MARWOOD GROUP

2022 Global MedTech CDMO Outlook

Executive Summary and Outline

Original equipment manufacturers (OEMs) of medical devices are increasingly utilizing contract development and manufacturing organizations (CDMOs) for support. Rapid innovation in the sector, including the convergence of device, digital technology and therapeutics has OEMs seeking long term partners that can provide operational efficiencies from both an engineering and regulatory perspective, specialized expertise and enhanced quality to support device development and commercialization. Herein we focus on the medtech sector, turning to biopharma in the second installment of our two-part series on CDMOs.

I. Introduction

Over the past decade, MedTech industry consolidation via large M&A deals has created global, complex organizations with a need for operational efficiency. MedTech branded manufacturers (OEMs) have increasingly relied on outsourced development and manufacturing partners, CDMOs, to pursue these operational efficiencies along with cost savings and access to specialized materials and engineering capabilities that would give them a competitive advantage.

Prior to the introduction of multiplatform MedTech devices, it was common for branded manufacturers to feature vertically integrated captive operations and control most of the product value chain. The main outsourced activities consisted of materials sourcing and components manufacturing via services like injection molding, metal processing and electronics. As multiplatform devices have proliferated within the sector, the trend of farming-out more of the value chain has intensified. OEMs now seek out partnerships with full-cycle CDMOs that are able to integrate design, components manufacturing and assembly of finished devices, but continue to keep in-house IP-protected capabilities of critical and strategic importance to the core business.

OEMs outsourcing relationships are increasingly based on long-term value considerations such as quality, scalability and specific manufacturing know-how that allow OEMs to bridge competence gaps when approaching the development of new technologies or markets. These partnerships allow OEMs to consolidate multiple phases of the product life cycle that would be difficult to develop internally.

II. Medtech Sector Complexity Driving Demand For Full Service CDMOs

The convergence of technology platforms and business models outside of OEMs core technical competencies (i.e., digital) with complex material, manufacturing and supply chain considerations is driving ever increasing complexity in the MedTech sector. Combining the mixed platforms of device, drug and digital with changing regulatory guidance by market, the sector is experiencing increased cost and liability risks when bringing devices to market. In order to allow OEMs to focus on market access considerations (i.e., clinical outcomes and economic value to payors), commercialization as

well as launch strategy, CDMO partners integrated across the value chain are increasingly considered as standard operating procedure (SOP), particularly by larger manufacturers.

CDMOs Assisting Across Value Chain of MedTech Product Development and Commercialization

- ***Design & Development:*** Prototyping, product design and engineering from concept to design for manufacturing, especially in the convergence of device, pharmaceuticals and digital
- ***Tooling***: Design and production of molds for industrial processes, driven by the rise of sophisticated technical and miniaturized plastics and high-performance polymers
- ***Component Manufacturing:*** Injection molding, extrusion machining, 3D printing focused on a variety of materials including polymers, metal, glass and composites, driven by demand for materials capable of combining mechanical, fluidics, and electrical capabilities
- ***Assembly:*** Clean room assembly and finishing of components into a final device, via an array of manual or automated processes and associated quality controls
- ***Packaging & Labeling***: Sterile or non-sterile packaging and printing of labels that meet market-based regulatory requirements, as part of an end-to-end solution
- ***Regulatory Guidance***: Provision of market-specific expertise on regulations impacting device approval and commercialization

III. The Expanding Global MedTech CDMO Industry

Currently the global MedTech CDMO market is estimated to be ~$50-$100B and growing at ~11% CAGR with leading sectors including drug delivery, fluid management and respiratory care. The industry is split between a handful of large integrated CDMO firms and a multitude of small and mid-sized companies with specialized capabilities. Concentration is abundant with the top 10 (>$600M annual revenue) accounting for 25% market share, a further 25% market share distributed across the next 50 mid-sized players ($100-$600M annual revenue) and the remaining small CDMOs (<$100M) making up the remaining half, although heavily weighted toward smaller players.[1]

Investment interest in CDMOs continues to grow as COVID-related impacts continue to disrupt other industries. Investors appear to be viewing the disruption associated with COVID-19 as a time to be opportunistic and proactively in the space. Along with private equity backed CDMOs, corporates have led industry consolidation into CDMO platforms with different growth strategies. We anticipate these trends will continue to fuel the creation of larger, more diversified and vertically integrated CDMO platforms that meet several key criteria:

- ***Capacity & 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.
- ***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.
- ***Downstream Vertical Integration:*** Specialized CDMOs (i.e., injection molders) may expand downstream and offer adjacent services (i.e., assembly) to capture more value from existing customers.
- ***Horizontal Capabilities Expansion:*** Acquiring new technical competences to strengthen the specific application expertise or manufacturing techniques (i.e., plastics or metal processing) is a current strategy pursued by many CDMOs.

[1] *Massachusetts Medical Device Industry Council. The 2021 MedTech Contract Manufacturing Report.*

In comparison to the United States, the European CDMO sector has seen less industry consolidation. Fragmented, highly specialized smaller organizations are a common feature of the European market. This has had a clear impact on the nature of the investment opportunity, with bolt-on M&A to support acquisition strategies an option for larger funds looking to develop their existing asset portfolio while small and mid-cap PE can find businesses at valuations that allow them to compete in the space.

IV. The Evolution of MedTech CDMO Regulation

While the industry may be shaped differently, all CDMOs and OEMs face the same regulatory barriers when looking at Europe from an opportunity perspective. Whether based in the US, Europe or rest of world, all products classified as a medical device will ultimately have to satisfy the new Medical Device Regulation (MDR) and In-vitro Diagnostic Device Regulation (IVDR).

In the US, quality, registration and monitoring requirements imposed by the FDA have increased the complexity of regulatory compliance for medical device manufacturers. In response to this trend, OEMs have adopted strategies to minimize the cost of their quality systems, including outsourcing. In 2012 the FDA required the registration of all manufacturers (including CDMOs) and providers of sterilization for finished devices, whether sold to end-users or to the OEM. If a device is marketed in the US, the facilities where it is manufactured will need to be audited regardless of location. Finished devices are defined as devices or accessories suitable for use or capable of functioning, whether packaged, labeled, sterilized or not.

In Europe, the new regulations should not come as a surprise to those in the industry. The European Council approved them in 2017, but the MDR did not formally come into effect until the 26th of May 2021, while the IVDR is expected to come into effect on 26th May 2022.

For medical device manufacturers, the regulations increase compliance requirements for quality and safety. It brings into scope products previously outside of regulations and existing products may be re-classified under the new risk profile. IVDs are particularly impacted, where it is estimated that 75% will require Notified Body oversight – as opposed to 20% under the current directive.

New regulations could support CDMO growth, as it may drive further outsourcing from OEMs. Since part of the CDMO value-add is the provision of focused expertise not necessarily developed in the existing OEM then the assurance of regulatory compliance both in the manufacturing element, and increasingly across the end-to-end development process, may help drive outsourcing to the sector.

Whilst there is a risk that the increased cost of compliance reduces the appeal of the EU as a market and may have a consequential impact on time-to-market, the trade-off for investors is the increased assurance that risk profiles of existing market products are aligned with current regulatory expectations, whilst new products will have faced more stringent safety and quality checks. This should reduce some of the regulatory risk associated with CDMOs operating in the medical device space.

PE CDMO Platform Investments Through Add-On Acquisitions

Investor	Platform	Platform Services	Add-ons
Ampersand	Confluent	Nitinol components, balloon-expandable stents and catheters, biomedical textiles, and guidewires	Guidepath, Interface Catheter Solutions, Modified Polymer Components, Biomedical Structures, Corpus Medical, Inc., Tube Hollow International
Water Street	Viant	Diagnostic, orthopedic, surgical and other medical products	Vention, Coastal Life Technologies, Integer, Meraqi Medical
American Securities	MW Industries	Orthopedic implants, cases, trays, surgical instruments, springs, fasteners, and metal bellows	Lavezzi, Ameriflex, Inc, Sussex Wire Incorporated
Lee Equity/ Blackbern Partners	Westfall Technik	End-to-end manufacturing solutions for the complete life cycle of molded plastic parts	NPI/Medical, MTSW, Delta Pacific Products
Linden	Flexan	Developer of silicone, rubber and thermoplastic components for a broad array of medical applications	Medron, IntroMed
SV	Ximedica	Fully integrated product development firm focused on bringing medical and diagnostics technologies from first concept to market launch	Bridge, AccelBiotech
Hardwood	Utitec	Design and manufacture of miniature, ultra high precision deep drawn tubular and flat stamped components	Axcelent, Veridian
Sverica Capital	Gener8	Rapid prototyping including rapid injection molding	Symbient Product Development
Graham Partners	Medbio	Precision injection molding, injection mold tooling, assembly, packaging, project management, and design support services	Aim Aimplastics
Kidd & Company	Nexcore Technology, Inc.	Contract manufacturer of electro-mechanical capital equipment	Phase 2 Medical Device Manufacturing
Audax Group	Katena	Ophthalmic surgical products including instruments, biologics, punctum plugs, lenses	Sensor Medical Technology, Eagle Vision, NuPak Medical Ltd, Rhein Medical Inc, Blink Medical, MWI
GTCR	Resonetics	micro manufacturing for life sciences: laser ablating, cutting, drilling and welding; nitinol shape setting and electropolishing, centerless grinding and photochemical machining, fiber optic sensing and thin wall tube fabrication.	STI, Medelec, Caribou Technologies, Medibrane, Trutech
3i	Cirtec Medical	Medical device fabricator	Vascotube, NovelCath, Cardea, Cactus Semiconductor, Metrigraphics
Eurazeo	In-tech Medical	development and manufacturing of surgical instruments for the Orthopaedic industry	Pyxidis, Bradshaw Medical
Kohlberg	Cadence	complex high-precision components and finished devices for advanced surgical and specialty industrial applications	Arcor Laser
AEA	Spectrum Plastic Group	Design, prototyping and development of medical devices. Extruded tubing. Balloons. Catheters. Injection molding	Earnan

V. Future Considerations

Marwood continues to follow the regulatory, legislative as well as downstream healthcare payor and provider impacts which may impact developments in the Medtech CDMO industry. For example, the awareness that medical devices that are effectively built around software is a clear area where the need for broader regulatory compliance may drive CDMO opportunities. A software company that develops an innovative product that falls under scope of MDR or IVDR is highly unlikely to have

invested in manufacturing capabilities or contain regulatory compliance expertise. CDMOs that are expanding their scope of work may have the opportunity to act as a partner across many stages of the product development process. We will investigate how these trends and others impact biopharmaceutical CDMOs in part 2 of this series.

About the Authors

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