



ONLINE

2026 Outsourcing Outlook Update: Navigating Global Innovation





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Key takeaways 1/2



The great bifurcation of pharma manufacturing

Pharma manufacturing is undergoing a significant transformation, marked by a bifurcation between high-value, specialised production and large-scale, commoditised operations. As advanced therapeutics like cell and gene therapies demand precision and innovation, manufacturers are increasingly focusing on niche capabilities. Meanwhile, traditional pharmaceutical production continues to scale globally, driven by cost efficiency and demand for generics.



Strategic partnership maturity and governance structures

Strategic partnerships in pharma are evolving, with maturity and governance structures becoming critical to their success. As collaborations grow more complex, robust frameworks are essential to ensure alignment, transparency, and shared goals. Governance structures now emphasise joint decision-making, risk management, and long-term value creation. Mature partnerships leverage trust and mutual understanding to drive innovation, streamline operations, and enhance market responsiveness.



Key takeaways 2/2



PE-backed transactions and CDMO M&As

Private equity-backed transactions and M&As in the CDMO sector are reshaping the pharma landscape. PE firms are driving consolidation, seeking to optimise operations and expand capabilities to meet growing demand for specialised services. These transactions are fostering innovation, enabling CDMOs to invest in cutting-edge technologies and infrastructure. However, they also bring challenges, such as integration complexities and cultural alignment. As the sector evolves, strategic M&As are expected to play a pivotal role in enhancing efficiency, scalability, and competitiveness in a dynamic market.



The impact of geopolitics on upstream supply chains

Global supply chains in pharma are under pressure as geopolitical tensions disrupt upstream operations. Trade restrictions, regional conflicts, and shifting alliances are creating bottlenecks in the availability of raw materials and active pharmaceutical ingredients (APIs). Companies are re-evaluating their sourcing strategies, prioritising diversification and resilience to mitigate risks. The heavy impact of these challenges underscores the need for agile supply chain management and proactive contingency planning. As the industry adapts, collaboration with local suppliers and investment in regional manufacturing hubs are emerging as key strategies to ensure continuity and stability.



Key takeaways 2/2



AI-driven partnerships gaining traction

AI is revolutionising pharma partnerships, enabling smarter collaboration and faster decision-making. AI-driven partnerships are gaining traction as companies leverage advanced analytics to optimise drug development, manufacturing, and supply chain operations. From predictive modelling to personalised medicine, AI is unlocking new possibilities, enhancing efficiency, and reducing costs. These partnerships foster innovation by combining technological expertise with industry knowledge, creating synergies that drive progress. As AI continues to evolve, its integration into strategic collaborations is set to transform the pharma sector, paving the way for more agile and data-driven approaches to healthcare solutions.



End-to-End or Expert-Led



End-to-End or Expert-Led

In our 2026 Pharma Trends Outlook Report, we took a brief look at a question that is shaping the current landscape of modern outsourcing – to specialise or not to specialise [1]. On one hand, the rise of complex modalities such as HPAPIs, biologics and targeted therapies, is driving demand for deep technical expertise. This is pushing some CDMOs toward niche specialisation where capability, containment, and scientific know-how area critical differentiators [2]. In these areas, sponsors are increasingly prioritising ‘best-in-class’ partners over broad service menus.

“We are witnessing a significant shift towards specialised manufacturing partners and outsourcing across various levels of the industry,” comments **Ashley Cox, CEO and Founder of Caledonia Life Sciences**. “CDMOs are poised for continued growth due to several factors – first, they offer greater cost and time efficiency. By streamlining processes and reducing the need for





handoffs between different stages, CDMOs eliminate delays and inefficiencies associated with upskilling each step. However, we are seeing an industry that is increasingly moving towards a more specialised and strategic approach to outsourcing. Larger end-to-end consultancies that initially aimed to manage assets throughout the entire lifecycle are now facing challenges due to shifting client needs, evolving questions, and changes in end stakeholders. These internal changes can create complexities that are difficult to navigate.”

Concurrently, the appeal of fully integrated, end-to-end CDMOs continues to strengthen. As pipelines grow more complex and timelines compress, pharmaceutical companies are seeking fewer, more strategic partners who can carry assets seamlessly from development through to commercial manufacturing. Such strategic partnership selection reduces tech transfer risks, improves continuity, and supports long-term co-investment and collaboration models.

“Biologics, biosimilars, and advanced therapies are driving a bifurcation rather than a clean shift from one model to another,” states **Bikash Chatterjee, President and Chief Science Officer at Pharmatech Associates**. “Large, integrated end-to-end CDMOs continue to grow and



dominate standardised, high-volume work such as mAbs and many biosimilars because they offer scale, platform, efficiency, and fewer tech transfers. At the same time, a fast-growing tier of highly specialised CDMOs is emerging for cell and gene therapies, viral vectors, nucleic acids, and complex conjugation, where deep modality expertise, bespoke facilities, and advanced analytics matter more than sheer footprint. These models are converging into what you would call an end-to-end CDMO within a modality, as big CDMOs bolt on advanced therapy units and niche players extend downstream into fill-finish and logistics.



“Sponsors are increasingly optimising for strategic partnerships that balance integrated services and modality-specific know-how to derisk CMC and accelerate timelines.”

Some experts like **Anil Kane, Global Head of Technical & Scientific Affairs at Thermo Fisher Scientific**, see the rise of complex therapeutics as an opportunity for more integrated CDMOs, stating that, “End-to-end CDMOs are well-positioned to support the increasing demand for biologics, biosimilars, and advanced therapies. Connected CDMOs alleviate some of the most common, and historically challenging, pain points in drug discovery, such as limited internal resources and increasing pressure to move quickly. As pharma and biotech companies tackle more challenging molecules, end-to-end CDMOs not only bring streamlined workflows and advanced capabilities but also the specialised expertise required to develop and manufacture these innovative therapies. This unique combination of capabilities, expertise, and capacity means that companies can get their therapies to patients faster, and that’s ultimately the difference between CDMOs and specialised manufacturing partners.” However, Kane does agree

that the development and manufacturing of specialised therapeutics requires a certain degree of expertise: “An equally critical part is having the expertise and know-how to effectively deploy the capacity CDMOs offer. In this era, for a CDMO to successfully support their customers, they must not only have the facility space but also an in-depth understanding of specialised technologies, the right talent and technical capabilities, and the ability to make informed decisions that are backed by science. Put simply, connected CDMOs have the potential to streamline the drug development and manufacturing process while providing the same expertise as specialised partners.”

The rise of therapeutics such as GLP-1s in particular is positioning CDMOs not just a support system, but as the fuel driving the drug commercialisation engine [3]. For example, with GLP-1s, major efforts are being made across the pharmaceutical industry to introduce an oral GLP-1 to rival the injectables already on the market. Innovations on well-known APIs and drug molecules increase the demand for specialised manufacturing capabilities [4].

“Current outsourcing models struggle most with capacity, complexity, and reliability for newer modalities, which translates into longer timelines, higher costs, and



uneven patient access,” states Chatterjee. Biologics and especially cell and gene therapies face persistent capacity bottlenecks, infrastructure gaps, skilled-labour shortages, and long lead times for fit-for-purpose facilities and tech transfers, so sponsors cannot always scale from clinical to commercial at the speed regulators and patients expect.”

Joon Ho Hwang, Vic President of Business Strategy at Samsung Biologics, states that “For resource-constrained biotech firms, the end-to-end approach can offer significant operational synergies. Managing the entire development lifecycle under one roof helps reduce administrative burden and streamline the transfer of data and materials. This integration can become a powerful tool for speed, allowing lean teams to focus more on innovation and less on vendor management. However, in the high-stakes world of biopharmaceuticals, convenience should never come at the expense of core performance. While an integrated end-to-end offering can be a competitive advantage, it remains secondary to the industry’s fundamental pillars: quality and technical expertise.”

In the US alone, the CDMO market projections show growth from US\$43.41 bn in 2025 to over US\$83 bn by 2034





– a CAGR of 7.47% further fuelled by growing demand for domestic and near/onshoring manufacturing [3]. With such intense need to fill manufacturing capabilities, many small and mid-tech biotechs and pharmaceutical companies might steer towards boutique, specialised CDMOs that can aid in the early-/clinical-stage programs of drug development, despite the potential inefficiencies from tech transfers and moving production elements.

“The decision between integration and specialisation often depends on the maturity of the modality,” comments Hwang. “For well-established modalities with standardised manufacturing processes, the end-to-end model provides clear efficiencies. Yet, for emerging and complex therapies like antibody–drug conjugates (ADCs), the preference is shifting towards specialised technical depth. ADCs require a sophisticated fusion of disparate disciplines – biologics for the antibody and complex synthetic chemistry for the payload and linker. Because these require vastly different technical environments, many developers prefer to de-risk their programs by selecting ‘best-in-class’ specialised partners who excel in their respective crafts rather than a single end-to-end provider with varying levels of expertise across the value chain.”

Some experts, such as **Hongene’s Chief Technical Officer David Butler**, suggest that two things can be true at once, with deep technical expertise being met with a degree of continuous oversight that may eventually become an integrated model.

“We are seeing both trends happen at the same time,” comments Butler. “In advanced therapeutics, especially oligonucleotides and mRNA, the underlying science and manufacturing requirements have become specialised enough that sponsors increasingly need partners with real modality-specific depth.”

That means not just generic cGMP capability but expertise in raw materials, impurity control, analytical strategy, next-generation manufacturing technologies and the practical realities of scaling complex nucleic acid processes. To reduce risk as programs move through the development life cycle, drug developers also increasingly prefer to minimise handoffs between vendors. Repeated tech transfers and duplicate quality control testing can create



delays, variability, and traceability issues. A vertically integrated supply model provides a structural solution. For nucleic acid therapeutics, that means combining deep technical expertise with continuity and aligning the building blocks and regulatory starting materials (RSMs) through to cGMP drug-substance and drug-product manufacturing. This is particularly important in oligonucleotide and mRNA manufacturing, where upstream material quality directly affects downstream process performance, impurity burden, and ultimately product quality. Consequently, we expect continued growth for vertically integrated supply models that combine specialised expertise with continuous oversight to meet the real needs of advanced modalities.”

“Specifically, in the pharmaceutical pipeline, the benefits of strategic partnerships are most evident for early-stage biotech companies,” Cox continues. “While good science remains critical, there is growing recognition of the importance of commercial considerations, such as addressing unmet needs in the market. Early-stage companies are realising the value of defining what ‘good science’ looks like in terms of market impact upon launch.” Cox adds that for all pharmaceutical players, large or small, specialised or not, early-stage collaboration is becoming a key factor in driving success and innovation. “Engaging with larger pharmaceutical companies earlier



in the development process is also becoming increasingly popular. This approach allows biotechs to showcase their direction, decision-making, and progress while receiving valuable input and guidance from established players. For example, large pharmaceutical companies may outline specific milestones, such as achieving certain results by the end of Phase II, which could lead to partnerships or deals for Phase III. This co-development and co-commercialisation model is gaining traction, especially as the industry landscape shifts, with a stronger focus on the US market due to factors like Most Favoured Nation policies and other regulatory uncertainties.”



Brave New World: Navigating Geopolitical Supply Chains

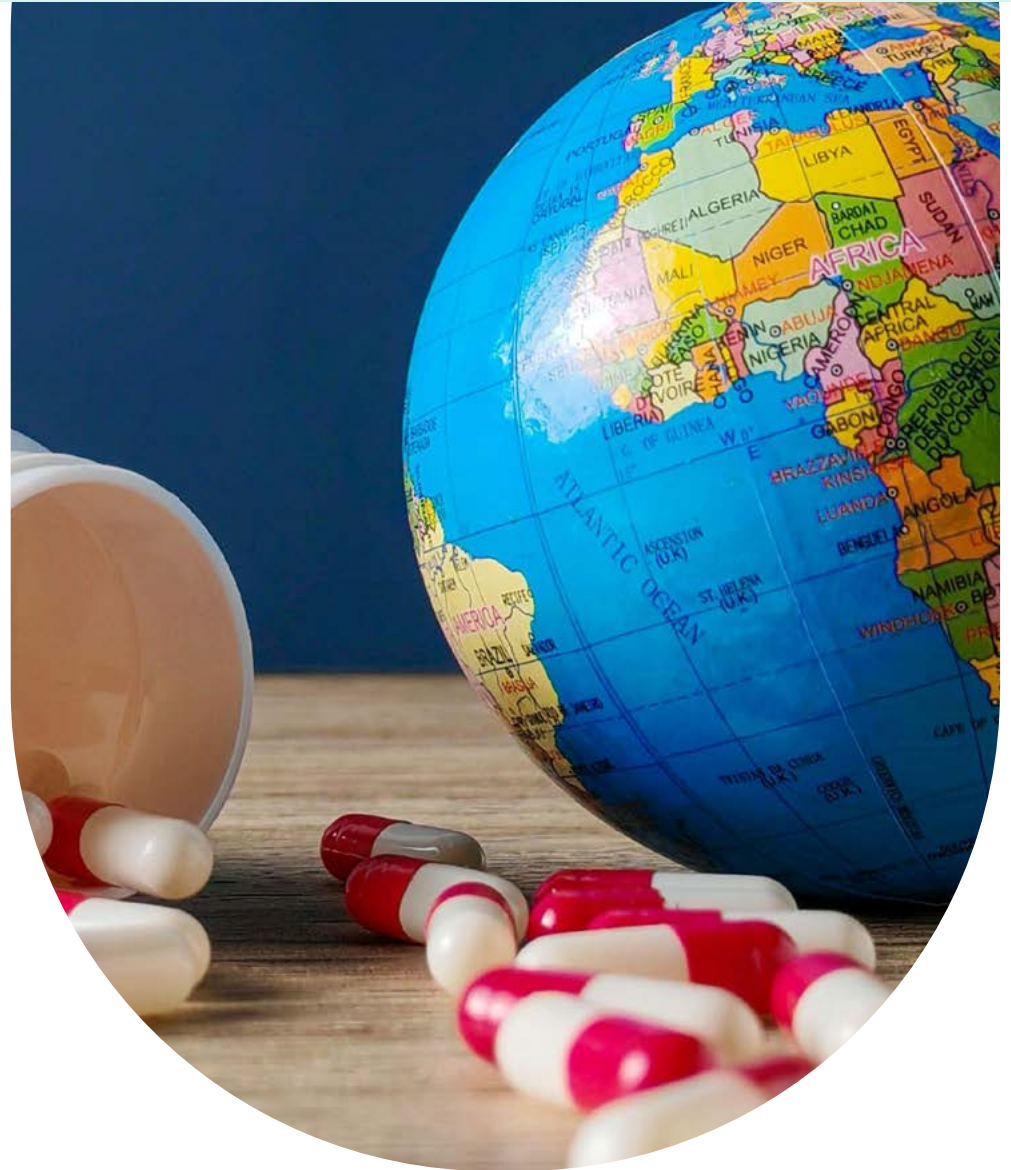




Brave New World: Navigating Geopolitical Supply Chains

The pharmaceutical industry, long reliant on global supply chains and outsourcing models to drive innovation and efficiency, is increasingly grappling with the continuous impact of geopolitical issues. Planning within a global trade context is nothing new for the pharmaceutical industry – demand for medications around the world has only risen in the last decade with aging populations, the rise of chronic diseases, and calls for healthcare access and equity in developing nations [5].

Yet, ongoing supply chain inefficiencies and fragility, first exacerbated by the COVID-19 pandemic,





underscore the continued efforts needed to reshape global pharmaceutical outsourcing models [6]. The once seamless flow of raw materials to APIs to drug product manufacturing across borders are under even more scrutiny than before, with both pharmaceutical sponsors and vendors unsure of how to respond or mitigate new and everchanging dynamics [7].

“Geopolitics is hitting the upstream parts of the pharma supply chain hardest, especially APIs, key starting materials, and bioprocessing inputs that are heavily concentrated in a few countries and dependent on vulnerable trade lanes,” Chatterjee explains. “Disruptions in export policy, energy costs, and ocean freight are amplifying lead times and volatility for these materials, which then cascade into finished-dose availability. By contrast, final fill-finish, packaging and regional release testing in major markets, along with established wholesaler and pharmacy distribution networks, have remained relatively more stable, so most visible shortages originate from earlier-stage constraints rather than breakdowns in the last mile.”

“Geographically, Europe is becoming less attractive due to pricing pressures and policies like ‘most favoured nation’ clauses,” comments Cox. “Companies are increasingly

recognising the value of partnering in markets like China and India rather than attempting to navigate these regions independently. These markets are complex and expensive to enter without local expertise, and investment needs to come from within. Additionally, lots of manufacturers are still looking to move back to the US, with major companies making billion-dollar commitments. This shift is definitely driven in large part by geopolitical events rather than long-term strategic planning as companies aim to secure control over their supply chains in their largest market





– the US. This ensures that global disruptions have less impact on the US market, which remains the largest in pharmaceuticals.”

“The shift toward nearshoring represents a strategic pivot from pure cost-optimisation to supply chain resilience,” Hwang states. “While the United States serves as a prominent example, nearshoring generally involves relocating production closer to the end consumer. The primary trade-off is financial; nearshore facilities often face significantly higher upfront costs, including elevated construction expenses and labour rates. These factors inevitably lead to higher service fees for sponsors. However, this model offers a critical advantage by insulating companies from volatile tariffs and geopolitical instability, ensuring a more stable and legally aligned supply chain closer to the target market.

Conversely, continuing to outsource to regions like China and India offers substantial advantages in terms of the headline price due to lower labour costs and mature manufacturing ecosystems. However, these regions now require a more nuanced evaluation regarding regulatory alignment and the gradually shifting global landscape. Companies must weight these immediate savings against

the potential for sudden adjustments in international trade policies or unforeseen logistical complexities that might impact the steady delivery of essential therapies to patients.”

While much can be debated over the geoeconomics of controlling the pharmaceutical supply chain, pharmaceutical companies and outsourcing partners are understandably preoccupied with protecting their already fragile supply chains [6]. Yet, how does one plan for the fickleness of geopolitics and the global economy?

“Most companies are adopting ‘right-shoring’ or hybrid models – maintaining competitive off-shore capacity while selectively nearshoring or reshoring essential APIs and high-risk products to balance cost with security of supply”

Chatterjee offers. “Nearshoring trades lower pure unit cost for greater resilience, control, and proximity, while continued offshoring to China and India preserves cost advantages but keeps companies exposed to



concentration risk and geopolitical volatility. Moving APIs or finished doses closer to end-markets can shorten lead times, improve oversight and IP protection, reduce tariff and logistics exposure, but it can require higher CAPEX, labour and operating costs, slower build-outs, and sometimes scarce local technical talent. Staying in China and India leverages existing scale, mature supplier ecosystems, and lower operating costs, which remain compelling for many generics and cost-sensitive therapies, yet it perpetuates dependence on a handful of geographies for critical inputs and leaves firms vulnerable to export controls, tariffs, energy shocks, and sudden quality or regulatory disruptions at distant sites.”

“Cost strategies are closely tied to capacity utilisation, modality, and geographic considerations,” adds **Fujifilm Biotechnologies’ Chief Strategy Officer Maria Andreasen**. “CDMOs and partners are optimising utilisation by balancing mid- and large-scale facilities with small-scale capacity. Modular networks reduce capital expenditures and engineering costs by standardising equipment, layouts, and processes. Hybrid sourcing, local-for-local production and dual-sourcing strategies help manage tariffs and logistics costs while maintaining supply chain resilience.”





“Product lifecycle is a good rule of thumb when it comes to strategic vs tactical positioning. Typically seen in the later stages of a product’s lifecycle, the activities that work best transactionally are when specifications are stable, outputs are easily measurable, and price., speed, or volume efficiency dominate.”

Joanne Anderson, CCO of Symbiosis.



The strategy behind strategic partnerships



The strategy behind strategic partnerships

In the pharmaceutical industry, CDMOs are continuing to navigate the increasingly complex and delicate balance between transactional contracts and strategic partnerships to meet the evolving needs of their clients. As the pharmaceutical landscape grows increasingly complex in scale and scientific prowess, and continued forecasted growth, CDMOs must carefully assess when to adopt transactional models versus strategic partnerships to better position their standing in an increasingly saturated, end-to-end sector and to optimise their processes to meet client demands [8].

“From a customer perspective, the biggest frustration is lost time,” states **Arul Ramadurai, Chief Commercial Officer at Axplora**. “Delays don’t come from just manufacturing itself, but from weak process





development or slow QC and analytics. Sponsors frequently bring processes that look viable on paper but break down at scale, or they face situations where production is fast but release timelines are not. At the core, customers need three things: reliability, speed, and efficiency.

“Without reliable, scalable processes, timelines slip. Without speed, clinical progress is delayed. And without efficiency, unnecessary costs are diverted away from new molecule research, which is at the heart of improving patient outcomes.”

“We are in an age of pharmaceutical manufacturing where drug formulations are becoming increasingly complex. At the same time, customers want to move their drugs through the manufacturing and development pipelines faster than ever before,” Kane explains. “Not only does this increase pressure on already tight timelines, but it also leave little room for errors or rework throughout the entire process.”

Regardless of the differentiation between choosing an end-to-end CDMO and a specialised partner, drug sponsors are increasingly looking for a partner that can deliver both stability and innovation while navigating geopolitical tensions, supply chain disruptions, and capacity limitations [9].

“Outsourcing models are often stressed by capacity mismatches, geographic concentration, and complex regulatory requirements,” adds Andreasen. “Mid- and large-scale biologics production is in high demand, yet capacity remains constrained in key regions, which can create delays for partners and ultimately for patients. Strategic partnerships are beneficial for complex, high-risk, or long-term activities where knowledge sharing, scalability, and regulatory alignment are critical. Examples include cell and gene therapy process development, large-scale mammalian biologics, manufacturing, and global supply chain planning. Collaboration between life sciences companies and CDMOs drives efficiency, accelerates timelines, and mitigates risks.”

Chatterjee adds that, “Strategic partnerships make the most sense for activities that shape the



molecule, process, and path to market such as CMC development, scale-up and tech transfer, clinical and launch manufacturing, and long-term commercial supply for complex products largely because they benefit from shared risk, co-investment, integrated quality/regulatory planning, and long-range capacity decisions. In contrast, standardised and easily substitutable activities like routine small molecule API or solid dose manufacturing, commodity lab services, basic packaging and labelling, storage, and one-off overflow testing are usually best handled through transactional, fee-for-service arrangements optimised for unit cost, throughput, and flexibility via a competitive bidding and shorter-term contracts – although even these have seen some evolution with some drug sponsors paying for FTE's dedicated to their services rather than a fee-for-service."

"Product lifecycle is a good rule of thumb when it comes to strategic vs tactical positioning," suggests

Joanne Anderson, CCO of Symbiosis. "Typically seen in the later stages of a product's lifecycle, the activities that work best transactionally are when specifications



are stable, outputs are easily measurable, and price, speed, or volume efficiency dominate. When an asset is as yet unproven, hence underdevelopment and/or clinical evaluation with the outcomes area uncertain and iterative, client success may be tightly coupled to supplier performance, and when failure could materially de-risk or destroy an asset, then those activities truly benefit from strategic partnerships. In many cases, assets evolve through initial strategic into a semi-strategic then a transactional model as assets mature and risks become operational rather than scientific."



“Admittedly, a purely transactional approach might seem attractive from an upfront cost perspective. For standardised services or simple, one-off manufacturing tasks, seeking the lowest bidder can improve short-term cost-efficiency. However, the pharmaceutical pipeline is rarely that simple. The true value of a strategic partnership becomes evident when challenges occur,” adds Hwang. In a one-off contractual relationship, issue resolution is often rigid and hindered by disputes over liability rather than focusing on solutions. In contrast a strategic partner is invested in the long-term success of the product. They are more likely to commit resources

and expertise to resolve bottlenecks quickly. Therefore, while the initial price tag might be higher, a strategic partnership is ultimately more cost-effective and efficient in the long run, as it minimises the risk of costly delays and ensures long-term operational stability.”

While the idea of strategic and collaborative relationships between drug sponsor and vendor can start optimistically, governance plays a pivotal role in shaping the relationships for success. Clear governance frameworks ensure alignment, accountability and transparency between both parties. Effective governance establishes structured communication channels, defines roles and responsibilities, and mitigates risks, enabling sponsors and CDMOs to navigate regulatory challenges, manage timelines, and maintain quality standards. Moreover, it fosters trust and collaboration, which are essential for addressing unforeseen challenges and driving innovation in a highly regulated environment. By prioritising governance, sponsors and CDMOs can build resilient partnerships that deliver consistent results while adapting to the dynamic demands of the pharmaceutical industry.

On current governance models, Chatterjee explains that,



“Long-term pharma-CDMO partnerships increasingly use formal, multi-tier governance as opposed to ad hoc oversight, but the level of formality varies widely across the industry. A typical model includes a joint steering committee at the top (senior sponsor and vendor leaders setting strategy, aligning objectives, managing risk, and serving as the escalation body), mid-level joint management or program teams for portfolio and lifecycle decisions, and operational working teams for day-to-day execution and issue resolution. These structures are usually underpinned by quality agreements and master service agreements along with structured communication routines to maintain transparency and joint accountability.”

“Customers increasingly expect partners who understand their pipeline needs, not just the project in front of them,” adds Ramadurai. “For CDMOs, that raises the bar. It requires structured, proactive governance built on early and continuous engagement, designed and actively maintained by both sides”

At the core is deep, consistent stakeholder engagement. High-performing partnerships connect across the full customer organisation, including External Manufacturing, R&D/CMC, Procurement, and senior leadership. Without that breadth, a CDMO is working with an incomplete picture. With it, they can anticipate needs, align resources for future demand, and support the customer’s wider strategy rather than reacting to individual programmes... Structured governance forums are what bring [partnerships] to life. Regular steering committee meetings, with the right level of seniority, enable fast decisions, early risk management, and clear alignment. These need to be practical, decision-focused sessions that actively remove barriers and maintain momentum.”

“A vital component of this model is a formal escalation protocol,” Hwang adds. “In the complex biopharmaceutical industry, technical roadblocks are inevitable. When issues exceed the decision-making authority of lower teams, a pre-defined path for immediate escalation ensures that critical bottlenecks reach senior leadership promptly. This allows for high-level strategic decisions to be made quickly without causing project stagnation or a loss of momentum.”



“The most common client mistake is declaring a partnership strategic then managing it through procurement playbooks”

It can be that clients underestimate their role in partnership success, though this can be built by assigning relationship owners, not just vendor managers and aligning procurement, technical, and commercial incentives and properly supporting governance processes (time, people, systems etc.) to allow their CDMOs to truly operate as part of the extended operating model, not an add-on,” concludes Anderson. “CDMOs are not passive participants and can materially shape the quality of governance. To be effective, CDMOs should be proactively proposing governance structures, coaching clients unfamiliar with partnership models, bringing uncomfortable truths early, and separating ‘account management’ from ‘relationship guardianship’. The best CDMOs trigger executive dialogues themselves, helping clients think portfolio-wide and invest before revenue is guaranteed. It’s important to remember that long-term partnerships do not happen because of goodwill or contract length; rather, they happen because

governance actively manages alignment under pressure. The best partnerships invest in fewer relationships, deeper governance, earlier escalation, and more honest conversations. We should accept the truth, which remains that fundamentally, while governance doesn’t prevent problems, it determines whether they destroy the relationship.”





Deal or no deal in the CDMO landscape



Deal or no deal in the CDMO landscape

Private equity is reshaping the pharmaceutical industry and particularly the CDMO sector. As large pharmaceutical companies divest in-house manufacturing capabilities, private equity firms are driving consolidation and enabling CDMOs to expand their services and scale operations [10]. Over the last several years, particularly in response to the COVID-19 pandemic, PE-backed transactions have consistently accounted for a majority of M&A activity within the sector [10]. However, such CDMOs can find themselves under greater pricing pressures and less flexibility in delivering innovative processes [10].

Chatterjee explains, "Private equity ownership tends to make CDMOs more focused on growth, margins, and exit value over a roughly 5-7-year window, which shapes





both strategic choices and day-to-day decisions. Private equity-backed CDMOs often pursue roll-up and specialisation plays, tighten pricing and customer segmentation, and push for operational efficiencies that can improve responsiveness, but also create pressure on capacity, staffing, and risk appetite. On the positive side, private equity can accelerate investment in leadership, technology, and new capabilities where there is a clear value-creation thesis, helping CDMOs move up the value chain into more strategic partnerships; on the other hand, shorter investment horizons and return targets can discourage very long-payback capacity projects or high-risk innovation unless they are clearly tied to near-term earnings before interest, taxes, depreciation, and amortisation (EBITDA) and valuation uplift.”

“Biopharma companies are looking for fit-for-purpose workshops to ensure on-time product delivery,” comments Ramadurai. “The key question for CDMOs is how to make the right investments with appropriate returns while building long-term capabilities. What matters therefore is alignment with future customer needs, investing based on real insight into pipelines and where complexity is heading. CDMOs that take this

approach are far better positioned to deliver consistent, reliable outcomes and become true partners. The private equity mindset rewards fast decision-making with commensurate risk-taking.”

The surge in PE firms in biopharma CDMOs can be attributed to the increasing demand for complex therapeutics, favourable policy trends, and perceived cost-effectiveness of outsourcing. Particularly in the US, CDMOs are seen as durable, offering a recurring revenue stream and significant growth across the value chain [10].

However, experts highlight that while opportunities are promising, critical risks exist for PE investors, including the complexity of tech transfers and the inflexibility of specialised manufacturing facilities. Advanced therapies like CGTs and viral-vector biologics need highly customised processes and facilities. Such inflexibility can lead to operational risks like idle infrastructure during demand downturns, which could impact ROI [10]. Both PE investors and CDMOs looking for funding must adopt a strategic approach to balance growth opportunities while thoroughly assessing operational and market risks.

“Private equity activity in the pharmaceutical sector, particularly with CDMOs, is certainly on the rise,” adds Cox.



“This reflects a growing focus on controlling the entire value chain. Furthermore, there has been a significant interest in AI within the industry, with many recent deals less focused on therapeutic assets and more focused on AI-driven drug development. For instance, companies like Velo have secured major deals with Novo Nordisk, valued at US\$2 billion, to identify new obesity and cardiovascular targets, and a deal of up to US\$3 billion with Merck to explore Parkinson’s disease treatments. These AI-driven partnerships are expected to streamline processes and accelerate drug discovery. While the outcomes of these deals remain to be seen, they highlight the industry’s growing interest in leveraging AI to reduce clinical development timelines. Faster approvals and market entry extend IP exclusivity, which is critical for maximising revenue.”

MERGER AND ACQUISITION ACTIVITY

M&A activities in the pharmaceutical CDMO space are reportedly experiencing a resurgence in 2026, driven by intensified therapeutic focus, premiums for innovation, and opportunities for cross-border collaborations [11]. Deals being made are increasingly focusing on acquiring capabilities in advanced drug modalities, CGTs, and

radiopharmaceuticals, aligning with growing demand in these therapeutic regions. Regionalisation trends are also encouraging consolidation and strategic acquisition, with supply chain disruptions and government incentives fuelling domestic drug production [11].





“[M&A activity] is not a one-off, but it is also not yet the dominant model; Novo-Catalent is an extreme illustration of a broader, selective shift toward vertical integration where manufacturing has become strategically constraining,” Chatterjee notes. “Novo’s acquisition reflects a pattern of targeted deals in which pharma buyers secure scarce capabilities (sterile fill-finish, radiopharma, high-complexity biologics) to de-risk capacity, protect key launches, and gain supply chain control, but most M&A activity still runs ‘horizontal’ – CDMOs buying CDMOs – rather than pharma systematically taking vendors in-house, because full ownership is capital-intensive, reduces flexibility across diverse pipelines, and can undermine the asset-light benefits of outsourcing. The GLP-1 ‘shockwave’ has since driven a broader scramble for high-throughput fill-finish and device capacity both through vertical integration moves like Novo-Catalent and through aggressive CDMO expansion so it has clearly accelerated the pattern of pharma locking up critical manufacturing assets where specific products are supply-constraining.”

“The recent surge in M&A activity between pharmaceutical companies and CDMOs is indeed



a defining industry trend, representing a broader realignment of global manufacturing assets. However, it is crucial to distinguish the directionality of these deals,” Hwang expands. “While the Novo Nordisk acquisition of Catalent is a high-profile example of a pharmaceutical giant acquiring a major vendor, this specific model of vertical integration remains the exception rather than a rule. The more dominant trend involves CDMOs acquiring manufacturing facilities from pharmaceutical companies. As Big Pharma shifts towards an ‘asset-light’ strategy to focus on core competencies like R&D and global marketing, they are increasingly divesting their internal production sites. This creates a significant opportunity for CDMOs to expand their footprints. Recent transactions, such as Lonza’s acquisition of Roche’s Vacaville site and Samsung Biologics’ strategic acquisition of the GSK Rockville facility, exemplify this prevailing trend. In these cases, the M&A activity serves as a symbiotic exchange; pharma companies reduce fixed costs and liquidity risks, while CDMOs gain validated, high-spec facilities and a specialised workforce. Ultimately, while M&A between these two sectors is accelerating, the primary driver is asset optimisation rather than total vertical ownership. Most pharma companies still prefer to leverage the

specialised expertise of CDMO partners rather than managing the complexities of a massive service-oriented manufacturing organisation themselves.”

“Biotechs are advancing increasingly complex molecules and therefore need the infrastructure to industrialise them at scale,” explains Ramadurai. “Investment is therefore focused on high-complexity areas like HPAPIs, ADCs, and targeted therapies, where expertise, containment, and scalability are critical. For biotechs, this makes partner selection more important than ever.”

Private equity and strategic investors are heavily prioritising disciplined, capability-driven transactions over speculative roll-ups, aiming to strengthen technical expertise and scale operations. This targeted approach reflects the need to mitigate risks associated with high failure rates in large-scale acquisitions while addressing the increasing complexity of manufacturing processes. As the CDMO landscape evolves, M&A is a critical tool



for some in expanding capabilities, meeting customer demand, and navigating tighter budgets [11].

“As the industry continues to scale aggressively, the most apparent investment we see is around development capabilities, manufacturing capacity, and facility expansions,” concludes Kane. “Choosing to partner with a CDMO investing in their global footprint can be especially impactful for small- to mid-sized biotechs. These organisations are often left navigating fragmented drug development ecosystems. This may mean managing multiple vendors, complex supply chains, and specialised manufacturing contracts with limited bandwidth, all of which make keeping up with shifts costly and time-consuming.”



Across the board, capital allocation is increasingly shaped by financial timelines so expansions tend to cluster where CDMOs can market technological prowess, secure premium pricing, and align new assets with visible late-stage pipelines, even if broader market demand is uneven”

Bikash Chatterjee,

President and Chief Science Officer at Pharmatech Associate



The future of resilient outsourcing capacity



The future of resilient outsourcing capacity

The industry-wide consensus on pharmaceutical outsourcing is that the sector is undoubtedly undergoing a profound transformation driven by advanced therapeutic modalities, evolving drug sponsor demands, and, above all, the continued need for supply chain resilience. Sponsors are no longer content with simple capacity provision – they seek CDMOs that can align manufacturing strategies with the unique complexities of their molecules.

“Advanced therapeutics are changing what customers are looking for in outsourcing partners,” explains Butler. “Sponsors are placing greater emphasis on partners that can align manufacturing strategy with the specific





demands of the molecule, particularly where those demands involve more complex architectures or the need to scale beyond the limits of conventional processes. This is especially true in oligonucleotide therapeutics, where traditional solid-phase oligonucleotide synthesis (SPOS) remains highly effective for many programs, but is beginning to reach its limits in some important applications. For example, large-volume siRNA programs for common diseases can require manufacturing scales beyond the reach of traditional SPOS.

“In this environment, outsourcing models are evolving beyond simple capacity provision toward a more platform-aware manufacturing strategy, which is creating greater demand for flexibility in how molecules are made.”

Rather than assuming a single default process will suit every program, sponsors increasingly value partners who can bring a broader technology toolkit to the table and apply the most appropriate platform to the construct in question.”

Chatterjee adds that, “Capacity expansion is being driven by a mix of genuine demand signals and financial/technology considerations, and the balance varies by segment. For large-scale mAbs and some traditional biologics, a wave of mega-plant builds has created pockets of overcapacity, so further expansion is now tightly scrutinised by investors and often tied to anchor contracts or clear utilisation cases rather than purely speculative growth. By contrast, high-value niches such as CGTs, complex injectables, and high-containment modalities still show structural undersupply, so CDMOs are adding highly specialised, tech-forward capacity (e.g., high-containment suites, advanced aseptic lines, etc.) that explicitly chases pipeline complexity and platform differentiation as much as near-term volume. Across the board, capital allocation is increasingly shaped by financial timelines so expansions tend to cluster where CDMOs can market technological prowess, secure premium pricing, and align new assets with visible late-stage pipelines, even if broader market demand is uneven.”

“Customers are increasingly wary of capacity that isn’t aligned with projected future demand, particularly in

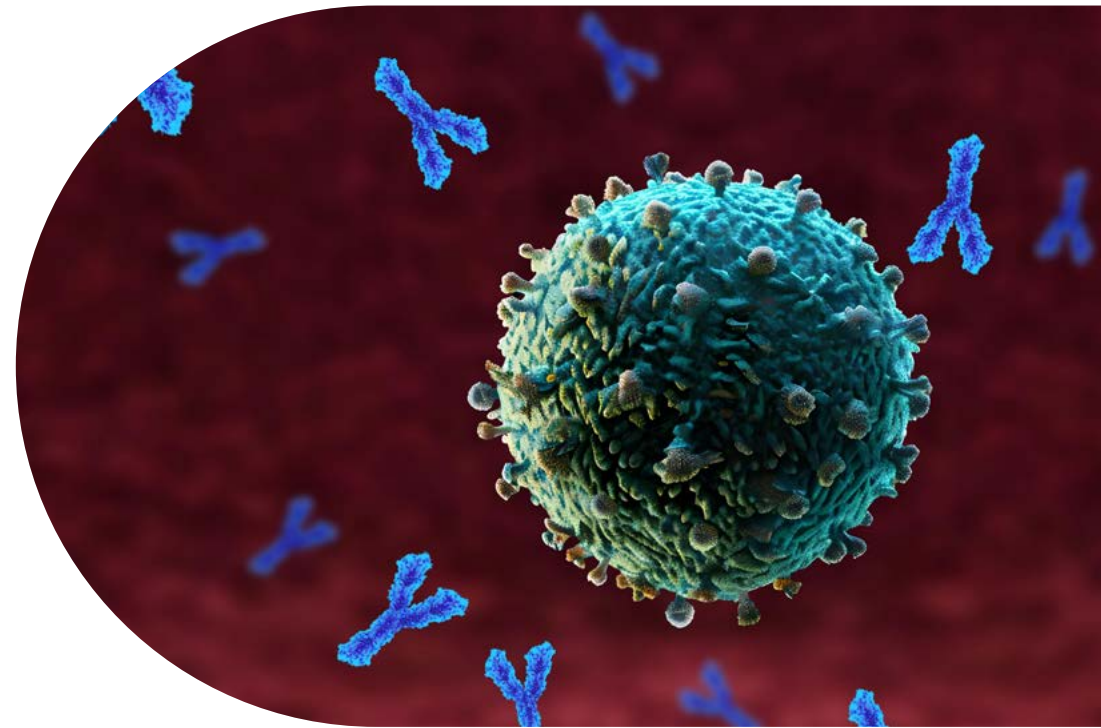


complex areas like HPAPIs and ADCs, where execution matters as much as infrastructure,” states Ramadurai. “The differentiator for CDMOs is investing with intent. Highly potent drugs account for a significant proportion of the global pipeline, with more than 1000 molecules in development. That demand is clear, but it requires the right capabilities. Financial timelines and technological prowess matter, but demand and delivery matter more.”

In an increasingly competitive and cost-sensitive pharmaceutical landscape, CDMOs are adopting strategies that both optimise manufacturing efficiency and reduce expenses, as Andreasen comments on Fujifilm’s experience with modular facilities: “Cost strategies are closely tied to capacity utilisation, modality, and geographic considerations. CDMOs and partners are optimising utilisation by balancing mid- and large-scale facilities along with small-scale capacity. Modular networks reduce capital expenditures and engineering costs by standardising equipment, layouts and processes. Fujifilm’s *kojoX* expansion at Holly Springs using a modular approach cuts design time by over 80% and engineering costs by 50%. Hybrid sourcing, local-for-local production, and dual-sourcing strategies help manage tariffs and

logistics costs while maintaining supply chain resilience.”

Hwang adds that “pharmaceutical sponsors and vendors are increasingly integrating AI into drug discovery and automating manufacturing processes. In the R&D phase, sponsors are utilising AI to accelerate the development pipeline. By employing predictive algorithms and deep learning, companies can identify high-potential drug





candidates more efficiently, significantly reducing the 'hit-to-lead' timeline. This 'fail-fast' approach is a major cost-saving driver, as it minimises the immense R&D expenditures traditionally wasted on late-stage clinical failures, thereby optimising the ROI during the early development phase.

These trends are reshaping the CDMO-sponsor relationship, highlighting the growing importance of flexibility, innovation, and strategic capacity and capital alignment in the manufacturing of advanced therapeutics. As outsourcing models evolve, so too do both drug sponsors and vendors to drive the future of pharmaceutical development and production.





Executive Summary



Executive Summary

The pharmaceutical outsourcing landscape is undergoing a period of significant transformation, shaped by evolving industry demands, technological advancements, and geopolitical pressures. As the sector adapts to these changes, several key trends are emerging that are redefining how CDMOs and their partners operate, collaborate, and innovate.

Of the most notable shifts in the outsourcing landscape is the “great bifurcation” of pharmaceutical manufacturing. The growing divide between large-scale, commoditised production and highly specialised, niche manufacturing could be shifting years of end-to-end, ‘one-stop-shop’ partners towards specialised partnerships in the years to come – or it could signal an industry looking to balance the two.

As outsourcing relationships evolve, the maturity of strategic partnerships between CDMOs and their pharma or biotech clients has become a critical factor in success. Sponsors are no longer merely looking for transactional





relationships; they are seeking long-term, collaborative partnerships that align with their strategic goals. Mature governance structures are playing a pivotal role in this evolution, providing a framework for clear communication, shared accountability, and joint decision-making. These structures enable both parties to navigate challenges more effectively, from scaling production to managing regulatory hurdles.

The pharmaceutical outsourcing landscape is at a pivotal moment, characterised by both challenges and opportunities. The great bifurcation of manufacturing, the maturity of strategic partnerships, the impact of geopolitical pressures on upstream processes, the rise of AI as a transformative force, and the trend towards earlier engagement are all shaping the future of the sector. As CDMOs and their partners navigate this evolving landscape, their ability to adapt to these trends will determine their success in meeting the complex and dynamic needs of the pharmaceutical industry.





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