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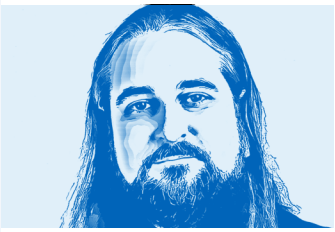

Outsourcing Drug Development and Manufacturing: How CMOS/CDMOS Drive Industry Growth

Tristan Passeggiati
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Tristan holds a Bachelor of Science (B.S.) degree in Biochemistry from Rutgers University. He brings a wide range of experience in sales and business development, including expertise in fluid management, contract research and manufacturing, as well as instrumentation. In addition, he has a background as a research biochemist and analytical chemist.

Over the last few years, the pharmaceutical industry has not only seen an exponential increase in supply and demand, but also a positive evolution in regard to the process of drug production in order to get products out to the market as quickly as possible without compromising quality. As the demand for vaccines and therapeutics increases, the influx of liquidity invested in drug development and manufacturing increases, along with costs. As a result, manufacturers must approach their product expansion from a business perspective. Questions that should be explored are: do we have enough budget, equipment, and space to be able to produce and are we optimizing the most out of our resources? That's where contract manufacturers come in handy and pharmaceutical sponsors rely on them more than ever. "Trends are very positive, and analysts predict that the CMO market will increase by almost 50% by 2025, reaching a global value of 162.1 billion US dollars."[1] While CDMOs focus on aiding in the drug development process and occasionally the manufacturing phase and CMOs strictly conquer manufacturing commercialized drugs, both are heavily used in many aspects of the medicine creation process depending on what type of product, at what scale of operation, whether the product is niche or not, whether specialty equipment and machinery are required and more.

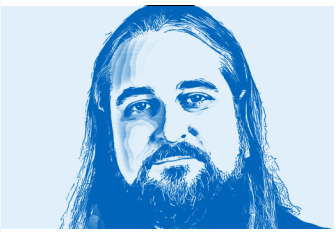
"Trends are very positive, and analysts predict that the CMO market will increase by almost 50% by 2025, reaching a global value of 162.1 billion US dollars.

Here are several ways that CMO and CDMOs companies benefit both small and large pharmaceuticals:

MINIMIZING EXPENDITURE AND MAXIMIZING FINANCIAL EFFICIENCY

Manufacturing pharmaceuticals come at a high cost and many small biotech companies lack industry knowledge, resources, and equity to be able to develop and deliver products in-house. "Cost pressures for generic products have been consistently rising for many years. Profit margins have been continuously squeezed, making control of drug development and manufacturing costs essential."[2] Pharmaceutical organizations can have greater financial flexibility by converting fixed costs into variable costs by relying on CMOs and CDMOs, which also lowers capital investment on premises and equipment.

[1] https://wp.pharmaoffer.com/blog/what-are-cmos-and-cdmos/
[2] https://www.pharmasalmanac.com/articles/maximizing-outsourcing-benefits-for-virtual-pharma-companies



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ACCESS TO ADVANCED TECHNOLOGIES

One of the essential reasons behind the increase of CMO and CDMO usage in pharmaceutical development is the growth of drug discovery techniques using AI. AI based discovery techniques significantly reduces research expenses and shortens the time it takes for novel pharmaceutical entities to hit the market. But because AI is still a newly integrated advanced technology with a naturally evolving nature in the development and production process, CMOs and CDMOs are beneficial in that they provide accessibility to specialized technology and machinery that can enhance a product's quality, yield, and scalability without the primary business having to make a direct investment in advanced equipment.

"Relying on the experience and resources of outsourcing partners can drastically cut down on the amount of time needed for commercial production and scale-up, resulting in novel medications reaching the market more quickly.

INCREASED SPEED TO MARKET

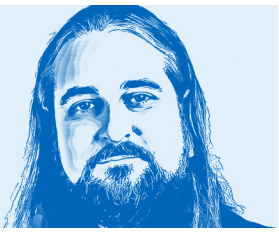
Relying on the experience and resources of outsourcing partners can drastically cut down on the amount of time needed for commercial production and scale-up, resulting in novel medications reaching the market more quickly.

SCALABILITY AND FLEXIBILITY

Without having to make new investments in internal capacity, outsourcing enables pharmaceutical companies to quickly modify production levels in response to changes in the drug development pipeline or market demands. This is particularly beneficial for smaller biotech companies looking to scale up, or even large pharmaceutical companies looking to develop and deliver new or niche products that require specific manufacturing techniques or specialized facilities.

EXPERTISE IN COMPLEX FORMULATIONS

The use of CMOs and CDMOs are typically divided by their differences in services whether they're aiding in the development phase versus the production stage, however, they can also be contracted based on product groups. The increasing complexity of new pharmaceutical formulations, including biologics and cell and gene therapies, requires specialized manufacturing processes and knowledge that CMOs and CDMOs are more likely to possess.



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FOCUS ON CORE COMPETENCIES

Companies that benefit from CMOs are anywhere from small startups all the way to big pharma. By reaching out a hand to CMOs who focus on the production aspect of an already commercialized drug, pharmaceutical companies can delegate their resources and efforts on key areas such as research and development, marketing, and drug discovery. Although a CMO can certainly aid in the development process, its main aim is to tackle the complexities of production for a company contracting them.

REGULATORY COMPLIANCE AND QUALITY ASSURANCE

As production volume increases and biotech companies tackle the bottlenecks that come with upscaling, pharmaceutical businesses can lower their risk of compliance difficulties by relying on CDMOs to utilize their own quality management systems, certifications, and expertise in navigating the diverse regulatory environments of certain new or niche drugs and the overall growth of production.

Although,contractors have many positive and beneficial attributes in the development and manufacturing process of therapeutics, they also have their own disadvantages. Since,CDMOs and CMOs act as a third-party liaison, a successful partnership requires better communication. If there is a lack of in visibility and consistent communication, there can be blackout areas for your business in certain parts of the manufacturing process such as packaging and shipping, which can create delays and possible errors. Furthermore, as the contracting company, you have the responsibility to make sure all your contractors are abiding by FDA regulations. Without thorough research, transparency, and communication, the consequences of not following regulations can fall back on your business.

Despite the outlined potential challenges of working with an external contractor, CMOs and CDMOs offer great approaches toward a private label process that ultimately reduces costs, meets production needs, reaches volume goals, and increases speed of product delivery while ultimately maintaining safety and quality. Beneficial for new and small organizations to big pharma, contract development and/or manufacturing is the solution to increased demand and production of novel drugs that are used to combat increasingly complex illnesses.

Questions?

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