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Value Creation in the CDMO Market

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The Authors

Jansen Jacob
Vice President

Asif Shahinsha
Senior Director

Akanksha Manglani
Associate

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Contract Development & Manufacturing Organisations (CDMOs) increasingly need to differentiate and establish their competitive advantage to effectively cater to the growing demand and to enhance their profitability. There is a greater demand for CDMOs offering broad-based best practice technologies, staff competencies and reliable delivery.

PharmaVentures is recognised as a leading transactions advisor and has advised on the strategic direction of over 40 facilities offering CRO/CDMO services and completed the sale of 14 operations globally.

In this white paper, we harness the knowledge from our extensive cross border transaction experience and industry research to look at the value drivers in the CDMO market that companies should keep in mind when they cultivate their strategies.

The demand for high-volume and high-quality drug product manufacturing services has risen dramatically in the past few years. CDMOs have adopted innovative technologies in areas like vaccine production, monoclonal antibody manufacturing, diagnostic testing and distribution logistics. To further enhance their competitive advantage, CDMOs need to expand their key capabilities and portfolios across production technology and along the value chain to deliver high-quality solutions at attractive prices to customers. This expansion across broader product offerings and skill levels allows the CDMO to better understand the client and become more integrated with a closer and more trusted relationship.

One of the trends seen in the CDMO sector over the years is increasing consolidation in this highly fragmented market.

Behind this trend are the larger CDMO's, with revenues above $250 million, while most targets are small companies with revenues below $50 million. Despite the proclivity of traditional, often family-owned businesses to resist being acquired and the increasing cost of borrowing for buyouts, consolidation in the CDMO market is likely to continue, especially with the growing involvement of private equity firms.

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Where does value lie within the CDMO Market?

The Pharmaceutical CDMO Market was valued at USD 184 Billion in 2021. It is expected to reach USD 290 Billion by 2027, registering a CAGR of 7.29% during the forecast period.

CDMO Market by Service

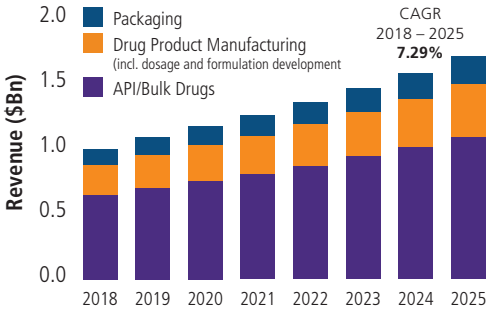

Figure 1

The traditional active pharmaceutical ingredient (API) segment dominated the market and accounted for the largest revenue share of ~65% in 2021. The growth is primarily driven by rising demand for targeted cancer and other treatments. Manufacturing and technology advancements, as well as manufacturer investments, are also contributing to the growth. While traditional small molecule API manufacturing is a low margin business that relies on higher volumes for profitability, the increasing development of high potency APIs, Biologics, Cell and Gene therapies etc., are manufactured at lower volumes. As seen in Figure 1, the trend concentrating on API manufacture is expected to continue to dominate the CDMO services market.

The API/bulk drug market has a healthy growth trajectory but what CDMO companies need to be mindful of is that investors tend to pay a premium for full-service CDMOs (development services, API and drug product) and bestow higher valuations as compared with pureplay API or drug product CDMOs.

The Pharma Services Value Chain

The breadth and depth of a CDMO's expertise and competence across the different technology types will enable it to cater to the needs of the different customers (*Figure 2*). Customers are increasingly prepared to pay a premium for high quality, consistently reliable CDMO services. These consumers, especially Big Pharma, are actively trying to interact with fewer suppliers for seamless integration and assimilation of multiple processes across the value chain. This incentivises CDMOs to provide one-stop-shop solutions allowing their clients to run coherent and smooth operations.

Pharma Services Value Chain

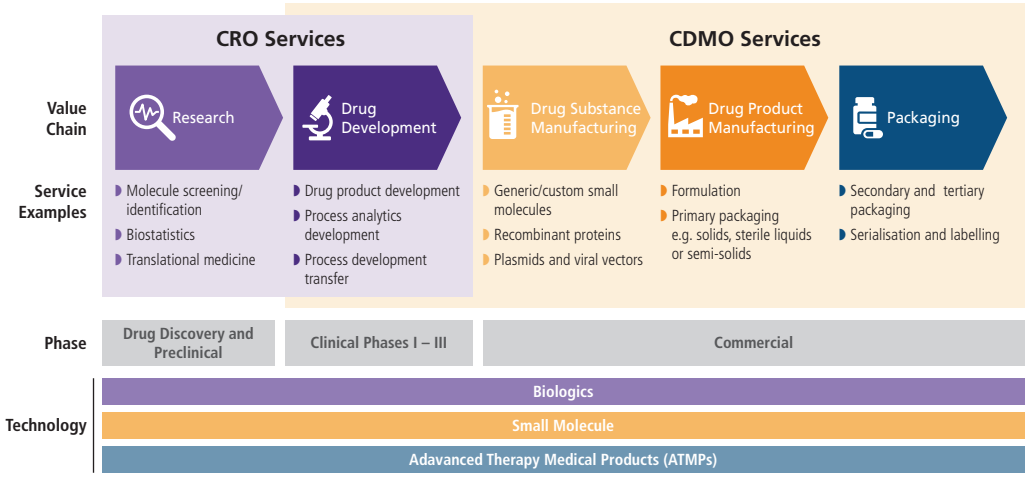

Figure 2

Source: PV Insights, Strategy& Analysis

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Small Molecule Drugs

High-potency active pharmaceutical ingredients (HPAPIs) require specific infrastructure and capabilities, including containment procedures for both the product and the operator, engineering controls during development and manufacturing at both clinical and commercial scale. There is a global shortage of such capability. CDMOs that invest in containment procedures and capabilities to handle these types of compounds using best practice would be better positioned to support the industry and benefit from significant barriers to competitor entry. Securing these measures requires a significant capital investment and several years to get a compliant facility up and running.

Biologics

In specialised fields like biologics and bioreactor development, CDMOs provide unique expertise that enable 'Big Pharma' and smaller innovators alike to bring products to market more quickly. The global biologics market is approaching a third of the entire pharma services market. Contributing to this trend is not only the continued development of blockbuster biologics (antibody, immunosuppressants, anticancer etc.), but the rise in the number of biosimilars being approved as patents continue to expire. Inorganic growth through acquisitions will contribute to CDMOs diversifying into different types of products quickly and efficiently to add to their existing capabilities.

Advanced Therapy Medical Products (ATMPs)

Acquisitions in cutting-edge therapeutic modalities, especially Cell and Gene Therapies (CGT) as well as mRNA, is a trend that is also expected to continue. The current addressable CGT market in the CDMO sector is estimated to be $2.5 Billion and expected to grow by at least 25% CAGR over next 5 years. Growth is being driven by the robust biotech funding environment and scientific innovation, fuelling rapid rise in the CGT pipeline. CDMO's are investing heavily in this sector as evidenced by CRL's acquisitions of Cognate and Vigene (2021), TMO for Brammer (2019), and CTLT for Paragon (2019) to further boost business prospects. ATMPs are expected to drive the use of more personalised medicines for which traditional bulk manufacturing methods are not relevant. One can expect to see more near-to-the-patient operations to address this small-scale personalised drug development and manufacturing requirement. This demand is likely to result in an increase in local or regional ATMP operations. CDMOs are well positioned to take the lead in the development of technology necessary to cater to this demand for personalised medicine.

While solid dosage forms have long been the largest finished dosage form segment, sterile liquids are currently enjoying the strongest growth, taking up an increasingly large share of the pharmaceutical development and manufacturing outsourcing market. The high growth in the sterile liquids segment is due to the increasing importance of biologics. Given the overall outsourcing trend in the pharmaceutical industry, outsourcing of development and manufacturing activities for solids, semisolids and non-sterile liquids will continue to increase as well, but at a slower pace than sterile liquids.

Strategy and Value Creation for CDMOs

The growing Pharma Services market presents CDMOs with several strategic choices to create and sustain value in a competitive operating environment.

One-Stop Solution v/s Specialised Services

CDMO management teams need to choose between being a 'one-stop shop' for development and manufacturing, and specialising in specific stages in the development process, or in certain categories of market segments (e.g., dosage forms). In a competitive market, carving out niches and specialist positions can pay dividends. For example, companies may opt to build capability in specific dosage forms that may be lower-risk, or to invest in high-demand technologies like sterile manufacturing where shortages are felt keenly through supply chains. For companies involved in drug development, the decision to concentrate on small molecules or biologics presents another important strategic choice.

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Cost Based Pricing v/s Value Based Pricing

Optimising sales and pricing effectiveness is another essential step for organisations planning organic growth. Scoping whether cost-plus pricing or value-based pricing makes sense can enhance each deal's revenue potential while preserving strong relationships with customers. This calls for new and innovative monetisation strategies, with the right approach to project pricing as a vital element. Price is the single most powerful lever to increase a company's profits. However, right now, CDMO's can choose traditional cost-plus pricing logics that are set based on pre-determined self-fuelling margin targets or replace it with harmonised costing methodologies, value-based pricing metrics, and systematic usage of internal project price benchmarks. These areas will enable CDMOs to develop a value-based price model that fully exploits price potential and monetises willingness to pay more for key factors such as reliable supply and higher quality.

Organic v/s Inorganic Growth

The preferred option between organic or inorganic growth for a CDMO is strongly linked to funds at their disposal and, strategically, where these companies choose to allocate these funds.

While looking for acquisitions/inorganic growth, CDMOs can either target facilities with similar capabilities to expand capacity or invest in focused customer mapping exercises to capture a larger market share of their current business or acquire existing firms with differentiated capabilities to add to their growing offering of services under the umbrella of the same firm.

It has been observed that there is a significant correlation between the size of the CDMO and profitability- i.e., larger CDMOs tend to have higher profitability. CDMOs looking for increased profitability should bear this in mind and consider increasing the size and breadth of their services to capture more customers.

Deal Trends in CDMOs

There has been strong investor interest in life sciences generally and in the pharmaceutical manufacturing industry in particular. The last five years has seen the CDMO sector blossom in terms of value and the significance of merger and acquisition (M&A) transactions.

In the Table 1 below, we have analysed M&A deals in the past two years to see the strategic rationale of companies that invested in the CDMO sector.

Why do PE Funds continue to be interested in the Pharma Services Industry?

The large global buyout funds and mid-market regional buyout funds continue to actively seek quality pharma services platforms. While large buyout funds have been active in the space for a while (e.g., Recipharm, Cambrex deals), there is increased interest from mid-market and lower mid-market private equity funds to invest in the sector. Western and Northern Europe markets provide several interesting opportunities where the current owners have either succession issues or struggle to scale capacity.

A well-established UK based PE fund stated as recently as Sep 2022 that they often encounter outsourced service providers growing sustainably at 20% or more p.a. with high profit margins and high pricing power commensurate with their know-how.

The main driver for this continued interest is that the growth in the CDMO sector outpaces the wider pharmaceuticals market, as the large-cap pharmaceutical and biotech companies increasingly outsource to control capital expenditures and reduce fixed costs.

Further, PE funds have been seeking to diversify beyond traditional provider services businesses, leading to a step up in valuation multiples to new highs across the sector.

Outside of large-scale commercial small molecule manufacturing, the market is extremely fragmented.

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M&A Transactions in the CDMO Sector

Date	Target	Buyer	Deal Rationale
Sep-2022	Korea Biopharmacueticals	Dx&Vx	Securing a GMP production base for their biohealth care business
Sep-2022	AcuraBio (Luina Bio)	Ampersand Capital Partners	Expansion for growth Increase production facility and new service offering
Aug-2022	TECHLAB	SSI Diagnostica	Consolidation in the US Market
Aug-2022	Tapemark	LTS Lohmann Therapie-Systeme	Expansion of operation Acquisition of a production base
Aug-2022	mAbxience	Fresenius	Expansion and growth in biopharma Broadening biosimilars portfolio Access to the distinctive development and manufacturing capabilities
Jul-2022	Drug Development Solutions	Alliance Pharma	Expansion of bioanalytical, analytical material testing and laboratory capabilities in cell and gene therapy, next-generation biologics, material sciences and protein characterisation
May-2022	Bionova Scientific	Asahi Kasei Medical	Expansion of business to add further value and higher customer satisfaction
Apr-2022	Biomed Diagnostics	DCN Dx	Expansion of footprint into the point of use testing and sampling markets in both human and veterinary verticals
Apr-2022	Arranta Bio	Recipharm	Expansion of biologics offering in the US
Apr-2022	Health Wright Products	International Flavors & Fragrances	Expansion of natural extracts and botanical business
Apr-2022	Nagase Medicals	Shionogi & Co	Entry into contract manufacturing
Mar-2022	Pillar5 Pharma	Anjac	Expansion of geographic footprint Product portfolio diversification
Feb-2022	Vibalogics	Recipharm	Further expansion of service offering into novel and advanced biological modalities
Feb-2022	TAAV Biomanufacturing Solutions	Asklepios BioPharmaceutical	Acquisition of an additional manufacturing site
Feb-2022	GenIbet Biopharmaceuticals	Recipharm	Growth in the Biologics market, with a particular focus on drug substance manufacturing of novel ATMPs
Jan-2022	Samsung Bioepis	Samsung Biologics	Strengthens biosimilar development capabilities and future performance in new drug development
Jan-2022	The Center for Breakthrough Medicines	SK	To create world's largest end-to-end cell and gene therapy contract development and manufacturing organization

Table 1

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PE Investments				
Companies	**Lead/Sole Investors**	**Investment Date**	**HQ Global Sub Region**	**Deal Type**
LumaBridge	Summit Partners	Aug-22	North America	PE Growth/ Expansion
Alliance Pharma	Kohlberg Kravis Roberts	Jul-22	North America	Buyout/ LBO
Kemp Proteins	BroadOak Capital Partners	Jun-22	North America	PE Growth/ Expansion
Veranova	Altaris Capital Partners	May-22	North America	Buyout/ LBO
LINK Medical Research	Serendipity Partners	Apr-22	Northern Europe	PE Growth/ Expansion
Upperton Pharma Solutions	Inflexion Private Equity Partners	Apr-22	Western Europe	PE Growth/ Expansion
Alcami	Ares Management	Jan-22	North America	PE Growth/ Expansion
Navitas Life Sciences	H.I.G. Capital	Dec-21	North America	Buyout/ LBO

Table 2

There are very few players of scale, providing private equity with the opportunity to build platforms.

Naturally, the funds that understand pharmaceutical services have been early movers, followed by funds that have expertise in contract manufacturing, either from an adjacent sector, such as medical devices, or even from outside of healthcare, such as industrial manufacturing. Armed with dry powder in the newly raised funds, PE groups find that these companies within the CDMO sector (or Pharma Services in general) often have years-long optionality to scale capacity, offer new services, and enter new geographies; to garner share of client's needs (*Table 2*).

Challenges in the CDMO Sector

The challenges for leadership teams at CDMOs tend to revolve around human capital planning, technology and systems scaling.

Rising Costs

The rise of energy costs is the most pronounced challenge which, depending on the country and the hedging policy in place, can range from 100% to 500%. That means personnel cost reductions, curtailing of all discretionary spend including maintenance, and a pruning of CAPEX are the potential consequences. While all of it helps in the short term, it jeopardises smooth routine production, and the ability to support the growth projects of customers. Prices need to be adjusted rapidly and more frequently in order to ascertain the financial viability of Pharma Service companies. This momentum of rising input cost is still accelerating, with labour negotiations for 2023 in many countries still outstanding. In the short term, everyone in the supply chain will have to pass on the rising prices, ultimately to the end consumer.

Supply Chain

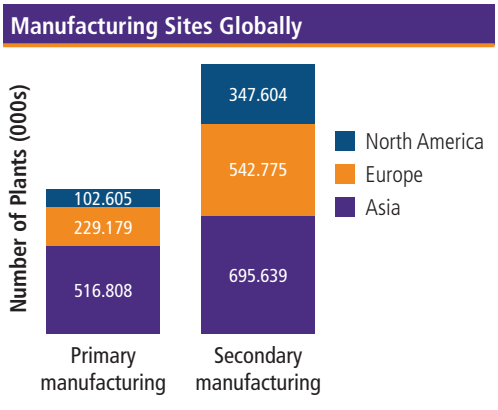

Figure 3

Reliability of supply from both internal and external sites is critical to the business' performance. Loose one critical raw material supplier and the whole supply chain can find itself in turmoil. In cases like this, CDMOs that understand the capabilities of their partners

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from the root of supply will prevail. Asia has 45% more primary manufacturing facilities (API, ingredients, excipients etc.) than Europe and North America combined. The reverse is true with secondary manufacturing facilities - Asia has 28% fewer Finished Dosage Form (FDF) facilities than in Europe and North America combined. If policy makers in Europe are serious about becoming less dependent on drug supply from out of Asia and want to stimulate local/regional production, they will need to create the right economic framework to allow European CDMO´s to make the needed investments for more local and modern operations. Asian firms are already trying to mitigate such plans of the West by actively looking to set up operations in the US and Europe.

Shortage of Skilled Talent

While biotech has always been a highly specialised and complex industry, more recent innovations in technology, methodologies and other enabling techniques, such as gene editing, pharmacogenetics and immunotherapy, have made the industry even more complex with not enough talent in these nascent areas to satisfy demand. This means that attracting top biopharma talent is challenging, due to fierce competition and limited candidate pools, particularly when hiring specialist skill sets.

Opportunities in the CDMO Sector

Emerging Biopharma

Emerging Biopharmas have a sole focus on developing their drug pipelines without having experience in manufacturing. A large number of small and emerging biopharma companies are involved in the development of over 4,500 products in R&D. That equates to 72% of global drugs under development, 65% of them without partnerships with big pharma companies. These companies have funded over 3,300 clinical trials that started in 2021, i.e., nearly double the number from 2016. They are responsible for 56% of new active substances (NAS) launched in the world. The number of products filed with the FDA by evidence-based products has quadrupled over the past decade, now representing 42% of all products filed with the FDA, compared to 11% in 2012. Charles River has made this an area of focus, having supported the development of >80% of drugs approved by the FDA over the last three years. These companies require an early integration of their operations with partnering companies in the drug development and manufacturing process.

Differentiated Technology

Promising CGT pipelines have lured investors looking to participate through derivative plays in suppliers, research tools, and support services. Derivative plays shield investors from direct pipeline risk while exposing them to much of the upside in this rapidly growing field.

Unmet Demand

Our recent research indicates that the capacity constraints across the biopharma services are complex, especially in early-stage discovery, preclinical biologics and CGT manufacturing. Customers of CDMOs are reporting increasing lead times for study and capacity bookings, which aligns with the growth and increasing durations of public company backlogs. This creates opportunity for small players to piggyback into demand unmet by established players.

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Conclusion

To create greater value, CDMOs need to customise their service offering with a breadth and depth of capabilities that offer tangible benefits to their customers. While the industry faces several challenges, such as rising costs, supply chain and shortage of skilled talent, there are immense opportunities for small scale CDMOs to tap into the emerging biopharma pipeline and invest in differentiated technology to achieve higher valuations. In terms of technology type, Biologics and CGT are "hot topics" and will continue to be key targets for acquirers. This, consequently, will command higher valuations for such assets.

Our team at PharmaVentures can help steer CDMOs and optimise their strategy for both organic as well as inorganic growth. We have completed over 1,000 assignments for global pharma, biotech, MedTech and healthcare companies as well as for financial institutions such as private equity firms and international banks.

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For more details, visit https://www.pharmaventures.com

PharmaVentures Ltd
One Kingdom Street, London W2 6BD
United Kingdom

+44 (0) 1865 332700
Email: enquiries@pharmaventures.com
www.pharmaventures.com