Defining New Rules

The Evolution of the CDMO Industry

Contract development and manufacturing organizations (CDMOs) have been on the rise in the last decade. Historically, CDMOs operated on a business model which predominantly focused on serving as external service providers for manufacturing pharmaceuticals. This model included the addition of capacity by the acquisition of manufacturing facilities from (bio)pharma companies or own capital investments. However, CDMOs have increasingly become innovation leaders and cover more areas of the pharma business, not just manufacturing, opening up additional revenue streams.

©ipopba - stock.adobe.com

This change of focus has been accompanied by a change in the M&A landscape in the market. Some CDMOs are expanding their services and swapping their "contracts" for "partnerships", evolving the term "CDMO" into "PDMO." By getting closer to their partners, CDMOs can move past some of the pressure and offer consultative support or innovation to develop products in new ways.

The evolution of the CDMO sector is propelled by rising manufacturing standards, the advent of groundbreaking therapies, and a shift towards personalized medicine. CHEManager asked executives and industry experts from a broad range of CDMOs to share their views on how their companies are dealing with this changing economic environment and the resulting opportunities and challenges. We proposed to discuss the following aspects:

- (How) have the rules of the CDMO market changed since the pandemic of 2020/21?
- What do you consider the most important growth drivers for CDMOs?
- What is your company's strategy to grow the market share in the CDMO industry?

Read the insightful answers of the experts here.

A Secure and Resilient Supply Chain is Crucial

Gavin Murdoch, VP Commercial Strategy, Abzena

"The Covid-19 pandemic has been a catalyst for change in the contract development and manufacturing organizations (CDMOs) landscape."

The Covid-19 pandemic has been a catalyst for change in the contract development and manufacturing organizations (CDMOs) landscape. It has underscored the critical importance of a secure and resilient supply chain, making us realize the necessity for having secondary and local suppliers to ensure the availability of essential materials and services. It has also focused onshoring activities and investment in captive capacity.

There is an increased emphasis on dual sourcing and onshoring. Companies are now prioritizing having backup suppliers and local partnerships to mitigate risks associated with geopolitical uncertainties and supply chain disruptions. The BioSecure Act has further accentuated the need for transparency and security in sourcing, making it crucial to know the origin of materials and ensuring they are not reliant on single points of failure.

The market complexity has also proliferated in therapeutic areas such as cell and gene therapy, ADCs, and complex biologics. The demand for specialized expertise across these fields means no single company can master all domains, thus driving the partnering internal capabilities with outsourcing from discovery to commercialization.

Abzena is not just reacting to these market changes but strategically positioning itself to capitalize on them. Our approach focuses on fully integrating offerings, from discovery and development to clinical support and commercial production. We also offer drop in service offerings to bridge gaps in internal bench strength to accelerate pipelines. By ensuring our clients have a seamless, end-to-end supply chain, we reduce the risk of disruptions caused by multiple failure nodes.

We are also investing in capabilities and capacity, particularly in high-demand areas like ADCs, bioconjugates and complex biologics. Furthermore, we are exploring innovative business models that foster closer collaborations with clients, transforming our R&D operations into virtual extensions of their teams. Resilience, flexibility, and strategic partnerships define the new CDMO rules. Abzena is adapting to these changes and leading this transformation.

A Pipeline Full of New Opportunities

Tom Sellig, CEO, Adare Pharma Solutions

"Companies that invest wisely and remain adaptable can stay ahead of the curve and seize emerging market opportunities."

The CDMO landscape is rapidly evolving, and companies that invest wisely and remain adaptable can stay ahead of the curve and seize emerging market opportunities. The significant biotech funding in so far in 2024 illustrates that we're in a favorable environment for innovation and development, providing more opportunities for CDMOs.

Technological advancements are a crucial growth driver. Companies like Adare with robust technology solutions are in high demand. We continuously evaluate new technologies to enhance the development and manufacturing journey for our customers. While this process requires substantial time and resources, we believe it's worth the effort to discover innovations that benefit our clients.

High potency compounds continue to play an important role in the pharmaceutical landscape, driven largely by the oncology sector. Approximately 40%-50% of the drugs in development are cancer drugs, and of those 75% are high potency. This underscores the vital importance to CDMOs of possessing both expertise and infrastructure in handling highly potent compounds, an area where Adare excels.

Pediatrics is another growing market segment, with a heightened awareness among sponsors of the need for tailored formulations to accommodate pediatric patients. As a result, pediatric formulations are now seen as essential component of a dedicated strategy to maximize a product's potential.

Additionally, there is a growing trend of reshoring pharmaceutical work to the US, which presents significant growth opportunities for US-based CDMOs.

In summary, these factors collectively drive substantial growth for the CDMO industry, which we've seen at Adare. Our development pipeline is full of new opportunities. We've experienced record proposal volumes this year and anticipate continued growth from both new and existing products. The dynamic CDMO landscape clearly offers sustainable growth opportunities for both Adare and the industry at large.

CDMOs Must Have a Clear Vision and Strategic Growth Plan

Neil Jones, Chief Commercial Officer, Aenova

"Both well-established pharmaceutical companies and emerging biopharma companies are turning to CDMOs for strategic partnerships."

The importance of contract development and manufacturing organizations (CDMOs) in the global pharmaceutical supply chain is growing rapidly. As the demand for new and innovative therapies increases, both well-established pharmaceutical companies and emerging biopharma companies are turning to CDMOs for strategic partnerships. These partnerships enhance the drug development and manufacturing process by making it faster, more efficient, flexible, and timely. The significance of CDMOs is evident in the market growth, which reached €206 billion in 2023 and is expected to expand to €293 billion by 2028, with a CAGR of over 7%.

To further grow our market share in this industry, we focus on three simple key aspects:

First, vision and strategy: A CDMO must have a clear vision and strategic growth plan. This involves investing in production capacity for rapid scalability and faster time-to-market, as well as being an innovative and flexible partner. CDMOs need to anticipate and support future customer needs with the latest technologies, such as improving the bioavailability of APIs or accelerating the time-to-market for new chemical entities (NCEs).

Second, customer-centric approach: Placing the customer — and consequently the patient — at the center of all activities is crucial. CDMOs have a significant responsibility in the development and manufacture of products that improve the health and well-being of people worldwide. This requires operational excellence to ensure the highest quality and reliable delivery every day. Additionally, it involves a collaborative mindset to address business challenges alongside customers through continuous communication.

Finally, prioritization and execution: Recognizing market position and setting clear priorities is essential for CDMOs. For Aenova, this means strengthening our presence by expanding growth platforms, enhancing operational excellence, and developing growth drivers, including extending development services and technologies for innovative medicines.

Without Sustainability in Your Vision, You Probably Will Fail

Torsten Wöhr, CCO, Bachem

"Currently, most CDMOs that have invested in a specific platform like to stay with it."

The CDMO market is very dynamic at the moment, and I think companies need to reflect this. Currently, most CDMOs that have invested in a specific platform like to stay with it. Especially in the peptide and oligonucleotide manufacturing business, one of the protectors of the niche is the capital you need to invest. There is a high entry barrier. I think this often provides a false sense of security. For example, we are currently an enabler in the market. You might think that is a comfortable position, but that should not be misunderstood as a position of strength. It is very important to stay humble. If there is huge demand not covered by supply, it is a matter of time until that gap is closed.

So, I think you need to reinvest some of the money you make to stay at the forefront with research and innovation; this is our trailblazing concept. You start 3-4 different processes based on different technologies in parallel, and you decide at certain milestones which ones you are going to eliminate, and which one you carry forward. Not every CMDO does this, that they put their own money in these platform questions. But I think that is key, also when it comes to future challenges. We have customers that say: "We have a CO_2 emission target by 2035, and you are part of it!"

So, I believe if you do not have sustainability in your vision, you probably will fail. All CDMOs have to react there as well.

Enhancing Supply Chain Flexibility and Resilience

Ashu Tandon, Chief Commercial Officer, Aragen

"We are very well positioned to manage future disruptions, ensuring seamless operations, even in uncertain times."

The pandemic reshaped the CDMO market, making diversity of supplier base a necessity and an important variable in the supplier selection process. In light of ongoing geopolitical tensions, customers are now looking again at options beyond China in their supply chain. This even extends to the back-end supply chains of CDMOs and reducing dependency on China and other overseas markets. In response, at Aragen, we've prioritized enhancing our supply chain flexibility and resilience, investing in capacities and adopting advanced digital tools, including AI and ML, to optimize efficiency and reduce errors. As a case in point, we've been working very hard to develop a local supplier base within India, including within 250 km radius of our labs to ensure continuity of materials. Additionally, imports of raw materials have reduced from around 60% of our total spend to about 20% in the last 3-5 years. As a consequence of these strategic investments, we are now very well positioned to manage future disruptions, ensuring seamless operations, even in uncertain times.

Aragen's growth strategy focuses on three key areas: investing in advanced facilities, expanding capacity and capabilities, and providing innovative solutions to meet customer requirements. We have been making strategic investments across all lines of our business. We recently strengthened our drug product service offerings by adding clinical manufacturing capacity that will allow us to provide integrated drug substance, drug product and related analytical services. While in our biologics manufacturing plant in Bangalore, we can now undertake non-GMP production for batches up to 50 L. And, by the end of the year, we will add further GMP manufacturing capacity that can deliver manufacturing batches at the 200 L to 2 KL scale. We have added large-scale biomanufacturing capacity at our campus in California. We are also strengthening capabilities in newer areas like oligonucleotides, peptides, and antibody drug conjugates (ADCs). Finally, we have also committed to an investment plan of around $250 million over the next five years — to expand both R&D and manufacturing facilities across the business.

Fostering Long-Term Collaborations

David McErlane, Group President of Biologics; and Aris Gennadios, Group President, Pharma and Consumer Health, Catalent

The CDMO market has adapted to the changes brought about by the pandemic by becoming more agile and flexible, to be able to rapidly respond to changes in market conditions, and more focused on high-growth areas such as biologics and cell and gene therapies. We have also seen more investment in digital technologies.

The Covid-19 pandemic highlighted the need for integrated and robust supply chains. Improved supply chain resilience that provides reliability and traceability can support the timely delivery of therapies to patients. A well-planned, integrated supply chain for critical raw materials and components becomes critical when high-value, individualized therapies such as cell therapies need to be manufactured and delivered in a time-sensitive manner.

There has been an increase in strategic partnerships between pharmaceutical companies and CDMOs. These collaborations are often more integrated, involving earlier stages of development and greater sharing of information to streamline the drug development process.

The emerging biopharma sector continues to drive innovation, and as a result, Catalent has seen a rise in demand for integrated services that streamline the drug development process from development to launch. As a critical partner to these companies, a CDMO's ability to offer comprehensive solutions not only accelerates timelines, but also ensures the successful commercialization of groundbreaking therapies.

We have also seen an increase in outsourcing driven by the need for flexibility, efficiency, and access to specialized infrastructure and expertise required to bring novel treatments to market. With global and industry volatility, many customers value the capacity and flexibility CDMOs bring to rapidly scale and adjust output quickly in response to changes in demand.

Of course, it has remained essential for CDMOs to provide reliable quality and maintain trust-based relationships with customers. In an increasingly competitive market, Catalent's commitment to excellence and transparency has become a cornerstone of our partnerships. By consistently delivering on our promises, we foster long-term collaborations that drive mutual success.

Create Access Equity for Biological Assets

Russel Miller, Vice President Global Sales & Marketing, Enzene

"Our expansion into the US market is a key element of our growth strategy."

Enzene's strategy to grow market share in the CDMO industry is anchored in our innovative fully connected continuous manufacturing process, EnzeneX. Through this technology, we aim to make biologics manufacturing more accessible and affordable for small and emerging biotechs, as well as animal health companies. We understand the challenges these companies face in achieving cost-effective production, and EnzeneX addresses these needs by ensuring high yields and quality outcomes — essential for the success of complex biomolecules like fusion proteins and bispecific/trispecific antibodies.

Our expansion into the US market is a key element of our growth strategy. The upcoming launch of the 54,000 sq. ft. facility in New Jersey, equipped with 500 L bioreactors and additional capacity planned beyond phase 1, will enhance our ability to serve the US market, bringing our continuous manufacturing processes closer to our clients and supporting both clinical and commercial manufacturing needs.

Our intention is to create access equity for biological assets whether human or animal and in any phase of development, by providing cost-effective local manufacturing. With the growing concerns over the uncertainty of the BioSecure act, a lot of biotechs are looking for alternatives and preferring US manufacturing, and the new site will create access equity by providing state-of-the-art, cost-effective continuous manufacturing to small and mid-size companies.

We constantly strive to improve our processes and are working on EnzeneX 2.0. This upgraded version of our technology is being designed to enhance various aspects of the manufacturing process, aligning with industry demands for greater functionality. Additionally, we are developing new cell lines capable of achieving 8-9 g/L yields, with the goal of breaking the $40/g cost barrier.

Lastly, both at our Indian site and in the US, we're expanding our services by launching a discovery arm, offering fully integrated services from discovery to commercialization.

Focus on Being in Close Contact with Partners

Frank Wegener, CEO, ESIM Chemicals

"Growth is driven via the willingness of the big players to allocate projects to a CDMO."

Actually, the rules have changed somehow. There has been a period up to the end of 2022, where customers have been very conscious about potential supply chain disruptions, focusing their operations on Europe or the US. This gave a push to all CDMOs. The consolidation of European CDMOs moved forward, especially on the back of rising energy prices and labor costs, the positive tailwind only lasted a short period of time. All companies, around the globe, are in the meantime considerably more digital and big parts of the work with the customer is done online.

Technical excellence, best-in-class service, agility. What does this mean: The growth is driven via the willingness of the big players to allocate projects to a CDMO. We therefore focus on being in close contact with our partners and trying to understand their most important needs for the specific project, which can vary a lot. It might be a fast implementation, an improvement of the process, flexibility in campaign volumes, … .

To focus on our core competences and further improve them in all areas of working together with our partners. We as ESIM are known for best-in-class operational excellence to further improve the processes and therefore the cost situation, on for example raw material usage, for our customers. Keeping the focus on further educating our workforce in operational excellence and best practice of project management. Together with a clear strategy, being one of only a few companies fully focusing on CDMO without a big line product business next to it, this will bring the tailwind for growing further the market share in the rather small world of CDMO industry.

Shift from Manufacturer to Technology Leader

Ludwig de Mot, CEO, EuroAPI

"CDMOs are addressing a broader range of therapeutic areas for chronic diseases such as obesity, diabetes and cardiovascular conditions."

In a diverse CDMO environment, EuroAPI is in a unique position to take advantage of market trends. The first of these is the shift from providing manufacturing services to becoming technology leaders. At EuroAPI, we partner a wide range of organizations, from biotech to big pharma companies, to address their needs for innovative molecules such as peptides and oligonucleotides, now growing at +10% CAGR. With the boom in precision medicine, we act as an enabler for targeted therapies notably in the domains of rare diseases, the central nervous system, oncology, and immunology. For example, we signed a partnership with the French biotech SQY Therapeutics for an antisense oligonucleotide to treat a genetic disease. We are also seeing increased demand for highly sophisticated peptides, oligonucleotides and conjugates. Among the 14 new contracts signed during the first half-year, EuroAPI contracted a new peptide-PMO conjugate project, making nearly 80 CDMO projects in our portfolio.

In a second major trend, CDMOs are addressing a broader range of therapeutic areas for chronic diseases such as obesity, diabetes and cardiovascular conditions. Although until recently the peptide market was less attractive than the oligonucleotide market, the trend has changed since last year due to strong acceleration driven by GLP-1 agonist drugs. The market now needs much larger-scale capacities for both peptides and oligonucleotides, so we are investing €17 million in these products.

Small molecules still have a key role to play but they are growing increasingly complex and more active. As a result they require a larger number of synthesis steps, and more sophisticated control of API physical quality and particle size. So to further complement its internal assets, EuroAPI has partnered with Basel-based SpiroChem to ensure the continuity of API development, and has invested in state-of-the-art high-potency GMP facilities, especially to produce sophisticated payloads for booming antibody-drug conjugates.

Prioritizing Strategic Partnerships

Kenneth N. Drew, Vice President, Flamma USA, Flamma

"The pressing question for many in the pharmaceutical industry is how to manage supply chain dependence on China."

The pressing question for many in the pharmaceutical industry is how to manage supply chain dependence on China. The global nature of the pharma marketplace makes this a complex issue. While finding a new supplier might seem straightforward, the reality is challenging.

Selecting a CDMO that has facilities in Europe as well as China can be challenging but can provide a stable supply chain. Having facilities in Europe provides an internal backup to China thus giving the innovator company the peace of mind they desire.

Most, if not all, innovator companies are scrambling today to find alternative sources for their small molecules. Due to various issues in our world (war, inflation, sluggish biotech stock markets, high interest rates, political uncertainty in the USA), many companies were in a holding pattern until recently. Now the race is on to locate a CDMO that can provide manufacturing services. This is causing CDMOs to make difficult decisions as to whom to service creating a highly competitive environment where locating a reliable CDMO partner has become critical.

Core customers deserve priority, but CDMOs also aim to expand their customer base. Many CMC leaders had previously warned their executives to address these issues yet they delayed decisions and have now placed CMC and procurement teams in a difficult position. High-quality CDMOs are now overwhelmed with CDAs, RFIs, and RFPs from innovators who have waited to act and the competition for capacity is fierce.

Innovators should build relationships with CDMOs that have diverse geographic footprints. This approach mitigates risks with supply chain disruptions in China but also ensures a more resilient and flexible production network. The companies that wait for China to have even more issues than the BioSecure Act, will be on the outside looking in. Prioritizing strategic partnerships can help secure stable supply.

Increasing Complexity in Clinical Pipelines

Gordon Bates, President, Small Molecules Division, Lonza

"Managing shortened development timelines for drug molecules will continue to be a top priority for drug developers."

Small molecules still make up the majority of the pharmaceutical market, with small and emerging biopharma companies increasingly driving the growth and innovation of small molecule-based therapies. Increasing complexity is evident in clinical pipelines, which demands both deep scientific expertise and strong process development and manufacturing innovation to resolve technical challenges. Much of this needed expertise resides with CDMOs, who, over many years, have gained unparalleled experience through exposure to thousands of molecules and are now harnessing this heritage with digital innovations to support drug developers' quest to bring innovative new therapies to market ever quicker.

Managing shortened development timelines for drug molecules will continue to be a top priority for drug developers. We observed that API synthesis has been becoming increasingly complex and lengthy — often requiring more than 20 synthetic steps — and limiting developers' speed-to-clinic.

To address this trend, our expert teams developed and implemented an AI-driven solution for route scouting that delivers route designs and associated robustness assessment of raw material supply chains.

Following the launch of this new AI-based route scouting service, drug developers are now provided with insights for optimal route design, leading to accelerated speed-to-clinic with confidence in an efficient and scalable API manufacturing process and supply chain.

CDMO Market Is Poised for Growth

Christoph Schaffrath, Head of Marketing & Sales, Lanxess

"Many Western countries have spoken out in favor of restoring local and Western supply and value chains to become independent of China."

Supply chains from China were disrupted during and after the pandemic. Due to monopolies on various drugs in China, there were shortages of various drugs in Western regions. The recent downturn in trade through the Suez Canal has once again proven the vulnerability of globalized supply relationships. As a result, many Western countries have spoken out in favor of restoring local and Western supply and value chains to become independent of China.

In meeting this challenge, Saltigo, a subsidiary of Lanxess, can provide customers with efficient support. Saltigo is a globally operating company specializing in custom manufacturing for the fine chemicals, crop protection, and pharmaceutical industries. The production of pharmaceuticals and especially active pharmaceutical ingredients, so called APIs, can be very complex. In particular, the complex intermediates require various technologies, such as hydrogenation, fluorination, nitration, etc. Ideally, these complex value chains should be served from a single source.

Saltigo is one of the world´s leading custom manufacturers with a very extensive technology portfolio, decades of experience and a large production network and the ideal partner for the CDMO market. As a true one-stop shop, we offer a comprehensive suite of services, from process development and regulatory support to in-house logistics and global sourcing. In addition, our company has a strong focus on sustainability and offers product carbon footprint optimized 'net zero' processes as a significant added value. Safeguarding the security of supply for our customers is an essential part of Saltigo's DNA.

Overall, the CDMO market is poised for growth, driven by the need for more secure, sustainable, and technologically advanced pharmaceutical manufacturing solutions. Companies like Saltigo, with their extensive technology portfolio and focus on sustainability, are well-positioned to capitalize on these trends.

Going Beyond Providing Just Services

Prasad Raje, CEO, LGM Pharma

"CDMOs capable of supporting all activities of drug development are becoming more desirable with customers seeking expertise in each area."

CDMOs were significantly disrupted along with the broader pharmaceutical industry. They faced similar challenges related to supply chains, talent retention, and acquisition. The demand for Covid-related medicines increased tremendously, but CDMOs proved their agility and adaptability by successfully meeting this demand.

Well-managed CDMOs with robust infrastructure, strong problem-solving abilities and diversity of service segments have been able to bear the shock of disruption as well as the recent pull-back in biotech funding. A general trend is emerging where CDMOs are going beyond providing just services, especially among diverse service segments capable of supporting R&D through to clinical trial material (CTM) and commercial manufacturing. They are forming partnerships with customers that resemble pseudo-funding arrangements, and in return getting returns when products are commercialized. While this business model is not entirely new, its prevalence is increasing.

CDMOs capable of supporting all activities of drug development are becoming more desirable with customers seeking expertise in each area. In other words, growth will come from being "best in class" rather than merely offering services. The ability to quickly capitalize on emerging opportunities is crucial for organizations. One classic example from 2023/24 is around the rise of GLP/GIP.

Since last year, LGM Pharma has continued to invest in infrastructure and talent. As biotech funding returns to its 'normalcy' we will be poised to address our customers' drug development challenges in the most efficient way. Our fundamental principle for success has not changed: being best in class for all our service offerings. Also, we are continuing to partner with our customers in various different business models when we see that interests and expertise can be aligned.

The Value of External Expertise

Federico Pollano, Senior Vice President Business Development & Client Program Management, Rentschler

"Growth is significantly fueled by a robust pipeline of next-generation therapeutics developed by innovative companies that do not possess their own production capabilities."

The international CDMO sector is experiencing substantial growth, driven by rising demand across therapeutic areas such as oncology, autoimmune, neurological diseases, infections, and rare diseases. According to Frost & Sullivan, the BioCDMO market is projected to grow at a compound annual growth rate of 14.3% from 2023 to 2029. Specifically, protein and antibody therapeutics are expected to grow at over 8%, while advanced therapies, including cell and gene therapies, are anticipated to surge by approximately 33%.

This growth is significantly fueled by a robust pipeline of next-generation therapeutics developed by innovative companies that do not possess their own production capabilities. These companies represent 70% of the R&D pipeline and increasingly depend on CDMOs for manufacturing support. Additionally, Big Pharma is increasingly outsourcing late-stage product candidates and market products to CDMOs, recognizing the value of external expertise.

At Rentschler Biopharma, we support clients from Phase I development through to commercial production for the market. Our recent contribution to successful FDA approvals — contributing to four out of 17 biopharmaceuticals approved in 2023 — showcases our ability to deliver integrated services, including world-class consulting, regulatory support, process development, technology transfer, and cGMP manufacturing.

We are also deeply engaged in the field of advanced therapies, which demands specialized expertise and cutting-edge technology platforms. Our objective is to assist clients in navigating the complex regulatory landscape and securing essential funding, thereby facilitating the advancement of innovative therapies.

In summary, the expansion of therapeutic areas, the rise of advanced modalities, and the growing reliance on CDMOs by both innovative and established companies are key drivers of growth in the sector.

Innovators Are Looking Increasingly at Agility in Execution

Davuluri Saharsh Rao, Vice-Chairman and Managing Director, Neuland Labs

"CDMOs are strengthening their position as integral partners, creating strategic, and agile collaboration with innovators."

The pandemic has reshaped the CDMO market significantly. Innovators are looking increasingly at agility in execution even as supply chain security becomes an important factor. While there is a bias toward one-stop shops, there is also a recognition that companies with specialized focus areas can deliver superior results through effective integration, whether at the innovator's end or at one of the CDMOs. Developments during the pandemic have opened the possibilities of much faster and efficient clinical development aided also by the advances in machine learning. This has led to a supply constraint, especially in the more specialized modalities like peptides, oligonucleotides and ADCs. Overall, innovators are looking at specialists who can be agile while simultaneously investing in capacity for greater control. CDMOs are strengthening their position as integral partners, creating strategic, and agile collaboration with innovators.

While capacity is essential to drive growth, a CDMO's capability and track record in meeting client requirements is also crucial. At the same time, staying ahead of the curve by investing in new capabilities and offering options to innovators will ensure that a CDMO will grow.

Neuland Labs differentiates itself through enhanced collaboration and agility in execution. The primary catalyst of our success has been our steadfast commitment to high quality standards. We plan to invest in new areas, offering our clients the opportunity to engage with us on more projects and provide innovative solutions to their existing challenges. Specifically, we are expanding our capacity and deepening our expertise in Peptides, with a new manufacturing plant catering to peptides.

Driving Growth through Collaborative Innovation

Tom Wilson, Pfizer CentreOne Global Head of Business Development, Pfizer

"The most important growth drivers for CDMOs include innovation, quality, and strategic partnerships."

Pfizer CentreOne is a global CDMO, leveraging Pfizer's scientific and technical expertise. We offer contract development and manufacturing services for oral solids, sterile injectables, small molecules, biologics, and regulatory services. The most important growth drivers for CDMOs include innovation, quality, and strategic partnerships and at Pfizer CentreOne we leverage these drivers to grow market share in the CDMO industry

We prioritize quality and reliability from development to commercialization, understanding that for the patient, time is life. Supply chain reliability and management are significant challenges today. However, Pfizer's extensive upstream relationships with suppliers of raw materials, active ingredients, biological drug substances, and componentry provide a competitive edge. These pre-approved, audited, and evaluated relationships allow us to bypass lengthy approval processes and deliver timely solutions, showcasing Pfizer's robust quality systems.

Manufacturing at Pfizer focuses on cost, quality, and customer service. Our upstream relationships enhance quality and customer service, reducing costs. Pfizer CentreOne utilizes the same workspaces globally for both Pfizer products and CDMO services, ensuring consistency and high standards. This means client partners benefit from state-of-the-art facilities and rigorous maintenance.

Pfizer's commitment to innovation merges our scientific expertise with that of our client partners, fostering groundbreaking outcomes. By leveraging Pfizer's scientific capabilities on behalf of other companies, Pfizer CentreOne differentiates itself in the CDMO industry and drives growth through collaborative innovation. This strategic integration of quality systems, innovative science, and efficient supply chain management positions Pfizer CentreOne as a leader in the CDMO market, delivering exceptional value to its clients.

Redefined Expectations on Drug Development Timelines

Rohtash Kumar, Senior Vice President, Chief Technology Officer, Veranova

"With an increasing focus on fast-to-clinic strategies, CDMOs require expertise and technologies to meet speed, flexibility, and safety demands."

Rapid development and scale-up of Covid-19 vaccines redefined the industry's expectations on drug development timelines. With an increasing focus on fast-to-clinic strategies, CDMOs require expertise and technologies to meet speed, flexibility, and safety demands. These strategies must accelerate development without negatively impacting safety, efficacy, and regulatory compliance.

Global supply chain vulnerabilities, particularly in the reliance on offshore manufacturing for essential supplies, were also exposed. In response, the industry has enhanced supply chain security, prioritized onshore manufacturing, and valued robust tech transfer, driving more pharmaceutical companies to partner with local, experienced CDMOs for a competitive edge.

Increasing demand for complex APIs highlighted the need to adapt to evolving trends. Leveraging artificial intelligence (AI) tools allows CDMOs to enhance drug development and manufacturing, yielding positive outcomes from enhanced supply chain logistics. Growing emphasis on patient-centricity in drug discovery and development has given rise to targeted therapeutics that deliver stronger efficacy at lower doses, spurring innovations in novel modalities, including drug-conjugate linkers and new delivery routes.

At Veranova, our core values — people, patients, and innovation — guide our market approach. People are our greatest asset, so we've focused on building a talented and diverse workforce by strengthening our senior leadership team and appointing a new advisory board.

Our commitment to patients has driven investments in capabilities to handle emerging therapies. The demand for more efficacious, patient-centered treatments has led Veranova to expand our capabilities in complex and highly potent APIs, and drug-conjugate linkers. This includes a mid-scale API expansion at our Edinburgh, UK facility, and a $30 million investment in our Devens, MA site. Innovation is central to our growth.

Veranova continuously strives to improve, exemplified by our collaboration with Phorum.AI, which is focused on enhancing our pharmaceutical manufacturing processes with AI to accelerate time to market for our clients. These strategic moves strengthen our position in the CDMO industry and help our partners deliver life-changing therapeutics to patients.

From Transactional to Collaborative Partnerships

Thomas Otto and Peter Soelkner, Managing Directors, Vetter

T. Otto: Since the pandemic, partnerships between biopharma companies and CDMOs transformed from transactional to collaborative. Fill and finish partners are heavily integrated into the drug development process from preclinical through to commercialization and long-term market supply. This has prompted a rising demand for CDMO services resulting in projected growth of the global market from $222.5 billion in 2023 to $249.96 billion in 2024, according to recent reports. The pandemic shone a light on the need for continuing production capabilities that don't inhibit quality, making the need for external support crucial for drug owners. Now, we're witnessing a rise in both small batch and blockbuster drug development as companies explore solutions for rare diseases while producing the most heavily relied-upon drugs. This is just one more area where CDMO expertise is valued for its unique infrastructure, specialized focus, and enhanced capacities.

P. Soelkner: In formulating our strategy for growing market share, we rely on lessons learned throughout our history as an independent, family-owned solution provider. The strategy comes down to several elements which we prioritize to meet our customers' needs. First, we invest proactively in the infrastructure, capacity, and technology needed to support new therapies and consequently customer demands which continue to arise. Simultaneously, we remain committed to the tried-and-true medications that will go on to serve a purpose in the market, and rather than replacing, we expand to leave room for what works and what's new. We place an equal focus on investing in our talented workforce who make it possible to provide the expertise our customers rely on. We are now represented by 6,600 global employees, over 1,000 of which are dedicated to quality tasks. Lastly, we prioritize a responsible role in the value chain. As a trusted globally-operating outsource partner, our actions reflect upon our customers. Therefore, we prioritize sustainable business practices that allow drug owners to feel confident in us as a critical extension of their teams.

A Need for Greater Variation of Manufacturing Assets

Chad Telgenhof, Chief Commercial Officer, Sterling Pharma Solutions

"Increasingly stringent regulatory requirements are making it more challenging for innovators to meet compliance standards on their own."

The current market growth for CDMOs is fueled by the continued focus of pharmaceutical companies on their core competencies of R&D and marketing, leading to the outsourcing of process development and manufacturing.

However, the role of CDMOs and the demands being put upon them are evolving. As pipelines and drugs in development change, with the rising demands for biologics and other new modalities — as well as niche and orphan drugs — customers are requiring specialized, diverse, flexible and scalable capabilities.

For small molecule APIs, lower volume demands are coming with increased molecular complexity, a greater number of processing steps and the likelihood of challenging, and often hazardous, chemical transformations. This means there is a need for greater variation of manufacturing assets to handle the necessary reagents and reaction conditions, as well as a broad range of vessel capacity to efficiently process potential swings in volumetric needs.

Another key factor is the expansion of pharma companies into emerging markets, and the need for local manufacturing capabilities. CDMOs offer cost-effective solutions through their economy of scale and flexibility for these situations, and larger CDMOs with wider manufacturing networks can assist in the security of supply chains by providing secondary sources of materials under the same quality framework, as well as back filling synthetic steps in processes.

Increasingly stringent regulatory requirements are making it more challenging for innovators to meet compliance standards on their own. As global regulations around drug development, manufacturing, and quality control become more complex and rigorous, companies are turning to CDMOs for their expertise in navigating these regulations efficiently. CDMOs have access to advanced technologies, supported by robust quality systems, and a deep understanding of global regulatory requirements, enabling them to deliver compliant solutions that meet the highest standards.

India's CDMO Market Is Growing Significantly

Alex Del Priore, Senior Vice President, Manufacturing Services, Syngene

"Today, the quality of science is perhaps the biggest differentiator for an outsourcing partner."

The Covid-19 pandemic has reshaped the CDMO market, notably altering outsourcing trends and global supply chains. Geopolitical shifts have prompted pharmaceutical companies to diversify their supply chains, reducing reliance on single-country sourcing, particularly from China. This shift benefits CDMOs like Syngene, as companies seek high-quality research and manufacturing solutions that India offers that are also cost-effective. As the world's second-largest holder of USFDA-approved facilities, India provides a skilled workforce and advanced technological capabilities. Today, the quality of science is perhaps the biggest differentiator for an outsourcing partner. In this respect, Syngene's sharp focus on innovation as well as our ability to provide science and scientific teams at scale really sets us apart.

The CDMO market in India is experiencing significant growth primarily driven by three factors: continued investment in biotechnology increasing the capacity, skills and experience available to outsourcers; the need to increase the resilience of supply chains through diversification; and geopolitical factors which are driving companies to seek new providers, particularly shifting away from China. As biotech funding rises, especially in the US, there is a surge in outsourcing activities, creating opportunities for CDMOs. Companies are looking beyond China for suppliers, opening growth avenues for CDMOs in regions like India. We are seeing companies setting up pilot projects across a broad range of services and often placing them with a select short list of suppliers. Their plan is to run these comparative pilots through the year and use this as a way of selecting future partners. Syngene's ability to deliver end-to-end solutions, its investment in cutting-edge technologies and its strong track record in quality assurance has positioned us well to capture the opportunities that are currently emerging.

We have also invested in expanding our capacity and infrastructure. Syngene sees biologics as a key driver of its future growth and has all the building blocks in place to become a major player in the biologics space.

The Future of the CDMO Industry Is Exciting

Greg Behar, CEO, Recipharm

"Demographic shifts, such as the aging global population and the growth of emerging markets, are expanding our customers' markets."

At Recipharm, we are witnessing significant growth in key areas, particularly in the demand for complex pharmaceutical products, such as advanced therapy medicinal products (ATMPs) in our ReciBioPharm business unit. This growth trajectory is closely tied to broader economic factors like interest rate trends, which impact funding availability. Additionally, there is a notable rise in demand for injectable sterile biopharmaceuticals, such as GLP-1 products and the development of highly potent drugs, highlighting the crucial role Recipharm plays in meeting these needs.

As more customers outsource production stages, we must strategically expand our capacity to deliver the required products efficiently and cost-effectively, and form genuine partnerships with our customers. From early-stage development, where we provide analytical support, to tech transfer and full-scale manufacturing, Recipharm is committed to being a reliable partner throughout the product lifecycle.

The geopolitical climate underscores the importance of supply chain security, a lesson emphasized during the Covid-19 pandemic. Prioritizing the robustness of our supply chains ensures that we continue to deliver the critical products our customers and patients rely on.

Demographic shifts, such as the aging global population and the growth of emerging markets, are expanding our customers' markets. To respond effectively, we must operate with efficiency and flexibility, anticipating the evolving needs of these markets.

Innovation remains central to our strategy. We are dedicated to leveraging cutting-edge technologies, such as artificial intelligence, to accelerate tech transfers, streamline production and enhance regulatory support.

The future of the CDMO industry is exciting. With strong customer relationships, a focus on innovation and a diverse portfolio, Recipharm is poised to fully leverage these growth opportunities and achieve success in the years ahead.

Speed Is Now a Crucial Factor in Judging CDMOs

Jordi Robinson, Chief Commercial Officer, Navin Molecular

"The reliance on a smaller supplier base leads to a partnership relationship model, rather than the more 'transactional' approaches of the past."

Since the accelerated development of vaccines in response to the Covid-19 pandemic, many pharma companies have been reviewing how development timelines for new drugs can be shortened. This has led to pressure being put on suppliers to provide extremely competitive lead times for projects, and especially for early-phase programs, where speed has always been critical. Speed is now a crucial factor in judging CDMOs, and has been used as a metric in customers' rationales for reducing the number of suppliers they work with.

The reasons for this are twofold: firstly, if a company is selecting a supplier principally on the basis of the timeline they offer, this can only happen if the two other key factors of cost and provision of a technically-sound proposal are closely matched across all suppliers; and secondly, if the customer is only working with a smaller number of suppliers, it follows that they need to be able to offer a wider range of services and technologies to fulfil the wide range of customer's needs.

Although this may appear that the customers are getting everything they want, there are also benefits for the CDMO in this scenario. The reliance on a smaller supplier base leads to a partnership relationship model, rather than the more 'transactional' approaches of the past. Despite the increased pressure for competitiveness, the likelihood of a long-term, and mutually beneficial relationship will result is increased, as each party is dependent on the continued performance and success of the other for the relationship to prosper. This leads to the potential of continued work for the CDMO, whether it be through access to new projects coming through the pipeline, or the continued supply as molecules progress through the development cycle. The result is that even if it appears that the supplier is working under ever-increasing pressure, those that are more agile and flexible can have longer-term benefits from this approach.