutical service providers, healthcare providers, and the patients themselves [31]. B2B pharma marketing will have to adopt an omnichannel approach to digital communications to nurture these multi-pronged

connections [31]. “The pharma industry now finds themselves with little choice than to adopt an omnipresent, integrated, and data-driven approach,” Sehgal states.





10

Accelerating Alzheimer's research



Accelerating Alzheimer's research

"The impact of neurological diseases (Alzheimer's disease, multiple sclerosis, Parkinson's disease etc.) is two-fold," states **Alan Palmer, CEO of Elixia MediScience**. "The first is morbidity and the second is mortality (death). Neurological disorders have such a profound effect that the term Disability-Adjusted Life Year (DAL) accounts for the number of years lost because of premature death due to the disorder and the number of years lived with a disability. For neurological disorders, the global number of DAL years is 270 million."

In a ground-breaking year for Alzheimer's disease treatments, the FDA granted accelerated approval for

lecanemab – a humanised monoclonal antibody targeting key abnormal proteins linked to dementia, beta-amyloid. This significant milestone followed the 2021 approval of another amyloid antibody aducanumab.

Landmark progress has been made in the past year for a phase III clinical trial that demonstrated that donanemab, a monoclonal antibody, significantly slowed cognitive and functional decline in patients [33].

It's important to note that the observed changes were small and the clinical meaningfulness is not yet entirely clear. Nevertheless, these findings pave the way for further exploration and hold great promise in the ongoing quest for effective treatments.

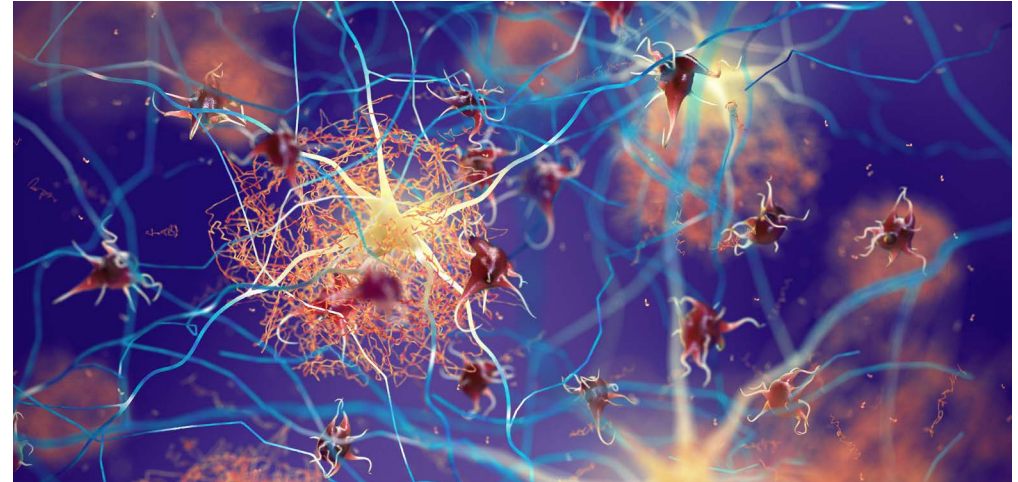
Successful study results have also probed the quantification of Alzheimer's disease biomarker proteins with a whole-blood test, which can be developed into a screening system for the detection of Alzheimer's disease before symptom onset [34].

For Palmer, 2024 will bring an increased focus to Alzheimer's



disease research development and therapeutic innovation. “Some of the biggest steps forward in the last year for the pharmaceutical industry regarding Alzheimer’s disease treatments are amyloid-based therapies approved by the FDA. These approvals have stimulated pharmaceutical industry interest, and the market for a drug that slows disease progression or delays disease onset (or preferably both) onset is huge,” he explains. Plans are in work for human clinical trials for novel neurodegenerative disease drugs such as biopharma company CuraSen Therapeutics, which received USD \$5.8 million in funding from the Alzheimer’s Drug Discovery Foundation to cover trial costs in 2024 [35].

“The baby boomer generation is aging and this is going to have a profound effect on the impact of neurological disorders in the near future,” Palmer explains. “The global incidence of dementia in 2019 was 57 million. By 2050, this number is expected to be 153 million. This will place huge pressures on healthcare systems across the globe. So the need is big and the need is growing starkly.”



“Some of the biggest steps forward in the last year for the pharmaceutical industry regarding Alzheimer’s disease treatments are amyloid-based therapies approved by the FDA.”

Alan Palmer
CEO of Elixia MediScience



11

What 2023 drug approvals mean for 2024



U.S. Department of Health and
Human Services
Food and Drug Administration





What 2023 drug approvals mean for 2024

By June 2023, 26 novel drugs had been approved, a staggering amount for halfway through a calendar year [36]. Key trends in drug development and approvals include, according to Radó, will be “the continued dominance of small molecule drugs, increasing adoption of biologics, and growing demand for personalised medicines.” Major drug approvals in 2023 include full, comprehensive US FDA approval of COVID-19 treatment Paxlovid, cell and gene therapies for oncology, and orphan drugs for rare disease treatments under FDA fast-tracked programmes [36].

Experts believe 2024 will prioritise the approval of drugs for so-called ‘first-world problems’ – diseases affecting mainly

wealthy nations [37]. Some treatments, such as in the case of GLP-1s, are repurposed from their original indications, and have since gained approval for others. Several GLP-1 receptor agonist treatments gained approval for indications like non-alcoholic fatty liver disease and diabetes, mainly acting on insulin levels within patients [37]. When weight loss effects were observed in these trials, manufacturers have since shifted their focus to weight loss-specific drugs [37]. Novo Nordisk’s Ozempic and Wegovy are the most well-known examples. Wegovy was approved specifically for obesity treatment in 2021, but Ozempic currently is only approved for use as a type 2 diabetes treatment, with off-label use for weight loss [37].

With these demands for off-label use of existing drugs, there’s been much discussion regarding accelerate approval schemes among regulatory bodies. During the BIO International Convention on June 7, 2023 in Boston, Commissioner of the FDA Dr Robert Califf addressed pressing issues concerning drug approvals and shortages. Accelerated approvals and legal challenges for the FDA have highlighted



where regulatory authorities can work with others to improve drug approval procedures: “I’m totally in favour of Accelerated Approval... There’s the FDA and the Centers for Medicare and Medicaid Services (CMS),” Califf stated during his panel at BIO. “The FDA [looks at what is] safe and effective. CMS – [what is] reasonable and necessary. It’s like a relay race. We run a lap and then we hand the baton to CMS. CMS doesn’t tell us what’s safe and effective. We can’t tell them what’s reasonable and necessary... That baton handoff is very dependent on an evidence generation system that doesn’t exist in our country right now... We need to have this data generation system that works and that should bring us together with CMS to make the transition smoother and better. [38]”

Cell and gene therapies in particular are expected to make up the most prominent approvals in 2024, with treatments for severe haemophilia A and sickle cell disease in the pipeline [39]. Continuing on from 2023, the approval of several monoclonal antibody treatments for autoimmune diseases and orphan drugs for rare diseases are set to make headlines in 2024 [39].





12

Middle East rising: an emerging market in focus





Middle East rising: an emerging market in focus

In December 2024, CPHI Middle East will launch in Riyadh, Saudi Arabia – a country responsible for 60% of the Gulf’s pharma market [40]. A strategic event for regional drug manufacturers and global suppliers to gather in Saudi Arabia, the event reflects the exponential increase in interest in the Middle East and Africa (MEA) pharmaceutical market and supply chain. According to research from IQVIA, in 2019 the pharmaceutical market in the MEA surpassed USD \$25 billion in value and demonstrated a CAGR of 8%, outperforming a global CAGR of 5.27% [41].

The Kingdom of Saudi Arabia and The United Arab Emirates are currently the largest regional markets for

pharmaceuticals within the Middle East. Saudi Arabia leads with a pharmaceutical market valued at approximately USD \$10.74 billion by the end of 2023 [42]. Multinational pharmaceutical giants present in the region include Sanofi, Novartis, and Pfizer, along with a strong global manufacturing presence – Saudi Arabia manufactures 22.55% of drug products in current global markets [43]. This growth in the region has multiple drivers.

Manel Chikh, CEO of Zaphyr Pharmaceuticals, comments: “The healthcare sector in the Gulf region is experiencing significant growth, presenting substantial opportunities for global healthcare companies. This expansion is driven by factors like population increase, aging demographics, and evolving consumption habits. The Gulf countries, including Saudi Arabia, UAE, Qatar, Bahrain, Oman, and Kuwait, are dedicating around 7% of their GDP to healthcare, with a combined population of 50 million. Significant investments, such as Saudi Arabia’s \$200 billion in its Vision 2030 for healthcare modernization, are underway.”

As part of the Saudi government’s Vision 2030 plan,



dedicated efforts are in place to develop the nation's healthcare and pharmaceutical infrastructure [44]. These efforts are in response to the nation's aging population and the rise of chronic diseases [44]. Drug accessibility and affordability are also top concerns for the region, influencing government investment [41]. With rising incidences of diabetes and cancer in the Arab population – Saudi Arabia has the second-largest diabetes prevalence rate in the Middle East, and seventh-largest in the world – the Kingdom is heavily invested in both establishing a global presence and bolstering domestic manufacturing capacity of both generics and innovator products [45].

Muased Alkholief, Professor and Management Consultant at King Saud University, comments: "The announcement of the inaugural CPHI event in Saudi Arabia in 2024 not only marks a significant milestone for the country's growing pharmaceutical and biotechnology sectors but also aligns seamlessly with the aspirations laid out in Saudi Vision 2030. Rooted in the Vision's strategic goals of economic diversification, the event is poised to attract

foreign investment and promote the growth of the local pharmaceutical industry, contributing to a more resilient and diversified economy. At the core of CPHI's beliefs are three guiding principles: to inspire innovation, enable collaboration, and drive change. These principles align perfectly with the transformative objectives of Vision 2030."

Saudi Arabia is also quickly becoming a critical location for multinational companies looking to increase their global presence and reach. Geographically, the country is a strategic hub to serve wider regional markets in the MEA region [44]. As of August 2023, the Kingdom boasts nearly 50 local pharmaceutical manufacturing facilities [46]. The Kingdom also saw a tripartite agreement between the nation's National Industrial Development Center, Jubail Pharma, and RR Holding Co. to boost local manufacturing of chemical compounds required in the production of pharmaceuticals [45].

Chikh states: "For healthcare companies seeking to enter this market, strategies must include local production, technology transfer, and creating job opportunities for nationals. The



market offers prospects in medical technology, construction and renovation of hospitals and clinics, knowledge transfer in MedTech and Biotech, and establishing local pharmaceutical branches.

Success in this market requires a deep understanding of local regulations, cultural norms, and standards. Building strong relationships with local health authorities and hospitals and adapting to local requirements are key for these companies to thrive in the Gulf's burgeoning healthcare sector."

Such partnerships will consolidate the manufacturing of APIs, intermediates, and other necessary pharmaceutical ingredients in the MEA region.

"The emphasis on inspiring innovation resonates with the Vision's commitment to fostering a culture of research and development, pushing the boundaries of scientific discovery in the pharmaceutical and biotech domains," Alkholief states. "CPHI provides a dynamic platform for local stakeholders to showcase their innovative solutions, learn from international best practices, and engage in discussions that can shape the future of the industry."





Talent attraction is also driving the rapid growth of the Saudi Arabian pharmaceutical sector. With largely tax-free salaries and a range of benefits seldom found elsewhere, 2024 may see an influx of top candidates to Saudi Arabia [42]. While an emphasis will be placed on local talent through nationalisation programmes within the MEA region, those who have experience working abroad or expatriates may find that the booming Saudi Arabian pharmaceutical market is where their career can grow [42].

“In the context of Saudi Vision 2030’s focus on healthcare infrastructure development, CPHI’s significance extends to the potential enhancement of research and development capabilities, the establishment of state-of-the-art manufacturing facilities, and the creation of high-skilled jobs,” Alkholief explains. “The platform not only provides an opportunity for local companies to showcase their capabilities but also for international player to understand and contribute to the evolving healthcare ecosystem in Saudi Arabia. We are excited to host CPHI in Saudi Arabia and I am certain that the event is going to contribute significantly to

the growth and development of the pharmaceutical and biotechnology sectors in Saudi Arabia and the region.”

The 2023–2024 forecast for the Saudi Arabian pharmaceutical market is proving to be pivotal time for its growth, with many experts agreeing that the Kingdom is one to watch for pharmaceutical investors and stakeholders.

“Hosting CPHI MEA, one of the world’s most prestigious pharmaceutical event, in Saudi Arabia underscores the region’s growing role in the global healthcare market. This event will foster international partnerships and will showcases the region’s healthcare advancements, aligning with its investment in healthcare development creating an ideal platform for foreign healthcare companies to explore local opportunities,” comments Chikh.



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