



CMO Management: Not all contract manufacturing organizations are created equal

Life Sciences companies can benefit from purposefully leveraging contract manufacturing organizations (CMOs) in a strategic or tactical approach to navigating through growth and disruption

Life Sciences companies have been known to outsource a significant portion of their manufacturing and other contracted operations externally for various reasons (see **Figure 1**). In 2020, experts¹ found that, Life Sciences companies were outsourcing approximately 44% of their annual production volume and 30% of their manufacturing activities (see **Figure 2**).

STRATEGY	EXAMPLES OF CMO ACTIVITIES	
New Platform	Incorporate innovation and emerging technologies to launch new therapies	— CMO A is significantly investing in developing new technologies to manufacture complex therapeutics; a strategic partnership will give access to the manufacturing capabilities required for the launch of next-gen therapies
Capability Integration	Provide CMO management services across the end-to-end supply chain	— CMO B provides CMO services from pre-clinical development to commercial-scale manufacturing – they are partnering with a logistics firm to simplify the supply chain in their area of expertise
Agile Capacity	Offer the capability and flexibility to quickly respond to market demands	— CMO C opened collaboration/innovation centers to optimize and expand single-use technology – these have been strategically placed next to manufacturing plants to receive real-time feedback and to balance capability utilization
Scaling	Leverage economies of scale to cost-effectively deliver high-quality products	— CMO D operates multiple manufacturing plants with consistent annual production capacity and many clients. CMO D is responsible for a third of the global capacity in their specific platform and has optimized operations for a number of years
Cost Reduction	Utilize low-cost regions/locations to set up manufacturing facilities	— CMO E has multiple facilities within China and constitutes over a third of the CMO market there; with the current expansion plans in China, they will be the largest biologics CMO in China, operating at a significantly lower cost base than peers in other countries

Figure 1. Examples of strategy-driven CMO activities

¹ Rigert, M. Disruptive Outsourcing Means Life Sciences Are Relying on CMOs More Than Ever. MasterControl (January 28, 2020). <https://www.mastercontrol.com/gxp-lifeline/disruptive-outsourcing-means-life-sciences-are-relying-on-cmos-more-than-ever/>.

According to Technavio², these figures are expected to grow dramatically — at a CAGR of 9% — between 2021 and 2025 as Life Sciences companies face various disruptions such as unforeseen global pandemics, supply chain risks and material shortages, and the development of new and specialized treatments (e.g., cell and gene therapies). In Heidrick & Struggles³ 2020 annual survey of the Healthcare and Life Sciences industry, senior executives revealed that, in recent years, the industry has been facing a continuous stream of disruptive pressure, both internally and externally. The survey also reported that 85% of executives felt that challenges would continue to increase over the next 18 months, but only 54% felt their organizations were ready to respond effectively to the disruptions.

The quality of the relationships between CMOs and Life Sciences companies is a key factor in why more than half of Life Sciences companies are not prepared to face unforeseen disruptions. According to the interviews Pharma IQ⁴ conducted with senior executives in late 2019, contract manufacturing relationships were still perceived to be in the early stages of maturity for most companies. Our Life Sciences Supply Chain Management team at FTI Consulting has also observed that Life Sciences companies typically select and engage with CMOs to merely achieve operational goals — thus only form a **tactical** relationship. Leveraging tactical CMOs can help companies achieve shorter-term business objectives such as cost reduction and capacity and geographic expansions.

For Life Sciences companies to realize longer-term benefits, strategically engaging with CMOs has become critical. Due to recent world events, organizations are re-evaluating their approach for strategizing and designing their network when it comes to onshoring and offshoring. In an April 2021 survey by PharmTech⁵, 500 executives predicted a push for supplier

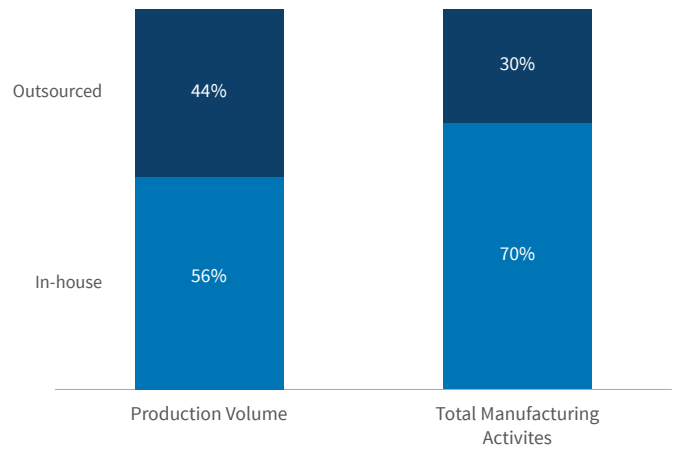


Figure 2. Prevalence of contracted manufacturing operations within the Life Sciences industry (Source: MasterControl¹)

repatriation because of the global supply chain disruptions companies experienced during the COVID-19 pandemic. Additionally, supplier repatriation has become an important initiative as 72% of drugs used in the US are currently manufactured abroad⁶. According to IndustryWeek⁷, the federal government under the Biden Administration also recognizes the importance of pharmaceutical products to national security. The administration is pushing for onshore manufacturing efforts through several initiatives such as The US Innovation and Competition Act of 2021, Country-of-Origin Labeling, Buy American Act, etc. Experts believe that as Life Sciences companies navigate the changing global supply chain landscape and assess financial impacts of repatriation, with the support from the federal government, the approach to Life Sciences manufacturing will result in a hybrid model with an optimized amount of onshoring and offshoring. Although manufacturing repatriation will increase supplier spend, companies will see value-added benefits in a hybrid model, provided they leverage a strategic management and governance approach.

² Contract Development and Manufacturing Organization Outsourcing Market by Product and Geography - Forecast and Analysis 2021-2025. Technavio (May 2021). <https://www.technavio.com/report/contract-development-and-manufacturing-organization-outsourcing-market-industry-analysis>

³ Disruption in healthcare and life sciences 2020. Heidrick & Struggles (2020). https://www.heidrick.com/en/insights/healthcare-and-life-sciences/disruption_in_healthcare_and_life_sciences_2020

⁴ The changes set to disrupt biopharma manufacturing in 2020. Pharma IQ (July 23, 2019). <https://www.pharma-iq.com/manufacturing/articles/the-changes-set-to-disrupt-biopharma-manufacturing-in-2020>

⁵ CPhI Post-Pandemic Survey Suggests Drive for Repatriation of Manufacturing. PharmTech (April 23, 2021). <https://www.pharmtech.com/view/cphi-post-pandemic-survey-suggests-drive-for-repatriation-of-manufacturing>

⁶ Sanchez, E., Muzzio, F.J. Reshoring Pharmaceutical Manufacturing to the US: Can We Do It?. PharmTech (February 2, 2021). <https://www.pharmtech.com/view/reshoring-pharmaceutical-manufacturing-to-the-us-can-we-do-it>

⁷ Collins, M. Much Is at Stake for American Manufacturing in 2021. IndustryWeek (July 20, 2021). <https://www.industryweek.com/the-economy/public-policy/article/21170067/much-is-at-stake-for-american-manufacturing-in-2021>

Strategic partnerships with CMOs allow Life Sciences companies to drive strategic goals and growth, operate collaboratively by leveraging common resources, and receive expertise and benefits from ‘*supplier-enabled innovations*’. Examples of these include:

1. **COVID-19 Vaccine Development⁸**: Since 2018, Pfizer and BioNTech has been collaborating to bring mRNA-based influenza vaccines to market. In March 2020, the partnership shifted focus to developing the COVID-19 vaccines for emergency use to combat the global pandemic. BioNTech’s expertise in mRNA technology and Pfizer’s development, regulatory, manufacturing, and commercial capabilities, enabled the group to produce 50 million vaccines before the end of 2020.
2. **Advanced Therapies Manufacturing⁹**: Danaher corporation acquired Cytiva to leverage its expertise in advanced therapies manufacturing (i.e., cell & gene therapy, personalized medicines, etc.). In 2019, 75%+ of the FDA-approved biological therapies relied on Cytiva’s technologies showcasing strategic partnerships and acquisitions can increase innovations in the Life Sciences industry.

In a notable case study, a global pharmaceutical manufacturer consolidated two CMOs and integrated them into a single “embedded CMO.” Prior to the consolidation, the pharma manufacturer was struggling to meet patient demands for its small-molecule drug because of increasing challenges to manufacturing a custom active

pharmaceutical ingredient (API). Tactical CMOs that were utilized in the past had disparate expertise across the industry, which resulted in a lack of control and limited collaboration. The benefits that accrued from embedding the CMO into the pharma manufacturer included:

- Setting up dedicated teams to control and directly manage the production of the customer API
- Leveraging the same facilities, technologies, and personnel to manufacture the API
- Mutual benefits from financial investments for both parties
- Collaboratively monitoring the quality of the products to the highest standards

Companies leverage tactical partnerships with CMOs/CDMOs (Contract Development and Manufacturing Organization) to achieve **specific business objectives**:

- Cost reduction
- Capacity expansion & economies of scale
- Expansion into emerging markets

Partnering with strategic CMOs / CDMOs offers ulterior **benefits in addition to tactical partnership**:

- Technological Compatibility
- Increased Competitive Advantage
- Enhanced Service Capabilities
- Collaborative Business Opportunities

⁸ Keown, C., Saigol, L. Here are 5 things to know about BioNTech and the married couple behind the COVID-19 vaccine developed with Pfizer. MarketWatch (December 8, 2020). <https://www.marketwatch.com/story/everything-you-need-to-know-about-biontech-and-the-married-couple-behind-the-covid-19-vaccine-at-the-front-of-a-global-race-11605032681>

⁹ Axelson, D. Introducing Cytiva – Global Life Sciences Leader. Cytiva (April 1, 2020). <https://www.cytivalifesciences.com/en/us/news-center/introducing-cytiva-global-life-sciences-leader-10001>



Figure 3. Representative benefits between tactical vs. strategic CMO engagement

Rethinking how you select CMOs and how you effectively collaborate with them after selection will allow you to realize additional qualitative and quantitative benefits (see **Figure 3**). A typical pitfall is to apply a blanket approach and make the CMOs operate in the way you operate your

own supply chain. Keep in mind that CMO operations are highly specialized and optimized; therefore, decreasing interference with the core processes will bring you more benefits. Focus on how *you* adapt to the CMO’s way of working, not the other way around.

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JOSEPH SLOTA

Senior Managing Director
+1 917.328.7201
Joseph.Slota@fticonsulting.com

RICK VAN DER VEGTE

Managing Director
+1 914.826.7318
Rick.vanderVegte@fticonsulting.com

MICHAEL TONG

Senior Director
917-499-3769
Michael.Tong@fticonsulting.com

PEERAPAK ADSAVAKULCHAI

Senior Consultant
+13128630782
Peerapak.Adsavakulchai@fticonsulting.com