

# Trends in the Medical Device Outsourcing Industry

*June 2020*



**AliraHealth**

MassMEDIC

# Trends in the Medical Device Outsourcing Industry



*How the pursuit of more efficient supply chain models will impact Contract Manufacturing Organizations (and why that matters during COVID-19)*

## 1. Introduction

By **Carlo Stimamiglio**,  
Partner

In the past decade, the medical device industry has increasingly leveraged outsourcing partners for many phases of the manufacturing value chain. As the market becomes more global and competitive, Medical Device OEMs<sup>1</sup> face complex operational challenges to maintain captive and third-party manufacturing operations, secure quality and continuity of supplies and achieve cost reductions.

The COVID-19 pandemic has stressed the current supply chain models, disrupting the global logistics chain ecosystem and causing severe product shortages and financial damage to suppliers. Potentially diminished revenue streams, combined with temporarily higher logistics costs, bring an exceptional financial risk to the industry. And most disturbing, a supply shortage of medical devices can have a devastating impact on public health and the healthcare system's ability to effectively treat patients.

The current health and financial emergency poses some questions on the way medical devices are manufactured and moved globally. How can supply chain models become more efficient and mitigate the risk and severity of logistics disruption? What role will CDMOs<sup>2</sup> play in a newly adapted global ecosystem?

This article, for which content was largely sourced from a global study of the MedTech CDMO market performed by Alira Health and commissioned by MassMEDIC<sup>3</sup>, investigates how Medical Device OEMs make supply chain decisions and how market and competitive dynamics influence the outsourcing industry.

The findings reported in this article are clear: the general trajectory of increased outsourcing, by both volume and value-add, will continue indefinitely. Medical Device OEMs prioritize their core competences of product innovation and commercialization and prefer to farm out non-core activities to specialized manufacturing partners to realize operational efficiencies. As CDMOs evolve into larger, global and vertically-integrated service providers organized as an extension of the OEM's captive capabilities, they will take a larger responsibility in maintaining business continuity at times of crisis. The relationships between OEMs and CDMOs will develop into long-term partnerships, founded on mutual financial incentives to pursue cost efficiencies and strategies to mitigate operational risks. Aspects like redundancy of supply sources and proximity between manufacturing site and end-market will assume greater importance in supply chain and outsourcing decisions.

1. OEMs: Original Equipment Manufacturers

2. CDMOs: Contract Development & Manufacturing Organizations

3. Alira Health, June 2020, "Medical Device Contract Development & Manufacturing: Global Trends & Opportunities"

## 2. Strategic Factors Driving Supply Chain and Outsourcing Decisions

Medical device companies operate in increasingly competitive markets, pushed by decreasing reimbursement, stricter regulatory standards and a need for continuous innovation. To thrive in this increasingly challenging environment, branded manufacturers must prioritize their two-fold core mission:



### 1. MARKETING

*of medical technologies in current and new markets*



### 2. PRODUCT INNOVATION

*with a focus on improving clinical outcomes and economic value for healthcare systems*

In some instances, maintaining a captive manufacturing and supply chain operation can be a strategic priority for MedTech OEMs. For example, a branded manufacturer may prefer to keep some phases of the value chain in-house to protect its intellectual property or trade secrets. In another case, a company may possess proprietary manufacturing know-how enabling a unique competitive advantage. Alternatively, sales of custom products may depend on a fast time-to-market, which justifies a captive control of operations and logistics.

However, as medical device makers become more global, diversified and complex organizations, and supply chain decisions tend to be informed by the pursuit of operational efficiency and variable costs, outsourcing to specialized CDMOs is critical to free resources for revenue-accretive functions.

In the past decade, four fundamental trends of the medical device industry have fueled a significant increase in the use of outsourced manufacturers.



### CONSOLIDATION

Large M&A transactions among the top 20 medical device manufacturers have increased the industry concentration and competitiveness in the past few years. The necessity to integrate, simplify and streamline complex operations post-merger have led branded manufacturers to increasingly rely on CDMO partners in the pursuit of scalability and cost savings.



### INNOVATION

Organic (internal R&D) and inorganic (via partnership and M&A) innovation is continuous in the medical device industry and results in a high number of product launches and operational complexity. CDMOs enable economies of scale and cost competitiveness for early-stage innovative devices.



### CONVERGENCE

(of technology platforms and business models). Medical devices increasingly combine digital, robotic and therapeutic capabilities. These are new, unfamiliar domains for many MedTech OEMs, which will seek development and manufacturing capabilities outside of their core technical competences.



### REGULATIONS

In the past decade, US and EU regulators have raised the standards of safety and quality necessary to bring medical devices to market. Such restrictions represent an increased cost and liability for MedTech OEMs, which often prefer to outsource larger portions of their value chain to CDMOs specialized in regulatory and quality compliance.

These trends are bound to continue in the 2020-2030 decade, as branded manufacturers seek third-party vendors not only for scalability and cost competitiveness of commoditized products, but also for higher value-add capabilities that bridge internal competence gaps when approaching new technologies or markets.

Primary interviews of large and global MedTech branded manufacturers have emphasized commonalities in the way they engage with outsourcing partners.

**Global coordination of local manufacturing footprint.** Make-or-buy decisions are coordinated on a global basis to identify the most cost-effective sources while optimizing the cost of logistics and time-to-market.

**Long-term partnerships with direct capital investments.** OEMs prefer the long-term stability of third-party vendors, founded on mutual goals and performance metrics, compared to short-term engagements focused on price reductions. To maintain and improve the reliability and consistency of supplies, OEMs frequently manage their CDMO vendors as an extension of their own captive operations, making capital investments in the outsourcing facilities and establishing two-way partnerships.

**Pursuit of Risk-Adjusted ROI.** Supply chain decisions are made based on all the direct and indirect costs necessary to successfully serve the customer. Alongside manufacturing, inventory and distribution expenses, this risk-based approach considers other variables like the cost of quality, customer complaints and business continuity. While this model has a long-term concern, it is constantly reassessed to maximize its financial ROI.

These findings support the conclusion that MedTech-branded manufacturers will continue to pursue outsourcing opportunities that reduce their overall supply chain cost and operational risk while maximizing quality, scalability and innovation. However, make-or-buy decisions will continue to be driven by specific financial and risk mitigation factors aligned with the core strategic priorities.

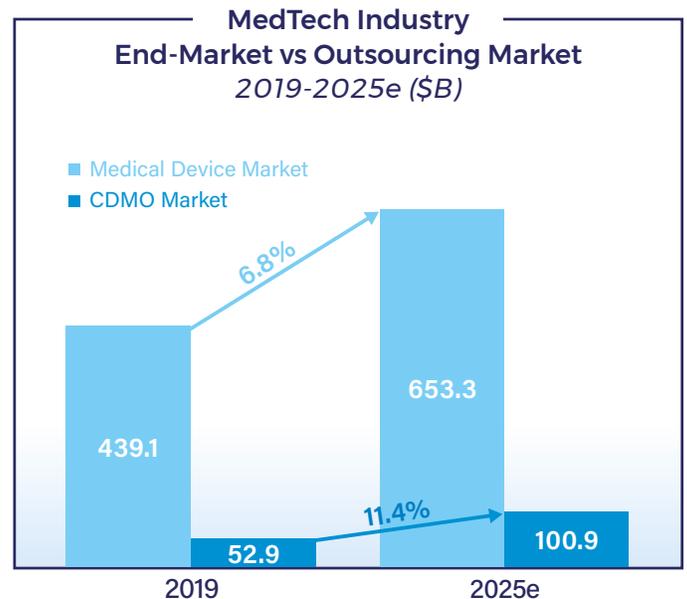
### 3. Market and Competitive Trends in the Medical Device CDMO Industry

As in the past decade, the growth of the MedTech CDMO market is expected to outperform that of the global medical device industry in the 2020-2025 period.

However, as overall industry competitiveness is bound to increase, not all the market players will participate equally in the growth trend. A distinct set of capabilities will enable CDMOs to take advantage of the current market trend:

Figure 1. Growth Trends in the Medical Device and CDMO Industry ►

- > **One-Stop-Shop.** Ability to serve the full product lifecycle and minimize the logistics burden for the OEMs, with diversified and technically-differentiated manufacturing capabilities.
- > **Innovation Capabilities.** Ability to participate in product design & development, particularly in markets outside of the traditional competences of medical device makers.
- > **Formulation Handling.** Ability to manage the full cycle of drug/device interactions or reagent-based diagnostic devices.
- > **Digital Capabilities.** Expertise in the development of digital products and features that are increasingly seen in medical devices, such as user interface, artificial intelligence and analytics
- > **Components Innovation.** Ability to manufacture miniaturized components at large scale and with high precision.



The diverse CDMO competitive landscape continues to adapt in response to the evolving demand as CDMOs develop capabilities that fit the market trends. Larger corporate and private equity-backed players have led this transformation by pursuing different strategic goals via organic or inorganic initiatives:

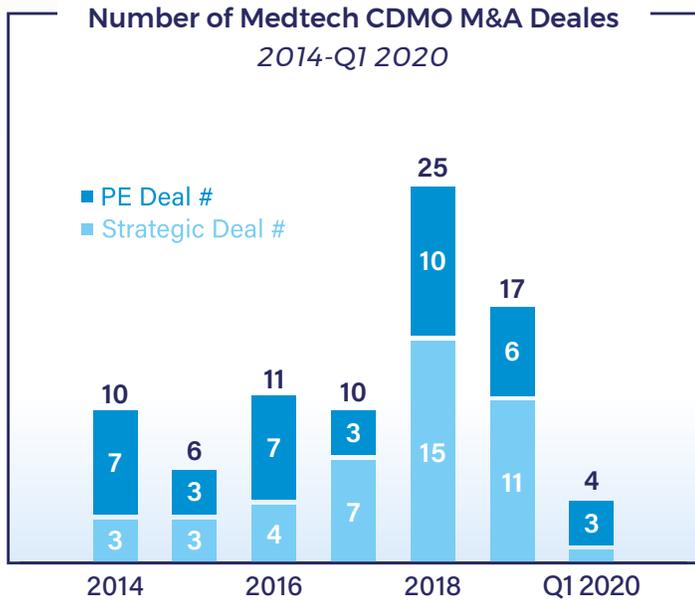


Figure 2. Number of Corporate & Private Equity MedTech CDMO M&A transactions between 2014 and Q1-2020

- > **Capacity and footprint expansion.** Scalability and global footprint are attributes valued by Medical Device OEMs. CDMOs have been keen on investing in an expansion of their capacity, also growing in geographies that enable proximity to OEM customers or access to low-labor cost.
- > **Downstream vertical integration.** Specialized CDMOs (i.e. injection molders) may expand downstream and offer adjacent services (i.e. assembly) and capture more value from existing customers.
- > **Horizontal expansion of capabilities.** Acquiring new technical competences to strengthen a specific application expertise or manufacturing technique (i.e. plastics or metal processing) is a current strategy pursued by many CDMOs.
- > **Upstream vertical integration.** In an emerging trend, large and mid-sized CDMOs acquire design and development capabilities to serve customers earlier in the product life cycle.

The competitive pressure to implement these strategies and accelerate growth has spearheaded a large volume of M&A activity in the past decade.

Private equity sponsors have been active, building outsourced service platforms by acquiring independent CDMOs with complementary capabilities.

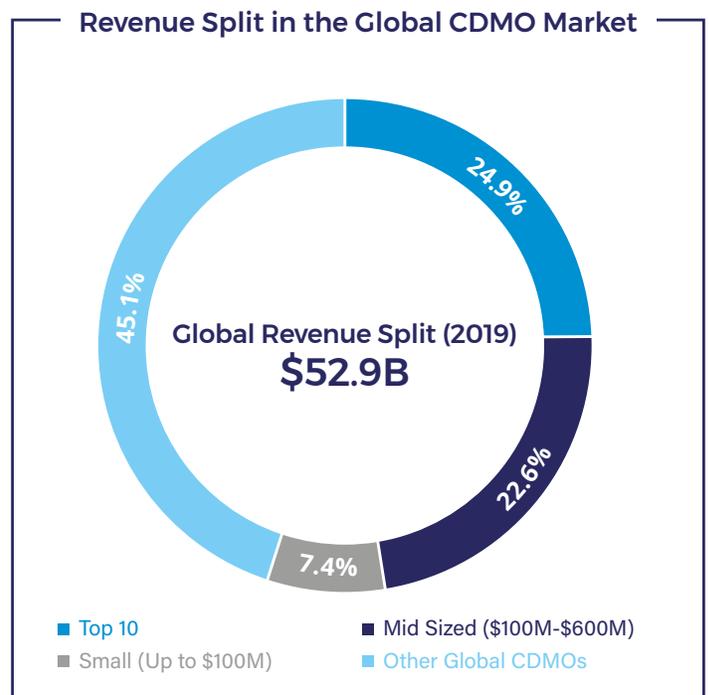
Corporate CDMOs have also been active, acquiring private equity-backed and independent targets to boost their growth and widen their portfolio of services.

Despite this consolidation trend, the industry remains fragmented. Alongside the top ten global players stands a multitude of smaller regional and specialized suppliers. The potential for continued consolidation is high.

This study included an analysis of approximately 300 medical device CDMOs with domicile or an operational footprint in the US<sup>4</sup>, accounting for \$29.0 billion (or 55%) of the global MedTech CDMOs revenue.

Among this group, the top ten players combine for a total of \$13.2 billion revenue, or 24.9% of the global market. A group of 50 mid-sized players with revenue between \$100 and \$600 million is worth an aggregate of \$11.9 billion and features high involvement in M&A transactions, aggregating independent CDMOs. The next 220 CDMOs in the sample by size combine for \$3.8B.

Figure 3. Market Segmentation by Revenue



4. The analysis excludes international CDMOs that do not have an operational footprint in the US. As illustrated by figure 3, this group represents 45.1% of the global market and was not an object of analysis.

While hosting nine of the top ten international Medical Device CDMOs, the US only generates 30.1% of the global outsourced manufacturing output.

Figure 4. Market Segmentation by Revenue & Location ▶

In addition, more than a third (37%) of the value produced by US-domiciled organizations is generated off-shore.

While EMEA is the largest region, on par with Asia, China and Mexico are the individual countries with the largest offshore presence of US MedTech CDMOs.

Within their regions, these countries hold the largest market share. Mexico hosts 55% of the operations of US CDMOs in the Americas. 42% of the capabilities of US-headquartered firms in Asia are in China.

#### Global landscape

TOTAL	US	Outside of the US
\$52.9B 100%	\$16.0B 30.1%	\$36.9B 69.9%

#### U.S.-Domiciled CDMOs

TOTAL	US	Outside of the US
\$23.3B 44%	\$14.7B 27.6%	\$8.7B 16.4%

#### International CDMOs

TOTAL	US	Outside of the US
\$29.6B 56%	\$1.3B 2.5%	\$28.2B 53.5%



Figure 5. Offshore Footprint of US-Domiciled Medical Device CDMOs ▲

Forty-four senior executives of international contract manufacturing firms, ranging from global, publicly-listed companies to regional independents were surveyed for this study. Their input was distilled to draw conclusions regarding five distinct trends in the CDMO industry:

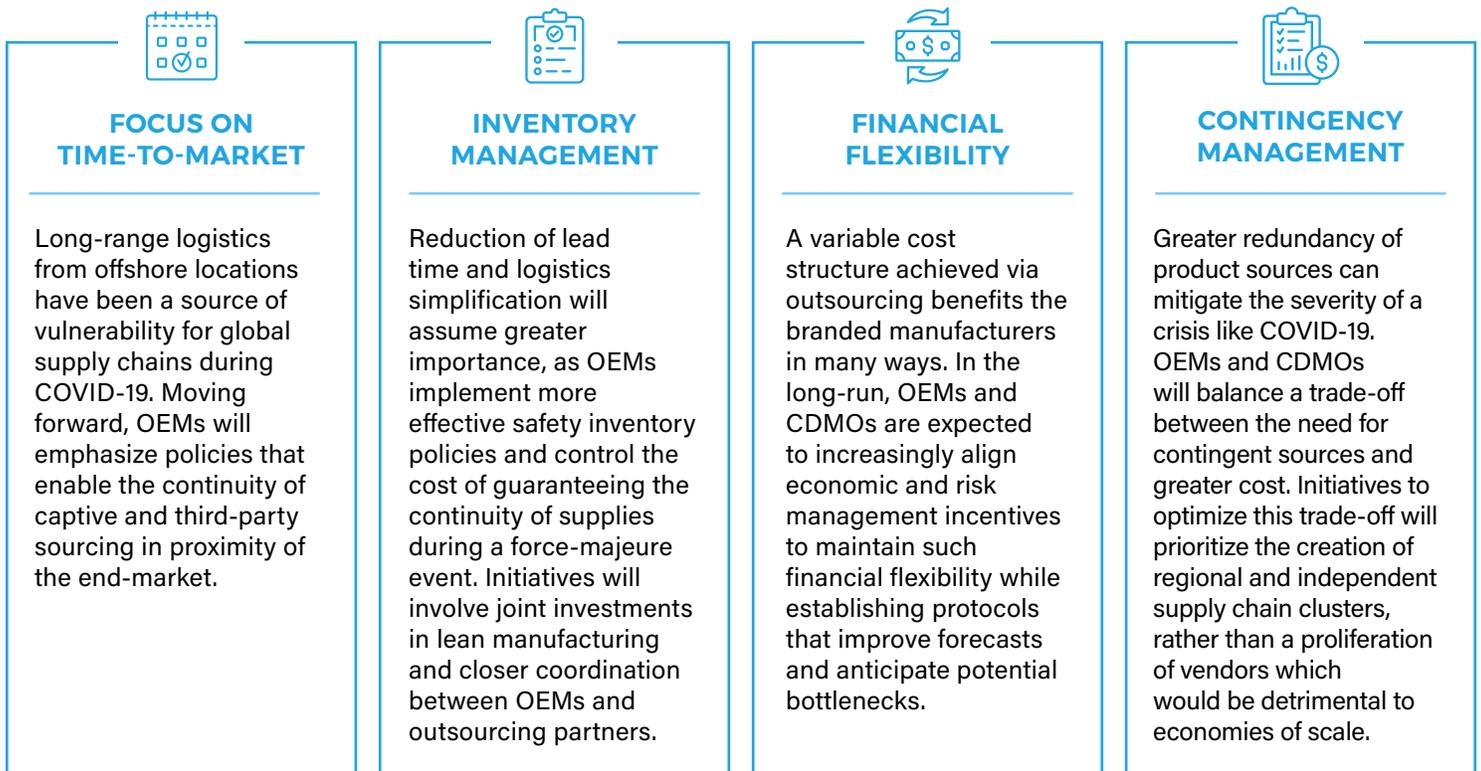
- Growing competitiveness.** As market participants become more vertically integrated and attract larger portions of the OEMs' business, overall industry competitiveness is bound to increase, exercising significant pressure on smaller, independent CDMOs that lack technically differentiated capabilities.
- Dual-Pricing Trajectory.** OEMs' continued effort to reduce their supply chain spend, combined with the tightening competitive landscape, will put pressure on prices of commoditized, undifferentiated manufacturing processes. Technically more complex components-making and assembly techniques will have lower price sensitivity and possibly affirm a strong pricing power by specialized CDMOs. While this dual trend will have a neutral effect on the overall industry profitability, CDMOs offering low value-add services will be heavily impacted.
- Upstream Integration.** Highly sophisticated technical competences will be key to success in the tighter competitive environment. As OEMs seek outsourced partners capable of enhancing their internal R&D and manage the full product life cycle, CDMOs will invest heavily in design and development capabilities and strive to establish long-term partnerships early in the R&D process.
- Continued M&A Activity.** Corporate and private equity acquirers will propel an unprecedented volume of M&A deals and reduce the number of industry participants, creating larger, global service providers.
- Globalization.** While the industry's offshore footprint will be maintained to access competitive labor cost, onshore outsourced operations will thrive. Globally, CDMOs will be leveraged as regional product sources to mitigate operational risk and ensure fast time-to-market.

## 4. Conclusions: Long-Term Trajectory of the Medical Device Outsourcing Industry

The trends described in this article indicate that outsourced manufacturers will continue to benefit from the long-term pursuit of cost savings and operational agility that drives the OEMs' supply chain decisions.

The challenges currently posed by the COVID-19 epidemic are not expected to influence the growing propensity towards outsourcing. However, the role of CDMOs will adapt to reflect the need of stricter operational risk management, which was exacerbated by the current crisis.

Such risk-based approach will impact both captive and third-party sources:



This evolving context presents continued growth opportunities for the medical device contract manufacturing market. Overall, CDMOs will establish themselves as an extension of the OEMs' captive operations. Longer-term outsourcing engagements focused on business continuity and productivity will resemble true partnerships between vendors and customers in the pursuit of financial ROI.

CDMOs will also play a key role in balancing the costs and benefits of the greater sources redundancy required by the medical device industry. Regional manufacturing clusters that favor proximity to the distribution channel and reduce logistical complexity will assume greater importance in the global ecosystem, favoring contract manufacturers with a domestic or near-shore presence.

To capture these opportunities and navigate a highly competitive environment, CDMOs will have to develop innovation capabilities and adapt to serve the entire product development and manufacturing lifecycle on behalf of their OEM partners. The continued trend of industry consolidation will augment this trajectory by reducing the number of players and creating larger global service providers.

By Carlo Stimamiglio, Partner. Copyright © Alira Health