



WHAT'S NEXT FOR CDMOs AFTER COVID-19?

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AS COVID-19 VACCINES AND therapeutics are rolled out worldwide, demand for the services of contract development and manufacturing organizations (CDMOs) is skyrocketing. CDMOs have gone to great lengths to meet the needs of their biopharmaceutical customers during the crisis. But a larger challenge remains unresolved: how to ensure that growth continues after the pandemic has ended.

CDMOs need to capitalize on their increased relevance to make their relationships with pharma companies more strategic. This requires gaining a deep understanding of the supply chain and manufacturing risks that pharma companies face, developing the differentiating capabilities that will fill these gaps, and changing the partnership model. Such an approach will allow CDMOs to capitalize on the current situation and unlock new opportunities for strategic collaboration, making themselves an even more integral part of pharmaceutical supply chains for the long run.

COVID-19's Impact on the CDMO Industry

CDMOs provide a wide array of services to pharma companies: drug development and clinical supply, commercial active pharmaceutical ingredient (API) and drug manufacturing, and packaging. These services allow pharma companies to reduce their development and manufacturing costs, timelines, and capital investments while benefitting from the most-advanced technologies.

PRE-PANDEMIC RELATIONSHIPS

Before the pandemic, most pharma-CDMO relationships remained largely transactional. When pharma companies needed more capacity or access to a new technology they didn't want to build in-house, they'd source manufacturing services from CDMOs on a project-by-project basis, most often using a fee-for-service or project-based contracting model. In the case of large pharma companies, the relationship was asymmetrical: pharma companies have more size and financial muscle and capture most of the value of the product,

whereas CDMOs only earn a margin on cost of goods sold—typically a small fraction of the price of the product.

For years, CDMOs have tried to deepen those relationships by building more-robust development, manufacturing, and relationship or account management capabilities. But those efforts have historically had little success, with around 80% of declared strategic partnerships faltering after a few years. As a result, while true strategic partnerships are pervasive in industries like consumer electronics, they remain very rare in pharmaceutical development and manufacturing.

REVERSAL OF FORTUNE

Overnight, the pandemic upended the balance of power. As the number of COVID-19 cases soared, so did the need for new COVID-19 vaccines and therapeutics, as illustrated by the efforts of governments and NGOs to fund development and production. Some governments even began considering localization regulations to ensure that sufficient quantities of vaccines and therapeutics would be produced domestically.

Pharmas suddenly were faced with the challenge of producing the many millions of doses that would likely be needed. To expand their manufacturing capacity, some pharmas formed collaborations with like companies and other institutions, as with the collaboration between Pfizer and BioNTech or between AstraZeneca and Oxford University. Others transferred non-COVID-19 biologics out of their proprietary manufacturing networks to make room for the new vaccines. A few companies began rethinking their manufacturing footprint to plan for the years ahead.

The largest source of additional capacity, though, was CDMOs. Pharma companies reserved—and sometimes even double-booked—significant amounts of factory space with contract manufacturers. Pfizer, Moderna, and AstraZeneca have publicly announced their large partnerships with a number of CDMOs, including Emergent Biosolutions, Catalent, and Lonza, among

others. Making the most of the opportunity, Catalent, Samsung Biologics, Cambrex, and several developing-country CDMOs have announced significant expansions to their plants.

These moves made one thing very clear: the pandemic has enhanced the position of the CDMO. But there is no guarantee that the shift will last for long. Some CDMOs are wondering if their growth prospects will fade when COVID-19 is over. If demand for manufacturing services subsides after global immunizations are completed, there could be a glut of capacity, which would raise costs and erode margins for years to come.

Pivoting to More-Valuable Partnerships

Now is the time for CDMOs to lay the foundation for more-strategic partnerships. In the short term, companies should expand their customer targets to pharmas looking to bolster the resilience of their supply chains as governments worldwide enact localization requirements. Government incentives to go local could change the economics of building new sites in locations that were previously considered too expensive. National health bodies are another potential source of customers.

To fully leverage the opportunity and increase their competitiveness in the long term, CDMOs need to pivot to a more strategic role that will make them even more integral to the pharma supply chain. (See the exhibit.)

Four steps are critical:

ASSESS POTENTIAL POST-COVID-19 RISKS TO PHARMA SUPPLY CHAINS

To proactively engage pharmas with a unique value proposition, CDMOs need to acquire a deep understanding of both their own capabilities and their clients' vulnerabilities. This means assessing pharma capacity and capability needs in light of unpredictable supply chain disruptions, geopolitical considerations, and the competitive landscape. CDMOs should:

CDMOs that Shift to Strategic Relationships Can Enhance Prospects for Growth

	Transactional		Strategic
 Network planning	Reactive growth via RFPs	➤	Long-term collaborative network planning with pharma clients
 Business models	Fee-for-service contract models	➤	Breadth of business models, contract types, dynamic pricing algorithms, and more
 S&OP visibility	Static monthly report	➤	Real-time digital transparency
 Quality integration	Execution per quality agreement	➤	Dynamic view of batch characteristics
 Enhanced tech transfer	Slow, manual transfer process through legacy tech operations	➤	Digitalized toolkit that accelerates tech transfer processes

Source: BCG analysis.

- **Build a strategic baseline and benchmark it against competitors.** If CDMOs haven't done so already, they should develop a detailed analysis of their own network footprint and the manufacturing technologies present at each site. They should then compare that baseline with those of competitors to identify areas of strategic advantage. For example, some CDMOs are globally recognized for their sterile fill-and-finish capabilities, while others are known for biologics drug substance manufacturing.
- **Get more intentional about network planning.** CDMOs also need to adopt a more forward-looking view regarding capacity planning. Using scenario assessments, companies can identify any potential gaps in their manufacturing network that need to be filled. They will then be uniquely positioned to avoid a capacity glut when the need for vaccines subsides.
- **Match capabilities to pharma needs.** Every CDMO needs to proactively identify the products and regions where pharmas may have excessive exposure to risk and where the CDMO itself has a strategic advantage. Those are the sweet spots to focus on.

DIGITALIZE SUPPLY CHAIN CAPABILITIES

To play a more strategic role with pharma clients, CDMOs should also focus on strengthening digital capabilities across their operations by engaging in:

- **End-to-end (E2E) supply chain visibility.** The heightened potential for localization regulations and other types of disruptions has further highlighted the value of supply chain transparency. Control tower solutions provide CDMOs with real-time visibility into the risks of tier 2 and 3 suppliers, including the status of critical materials, material inventory policies, and financial stability. At the same time, these solutions provide pharma companies with dynamic, real-time visibility into CDMO operations.
- **Long-term collaborative network planning.** CDMOs should build out the digital capabilities that enable them to do joint planning with their pharma clients. Such planning services could be an offering that CDMOs provide in the most strategic partnerships.
- **Dynamic pricing.** Predictive algorithms allow CDMOs to price products dynami-

cally based on current demand and supply. CDMOs can thus smooth out capacity utilization while capturing additional value when customers feel pressure to secure supply. And pharma can make real-time adjustments to price fluctuations to take advantage of cost savings that arise.

- **Dual sourcing.** Using integrated scenario planning, CDMOs can simulate single and dual sourcing strategies—just as their customers would—to illustrate the costs and benefits of different strategies. This would enable CDMOs to better influence the sourcing approach of their customers.

BUILD OUT CAPABILITIES TO COMPLEMENT MANUFACTURING

CDMOs should also expand production capabilities that complement those of their pharma clients through:

- **Technology transfer.** If a pharma needs to qualify a second source of supply, the ability to conduct tech transfers faster than competitors is an important source of differentiation. CDMOs that leverage data from the pharma's manufacturing process can learn how to replicate that process more rapidly.
- **Regulatory expertise.** CDMOs with best-in-class regulatory teams can help a pharma client accelerate approval for any new production process that the company transfers to them. This would reduce the burden on the pharma and accelerate time to market for the backup supply.
- **Quality compliance.** To meet the rising tide of regulatory expectations, CDMOs should invest in being at the forefront of quality compliance, especially in highly complex areas like fill and finish. Quality-focused culture, systems, and capabilities will all be key. Where appropriate, companies can also play a more active role in shaping the regulatory compliance agenda, for example by participating in industry associations.

CHANGE THE PARTNERSHIP PARADIGM

CDMOs should work with their pharma customers to change the collaboration model. Pharma companies themselves have been reflecting deeply on how to create more-powerful partnerships, so the timing couldn't be better. Together, CDMOs and pharma should:

- **Adopt a wider range of contracting models.** CDMOs and pharma companies should shift from fee-for-service or project-based arrangements to other kinds of contracts. Examples include take-or-pay and reserved capacity models, which allow the pharma company to reserve a set amount of capacity for an agreed-upon time that it can use for a portfolio of its products, and co-investment models, which give both parties the right of first refusal on capacity. Any unused capacity could be marketed to other third parties.
- **Assess the other party's preferences, risk factors, and payouts.** CDMOs should ascertain what each pharma customer needs most from the relationship, whether it's quality, speed to market, reliability of supply, or price. This information is crucial for tailoring the offering and the pricing model appropriately.
- **Enhance transparency and accountability.** Deeper relationships call for greater transparency and accountability. Within the limits of quality compliance and competition law, CDMOs and pharma companies can more effectively share contract-level information about expected volumes, capacity, delays in supply, and quality issues as closely as possible while respecting arms-length requirements. Such transparency would boost the pharma company's confidence in the CDMO and likely lead to more outsourcing.
- **Develop and execute against a strategic partnership playbook.** While each partnership will be different, every company should codify its

own approach to building strategic partnership, including processes, decision-making bodies, contracting, and relationship management practices based on customer needs. Following and amending the playbook with lessons learned from previous partnerships will help streamline the development of new ones.

Getting Started

CDMOs need to begin by reassessing their network strategy in light of COVID-19 with the confidence that the right capacity and capabilities will unlock new opportunities for strategic collaboration with pharma customers.

That means first modeling demand and supply scenarios to understand how various events could impact the CDMO net-

work. This assessment will help illuminate where and what kinds of manufacturing capacity pharma clients may require.

At the same time, CDMOs should review their portfolio of digital, supply chain, manufacturing, and relationship management or strategic partnership capabilities to see where there are opportunities for differentiation. They should then determine which capacities and capabilities should be built first and focus investments there.

THE PANDEMIC HAS provided a temporary opportunity for CDMOs to adjust the balance of power in their pharma relationships. Companies that seize the moment can create a source of growth that is likely to last long after COVID-19 has ended.

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