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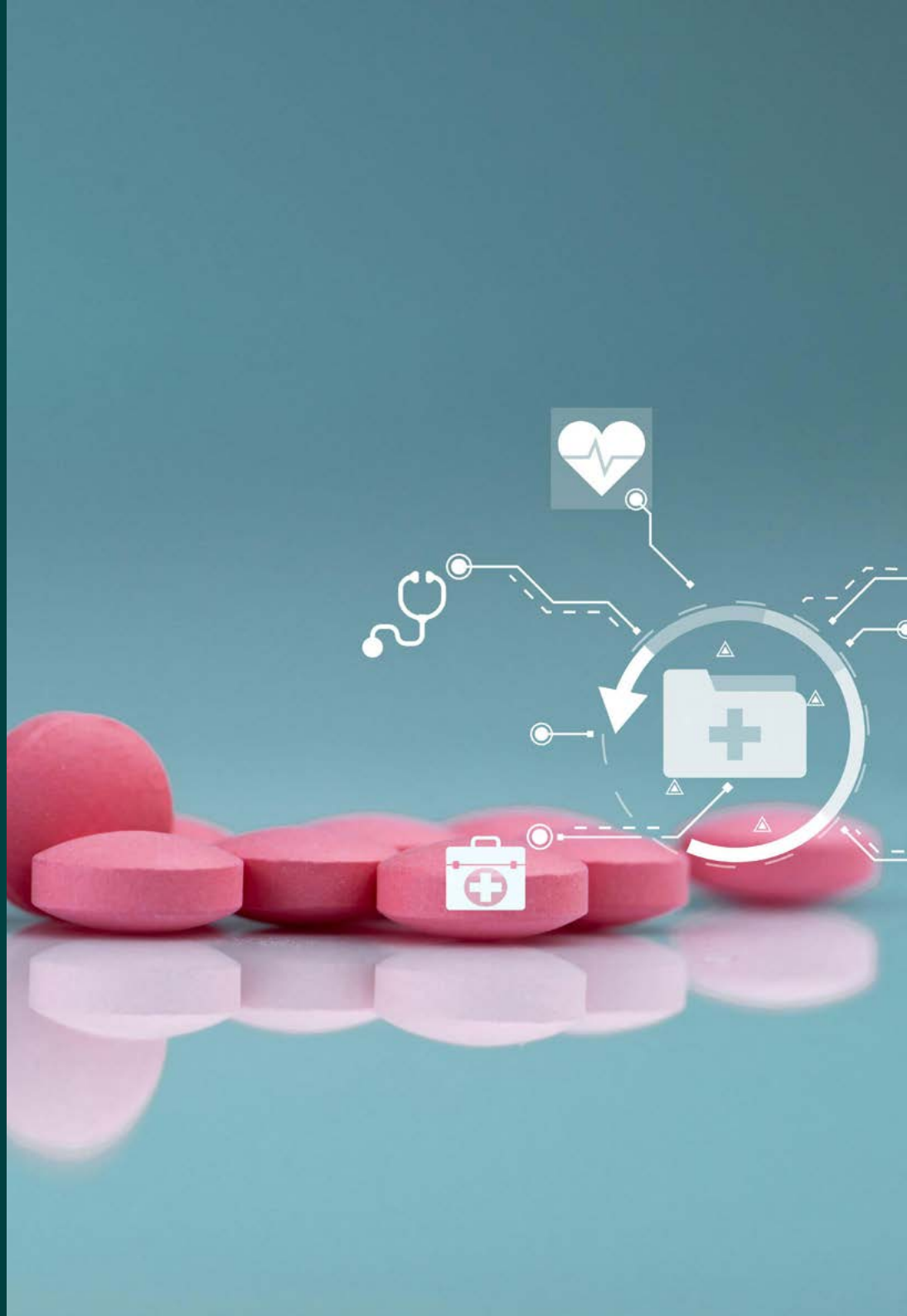
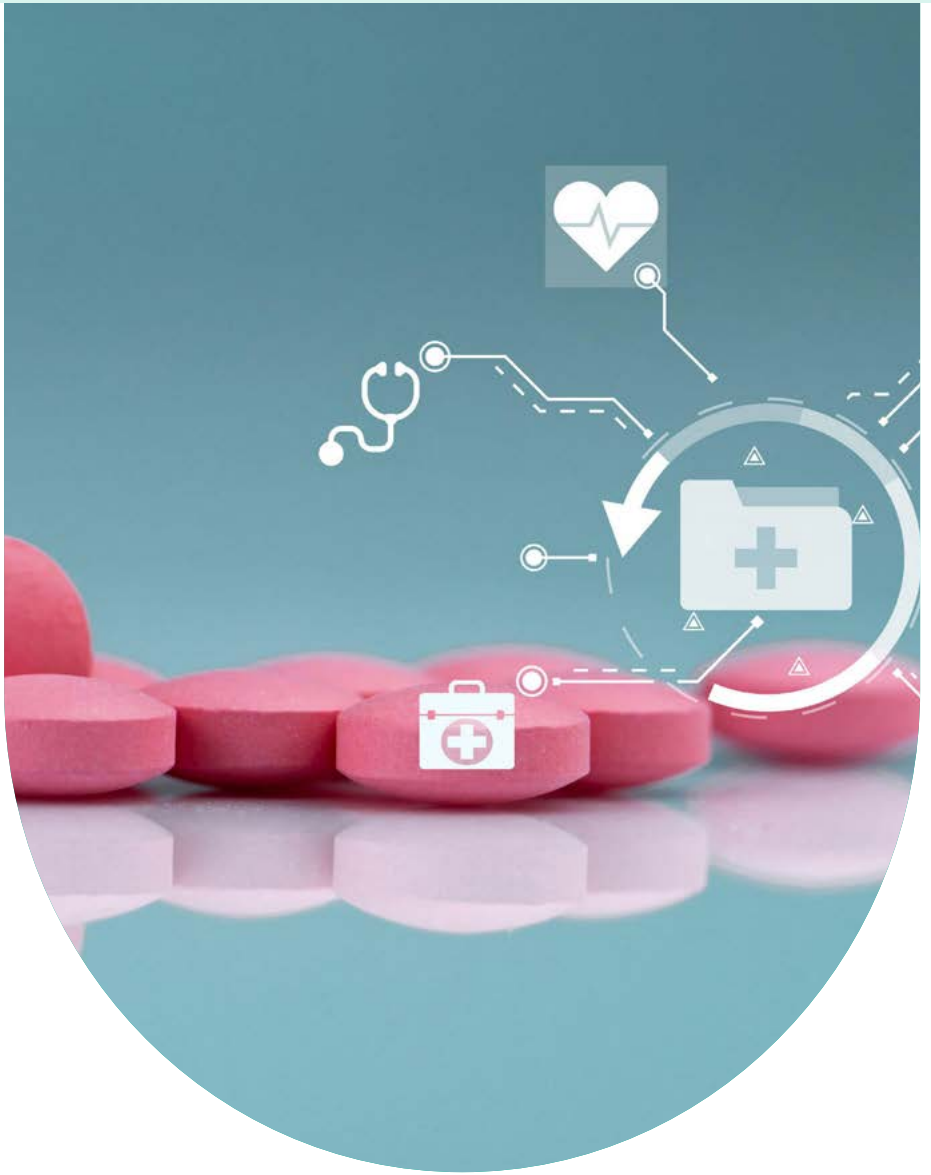
2026 Pharma Trends Outlook: AI Governance and an Interdisciplinary Industry





Welcome

Thank you for downloading the 2026 Pharma Trends Outlook Report, our annual CPHI Online publication heralding in the top challenges and opportunities facing the pharmaceutical supply chain for the year ahead. In these reports, we reflect on the past year of dynamic innovation, strategic priorities, and market pressures to inform expectations for the next year.

Our report last year cited many disruptions to the pharmaceutical supply chain, including legislations like the BIOSECURE Act, ongoing conflicts in Gaza and Ukraine, and changing partnership structures between vendors and sponsors, to hail some of the biggest shifts the industry has witnessed to date. As we start 2026, how have these predictions shaped the next wave of changes?

As one of the premier B2B event platforms for the pharmaceutical industry, we at CPHI are continuously aware of the evolution of partnership models within the pharmaceutical supply chain. As many vendors make the move towards a one-stop-shop, end-to-end structure, where does that leave companies looking for specialist manufacturers? Moreover, targeted therapeutics, biologics,

biosimilars, and personalised medicines are demanding more specialist manufacturing capabilities than ever before. How vendors respond will likely shape the next generation of CDMOs.

GLP-1 agonists continue to be breakthrough therapeutics for metabolic diseases, but the industry is also seeing innovative surges in targeted therapeutics, driven by evolving patient needs and the growing prevalence of chronic and complex diseases [1]. Top therapeutic areas continue to include those such as oncology, neurological conditions like Alzheimer's and Parkinson's, while rare diseases and cell and gene therapies are gaining momentum as precision medicine transforms healthcare [2].

Among the most pressing concerns for pharma is the integration of AI in the industry. While an invaluable tool revolutionising drug discovery, clinical trials, streamlined manufacturing and supply chain processes, and patient care, its use has also raised critical concerns regarding regulatory oversight [3]. As AI technologies become more sophisticated, governments and regulatory bodies worldwide are under increasing pressure to establish the necessary frameworks that ensure ethical use of data and protecting privacy and safety [4].

2026 will see rapid advances in healthcare and technology coming up against shifting regulatory landscapes, all while balancing patient expectations and industry demands. The trends outlined in the 2026 Pharma Trends Outlook Report will not only redefine how medicines are discovered and delivered, but also shape the competitive dynamics of the sector for years to come. Understanding these forces is essential for organisations seeking to remain resilient, relevant, and positioned for sustainable growth in an ever more complex healthcare ecosystem.

Vivian Xie
Editor – Pharma
Informa Markets

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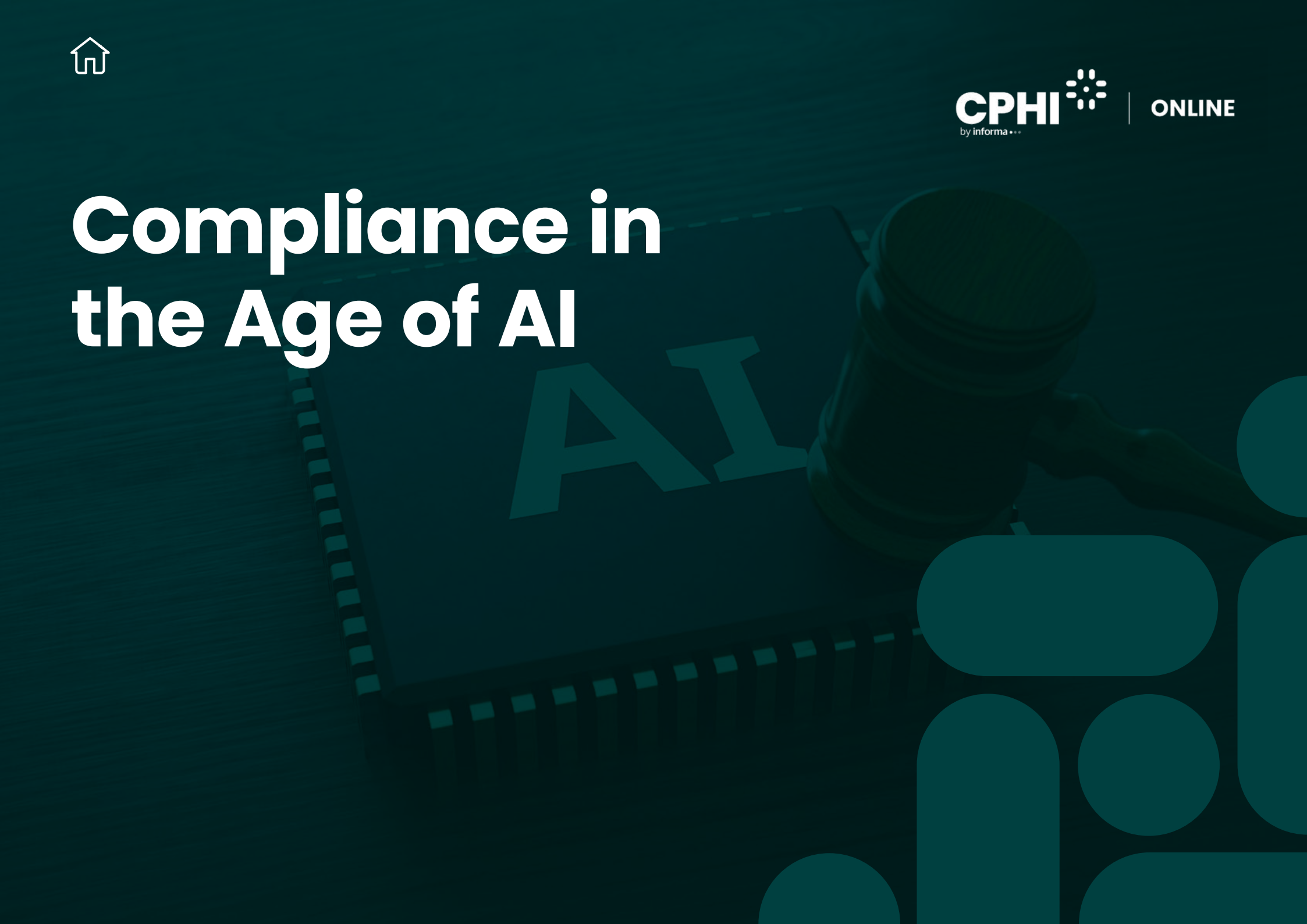
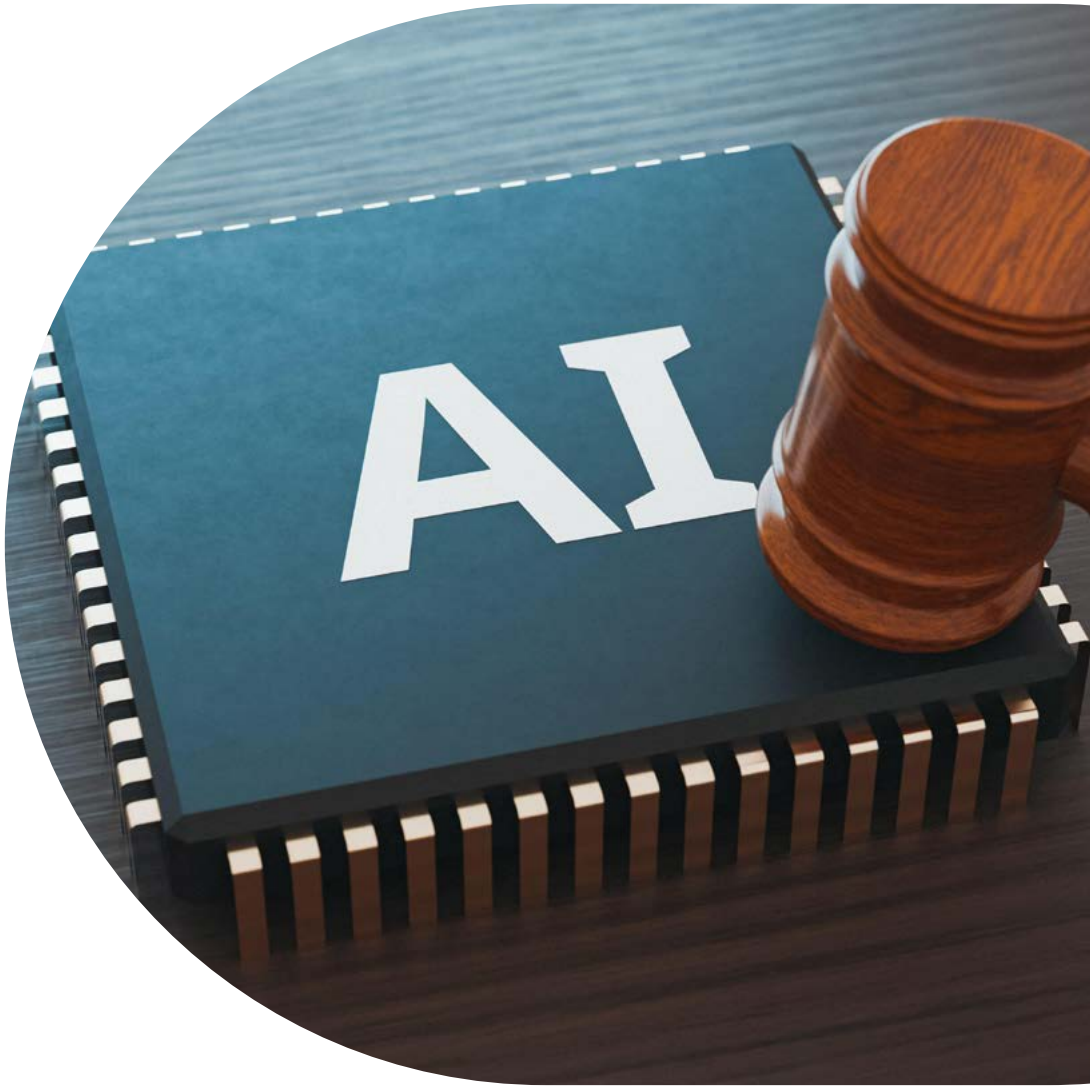
Compliance in the Age of AI



Compliance in the Age of AI



As AI becomes increasingly embedded across the pharmaceutical value chain, the urgency to establish clear, trustworthy regulatory frameworks has never been greater. While companies are already using discovery algorithms for new drug candidates, screening clinical trial participants, streamlining manufacturing processes, and analysing trial and post-market data, technological innovation is clearly outpacing policy [4]. Remaining competitive in such an uncertain landscape risks not only operational efficiency, but also patient safety and public confidence. Moreover, while AI is accelerating efficiency across the supply chain, the human factor of technology remains indispensable [5].

Current use of AI spans a number of disciplines within the pharmaceutical industry, including some start-ups at CPHI Frankfurt exhibiting exciting new ways of implementing AI technologies. **Will Cao, Co-Founder and CEO Pando Bioscience** is just one of these start-

ups, but she comments on the current state of AI with a bit of trepidation. “When it comes to AI for life sciences, the landscape is very different – tools like ChatGPT are excellent for training in literature, Youtube, or Wikipedia, but we still lack a robust ChatGPT equivalent for biology. For example, small molecule prediction and protein structure modelling are effective because we have a wealth of well-defined crystal structures to train AI models on. But when we delve into enzyme activity or selectivity, we’re dealing with much more complex properties, which require high-quality datasets to train models effectively. Generating and curating high-quality datasets to train these models is more critical for biology than simply creating better models.” Such requirements for high-quality datasets and their analysis naturally demand a certain level of privacy and security, one that is yet to be implemented.

“In the context of pharma and AI, particularly when experimenting with these technologies, it’s entirely possible to have AI generate something like a dossier for you,” adds **Yassin Helmy, CTO of Pharco Corporation.** “On the surface, this dossier might appear polished and credible, but in reality it could be filled with overly elaborate language and completely made-up stuff. This raises a critical question: how can we trust that regulatory

authorities will discern whether such submissions are genuine, or just a collection of fabricated, impressive-sounding terms? If AI becomes more widely adopted in regulatory processes, it could lead to a situation where authorities are overwhelmed – imagine 300 new drug applications but the capacity to review only 30. If this scenario unfolds, it would fundamentally change the landscape of the industry. While many companies and individuals operate ethically, there will always be those who cut corners in a race to be first-to-market. This is why it’s important for regulatory bodies to take their time and ensure that decisions are made carefully and responsibly. It’s not enough for one authority to approve something

and for others to follow suit without due diligence."

Perhaps the key to unlocking true AI regulatory harmony is a word that continues to crop up in all aspects of the pharmaceutical industry – collaboration. **Sun Chau Siu, Executive Director and Head of Regulatory Affairs and Project Management at Altruist Biologics**, offers, "While some regulators are already engaging seriously with AI, many may only be familiar with it as end-users with tools like ChatGPT. That gap highlights the need to bring together the right mix of expertise to establish a credible harmonisation or framework. This raises fundamental questions. Should AI in healthcare fall under the remit of existing bodies such as the ICH? Do we need a dedicated working group for this, and if so, who should be involved?

Subject matter experts, regulatory professionals, and technology specialists all need a seat at the table. These are important questions, but we're still at an early stage. To make real progress, the priority should be establishing clear structures and governance, and ensuring decisions are informed by the right expertise from the outset."

Interdisciplinary Integration of Tech and Pharma

Interdisciplinary Integration of Tech and Pharma

2025 saw a wave of inter-industry collaborations between Tech and BioPharma – that of Pfizer and PostEra [6], AstraZeneca and China's CSPC [7], and most recently Eli Lilly and Nvidia [8]. The last few years also witnessed partnerships signed between the likes of Boehringer Ingelheim and Google, and Syneos Health and Microsoft. Such moves point to a larger trend of exploratory pilot programmes for large-scale adoption of AI-native infrastructure, setting the stage for a new wave of partnerships that could reshape how medicines are discovered, developed, and delivered.

"A lot of the technological disruption we're discussing right now hinges on interdisciplinary collaboration," comments **Allison Colbert, an Independent Health Policy Advisor.**

The real challenge – and opportunity – is fostering effective cross-sector translation. How do we get data scientists, ethicists, policymakers, and others into the same room, speaking a common language, and working towards shared goals?

It may not always be the most disruptive or efficient path, but it's essential if innovation is to translate into real-world impact. The question is how we create the frameworks and environments that enable this kind of meaningful collaboration."

"This transformation isn't confined to the biopharmaceutical industry," Siu adds. "It's much broader. What we increasingly need is talent that can bridge healthcare and technology - individuals with multidisciplinary skill sets who are comfortable operating at the intersection of both fields. That, in turn, requires an evolution not only within industry but also within society more broadly, particularly in how we educate and develop future talents. Building these capabilities is essential if we are to sustain progress and meet the demands of this next phase of innovation."

The interdisciplinary integration of pharma and tech represents a pivotal opportunity to revolutionise healthcare. By combining the scientific rigour and clinical expertise of the pharmaceutical industry with the scalability of innovative digitisation from tech companies, we can address some of the most pressing challenges in medicine. Collaborations such as those by Eli Lilly and Nvidia have the potential to accelerate drug discovery, personalise treatments, improve patient outcomes, and drive operational efficiency to an unprecedented scale.

However, achieving this requires more than just technological advancements – it demands a workforce equipped with multidisciplinary skills, a reimagined education system to develop and upskill talent, and a shared vision that bridges the cultural and operational divides between sectors.

Humanising a Digital Workforce

Humanising a Digital Workforce

The pharmaceutical industry, as with all other healthcare industries, likes to be clear on who they are serving at the end of the day – patients and people. However, the logistical reality of such goals can prove to be difficult, even more so with the looming threat (or opportunity?) of AI use in pharma.

Perhaps the most acute impact AI may have on pharma is on the people who currently operate within it [9]. Workforce skills gaps and mismatches have been a continuing discussion throughout the industry with the rise of advanced therapeutics and innovative manufacturing technologies, and are being made even more obvious with the adoption of AI [9].

"There is certainly a way to evaluate an individual's strengths, but it's also about the individual choosing pharma as an industry to develop their career," posits **Jack Shute, Managing Director at Vector Talent,** offering

a variety of potential opportunities AI adoption poses for both the workforce and the companies that need these skills. "People have options – they can go into tech, law, or any number of other fields. In the CDMO sector, we face the same challenge. Many graduates come out of university with pharma as their first thought, but they often lack awareness on CDMOs and the pharma services sector. It's essential to educate them about these areas. Similarly, the industry as a whole finds itself in this position when it comes to data and AI – individuals simply do not know about the opportunities for data and AI in pharma. It's crucial to build a talent pipeline to attract and develop the right expertise in these fields."

A 2023 study conducted by the Deloitte Center for Health Solutions surveyed 105 biopharma supply chain leaders to gauge the sector's current understanding and implementation of digitisation, including AI technologies [9]. 66% of survey respondents stated that, despite recognising the importance and business imperative to digitise, many still lack clarity on what changes are needed to evolve current roles and skills, and tend to be largely reactive towards a short-term skill hiring approach [9].

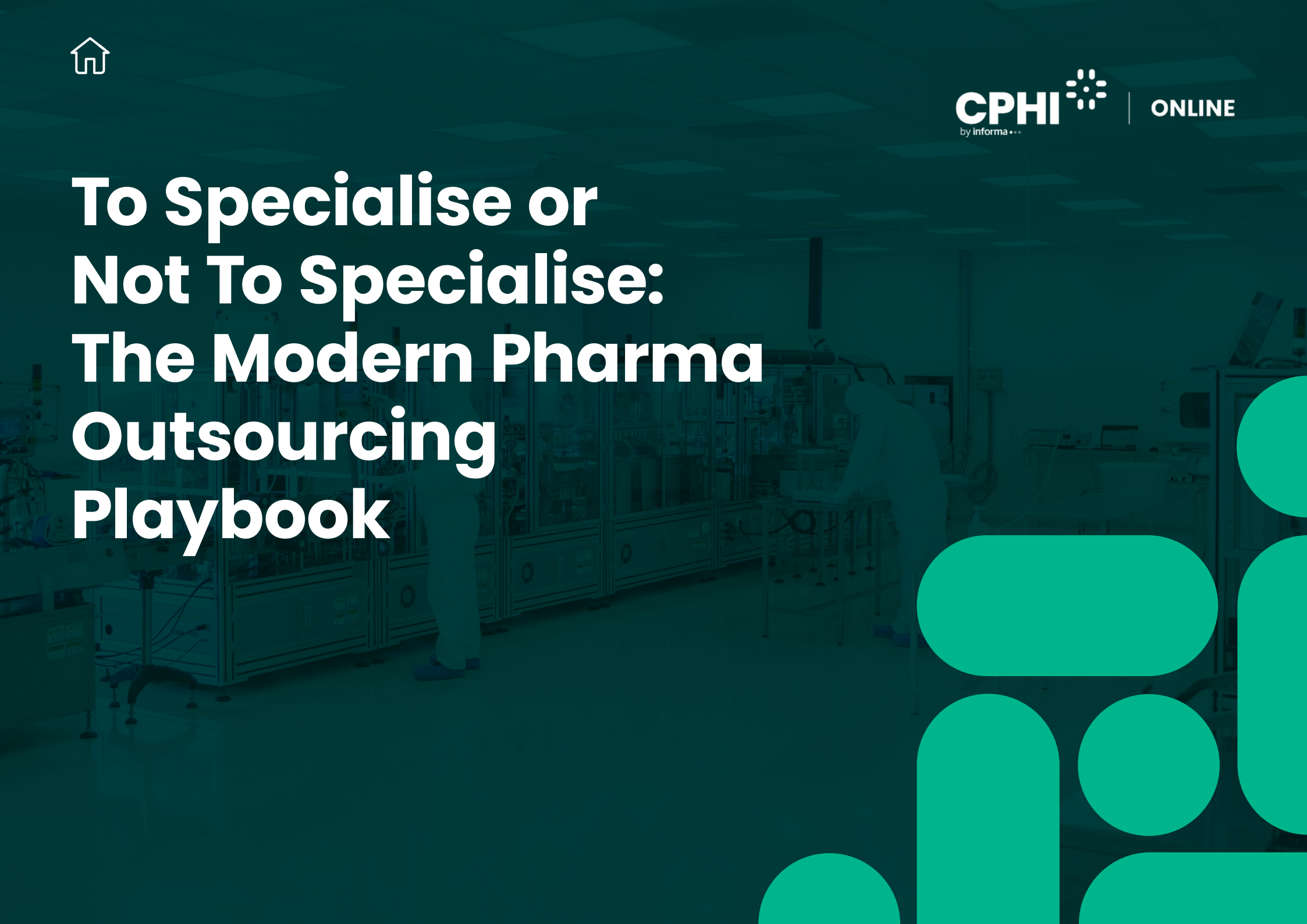
"As someone trained in synthetic biology, and with my co-founder being an AI protein engineer, I can see how AI is flourishing," Cao adds. "Machine learning and AI are undoubtedly among the hottest fields right now. However, domain knowledge is equally as crucial to areas like biology. We've hired mathematicians who develop AI algorithms, but when tasked with interpreting protein structures or outputs from said AI models, they lack the necessary scientific understanding. Recruitment in this field also requires careful consideration. It's not enough to hire someone based solely on their expertise in AI algorithms or architecture; they need domain knowledge to truly excel."

Frank Platte, an Augmented Reality Consultant at 3DQR, offers a perspective on the transformative potential of combining AI and augmented reality (AR) in addressing workforce challenges, stating that "AR systems can guide people step-by-step through complex tasks, enabling them to perform actions they wouldn't be able to manage without AR providing real-time advice and instructions. This integration is especially promising for countries like Germany, where there is a shortage of skilled workers for specific, complicated processes. While

this is already happening to some extent, the next level is to combine AR with AI. This would allow AR systems to provide dynamic, data-driven insights during long or intricate processes, such as machine operations, adapting to changes and offering tailored guidance in real time. This is the direction I believe we are heading, and it holds immense potential."

Ensuring the next generation of skilled workforces in the pharmaceutical and biopharma spaces will require a conscious effort from industry leaders to educate and evolve both their companies and their workforces.

To Specialise or Not To Specialise: The Modern Pharma Outsourcing Playbook



To Specialise or Not To Specialise: The Modern Pharma Outsourcing Playbook

The pharmaceutical manufacturing landscape is at a crossroads on the future of the modern pharmaceutical outsourcing model – while end-to-end solutions offered by a single partner, from development to production, has gained significant traction for its convenience and efficiency, the growing complexity of drug development and advanced therapeutic manufacturing has sparked debate about whether specialised manufacturing facilities will become essential to meet these unique demands [10].

"I currently see two main trends," states Siu. "Many CDMOs are moving toward vertical integration, offering end-to-end solutions that span development through to production. While this model is attractive, it is also challenging, requiring significant investment and a broad depth of expertise expertise to manage the entire value chain effectively. At the same time, there is a growing number of specialised CDMOs focusing on specific areas – such as ADCs – and aiming to excel in well-defined niches rather than offering commprehensive end-to-end services."

"Everyone wants to be end-to-end but the reality is far more complex," adds **Anna Czubatka-Bieńkowska, PhD and Project Management Manager at Mabion S.A**. "When my company started as a CDMO, we aimed to cover everything but as the industry evolves, we've had to adapt our strategy. It's incredibly challenging to manage end-to-end operations, especially when specialised knowledge and expertise are required for certain areas. We've recently entered partnerships to address critical aspects of ADCs."

Rethinking the popular end-to-end service models that has dominated the sector in the last 5 years has certain CDMOs exploring how a shift toward specialisation could better align with market demands for advanced therapeutics, enhancing operational efficiencies and allowing them to focus on areas where they can deliver the most value and innovation. "In our case, we've partnered with robust linker technology providers to handle early-stage clinical trial material, where the quantities are small enough to make outsourcing more practical," explains Czubatka-Bieńkowska. "However, for commercial manufacturing, we plan to bring the technology in-house, transferring it from our partners to our own facilities.

This shift reflects the broader trend in the industry – while many companies aspired to be fully integrated a few years ago, the focus now is on balancing specialisation with strategic partnerships. Even major players like Merck, with their subsidiaries like Sigma and BioReliance, operate as a network of specialised entities rather than a single, unified end-to-end provider.

Similarly, in the small molecule space, we're seeing companies expand into biologics to diversify their portfolios, but this requires a deep understanding of both fields, which are fundamentally different. Ultimately, the CDMO landscape is evolving to embrace a mix of integration and specialisation to meet the demands of the market."

When navigating the increasingly complex landscape of pharmaceutical development and manufacturing, experts often highlight the distinct administration challenges that come with choosing between end-to-end CDMOs and highly specialised providers. "One of the biggest challenges we face with our clients is that when you start piecemealing steps of pharmaceutical manufacturing, you often accumulate significant administrative delays," states **Edgar Pogna, Director, Life Sciences at L.E.K. Consulting**.

"I'm not sure how well the concept of end-to-end services translates in the real world from a client's perspective," offers **Ashley Cox, CEO and Founder of Caledonia Life Sciences**. "While there's certainly a desire for support at every step, we've seen especially from experience in larger consultancies that the handoffs between stages can be quite challenging. That's why there's still a significant need for smaller, independent boutiques to fill specific gaps. Over the last 5 years, the industry has leaned heavily toward the end-to-end model, but whether that approach will stay or evolve into something more specialised remains to be seen – it's going to be an interesting one to watch."

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“From a technical perspective, working with different partners makes sense – you gain more expertise and specialisation – but the reality is that it can take months to align on internal standards and manage the flow of information. The more fragmented the process becomes the more it risks turning into a year-long delay. How do you ensure that collaboration works effectively from an administrative and legal standpoint?”

Edgar Pogna,
Director, Life Sciences at L.E.K. Consulting

Czubatka-Bieńkowska offers her perspective on where the administrative responsibility lies: "As a CDMO, it's your responsibility to act as the main point of contact for the client. Whether you build partnerships to gather the necessary information or manage the process internally, your role is to ensure the client gets exactly what they need. Some clients prefer to be engaged in the process, but many simply want results without being burdened by the details. For example, they don't want to know if a formulation needs regulatory approval in a specific location; they just want to know that it's handled. It's our job as CDMOs to align everything seamlessly for the client so they don't have to worry about the background work."

"It's definitely easier to work with one CDMO than to manage four or five," Siu counters. "Once you start transferring data and responsibilities across multiple CDMOs, it can quickly become a logistical challenge. And the issues aren't just legal – they're also regulatory. In China, the NMPA (National Medical Products Administration) has historically taken a restrictive stance to multi-site manufacturing of biologics. For products such as ADCs and monoclonal antibodies, commercial manufacturing has typically required antibody intermediate, drug substance, and drug product to be produced at the same site, which limits how fragmented the supply chain can be. That said, the NMPA is beginning to show early signs of flexibility. More segmented manufacturing models are starting to be explored on a case-by-case basis, allowing certain components to be produced at different sites. This is still at an early stage, so it remains to be seen how broadly this approach will be adopted."

Hong Jiang, a CMC Strategy Expert at Pharmablock, gives her insight on where pharmaceutical players should focus their time, effort, and money: "The key is to focus on what you're good at – whether that's strengthening the small molecule platform and leveraging platform reusability, or working collaboratively on linker payload etc. These are cumulative technologies, and no single company can do it all. Collaboration will be essential to accelerate development and bring these innovations to market more efficiently."


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Value Chain Resilience Amidst Geopolitics

Value Chain Resilience Amidst Geopolitics

2025 was a year defined by geopolitical volatility – from the tenuous status of the BIOSECURE Act to everchanging tariff legislation, value chain resilience is a strategic imperative for the pharmaceutical industry [11]. As companies confront a world where political dynamics can change as rapidly as scientific ones, strengthening the agility and robustness of global value chains is no longer optional – it is central to safeguarding patient access, ensuring business continuity, and sustaining long-term innovation.

"Over the last 10 years, we've seen a significant shift in policy frameworks aimed at making manufacturing supply chains more locally stable, particularly for emergency-use cases," states **Sabine Kapasi, Co-Founder and MD at Enira Consulting, and Global Strategy Advisor for the UN**.

"The pandemic in India, for example, accelerated this trend, and we're now seeing it reflected across the entire global structure. Policies are emerging to support production hubs in various regions, with every country striving to become at least partially self-sustainable.

> **This trend is very real – countries no longer want to rely on third parties to regulate critical supplies, especially given historical instances where local populations suffer due to external dependencies. While there are pockets of innovation and exceptional talent in certain areas of the world, when it comes to emergency medicine and supply chains, nations are prioritising self-sufficiency. This focus on building resilience and reducing reliance on external sources is only going to intensify in the coming years."**

"The practical consideration, now at least, has shifted," Pogna adds. "Previously when deciding where to establish new manufacturing facilities or plants, the focus was on creating the most efficient value chain. Now, the question has become about building resiliency. It's not just about moving volume, but also strategically deciding where to invest. This includes addressing security gaps by ensuring that a certain amount of production is nearshored, providing greater stability and reliability in the supply chain."

Countries seeking to build self-sufficiency are forcing pharmaceutical supply chain players to combine strategic investment with regulatory incentives to bring the localised manufacturing nations are looking for. So far, these incentives have yet to materialise the desired outcome[12]. "Tariffs have had a limited impact on reshoring efforts," states **Markus Felgenhauer, Co-founder and CEO of QYOBO**. "Interestingly, we've seen companies relocating biosimilar manufacturing to US territories to secure their market position. However, what's becoming more apparent is that some generic manufacturers are already preparing for potential write-offs, especially when working with government sectors. They are bracing for non-tariff measures that may require US-based manufacturing supply chains. From a commercial supply perspective, there are products that

can feasibly be manufactured in the US and some that still require overseas production. Several molecules can no longer be produced domestically, whether it's the drug substance or the finished product, due to supply chain limitations."

"Geopolitics is undoubtedly a major factor, but it's not the only one," Siu states. "Take the BIOSECURE Act – it has not been enacted into law yet, but it still had an impact. The real impact was from the uncertainty it created. And that uncertainty isn't just from geopolitics. COVID-19 severely disrupted global supply chains, making raw material sourcing extremely difficult and accelerating a shift in thinking toward localisation. Now, companies are also having to navigate evolving tariff and trade policies. The geopolitical landscape is increasingly complex and fluid. In response, companies are localising operations in key hubs, while at the same time diversifying their footprints and building multiple hubs to reduce exposure to these uncertainties."

Experts are divided on whether demand is enough for pharmaceutical companies to localise manufacturing in emerging markets, or whether the value of investing in these hubs play a critical role in decision-making. "For a long time, the industry has focused on per capita demand and capability, but we must also account for how the current debt situation will impact sectors like healthcare in countries such as the US and Australia." claims Kapasi. However, Pogna states that "I'm not sure the concern is solely about demand; it's really about value. Value is critical – if you can generate more value in the US, that value is likely to stay within the US, and I believe that dynamic is going to persist."

Milton Boyer, CEO of Kindeva Drug Delivery, proposes an ultimate result: "If you marry theses observations, we can almost universally agree that the result will be increased prices. The uncertainty in supply chains, which are already complex, creates significant disruption.

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Geopolitics are evolving faster than pharma can adapt – you simply can't decide to build something somewhere and start producing tomorrow. Supply chain disruptions are thus inevitable, and the impact will be higher costs. Who ultimately bears those costs is debateable, but anytime there's uncertainty, disruptions, or shortages, prices inevitably rise. It's a complex situation but the reality is clear; prices are going to go up, especially in the face of shortages."

Milton Boyer
CEO, Kindeva Drug Delivery

Sandra Hartbach, CEO of DREHM Pharma, adds "There's a common understanding that the additional costs to prevent and buffer supply chain disruptions must be absorbed, yet there's resistance to cover resulting costs from reshoring and eventually paying higher prices for drug products. From a European perspective, it is frustrating to observe that political leaders often fail to grasp the seriousness and complexity of this issue. Other regions like the US seem to be more determined in their reshoring goals. In the EU however, we are missing unity towards this common aim. This creates significant differences in how these challenges are approached. The political and geographical disparities between European markets are stark."

As these pressures converge, the industry is entering a transition period in which strategic choices becomes as important as operational efficiency. Tariffs and similar legislative updates, even when limited in direct impact, have amplified board-level conversations about geographic exposure, prompting firms to map their supply chains in finer detail and assess when capabilities are strategically essential to retain or repatriate [11]. Though localisation can indeed buffer against supply chain disruptions, is not necessarily a prescription for

success. Overconcentration on domestic capacity carries its own risks – increased costs, potential inefficiencies, and regulatory vulnerability are all potential downfalls of such strategies [13].

Industry and policymakers must embrace a balanced resilience strategy; one that blends localised production with geographically diversified supply, underpinned by regulatory foresight and flexible manufacturing. Otherwise, the alternative system risks undermining innovation and patient access due to geopolitical, environmental, or logistical supply shocks [13].

Manufacturing Patient Empowerment and Accessibility

Manufacturing Patient Empowerment and Accessibility

The pharmaceutical manufacturing sector plays a fundamental role in translating scientific discovery into real-world patient benefit. The production of safe, effective, and affordable medicines at scale and ensuring those medicines reliably reach patients when they need them relies on a robust supply and value chain – one where pharma players are harmonised in their goals and practices [14]. Equally as important are the emerging markets composed of low- and middle-income countries that depend on a few global manufacturing hubs for essential medicines [15]. As supply chain resiliency remains a central conversation for pharmaceutical players, it is equally important for all to balance their operations with

strengthening global access to medicines and empowering those they ultimately serve – the patients [15].

Moreover, the surge in interest around GLP-1 drugs in the last year and their growing off-label use for weight loss has empowered many patients to take their prescriptions into their own hands, fundamentally shifting demand dynamics in the pharmaceutical sector [16] This consumer-driven demand has only served to expose further supply chain vulnerabilities, giving rise to unprecedented drug shortages, even those meant for medically necessary uses [17]. These experiences have prompted structural changes in the pharma supply chain ecosystem, with contract manufacturers investing heavily in expanding sterile fill-finish capacity, cold-chain logistics, and overhauling the overall supply chain architecture to support these demands [18].

"Reflecting on the GLP-1 trend, the off-label use had a significant impact, largely driven by the social media frenzy surrounding it," Hartbach states. "This was unprecedented, especially at such a scale, and it marked a disruptive moment for forecasting methods we had previously relied on. This shift represents a fundamental change in how we approach the future of manufacturing. In this context, AI

becomes incredibly relevant. With AI-driven predictions, we can better manage supply chains, monthly planning, and other critical areas. The value of AI lies in its ability to adapt and learn from experiences like this, addressing factors that were previously overlooked or underestimated at this scale."

"The GLP-1 trend and the broader obesity market have fundamentally transformed the healthcare landscape," adds Cox. "Entire markets are shifting, particularly in how patients access treatments. For example, in the UK – where pharma has traditionally faced significant communication with patients – there's now a growing trend of bypassing traditional pathways; patients no longer need to visit their physicians for every prescription. Instead, they can access

private prescriptions and pay for treatments themselves through intermediary services. This shift is also evident in areas like oncology, where private prescriptions are becoming more common, reflecting a broader trend of patient empowerment."

This paradigm shift is increasingly being shaped by the increasing adoption of personalised medicine, powered by rapid advances in genomic technologies and biomarker-driven diagnostics. These allow clinicians to better predict how patients will respond to specific therapies and to tailor dosing, timing, and therapeutic strategy [19]. In an era marked by growing burden of chronic diseases and aging populations, paired with the rising consumer demands for specific medications, the growth of patient centricity and personalised medicine demands a shift in how care is delivered – one that is customised, predictive, and patient-centric [20].

It seems, then, that patient centricity, empowerment, and personalisation has stemmed more from self-sufficiency on the part of the patient rather than the pharmaceutical supply chain. How, then, can manufacturers bolster both themselves operationally and their patients in meeting these demands? The reality may be less than optimistic.

"I believe we'll see personalised access to healthcare emerge before we full realise personalised medicine, adds Boyer., This trend has both positive and negative aspects. On one hand, it's empowering for patients to have greater control over their healthcare. On the other hand, not everyone is equipped to manage their own treatment effectively. While personalised access is a promising development, it's crucial to strike a balance between patient empowerment and professional oversight."

"The shift toward personalised medicine, such as CAR T-cell therapy, presents significant challenges for manufacturing," explains Czubatka-Bieńkowska. "Currently, most manufacturing facilities are designed for large-scale production, using bioreactors to produce massive quantities of drugs. Transitioning to small-batch production for personalised therapies such as mAbs at scales of 50-200 litres, is feasible for clinical trials and studies but not yet practical for widespread use. While personalised medicine is an exciting frontier, the infrastructure and readiness for small-batch manufacturing are still evolving."

Siu, however, adds his perspective from a larger CDMO point of view, specifically regarding CAR-T therapies: "CAR-T highlights how truly personalised medicine challenges traditional manufacturing models. Unlike conventional biologics, which are produced in large batches, autologous CAR-T manufacturing is inherently complex, labour-intensive, and difficult to scale, which contribute to high costs and limited patient access. That's why there is growing interest in approaches such as allogeneic and modular CAR-T. Both are still in early development, but they represent potential pathways toward more efficient manufacturing models, improved scalability, and, ultimately, broader access if underlying scientific and regulatory challenges can be addressed."

Helmy offers a forward-looking perspective: "I believe advancements in AI and drug discovery are reshaping the pharmaceutical landscape. Looking at GLP-1 drugs, there are nearly 300 compounds now in development. We're clearly moving away from the traditional 20-year blockbuster cycle. Instead of a handful of first-line treatments prescribed to most patients, physicians will soon choose from a wider range of therapies with distinct advantages—oral vs injectable, weekly vs monthly dosing, cardioprotective or weight-lowering benefits, and more—allowing for far more personalised care and potentially better clinical outcomes.

As for the patent holders, their traditional 20-year cash-cow cycle will also shorten, as newer and potentially better medicines may emerge much earlier, reducing the duration of market dominance.

This shift brings some challenges. Historically, economies of scale allowed API manufacturers to produce massive volumes of a few molecules, driving down costs and enabling affordable generics.

“Unlike large-scale production, personalised treatments involve processes like extracting patient’s blood leukocytes, modifying them, and returning them within a short timeframe – often just a couple of days. This approach comes with extremely high costs and requires specialised manufacturing facilities, which are not yet fully equipped to handle such demands.

Anna Czubatka-Bieńkowska,
PhD and Project Management Manager, Mabion S.A.

As the market fragments into many smaller-volume products and with frequent changes in top leading molecules, global production tonnage will decline, forecasting becomes harder, yields become less optimized, and costs will likely rise. Geopolitical pressures and declining trust in global supply chains further worsen the situation. The push toward more localised production and self-reliance—driven by fears around access to essential medicines—erodes scale efficiencies and increases overall production costs, ultimately raising medicine prices. And with declining birth rates globally, the question of who will operate and sustain all these new manufacturing facilities becomes an additional concern.

The only sustainable way forward, in my view, is to focus on prevention. Wearables are now generating an unprecedented amount of personalised health data, and when this is combined with AI, it can help individuals truly understand their own health risks and intervene early. This shift toward early detection and proactive action means that prevention will become the cornerstone of healthcare innovation.

At the same time, the loss of trust in global supply chains the inability of some companies to secure partnerships due to political tensions exacerbate the challenges. This lack of trust leads to higher costs and inefficiencies, as countries and companies prioritise self-reliance over collaboration. While this approach may be understandable for wealthier nations, it underscores the need for a balance between self-sufficiency and global cooperation to ensure a more sustainable and equitable healthcare system."

Second Mover Advantage? Breakthrough Therapeutics and Breakthrough Strategies

Second Mover Advantage? Breakthrough Therapeutics and Breakthrough Strategies

With the seismic shift in market dynamics paved by the GLP-1 market, pharmaceutical companies are increasingly looking for the next big blockbuster drug in several different therapeutic areas; from metabolic diseases to oncology, neurological disorders and immunology, the race is on for the next big therapeutic [21]. Pharma is now at an inflection point, hunting for harder-to-reach targets through high-tech discovery and design [21].

"Don't wait. Plan," Pogna prompts. "In the pharmaceutical industry, success often comes down to timing and preparation, not just intelligence or strategy. Some companies act as though winning the lottery means they were smarter than others, but in reality, it's often luck. This was evident after Novo's acquisition of Catalent sites, which prompted many companies to rethink their strategies and ask 'Should I do the same?' The answer is yes – IF you have a major blockbuster product that requires it. However, many companies didn't act because they failed to recognise the scale of their products or anticipating potential bottlenecks. They didn't prepare their pipelines adequately, and now they're facing mismatches in their platform systems.

> **The key takeaway here is simple; don't assume you're smarter or that success will come without preparation. Pharma is, in many ways, about luck – but luck favours those who plan ahead."**

While being first to discover and prepare commercial-scale production of a game-changing drug clearly has its benefits, so-called 'late' or 'second' movers can still dominate with successful product launches and scaling [22], particularly where collaboration with larger companies is available [22].

"The second-mover advantage is a powerful strategy," Cox adds. "It allows you to learn from the mistakes of the first movers, adapt your approach, and position yourself to address any unmet needs more effectively. At the same time, it's crucial to capitalise on opportunities where the first mover stumbles – whether they go out of stock, shift direction, or lack a solid lifecycle management plan to sustain momentum. This is especially relevant in rapidly evolving markets like the obesity and metabolic disorders space, where there are 360 drugs in development. It's a clear example of how quickly and entire market can shift from zero to full speed. While this surge brings challenges such as IP issues and the influx of generics, it also highlights the importance of being prepared to act decisively in therapy areas that can transform almost overnight."

As these therapeutic races accelerate, global market dynamics are shifting just as rapidly. Regions such as APAC, LATAM, and parts of MENA are emerging not only as high-growth markets but also as increasingly influential

centres for R&D, biologics production, and advanced, flexible manufacturing [23]. This geographic diversification is forcing pharma companies to rethink where they place their bets – and how quickly they can scale when an opportunity emerges. The combination of rising patient demand, localising manufacturing capabilities, and regional investment in life science infrastructure means the next blockbuster may not only come from a new modality or therapy area, but from a new region entirely [24].

"The case with GLP-1s is incredibly hopeful – not just in terms of supply but, more importantly, for patients themselves," Kapasi adds. "NCDs (non-communicable diseases) have been a persistent challenge for so many, and seeing breakthrough therapies emerge at the forefront offers a renewed sense of hope for all.

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Over the last 25 years, we have witnessed a significant shift in how we approach drug development, therapy innovation, and our understanding of disease pandemics, fundamentally changing the way we bring greater equity and accessibility to patients across different regions."

Sabine Kapasi
Co-Founder and MD, Enira Consulting

Recalibrating Pharmaceutical Pricing Strategies

Recalibrating Pharmaceutical Pricing Strategies

The pharmaceutical industry is also undergoing marked shifts in how drugs are priced, reimbursed, and brought to market. Several converging forces, from regulatory pressure, payer demand, and novel business models, are reshaping how the industry makes drugs accessible to patients while keeping business as usual.

In past decades, many drugmakers relied on annual list-price increases as a core revenue lever. However, this model is increasingly under pressure. In 2025, the research firm 3 Axis Advisors showed that nearly all drug prices increases were below 10%, with a median increase of 4.5%, all modest amounts compared to previous years [25]. Moreover, payer resistance, public scrutiny, and regulatory reforms – especially in major markets – are making aggressive price hikes riskier. Many companies are thus limiting price increases or even reducing list prices for certain products including Boehringer Ingelheim's Atrovent and Merck's Januvia [26]. In anticipation of IRA (Inflation Reduction Act) negotiations, IRA products are seeing some of the lowest average price increases. Companies are now including evolving price adjustment strategies into a drug product's lifecycle management strategy to limit the risks to both patient access and commercial success [26].

Beyond standard list-price models, pharmaceutical firms are increasingly experimenting with alternative pricing and payment models better suited to modern therapies for specialty drugs, biologics, gene therapies, or multi-indication products

[27]. Value- or outcome-based pricing, where payment is linked to real-world patient outcomes or effectiveness rather than the volume of doses sold, can help align pricing with actual value delivered, and ease payer and policy-maker concerns about high upfront costs [27]. Novartis' agreement with US insurer for Kymriah (a CAR-T therapy for certain leukaemias), for example, only receives full payment when patients respond to treatment within a specified timeframe [28]. Other pricing models include subscription-style pricing for one-time or curative therapies, with a lump-sum price spread over several ongoing payments [27].

Pharma firms must become far more sophisticated, no longer using pricing as a blunt instrument. Simply raising list prices annually is being replaced by strategic levers turned to value, indication, outcomes, and payer environments.

The growing adoption of different strategies such as value- and outcome-based pricing and subscription style pricing models demonstrate the early engagement and planning with payers and health systems required, especially for high-cost and/or high-value therapeutics [27].Meanwhile, companies with legacy portfolios comprising older biologics reaching patent maturity or small-molecule drugs increasingly face downward pressure from rising competition from biosimilars and generics [27].This reality accentuates the need for continual innovation, careful lifecycle management, reformulation, and differentiation to protect value.

Ultimately, success in coming years will depend not just on scientific innovation, but also on operational and commercial agility. The firms that van align value, pricing, access, and real-world outcomes will have the greatest chance of thriving in a landscape where cost pressures, competition, and demand for accountability are only set to increase.

Evolving the Green Pipeline: The Future of Sustainability in Pharma

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The pharmaceutical industry is increasingly focusing on sustainability as a core part of its operations and strategies for 2026. The industry has been recognised for some time as one of the largest contributors to greenhouse gas emissions and the environmental impact on the planet. In recent years the pharmaceutical and healthcare industry has been included in major global discussions, such as COP, in the plannings to reduce the human impact on the planet.

There are several ways in which the pharmaceutical will be advancing sustainable initiatives in the future, including the use of green chemistry, biobased materials, biocatalysts, adoption of circular economy practices, and

a number of other practices. In this chapter, we cover a few trends that will be shaping the environmental side of the pharmaceutical industry in the next year.

In 2026, the pharmaceutical industry's use of PFAS is expected to be influenced by evolving regulatory frameworks amid environmental concerns. Key developments across markets include:

1. Regulatory Deadlines: The US Environmental Protection Agency (EPA) has extended reporting deadlines for PFAS-related data under the Toxic Substances Control Act (TSCA). Most manufacturers, including those in pharmaceuticals, must submit detailed information on PFAS use, disposal [29], and health impacts by October 13, 2026. This data will inform future regulatory actions and policies.
2. European Union Restrictions: The EU continues to work on enforcing stringent restrictions on PFAS, with Germany, the Netherlands, Norway, Denmark, and Sweden working together towards a universal PFAS restriction. After the proposal was started in 2023 a background document has now been completed with feedback in 5,600 comments from stakeholders [30]. If progress continues, a universal guideline could be completed by 2027.
3. In Asia several countries are adopting new regulations, such as Vietnam implementing a new chemical law from the 1st January, which will mandate licenses for certain PFAS compounds among other things [31].
4. Global Reporting and Compliance: Manufacturers will need to prepare for comprehensive reporting requirements, including data on worker exposure, environmental effects, and disposal practices. This aligns with broader efforts to manage and remediate PFAS contamination.

The pharmaceutical industry must adapt to these changes by prioritising compliance, exploring sustainable alternatives, and addressing the environmental footprint of PFAS use in its operations.

It is no secret that artificial intelligence is a building trend for the future, and that the use of AI will have many positive impacts on the environment. The technology can already be used to streamline processes and reduce waste in R&D, in manufacturing, distribution, and product end of life. The investment companies are making into smart factories and automation is demonstrating a large-scale commitment across the industry.

The hidden side to AI is the logistics of implementing such a system. And when there is a system in place of such magnitude, there is, by default, an environmental footprint. The infrastructure used to house AI servers use vast amounts of electricity and produce a tremendous amount of electronic waste. These plants also consume a high amount of water – an increasingly scarce commodity in some areas.

“There is still much we don’t know about the environmental impact of AI but some of the data we do have is concerning,” said Golestan (Sally) Radwan, the Chief Digital Officer of the United Nations Environment Programme (UNEP). “We need to make sure the net effect of AI on the planet is positive before we deploy the technology at scale.” [32].

However important this point is from Radwan, the reality may in fact depend on the voices in power. AI has exploded in popularity in recent years, which may result in uninhibited progression, without necessary safeguarding in regard to the planet being put in place. With the advances in technology that AI can provide, there needs to be control measures put in place to ensure any environmental implications are also taken into consideration, mitigated before further advancement, and avoid any resulting irreparable damage.

At a pivotal moment for global climate action, COP30 has boldly opened the discussion on transformative future actions, with significant implications for the pharmaceutical industry and its role in addressing the climate crisis.

Recognising the critical need to strengthen multilateralism, connect climate action to people, and accelerate the implementation of the Paris Agreement, COP30 approved a comprehensive package of decisions that will shape the next phase of global climate efforts.

In Belem, Brazil, a global political debate was conducted on the future use of fossil fuels. The topic proved to be extremely divisive, with half of the assembled countries supporting the idea to formalise targets for phasing out fossil fuels entirely, and half opposing such iron clad language. Even in the face of this uncertainty, Brazil took a firm stance, announcing their own two roadmaps for the future:

- Transition to a fossil fuel-free economy in a just, orderly, and equitable manner;
- Forest and Climate Roadmap to halt and reverse deforestation.

For the pharmaceutical industry, this signals a call to reduce reliance on fossil fuels across the supply chain, from manufacturing processes to transportation. Companies will need to adopt renewable energy sources, invest in green chemistry, and explore sustainable packaging solutions to align with this transition.

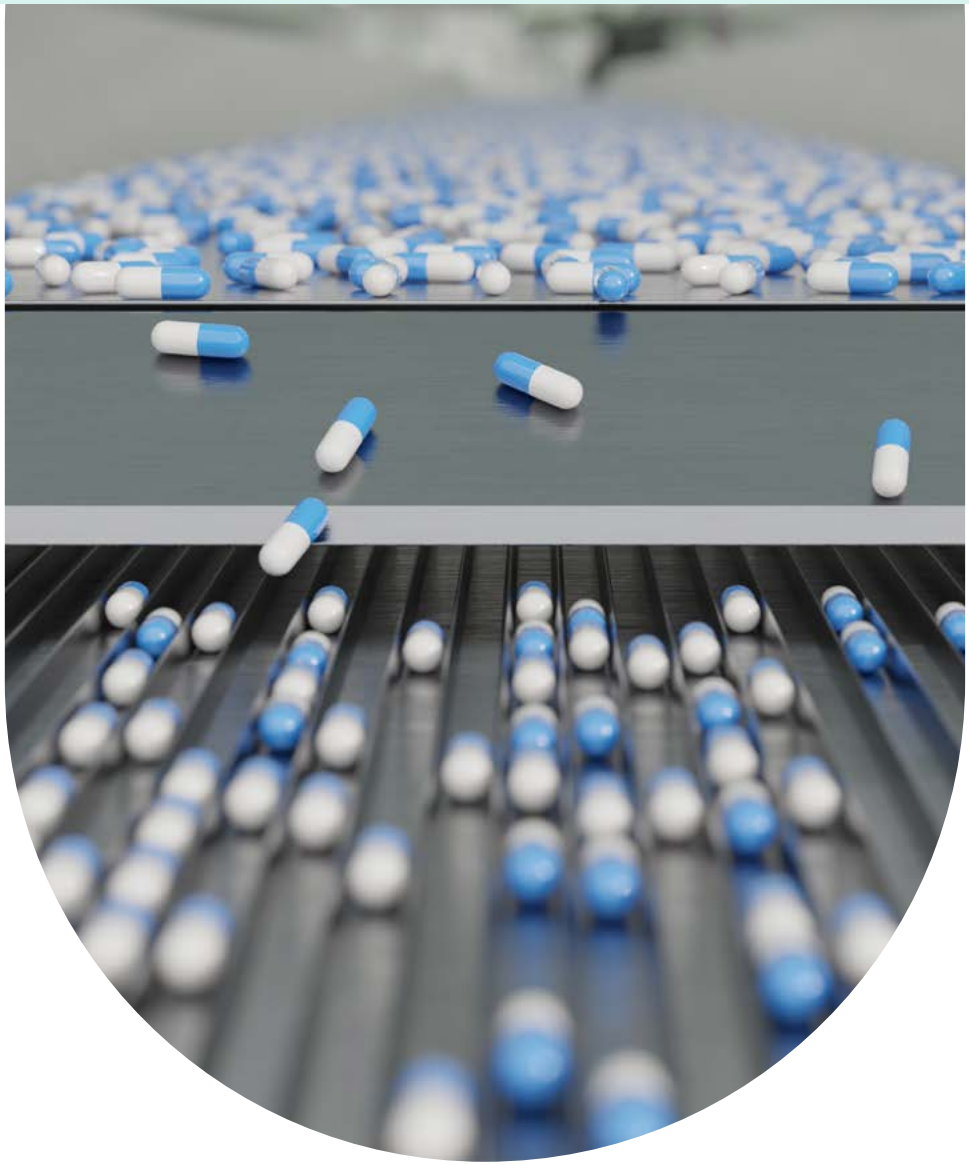
The Forest and Climate Roadmap aims to halt and reverse deforestation, highlighting the importance of preserving biodiversity. The pharmaceutical sector, which relies heavily on natural resources for drug discovery and development, will be encouraged to support conservation efforts and sustainable sourcing of raw materials. Partnerships with initiatives like the Tropical Forests Forever Facility (TFFF) could become a cornerstone of corporate responsibility strategies.

> **COP30's outcomes represent a turning point in global climate governance, with a shift from negotiation to implementation.**

For the pharmaceutical industry, this is a call to integrate climate action into core business strategies. By reducing emissions, supporting biodiversity, advancing sustainable technologies, and addressing climate-related health challenges, the industry can contribute to a resilient and sustainable future while aligning with the global momentum towards climate justice. We look forward to 2026 to see how this will manifest [33].

Executive Summary

Executive Summary



The pharmaceutical industry underwent significant transformations in 2025, and this broad evolution is only set to continue in 2026. Driven by advancements in AI technology, shifting geopolitical landscapes, evolving patient demands, and regulatory pressure, it has never been more important for the pharmaceutical industry to plan ahead and remain agile.

AI is revolutionising drug discovery, clinical trials, manufacturing, and patient care, but its rapid adoption is outpacing regulatory frameworks. The need for high-quality datasets, ethical oversight, and interdisciplinary collaboration is critical to ensure AI's effective and responsible adoption. Partnerships between tech and pharma highlight the potential for innovation but also underscore the importance of bridging gaps between sectors.

Geopolitical factors such as tariff legislations and national self-sufficiency are reshaping global supply chains. Companies are increasingly localising manufacturing to

mitigate risks, but this approach risks higher costs and inefficiencies. A balanced strategy combining localised production with diversified global supply chains is essential to maintain resilience and ensure patient access.

While first-mover advantages in drug development remain significant, second movers can capitalise on market opportunities by learning from early entrants' mistakes and address unmet needs. The rapid evolution of the obesity and metabolic disorders markets, along with oncology, immunology, and neurology demonstrate the importance of preparation and adaptability of a firm's product lifecycle management.

The rise of personalised medicine and patient-centric care is reshaping healthcare delivery. Advances in genomic technologies and biomarker-driven diagnostics enable tailored treatments, but manufacturing infrastructure must evolve to support small-batch production for therapies like CAR-T. Additionally, patient empowerment id driving demand for specific medications, challenging traditional supply chain models.

Traditional pricing models are evolving into innovative approaches due to regulatory reforms, payer resistance, and public scrutiny. Strategies such as value-based pricing, outcome-based models, and subscription-style payments are aligning drug costs with real-world patient outcomes – it will be a critical time for companies to balance affordability, accessibility, and commercial success.

The pharmaceutical sector is navigating a period of profound transformation marked by the evolving relationship between pharmaceutical supply chains, sponsor drugmakers, and patients themselves. Success in this dynamic landscape will depend on operational agility and strategic foresight, aligning scientific innovation with commercial and ethical imperatives.

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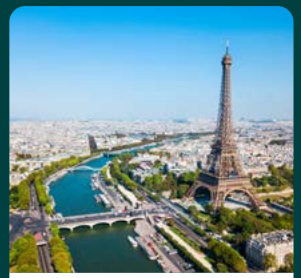

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