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2016 | Contract Manufacturing Industry Trends

The contract manufacturing industry has changed dramatically over the last decade. As large pharmaceutical companies increase their focus on orphan and specialty drugs, they are also seeking ways to reduce operating expenses and remove excess capacity—which directly impacts contract manufacturing organizations (CMOs). CMOs, under similar pressures to reduce costs, improve efficiency and agility, and adhere to stringent global regulations, must consider the opportunities available in this highly competitive landscape. They must also determine if they want to make the investments needed to enter into the contract development and manufacturing (CDMO) arena.

Below are five key trends that contract manufacturers will need to consider and address in the coming year, along with strategic guidance for each.

01 | NEW GLOBAL GDP REGULATIONS

Good Distribution Practices (GDP) regulations are now harmonized by the World Health Organization and most global regulatory agencies,[1] with the intent to maintain the quality, safety and efficacy of products throughout the supply chain.[2] Since the new regulations share similar content and structure, the approaches that companies employ to secure the supply chain should be synchronized, as well. Life science companies, CMOs and distributors are incorporating changes into daily operations and evaluating potential business impacts—which may include solutions to transport product, new documentation requirements, or longer lead times as products go through customs—to ensure compliance.

02 | COLD CHAIN MANAGEMENT

With the new GDP regulations, companies must prove that their products have been moved through the supply chain in accordance with the products' FDA registered temperatures. There are a range of solutions, from lower cost thermal covers to more sophisticated transport with GPS and alarmed sensors. In addition, many of the top global logistics providers predicted more stringent global regulations regarding the movement of temperature-sensitive products, so they already have supporting infrastructures in place. However, due to reduced profit margins, reliance on multiple logistics providers, and lean organizational structures, CMOs may not have the resources to address this issue.

03 | SUPPLY CHAIN EFFECTIVENESS

Through corporate reorganizations, downsizing and budget reductions, many companies have lost focus on operational metrics and compliance with internal processes. With increasing turnover, and the importance of effective knowledge capture and transfer, renewing the emphasis on core supply chain processes—such as production planning, capacity planning and sales and operations planning—is critical. With in-control processes, CMOs can improve metrics (through a more efficient supply chain), reduce issues during day-to-day operations, and decrease costs of product write-offs, allowing employees to focus on core competencies and areas of improvement.

04 FOCUSING ON CUSTOMER SERVICE

Due to Big Pharma spinoffs and facility closures, many CMOs and new-to-the-market investment firms now have high volume manufacturing sites and packaging equipment, with more small volume customers. With tight profit margins and strained resources, some CMOs are struggling with how to best serve their customers. Large-scale changes that improve customer service requires CMOs to invest in new areas, such as project management, contract development & execution, enterprise technology, capacity management and quality. These efforts often involve bringing in new in-house resources or skilled external partners to assist with implementation and change management.

05 INNOVATION & DIFFERENTIATION

The contract manufacturing model has traditionally offered customers lower costs, improved flexibility, increased order turnover, and reduced product transfer timelines. Today, however, CMOs are under mounting pressure to increase profit margins as core pharmaceutical manufacturing capabilities become commoditized. Traditional CMOs need to determine if they are going to add the scientific and development assets necessary to move upstream in the pharmaceutical value chain, or if they will continue to compete through scale and price. Whether considering emerging opportunities such as biosimilars or adding assets, CMOs should examine their core competencies and determine how to best partner with pharmaceutical clients to capture market share in an increasingly crowded landscape.

RELEVANT INSIGHTS

- Report: *2016 Life Sciences Trends*
- Interactive Report: *Leading Global Serialization Programs*
- Viewpoint: *Strategies for Global Serialization and Track & Trace Implementations*
- European Commission: *Guidelines on Principles of Good Distribution Practice of Active Substances for Medicinal Products for Human Use*
- Health Products Regulatory Authority: *Guide to Good Distribution Practice of Medicinal Products for Human Use*

REFERENCES

1 European Commission for Public Health. “Medicinal Products for Human Use: Good Distribution Practice.” European Commission website. Retrieved November 15, 2015.

2 United States Pharmacopeial (USP) Convention. Briefing on General Chapter <1083> Good Distribution Practices – Supply Chain Integrity. December 20, 2011.

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