# How Collaborative Value Engineering and Continuous Improvement Enhance the CDMO Relationship

Regular assessments of a partnership's value in terms of supply chain, operational efficiency, data analysis, and more can optimize and extend the product life cycle.

The search for vaccines and treatments throughout the COVID-19 pandemic, combined with the backlog of non-COVID therapies that piled up during the pandemic's initial months, has driven a surge in demand for contract development and manufacturing organization (CDMO) production capacity. As CDMOs have transformed to meet that need — adding new facilities and equipment, as well as introducing operational strategies to overcome burdens related to the pandemic — the challenge for commercial pharmaceutical companies has evolved from simply finding a CDMO partner with adequate capacity. Pharmaceutical companies now require a rightsized partner that shares similar values and vision, as well as an understanding of the competitive hurdles and market dynamics they must navigate.

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Commercial pharma companies require a CDMO partner focused on continuous improvement and value engineering to maintain viable margins: cost structure and supply chain risk mitigation, as well as overall product portfolio management. This need is particularly pressing for pharma companies operating in the generics or branded over-the-counter (OTC) spaces, since extending the product life cycle depends on lowering costs in response to competition-driven price pressure. To this end, a collaborative partnership model is effective in optimizing profitability management and product life cycles.

## About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,300 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

## Collaboration is Rewarding, But Challenging

Pharma clients can engage CDMOs in a multitude of ways. Some companies might manage their CDMO through a basic procurement team, simply to maintain an inventory of pharmacy-only products. Other pharma companies have more elaborate structures involving multi-functional personnel. Although such companies are better equipped to allocate resources to CDMO collaboration aimed at process improvement, the individuals involved usually have numerous internal priorities that prevent them from having the bandwidth to fully engage their CDMOs.

In any scenario, understanding the value in CDMO collaboration to serve value engineering and cost structure improvement is critical. However, the need to mitigate cost increases, or to cut costs where possible, also renders many pharma companies unable to effectively create sustainable collaborative structures, which require time, relationship-building, and investment to thrive. Rather than a demand/deliver mentality, portfolio management means working as a group to identify and leverage opportunities together.

Similar to many other aspects of the client/CDMO relationship, early engagement (as early as the bid process) is vital. It empowers the partners to find more opportunities, with greater impact, to align on value creation and continuous improvement, helping the client to maintain or increase its market share. Of course, this is not always possible. Some clients may be having supply issues; they are open to value engineering, but they require product transfer as soon as possible. This is suboptimal from an operational excellence standpoint, as it is more effective and less costly to optimize the process before it is transferred, versus attempting to improve the process once it already has been installed in a new facility. This exercise can be fruitful for equivalent volume transfers, scale-ups, and downscaling efforts alike.

## Value Engineering Through Collaboration

Cambrex leverages several strategies to value engineer processes surrounding existing commercial products. We start by assembling a dedicated, cross-functional team touching on all impactful areas, including quality, regulatory, process engineering, and procurement. That team identifies opportunities to create value and presents its findings to the client (be it a similar cross-functional team or a project management team). Then, both parties align on priorities and present their findings, as well as proposed solutions, to their corresponding senior leadership on a monthly, quarterly, semi-annual, or annual basis. Based on that information, leadership at both Cambrex and the client can appr ove an aligned, regularly updated strategy that considers changing priorities and upcoming milestones.

A key benefit of collaborative focus on continuous improvement and value engineering is data sharing: Cambrex can provide clients with access to trend data that can assist in decision-making. Moreover, our internal teams can sift through and contextualize that data for clients. Clients can cross-reference that information against data they already possess — about market, about forecast variation, about all kinds of metrics — generating useful insights on specific products.

Risk mitigation is at the heart of this exercise, which often begins by assessing supply chain vulnerability — an evergreen pharma concern exacerbated by disruptions resultant of the COVID-19 pandemic. At Cambrex, these challenges prompted analysis of all client products in terms of supply dynamics like raw material lead times, shipping risk, and anything else that could impact our ability to supply. Then, we met with clients to discuss obstacles to on-time delivery of their products, an exercise that included providing a list of all materials on our radar for risk of disruption. Solutions then could be devised through manufacturing process efficiencies, alternative sourcing of raw materials/APIs, and purchasing frequency adjustments, to name a few.

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Collaboration is critical in these exercises because each party is subject to both risks and benefits ( e.g., cost savings). For example, with respect to alternate raw material sourcing, pharma clients may be reticent to tweak a formulation because the need to validate a new material could expose them from a regulatory perspective (i.e., agency review of the file submission may lead to older products becoming subject to new more contemporary data requirements). Accordingly, the partners must be strategically aligned regarding the products and molecules undergoing value engineering exercises.

Consider, too, minimum order quantities (MOQs) related to acquisition of excipients or API. MOQs dictate how much can be purchased at once to derive cost benefits from economies of scale, viewed through the lens of expiration date and excess inventory management. Both pharmas and CDMOs are reluctant to carry excessive inventory because, if the market collapses and their contract with the client does not contain provisions related to inventory, they could be left to absorb that cost.

The same principle applies to packaging: packaging operations, component selection, and purchasing strategies have a crucial impact on profitability and logistics costs. Value engineering and collaboration can provide not only financial benefits, but improved CDMO efficiency, which contributes enhanced service quality. For these reasons

and more, it is important for collaborating CDMOs and the pharma clients to create contractual obligations for most elements of the partnershi. These elements could include meeting frequency, milestones, and continuous improvement stipulations — essentially codifying the agreed-upon culture, structure, and mechanisms within contracts between the CDMO and the customer. These usually represent unilateral targets and are increasingly common in such contracts.

In short, continuous improvement means constant reassessment. Regular back-and-forth sessions between cross-functional teams allow each partner to regroup and reassess. Contracts need not be set in stone; the reality of the market, client needs, or internal CDMO needs can evolve, and it makes more sense to adjust to those factors regularly, versus ending up with a woefully obsolete contract after a year or two. In such scenarios, one partner may end up in breach of the contract or in conflict with the other party, undermining the benefits each side should be drawing from the partnership.

## Final Thoughts

Collaboration between CDMOs and pharma clients can occur at many different levels. Some pharma companies are very hands-on with their products and know exactly where they would like to focus value engineering efforts. For example, a recent Cambrex client started working with us as they closed their own liquid facility plants, so they had deep knowledge of their products, testing, and operations. Conversely, a client transferring its product from another end-to-end CDMO after a decade of partnership might not have detailed knowledge of the manufacturing process.

Cambrex embraces the fact that all organizations have a different definition of " turnkey". We respect that some companies' improvement efforts are finance-driven, while others may stem from security of supply. Regardless, time constraints nearly always dictate whether, or how much, we can value engineer. In some cases, the process already is optimized. We shape our approach accordingly, providing services that address specific product needs we've identified together with the client. Philosophically, the same elements guide e very partnership; the deliverables simply change based on client need and culture.

### Authors


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