Enabling CDMOs to focus on core priorities

Outsourcing supply chain and buffer preparation activities

As the biopharmaceutical market evolves and continues a steep upward trajectory of growth, biopharmaceutical drug innovators increasingly rely on contract development and manufacturing organizations (CDMOs) to help them achieve their mission.

The CDMO market segment is expected to achieve a CAGR of 11.3% by 2024.[1] There are several factors contributing to this growth:

- An increase of emerging innovator companies without the resources to scale-up quickly to commercial manufacturing
- A shift in therapeutic trends toward gene and cell therapies, biosimilars, and the emergence of monoclonal antibody-based (mAb-based) modalities under development, including antibody drug conjugates (ADCs), fusion proteins, and bispecific antibodies (bsAbs)
- A continued increase of traditional modalities such as mAbs, vaccines, and classical recombinant proteins

Given this growth and the reach it has across the Americas, Europe, and Asia-Pacific, it is critical that CDMOs are strategic in their growth models, finding ways to focus on unmet needs, deliver innovative solutions to capture investment opportunities, optimize costs, and reduce inefficiencies.

Successful growth requires focus on core areas

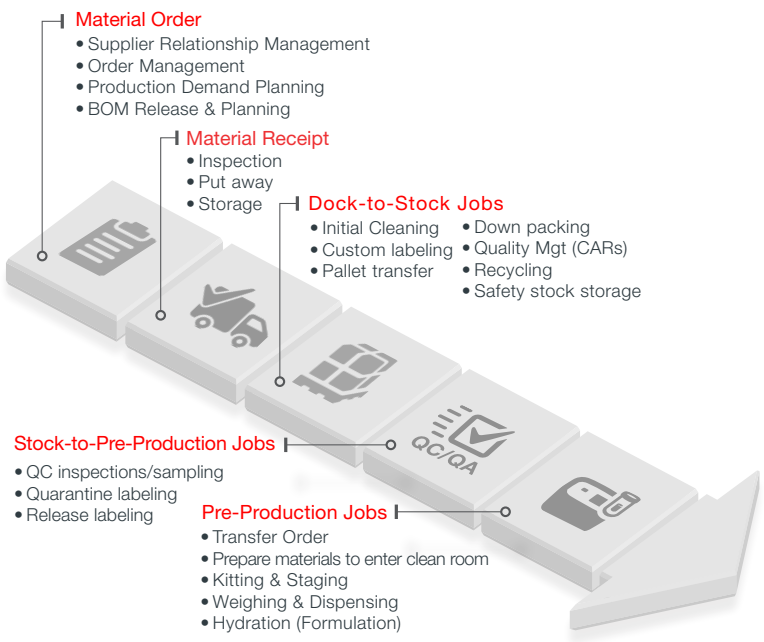
The work of CDMOs allows major pharmaceutical companies to outsource aspects of their business, enabling them to scale their manufacturing and focus on drug discovery and drug delivery. Just like their client partners, CDMOs need to focus on their core mission to develop and manufacture drugs for their clients. Since CDMOs are paid a contracted rate, controlling operating costs and focusing intellectual resources are business necessities to remain competitive and deliver value to their stakeholders.

Pre-production processes are costly and distracting

For CDMOs, their focus should be on optimizing the manufacturing process, improving speed-to-market for their clients, and delivering accretive value to their shareholders. As such, a well-managed CDMO will seek out cost effective solutions for any non-core activities leading up to the core production jobs involving drug manufacturing. See examples of non-core, pre-production activities in Figure 1.

While these pre-production activities pose financial and operational challenges for most CDMOs, it is possible to partner with industry experts that can help CDMOs streamline these workflows. Such an industry collaboration with specialized partners generally results in greater efficiencies, lower operational costs and avoidance of capital expenditures, which are difficult to realize when trying to build pre-production capabilities in house.

Figure 1. Supply Chain and Pre-Production Activities



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Partnership to accelerate drug manufacturing

At the core of all drug manufacturing is the use of cGMP, multi-compendial production chemicals. In the area of supply chain management, the selection of a cGMP distribution partner enables consolidation of spend, leverage of the distribution partner's supplier management capabilities, and improvement of supply chain performance. A customer-focused distribution partner will perform critical dock-to-stock jobs and stock-to-production jobs. Additionally, they will maintain inventory of critical materials, on behalf of the CDMO, for assurance of supply and provide just-in-time (JIT) delivery at the chosen manufacturing location such that maintaining on-site safety stock inventory is minimized or eliminated.

Beyond supply chain solutions, customer-focused cGMP chemical suppliers are innovating further by providing CDMOs with process liquid/buffer workflow solutions—pre-weighed and dispensed dry powders and pre-made process liquids/buffers. This type of partnership simplifies the process liquid/buffer preparation workflow so that the CDMO can intensify their focus on optimizing and executing the drug production process itself.

Mapping the process to find the pain points

Since different CDMOs have different manufacturing workflows, designing an appropriate workflow solution requires a sophisticated and detailed analysis of the CDMO's pre-manufacturing process. Best practices include performing a Gemba Walk of the work area to create a process map and analyze the pre-manufacturing workflow. Subsequently, Lean principles are applied to identify bottlenecks and propose solutions. For maximum impact, a Gemba Walk should include the entirety of the supply chain journey, from supplier selection all the way to pre-production weighing, dispensing, and hydrating/formulation of chemicals.

Industry leading chemical workflow solution providers, such as Thermo Fisher Scientific, have expanded their capabilities in the streamlining of pre-manufacturing workflows. By starting with a fact-based assessment of the pain points and designing a full end-to-end solution, the result is a tailored workflow which is managed by the chemical solution provider on behalf of the CDMO. The total solution—including the procurement of raw materials as well as the required handling and preparation steps—results in significant aggregated cost savings for the CDMO.

A complete chemical workflow solution provider adds value with:

- **Full supply chain support**, with JIT delivery of QC/QA released material
- **Trusted-weight dry powders**, with customer-specified chemical (brand and grade) in a customer-specified container (brand and configuration)
- **Pre-made liquid solutions**, with customer-specified formulation in a customer-specified container (brand and configuration)

As a direct result of improving operational efficiencies in the process liquid/buffer workflow, these workflow solutions reduce total cost of ownership of raw materials. Furthermore, it is possible to eliminate or greatly reduce the capital infrastructure required to manage the movement, storage, weighing and dispensing of production chemicals. Therefore, a chemical solution provider such as Thermo Fisher can reduce a CDMO's ongoing operating expenditures (OpEX) as well as the need to invest in capital expenditures (CapEX) for equipment and facilities.

These types of full-service workflow solutions result in a turnkey customer experience. They also refocus the organizational mindset of the CDMO toward their core mission: to be a manufacturing partner to support their customers to deliver innovative medicines for patients.

References

1. MarketsandMarkets. *Pharmaceutical Contract Development and Manufacturing Market – Global Forecast to 2024* (2019): 28.

Learn more at: **thermofisher.com/simplifybufferprep**

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