CPHI Online

CPHI Online Trend Report

Global CDMO Trends: the 2024 outsourcing forecast

Key findings

Key findings 1/3

Equal responsibility for a successful partnership

While outsourcing partnerships of the past focused on the capabilities of the CRO/CDMO and reigning in the core capabilities of the drugmaker, successful partnerships of the future are built upon a relationship of equals. Both parties are responsible for bringing their own competencies, knowledge, and capabilities to the table and optimising a balanced working partnership.

Integration is the new frontier

End-to-end services and 'one-stop shop' contract organisations continue to offer attractive services to drug sponsors looking for solutions in speed, scalability, and customer support.

Key findings 2/3

Collaborative risk management in a risk-averse sector

Risks for both CDMOs/CROs and their customers incentivise a collaborative focus on accountability. While there are challenges to establishing true risk-sharing models, optimising a penalty-based structure towards a bonus-penalty rewarding achievements adds depth and trust to outsourcing partnerships.

M&A driven market shifts

Recent merger and acquisition activity, such as the Novo Holdings' acquisition of Catalent, has the industry on edge as both drug sponsors and contract partners anticipate a potential market shift in outsourced manufacturing.

Key findings 3/3

Diversifying operations requires diverse considerations

Optimising a global pharmaceutical supply chain requires a diversity of thought when considering regulatory challenges and balancing multiple stakeholders across borders. It is important for organisations to consider the inherent reason for geographic diversification and reach to better develop their outsourcing partnerships.

Treating pharmaceutical pain points:

A fluctuating market

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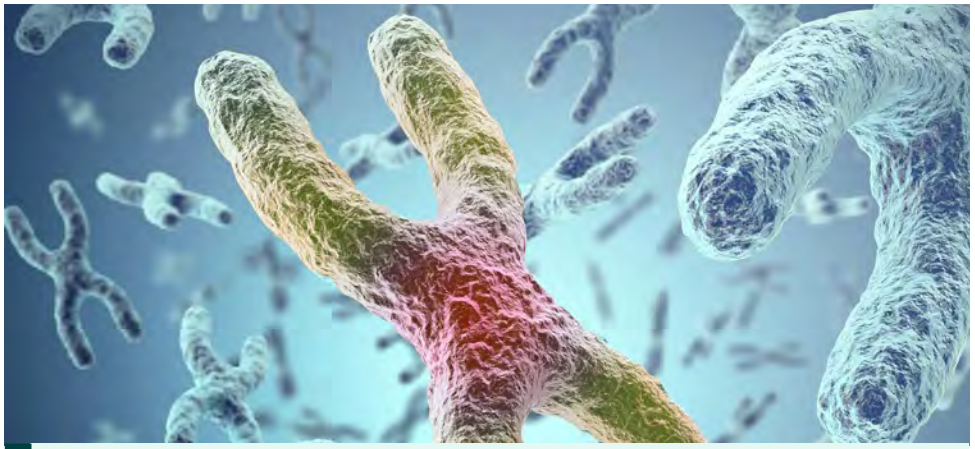
In recent years, it has become an inevitability that pharmaceutical companies of any size will outsource some percentage of their operations[1]. The activities of contract manufacturers and research organisations have thus shifted in response to changing priorities from pharmaceutical companies and biotechs, experiencing both drastic highs and lows[2].

For example, the onset of the COVID-19 pandemic witnessed a surge in financing for biotech companies – between 2019 and 2021, capital investment in emerging biologics companies reached a record high, with 2021 alone observing US$44.1 billion in financing[3]. However, starting in 2022, global events such as the War in Ukraine,

the Suez Canal blockage, and the re-opening of China contributed to a financial slowdown for pharma and biotech[3]. By the end of Q3 in 2022, biotech investment dropped to US$16.9 billion around the world.

Despite the economic uncertainties facing pharma and biotech, the market remains a highly dynamic environment – biologics are outpacing all other therapeutics with estimated valuations of over $500 billion by 2030 while small molecule drugs in unbranded generics are providing less and less revenue[4]. This comes despite an increasing demand for prescriptions drugs[4]. However, biologics market dominance may be headed towards a slump as products begin to lose patent exclusivity and biosimilars enter the market[4]. While the biologics market accounts for 46% of spending in the pharmaceutical industry, 14% of these molecules already face biosimilar competition, with another 70% facing potential biosimilar competition in the future[4]. Though this spells some relief for patients and their insurance coverage, pharmaceutical companies will need to contend with a highly dynamic market swinging between innovative therapeutics and profitable generics[4]. Pharma and biotech companies large and small are thus contending with where to focus their investments and reduce associated risks. Research and development of novel therapeutics, or production and manufacturing of products with a lower risk profile? When and where do pharmaceutical companies find a partner to share this risk?



Biologics are outpacing all other therapeutics with estimated valuations of over $500 billion by 2030, while small molecule drugs in unbranded generics are providing less and less revenue[4].

Delivering Transformational Value

The biggest contract service providers in the pharmaceutical outsourcing arena encompass contract research, development, and manufacturing. The Contract Manufacturing Market alone is expected to account for over US$200 billion by 2032[5]. The Contract Research Organisation market is also expected to grow at an estimated US$63.35 billion between 2023 and 2028[6].

Changing priorities among pharmaceutical and biotech companies are influencing the outsourcing decisions they make. Emerging as an industry almost 40 years ago, pharmaceutical contract manufacturing was viewed as an occasional service provider in emergencies, during workforce shortages, technical requirements, or short-term increased orders[7]. In the past decade, however, the pharmaceutical industry has come to rely increasingly on outsourcing providers less as occasional services and more as long-term strategic partnerships[7]. Competition rose steadily as generics entered the market and has remained steady as biosimilars take over once patents expire[7]. As a result, pharmaceutical companies are shifting their business operations to remain competitive, focusing on the production of patented innovator products and the search for the next breakthrough therapeutic[7].

"More generally, we see Big Pharma outsourcing larger shares of their discovery pipelines to trusted partners, as it expands their ability to explore many more targets simultaneously," states **Sibaji Biswas, Chief Financial Officer at Syngene International Limited.**

> **"Big Pharma prefers familiarity and trust which forms the key pillar in their outsourcing decisions. A case in point is the BMS research centre in India that is now the largest outside of the United States."**
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> **Sibaji Biswas**
> Chief Financial Officer, Syngene

This has thus changed how their working relationships with outsourced pharmaceutical service providers are viewed – that of strategic partnerships. CDMOs, CROs, and CMOs are thus under a new set of expectations to meet in this current landscape.

Additionally, global challenges have impacted how the pharma supply chain operates as a whole. **Peter Bigelow, President of xCell Strategic Consulting,** explains:

> **"The relationships between Service Providers and Sponsors have become a more important aspect of a company's strategic plan and risk management position. Driven by the supply chain woes experienced during the pandemic, geopolitical concerns, and the very high value of many new therapies, Boards and Executive Teams are increasingly involved in outsourcing decisions and very concerned about performance risks from outsourced partners."**

Peter Bigelow
President of xCell Strategic Consulting

Anil Kane PhD, Executive Director, Global Head of Technical & Scientific Affairs at Thermo Fisher Scientific, emphasises the transformational value these partnerships can have when both parties are in mutual alignment, rather than a transaction of one service for another. "In the evolving pharmaceutical landscape, CDMOs must deliver transformational value through access to cutting-edge technologies, critical data-driven insights, advanced materials, and innovative manufacturing processes – at a minimum," he states. "In addition to these must-haves, our pharma partners are seeking out strategic engagement and the intangible elements of partnership that enable them to meet their individual needs."

Strong partnerships with 'intangible' elements are at the heart of these strategic agreements – it is no longer enough to ensure a tit-for-tat relationship[8]. While more pressing priorities may make viewing contract partnerships as strictly transactional a tempting perspective, many pharma and biopharma organisations will be hard-pressed to find compatible CDMOs in today's landscape[8] "Pharma and biotech partners are looking for CRDMOs (Contract Research, Development, and Manufacturing Organisations) partners that have the knowledge and experience to map a project's entire journey from discovery to commercialisation," says Biswas. "The knowledge of an outsourcing provider is now

integral to a product's ultimate success. The relationship has evolved significantly, and most biopharma and biotech companies are looking for longer and deeper partnerships with CRDMOs." CDMOs themselves must also anticipate and overcome any relationship challenges with clear communication and a mutual trust in expertise from both parties[8].

Shared risk, shared reward

The pharmaceutical industry is historically a very risk-averse industry – even with strict regulations and standards, the consequences of errors in medical devices and drug products weighs heavily on pharmaceutical and biotech companies and their operations[9]. Yet, such aversion to risk may result in a loss of innovation and increased bureaucracy, consequentially leading to inefficiency and greater time and monetary costs[9].

Increasingly, the role of pharma vendors is seen as a potential risk-sharing business model for the supply chain. Risk-sharing partnership models, as such, often takes the form of a financial agreement to align the interests of investment return for both the sponsor and the vendor. In this capacity, the relationship theoretically encourages the mutual collaboration and commitment to a project until successful completion. It is important, however, to consider risks other than cost to share among partners. **Jason King, Director of Business Development at Ascend,** explains:

> **"There are technical and business risks for both CDMOs and their customers. Drug development in general is risky, and while risk-sharing is often assumed to be cost-sharing, it can also include sharing the risk associated with drug development. While not a risk, sharing of learnings (translated as intellectual property) during process and formulation development must also be considered."**

Jason King
Director of Business Development at Ascend

Clear communication is the key: "The challenges to all these different types of sharing are making sure they

are clearly defined upfront and well understood by both parties – in other words spelled out precisely in the service agreement/contract. The benefits arise because both parties are more vested in the outcome and neither feels their participation will be solely dictated by the other party. There is, in fact, a greater incentive to be transparent and truly collaborate."

Stephanie Gaulding, Managing Director at Pharmatech Associates, also cites a shift in focus toward core competencies and the opportunity to leverage strengths from partners as beneficial in a high-risk environment. "One of the biggest benefits of risk-sharing in outsourcing operations centres on both organisations focusing on their core competencies and leveraging the strength of their partner," she states.

> **"This often means that drug sponsors have access to experts in processing technologies, laboratory methods, and other competencies that may not be resident in their own organisation and similarly for the outsourcing organisation, they can lean into the drug sponsor for expertise in the patient profile, including severity assessment and impact, for identified risks and mitigation strategies."**
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> **Stephanie Gaulding**
> Managing Director at Pharmatech Associates

King echoes: "For projects involving novel technologies, biopharma companies are more likely than in the past to co-invest with CDMOs on installation of necessary

equipment and development of the needed expertise. Similarly, in general, there is a trend towards more risk-sharing, particularly for early-stage projects, so CDMOs don't get left empty-handed if a biopharma company halts a project mid-stream."

Bigelow comments that "The benefits of risk sharing are well known – partnerships where each partner has a financial stake in good performance results in better accountability and focus." However, he cautions that it is more difficult to find in practice. "True risk sharing between service providers and sponsors is rare. The financial structure of the businesses are very different – operating companies are set up to take risk; service providers are not. Limited risk sharing such as bonus/penalties, liability for manufacturing losses, and pay for performance are common and represent best practice for the outsourcing industry."

Gaulding cautions on the necessary steps and cultural attitudes that must accompany such agreements. "Cultural and organisational misalignment can be one of the biggest challenges in risk-sharing in outsourcing operations by causing breakdowns in communications,

inaccuracy in assessing risk, and determining appropriate mitigation strategies, slowing down decision-making," she says.

Additionally, the biotech slowdown of recent years, driven in part by a decline during the pandemic years (2019-2022), caused the contract services industry to similarly result in slower growth – but growth nonetheless. In February 2024, Thermo Fisher forecasted annual profits and revenues below market estimates, with less-than-optimistic expectations for demand in key markets like China to improve[10]. Similarly, China's own WuXi AppTec and WuXi Biologics have witnessed shares dropping in February 2024, with a US congressional committee introducing a China-focused bill that will restrict federally funded medical providers from contacting WuXi AppTec and similar Chinese biotech companies[11].

Yet, such challenges aren't stopping these partnerships from occurring – a GlobalData study found that risk-sharing agreements are growing at a rate of 24%[12]. **Kerri McCaul-Claus, VP, Solutions Consultants & Biometrics** and **Neil Berger, VP FSP Commercial and Operational Strategy at Parexel,** both suggest that "as the types of outsourcing models evolve – specifically, key oversight responsibilities shifting from CRO to sponsor and vice versa – the opportunities for risk sharing also change."

> **"The most rapidly emerging trend in this area is the mutual nature of risk sharing. A shift away from penalty structures to reliance on a bonus-penalty that rewards achievement of goals is a major advancement in the depth of outsourcing partnerships and directly contributes to improved performance when the targets are based on tangible behaviours that staff are empowered to control. Additionally, the types of risks have significantly changed. Take geographic risk (due to natural disasters, political instability, etc.) as an example. Outsourcing decisions today carefully consider these when outsourcing operations."**

Kerri McCaul-Claus
VP, Solutions Consultants & Biometrics, Parexel

Neil Berger
VP, FSP Commercial and Operational Strategy, Parexel

Evolving Trends and Strategies in Outsourcing

Evolving Trends and Strategies in Outsourcing

Integration is the new frontier

Across the board, pharmaceutical industry experts agree that integrated CDMO/CRO partners are at the forefront of outsourcing relationships. Kane states, "When entering into an outsourcing agreement, companies are increasingly looking for an integrated CDMO/CRO partner with end-to-end solutions focused on speed, scalability, and supporting customers across the drug development journey – all important factors in getting new medicines and vaccines to market faster."

Stuart Needleman, Chief Commercial Officer & Chief Patient Centricity Officer at Piramal Pharma Solutions, agrees. "Sponsors are picking companies that can do more for them," he comments.

> **"Other emerging strategies we often see are increasing emphasis on ESG, business resiliency, diversity and inclusion, and cybersecurity. This is a change from the past, where technical expertise trumped all else."**

Stuart Needleman
Chief Commercial Officer & Chief Patient Centricity Officer at Piramal Pharma Solutions

This pursuit for integrated services may, in part, be in response to the need for innovative treatments with improved ROI from development projects[13]. Additionally, the data revolution is causing pharma and biotech to re-prioritise the technical capabilities of their partners[13]. While some larger pharmaceutical companies may choose to directly acquire their own data capabilities – such as Roche's US$1.9 billion acquisition of analytics firm Flatiron, or Sanofi's recent partnership with Google – smaller pharma companies and biotechs are relying on their outsourcing partners to provide these capabilities in addition to good manufacturing practices[13].

"End-to-end service offerings are attractive and may represent a better way to ensure a more reliable and responsive relationship between sponsor and service provider," Bigelow states.

"There are many benefits to a partner that can provide end-to-end services, as transferring from one partner to another can be costly and time-consuming, ultimately slowing the process of getting medications to patients," Kane echoes.

"I've been fortunate throughout my career to be associated with companies who understand the value of integrated services and acted as either pioneers or champions of the concept," Needleman comments. "Integration is the future of the CMDO industry. When developing a drug, the ability to see the big picture is incredible useful because it provides the ability to address challenges before, they become issues. This leads to time savings and, in some cases, cost savings too – exactly what customers expect of a CDMO."

Though the vogue for a one-stop shop solution for manufacturing has seen a rise of M&A activity, as outsourcing companies look to increase their portfolio

offerings, integrated services are by no means the only route possible or available in today's industry climate[14]. Bigelow cautions on the possibilities of integrated services, advising pharma and biotech companies to really consider what services they require from their partners. "In practice, it does not always provide the type of performance improvements that were hoped for. Such offerings as analytical services, API manufacturing, dosage form manufacture, and packaging are distinctively different capabilities."

> **"Not many companies are good at everything and therefore it often makes sense to split these activities among the 'best of the breed' suppliers. In some instances, such as biologic manufacturing, where cell line development can be combined with product development and analytical support, there is a strong case to bundle these services to concentrate accountability and product knowledge."**

Despite the challenges in fusing the capabilities of different parts of the supply chain, pharma and biotech companies are still driving many outsourcing partners to integrate as many activities as they can into their portfolios[15]. Whether by a partnership agreement or an outright M&A business decision, CROs and CDMOs are also increasingly being driven to integrate their services[15]. The importance of establishing relationships between those involved in the pharmaceutical supply chain can thus extend to that of the CRO/CDMO partnership[16]. These integrated services across contract organisations also offer simpler supply chains across the globe, bridging global service firms and all the skills, expertise, and facilities each bring with them[15].

Cultivating perfect partnerships: from CDMO to PDMO?

Ultimately, it will be up to the drug sponsor to make the right decision for themselves when choosing a CDMO partner. "Ideal pharma and biotech customers should come to outsourcing projects prepared," King states.

> **"They understand what they do and do not about each specific process/product for which they are seeking outsourcing support and can clearly delineate their needs. This information is used to thoroughly vet potential partners and ensure selection of an appropriate service provider, with whom the information is shared upfront. As projects advance, they maintain open channels of communication with their CDMO partners and work collaboratively to overcome any unexpected obstacles."**

Jason King
Director of Business Development at Ascend

Gaulding expands on this, including the most important relationship for the industry: that with the patients. "One of the things I like to say about the drug sponsor side of the relationship is that it's our job to do the right thing, not the easiest thing. This means putting patients first and possessing the necessary regulatory intelligence to stay on top of new or evolving requirements specific to our products. After all, as marketing authorisation holders, we can pass on our accountability for the quality, safety, and efficacy of the medicines that may be made or tested by our partners."

However, this does not mean that both drug sponsors and contract organisations cannot position themselves to best deliver a working relationship. In recent years, the term 'PDMO' (a Partnerships Development Management Organisation) has seen an increase in interest[17]. A seemingly minute change in title signals a major change in attitude towards the work between a pharma/biotechs and contract organisations. Whether the arrangement is with a company that calls themselves a PDMO or a CDMO, they both must offer trust and reliability[18]. When asked what some of the most important qualities for a contract organisation to possess when entering a partnership agreement, almost all experts agree that integrity and communication are key.

The infrastructure of PDMOs offers a dedicated autonomous manufacturing capacity for clients to use a particular facility for the entire drug pipeline[18]. There is an initial fee the client will pay to customise

the manufacturing facility and a monthly service fee, not dissimilar to a CMDO reservation fee[18]. The main difference between a PDMO arrangement and CDMO proposal is the elimination of fees per product introduced into a CDMOs system[18]. The right CDMO partnership, however, can provide the required expertise and phase appropriate systems that may be difficult to replicate within the infrastructure of PDMOs[18]. CMDOs are highly regulated to ensure safety and efficiency. Whichever model a contract organisation decides to offer, the driving principles behind any partnership remain the same – trust, reliability, and communication.

"First and foremost, CDMOs must have a track record of excellent performance from quality, regulatory, and on-time delivery perspectives, as well as a strong reputation for going beyond expectations, especially with respect to delivering on their promises," King comments. "Excellent customer service, a culture of transparent and open communication and collaboration, and a willingness to participate in creative contractual agreements are also important."

Kane adds: "As a foundation, the key elements of trust, communication, and collaboration are critical in a relationship between a CDMO and a pharma customer. Also important is the need for a quality mindset, where 'quality' goes above and beyond product quality to include process and performance quality – a reflection of the organisational culture. As more players enter the pharma market, there is a need for CDMOs to differentiate and stay agile. The move toward personalised medicine in particular requires production methods that can cater to individual needs." Kane also highlights the importance of contract organisations integrating flexibility into their manufacturing approaches in response to market needs.

In an expert content session delivered at CPHI Barcelona 2023, **Federica Fraschetti, Associate Director, ExM Large Molecules Tech Ops at MSD,** summarised the joint responsibilities between a drug sponsor and contract organisation:

> **"The moment you sign a contract with a [CDMO], you're not just signing a contract for the service itself – you're signing for a relationship."**

Novo Holdings, Catalent, and beyond: what this means for outsourcing

On February 5, 2024, Novo Holdings announced their intention to buy American CDMO Catalent, taking the company private and selling three drug product manufacturing facilities to Danish drugmaker Novo Nordisk, of which Novo Holdings is the major shareholder[19]. News of this acquisition took the pharmaceutical outsourcing sector by storm.

For all this talk about partnerships, mergers and acquisitions are nothing new for pharmaceutical outsourcing partners. Thermo Fisher acquired Patheon in 2017 for US$7.2 billion, while Danaher Corporation purchased Aldevron for US$9.6 billion in 2021[20]. The integration of more and more capabilities within a single firm's portfolio of offerings drives many of these M&A-type activities. However, Novo Holdings' acquisition seems not to be driven by such requirements for third-party manufacturing capabilities. In an uncommon move, a pharmaceutical firm snapping up a CMDO's existing manufacturing facilities and expertise may point to a potential return for drugmakers to bring manufacturing

in-house[20]. With the pharma supply chain facing unprecedented GLP-1 receptor agonist (RA) shortages, Novo Nordisk may be looking to solidify their own internal supply chain to ensure production and delivery of their blockbuster weight-loss GLP-1 product Wegovy, as well as off-license use of diabetes treatment Ozempic[21].

On the acquisition, Bigelow comments: "I suspect there is some unused capacity in the Catalent injectables facilities with the downturn in the COVID vaccine and therapeutics volumes. That extra capacity can be turned over to partially meet the needs of Novo products pretty quickly. However, Novo is making the acquisition to provide capacity for their own products... I would be scrambling right now if I had sterile fill/finish products contracted with Catalent – and would be looking at alternative suppliers."

AstraZeneca's CEO Pascal Soriot made a statement on the acquisition, considering his company's current partnership with Catalent for some of their drug manufacturing: "It really means for us that we need to be as independent as we can in terms of our own supply." The comment came as part of an announcement of AstraZeneca's continued investment of US$300 million in a Maryland facility for the discovery and development of cell therapies[22]. This has sounded alarm bells throughout the industry regarding a potential shift back to in-house manufacturing. Bigelow comments:

> **"The acquisition of a pure play CDMO by an operating company is rare but might make more and more sense as operating companies need to obtain capacity quickly. Expect to see more of these types of deals."**

Peter Bigelow
President of xCell Strategic Consulting

The type of acquisition deal struck between Novo Holdings and Catalent is uncommon in a landscape of M&A agreements between contract organisations – whether they are looking to integrate services between them or partnering to offer joint clients end-to-end services[23]. However, just because the Novo/Catalent acquisition may also be driven in part by various issues

plaguing the CDMO may not mean outsourcing firms will need to worry just yet of a seismic shift back towards in-house manufacturing.

Dan Stanton, Managing Editor of Bioprocess International, writes: "The repercussions in the blooming GLP-1 space will be huge – Novo's rival Eli Lilly, which has also named Catalent as being part of its own diabetes and obesity network, spoke recently of its own concern with this deal – but the knock-on to the wider CDMO industry and in particular the cell and gene therapy (CGT) sector could be even bigger... Catalent is one of the dominant CDMOs in a field that has long been dependent on outsourced manufacturing. The firm supports at least wo commercial gene therapies – Novartis' Zolgensma (onasemnogene abeparvovec) and Sarepta's Elevidys (delandistrogene moxeparvovec) – and many other candidates in development. Add alleged shortages of viral vector capacity, the whole industry is cagily awaiting to hear Novo Holdings' plans for Catalent's CGT network... If Catalent's CGT network proved to be too much of a headache for Novo, it could well be next on the divestment agenda. Then, of course, the question moves on to whether the new buyer(s) – whether a third-party, Big Pharma, or [insert leftfield acquirer here] – will continue the ripple or cause a full-out tsunami across the advanced therapy space"[20].

With the Novo Holdings/Catalent deal shaking things up at the start of 2024, it will remain to be seen how the pharmaceutical outsourcing market will respond – will the move be to solidify capabilities through agreements between contract organisations or is Big Pharma taking back control of their manufacturing operations? If all eyes weren't already on the outsourcing sector, they will be now to see where it goes from here.

Innovative advanced therapeutics require innovative advanced solutions

Outsourcing parts of the pharmaceutical supply chain must also consider the capabilities of the partners they choose to work with. Advances in pharmaceutical products and therapeutics must be matched by advances in the technologies and expertise needed to develop, analyse, and deliver them. The aforementioned 'PDMOs' of the industry are already

locking in opportunities to better position themselves as experts for advanced therapeutics development and manufacturing[24]. Singapore-based 'PDMO' Genetic Design & Manufacturing Corporation recently received US$21 million in funding to bolster the production of therapeutic modalities such as mRNA, lentiviral vectors, and plasmid DNA for the US and Asia-Pacific regions[24]. Genetic Design & Manufacturing Corporation terms themselves as a PDMO due to their 'targeting a smaller number of clients with a longer-term relationship with multiple products in the pipeline'[24].

Whether a PDMO or a CDMO, contract organisations are also prioritising keeping up with the latest in advanced therapies alongside partnership and relationship management[24].

"A number of innovations and emerging therapeutics are transforming the pharmaceutical industry's approach to drug development, manufacturing, and clinical operations," explains **Bikash Chatterjee, President, Chief Science Officer at Pharmatech Associates.** "The transformation is driven by these four factors:

1. Personalised Medicine Impact: The advent of personalised medicine, especially autologous therapies, is reshaping outsourcing dynamics. The need for proximity between patients and manufacturing facilities imposes logistical constraints. CDMOs must adapt their facilities and processes to accommodate the live vectors integral to manufacturing cell and gene therapy products. On the regulatory front, over 60 percent of the novel drug therapies approved by the FDA used expedited approval mechanisms. This reality places immense pressure on drug sponsors and their outsourcing partners to prepare for a swift commercial

introduction. Such urgency in the development timeline requires streamlined and efficient collaboration between pharmaceutical companies and their outsourcing counterparts to ensure the commercial systems ar in place.

2. AI and Machine Learning Revolution: While the adoption of Artificial Intelligence (AI) and machine learning is recasting pharmaceutical operations, it also raises questions in terms of compliance and data integrity. Applying AI and ML technologies to manufacturing unit operations demands new skill sets to effectively manage and govern the evolving systems.

3. High Potency Active Pharmaceutical Ingredients (HPAPIs) and ADCs: The rapid growth of Antibody-Drug Conjugates (ADCs) has fuelled the demand for High Potency Active Pharmaceutical Ingredients (HPAPIs). This trend increases the necessity for specialty operations capable of safely handling compounds falling within the Occupational Exposure Band (OEB) 3-5. CDMOs must adapt their capabilities to meet the unique requirements of these potent compounds.

4. Clinical Trial Innovations: On the clinical side, Contract Research Organisations (CROs) are turning to AI to enhance recruitment times. Also, drug sponsors are turning to adaptive clinical trial designs and leveraging Real-World Evidence (RWE) to counter conservative health authority positions on demonstrating efficacy and safety."

King similarly offers the following emerging therapies and innovations as the biggest influences on the outsourcing industry's activities: "For biologics, cell and gene therapies/viral vectors, mRNA, and antibody-drug conjugates (ADCs) stand out. Manufacturing of these newer modalities requires specialised and, in some cases, unique areas of expertise, such as *in vitro* transcription for mRNA and both small- and large-molecule capabilities and specialised production suites for ADCs."

Those operating in the CDMO space reflect on the steps taken to keep up with innovations in pharmaceutical products. Biswas elaborates: "Over the last 30 years, we have expanded our scientific expertise, enabling us to offer integrated services across discovery, development, and manufacturing. Today, we are well established in the contract research market with a strong emerging

presence in development and manufacturing services. We believe it is the integrated approach that drives innovation and helps us develop value-added solutions for complex scientific challenges. Over the past 11 years, Syngene has undertaken development work on several monoclonal antibodies for use in animal health, including manufacturing clinical supplies of a treatment for allergic or atopic dermatitis."

Biswas also mentions in particular the manufacturing of biologics and large molecule therapeutics:

> **"I think the biggest opportunity for newer manufacturing methodologies is in the area of large molecules. When you look at overall contribution that comes from the process of making a mAb, there is a heavy weighting on the raw material and the performance of the process. Technologies like the intensified fed batch or perfusion will therefore help drive the efficiency and quality further."**
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> **Sibaji Biswas**
> Chief Financial Officer, Syngene

Kane mentions similar emerging therapeutics driving CDMO innovation: "Medicine is advancing at a fast pace, with new life-saving medicines in emerging areas of science – from cell and gene therapies to oral solid dose technology to pre-filled syringes. As a CDMO/CRO partner, we enable the scale and production of new cell and gene therapies, mRNA therapies, and many more innovative new treatments that are changing patients' lives. To support our customers through innovation in these areas, Thermo Fisher has recently expanded in biologics, steriles, viral vector services, advanced therapies, and clinical supply chain, and our expertise and capabilities have helped pharmaceutical and emerging biotech companies accelerate time-to-market across a wide range of modalities and platforms."

Whatever the model of partnership chosen between contract organisations and drug sponsors, it is up to the manufacturer to keep pace with pharma's speed of progress in new and evolving therapeutic modalities with the right manufacturing technologies and processes[25].

Long-distance relationships:

Global pharmaceutical outsourcing trends

Long-distance relationships: **Global pharmaceutical outsourcing trends**

Global events such as the COVID-19 pandemic, the war in Ukraine, and the Israel-Palestine conflict have showcased the delicate nature of the pharmaceutical supply chain[26]. In response, the optimisation of supply chains and their resiliency has been a priority for the whole pharmaceutical industry. Strategies include upstream visibility through dedicated digital tools and intentional partnerships, joint manufacturing hubs, and optimisation of regulatory requirements across borders with AI and machine-learning models[26].

Managing and optimising a global pharma supply chain

Chiefly, the common thread in these strategies include a diversification and broadening of partnerships between pharmaceutical players. The last 2 decades has seen a sixfold growth in the worldwide value of pharmaceutical goods from US$113 billion in 2000 to US$629 billion in 2019[27]. Undoubtedly, pharmaceutical supply chains stretching from one corner of the globe to the other are more complex than ever before. A McKinsey report found that cyberattack events and trade disputes were of particular concern to pharmaceutical supply chains, with such events becoming more commonplace[27].

> **The last 2 decades has seen a sixfold growth in the worldwide value of pharmaceutical goods from US$113 billion in 2000 to US$629 billion in 2019.**

"Drug shortages continue to plague the industry and have gotten the attention of Ministries of Health, Legislators, and the public," Bigelow analyses.

In an effort to curb these challenges, companies can regionalise and diversify operations, reducing exposure to single sources and supply chain risks[27].

> **"More than ever, the pharma industry is prioritising the need to make products available when needed and avoid the types of events that cause stock-outs. However, the situation is complex and there are many contributing factors."**
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> **Peter Bigelow**
> President of xCell Strategic Consulting

It is also important to note the ever-changing demands from key stakeholders within the pharmaceutical supply chain[28]. Relocation of manufacturing operations in Europe, Asia, and Latin America may bring tax rate incentives, but the time and cost spent in transferring the people, products, and technologies to a new site may bring short-term losses[28]. Also thrown into the pool of questions to ask is whether it is better to have one partner who can do it all, or more than one partner? Contract

organisations can position themselves to be better global partners to their drugmaker clients by understanding the reason for their client's search of a global partner. The management of key stakeholders across the entire value chain is of utmost importance.

Says **John Aikens, Biologics Practice Lead at Pharmatech Associates.** "CRO/CDMOs must prepare to manage a stakeholder network to achieve successful deal timing, accountability, and communication. A single individual

> **"Partnership agreements describe the elements of a collaboration from a legal, technical, financial and operational perspective."**
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> 
> **John Aikens**
> Biologics Practice Lead at Pharmatech Associates

who appears on the signatory line of a partnership agreement masks a network of teammates necessary to align, validate, and manage the partnership. Teams influence a successful collaboration. Multiple stakeholders are involved in the partnership development process to address participants, roles, scope, timelines, deliverables, and budgets. Organisation size impacts the structure and complexity of agreements: smaller, more nimble companies can become frustrated dealing with layers of bureaucracy in large organisations. Pre-agreement diligence and validation between the partners to map organisational networks can minimise logistical challenges. A structured process can anticipate that a technical scoping exercise expands to include business development, legal, operational, and financial stakeholders. The scale and complexity of the agreement workflow also determines who will be engaged. Agreement principals or other

subcontractors and vendors may be integral participants that become stakeholders. In addition, the role and timing of each participant are important to efficiently frame agreement discussions. Recommenders may be business or technical players. Evaluators may be legal, senior technical, business development, or operational. Agreement value will determine the ultimate approver, such as a program manager, a senior manager, a C-suite executive, or the board of directors."

"Global but local are the buzzwords, with good reason,"

adds Needleman. "We have 15 sites across North America, Europe, and India, so we can deliver programs that address the sponsor's needs. Where is the drug being launched? Does development and manufacturing need to be on-shored or off-shored? Is cost the most important factor in selecting a CDMO, or is it proximity, quality, or regulatory? It's important to be able to offer your customers options based on their responses to these questions."

McCaul-Claus and Berger emphasise the importance for both drugmakers and contract organisations to assess what the reason for accessing geographic diversification in order to optimise the partnerships they enter: "Access to local expertise for access to patients is fundamentally different from seeking geographic diversification to reduce cost and de-risk (natural disasters, political stability etc.) In the former, confidence in the local leadership to form the requisite relationship with staff, sites, and patients is critical. In the latter, building a unified talent organisation that adheres to global productivity and quality standards are critical. Assessing these two mindsets are important considerations when selecting international partners."

Regulatory considerations

There might also be other reasons for a drug sponsor to consider diversifying their partnerships across the globe. "[It] depends on the target market(s) for the drug candidate under development. If the goal is ultimately global distribution, it is essential to partner with a CDMO that has global experience meeting regulatory requirements for the anticipated markets," King explains. "In addition, some nations require at least the last manufacturing steps (fill/finish and packaging) to be performed in-country for drug products to be sold on their markets. That requires partnering with a CDMO with fill/finish capabilities (or possibly multiple CDMOs or domestic pharma companies). Furthermore, increasingly, drug companies are seeking to develop different formulations designed to meet the cultural and other expectations of local regions. Here again, CDMOs with at least multiple development/technical centres around the world, if not manufacturing sites, can more easily support varying customer needs from a regulatory and cultural perspective."

Chatterjee adds: "Evolving regulatory frameworks for advanced therapy medicinal products (ATMPs) compel

> **"The various sites must be integrated and cannot simply be facilities that operate independently under a brand. They must have the same quality and other systems, aligned manufacturing schedules, well-established tech-transfer protocols, and so on, to ensure seamless movement of materials from one site to the next and consistency of final products with respect to key quality and other aspects."**

Jason King
Director of Business Development at Ascend

outsourcing providers to continually adapt, balancing the latest compliance and regulatory expectations while upholding commitments to existing partnerships."

However, King caveats:

Access to patients and expertise: getting the right product to the right customer

Of importance to the conversation around global partnerships is perhaps the most critical partnership of them all: that with the patient. Access to the right pool of patients and ensuring the supply chain is resilient enough to deliver the right therapeutics to this pool of patients must also be on both the drugmaker's and contract organisation's radar.

Patient-centricity is no longer just a buzzword – it should be at the core of every pharmaceutical organisation's ethos[15]. The expectation demanded on both the drugmaker and contract provider's side must be intentional in setting their values and sharing them with the right level of communication and knowledge-sharing[15]. "This is sponsor–company specific, since their commitment to patient centricity can vary. Most are

patient-centric in both word and deed, and by being a patient-centric CDMO, we are aligned with their goals and their values," Needleman states.

Contract organisations can also do their part in walking the talk when it comes to patient centricity. "Pharmaceutical companies are focused on getting life-saving therapeutics to patients, faster, and using technologies that enable patient-centric healthcare can help them do that," Kane explains. "For example, clinical research is advancing in a way that could be life-changing for clinical trial participants. Patient-centred, decentralised trials – and especially advances in smart packaging and enhanced trial set-up and planning – could allow flexibility such as fewer in-person doctor's appointments, without compromising data integrity.

Smart packaging solutions support remote patient monitoring and adherence through remote visibility and reporting. Patients save time through decreased office visits, and clinical sites can prioritise interventions based on adherence dashboards... Operating in a global market means pharma companies have to be prepared to cater to diverse needs, manage global supply chains, and respond to varied regulatory environments... Post-pandemic, the pharmaceutical industry has preferred

> **"CDMOs with a global presence can leverage their network of sites to support pharma partners in this way. For example, clinical research is advancing in a way that could be life-changing for clinical trial participants."**
>
> 
>
> **Anil Kane, PhD**
> Executive Director, Global Head of Technical & Scientific Affairs at Thermo Fisher Scientific

to have a regional/local presence to avoid delays due to supply chain or regulatory challenges and the cost and time associated in bringing effective medicines to patients in different parts of the world."

Summary

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The relationship between contract organisations and pharmaceutical companies is constantly evolving to meet demands from the market, shareholders, and all relevant stakeholders like patients and healthcare providers.

"Today's outsourcing decision is a strategic endeavour focused on identifying synergies that can be harnessed by drug sponsors to ensure optimal business performance of drug sponsors and the overall success of programs," Chatterjee states. "Outsourcing dynamics have shifted from mere cost and bandwidth considerations to more strategic criteria... The bottom line is the outsourcing partner has a profound effect on how quickly and easily a drug moves through the development lifecycle."

Models and ways of working will vary between agreements established between sponsors and service providers, from risk-sharing partnerships to strategic relationships, but communication and shared values and visions remain a staple of successful outsourcing

Summary 2/2

partnerships. While some industry activity such as Novo Holdings' acquisition of Catalent and the stagnant growth of CDMOs in the last year has stakeholders watching the pharmaceutical outsourcing market closely, both drugmakers and contract organisations are equally responsible for the success of their products. "Executive sponsorship goes both ways and should be embraced by the sponsor pharma company as well as the CDMO partner," Needleman adds.

> **"Clarity, communication, and transparency are extremely important in any business partnership and this is no exception. There is sometimes a discrepancy between talking the talk and walking the walk, which can lead to problems."**

McCaul-Claus and Berger echo: "Integrity and heart [are the most important qualities to possess]. Contract outsourcing partnerships are long-term and complex relationships. Both the contract organisation and the pharmaceutical partner should enter the agreement with a true intent to partner. The pace of change is the reason this has quickly become a priority over traditional capabilities benchmarks (size, scale, systems, etc.). Tools, processes, and geographic footprint are all characteristics that can (and will) develop to meet the specific needs. But you need a shared will, passion, and core drive to enable a healthy partnership to grow."

> **The relationship between contract organisations and pharmaceutical companies is constantly evolving to meet demands from the market, shareholders, and all relevant stakeholders like patients and healthcare providers.**

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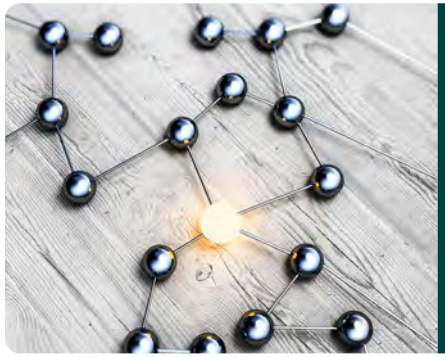

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