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WHITEPAPER

Telltale signs you're with the wrong CDMO

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Abstract

Late-stage drug development efforts have many moving parts as projects push toward commercialization. During this critical time, companies often take a good long look at their vendors and evaluate their options for scale up to commercial launch. Is your CDMO an asset or a hindrance in this process? How can you recognize whether your partners really contribute everything they can to your end goal of commercialization?

This whitepaper focuses on 10 red flags that could signal it is time to start looking elsewhere for a CDMO that can efficiently bring your project to commercialization while steering clear of potential roadblocks along the way.

Your network of partners is complicated.

Some drug developers believe it takes a village of vendors to bring a molecule through development and into clinical and commercial production. A network of vendors can quickly balloon to upward of 10 partners, including a cell-line developer and master cell-banking services for biologics, a process development specialist, a clinical manufacturer, a commercial manufacturer, analytical testing providers, packaging experts and regulatory consultants.The risks associated with using several different vendors include inefficiencies, communication issues and delays in decision-making. Ultimately, these risks can lead to overall timeline delays, additional costs and redundant work.

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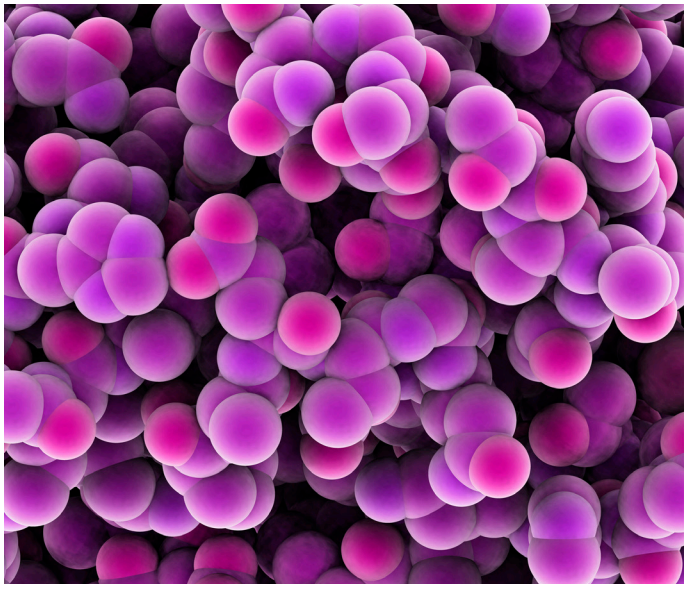
Innovators—many of which are up against tight development timelines—could greatly benefit from streamlining their vendor network. For instance, the Quick to Care™ approach for large molecules and the Quick to Clinic™ program for small molecules from Thermo Fisher Scientific simplifies multiple vendor relationships with just one to manage for the entire process—including drug substance and drug product manufacturing, transportation and storage, clinical trial packaging and labeling, as well as clinical trial distribution.

With these programs, three to four lead team members work on each program and a program ambassador oversees all activities and serves as a client's main point of contact. The program ambassador controls the timeline, facilitates the transfer of information and drives the completion of activities.

You're stalled moving from drug substance to drug product.

Significant efficiency is gained by doing concurrent drug substance and drug product work. When these teams work closely under the same umbrella, developers can avoid redundant activities and delays when releasing materials for drug product manufacturing. For instance, projects leveraging the Quick to Care or the Quick to Clinic network can overlap drug substance and drug product preparedness efforts and reduce testing requirements normally required during transfers, thereby slashing timelines by up to 1–1.5 months. This kind of efficiency is impossible to achieve when using separate suppliers.



Moreover, a project manager that is in close communication with both the drug substance and drug product teams can schedule concurrent activities with an eye on efficiency. For instance, he or she will be in a position to match a drug product fill date with the drug substance release date, which is an especially important advantage in the biopharmaceuticals market because drug product manufacturing slots tend to book up several months in advance and lead time is even longer for drug substance manufacturing.

Vendors have limited regulatory and CMC expertise.

Researchers have estimated that the probability of a drug molecule successfully making it through drug development and into commercialization is just 13.8%.[1] While numerous issues can derail a project, one common mistake is not collecting the correct chemistry, manufacturing and controls (CMC) information, or enough of it, to ensure a successful biologics license application (BLA) or new drug application (NDA).

It is a huge risk to work with an inexperienced partner who cannot leverage experience from past projects similar to yours, and who cannot anticipate what data the agency requires for your molecule.

Such partners likely do not have established processes for validation, scale up and commercial launch, and may not be able to recognize project challenges or identify gaps in your CMC package.

It is absolutely critical to work with a CDMO that has the experience and expertise to understand the regulatory requirements and mitigate the risks for your molecule and manufacturing process.

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Experts will be accustomed to using quality-by-design approaches to ensure that there are no gaps in a BLA or NDA and will not rush to develop methods for Phase I or II work that may not hold up down the road.

A CDMO partner with this high level of expertise will help ensure that your process characterization and process validation studies are designed appropriately to cover all potential risks and demonstrate to regulatory agencies that your process is controlled, as well as that all of the risks to product quality associated with the process were evaluated.

Forecasting of biopharmaceutical raw materials supply is not done well.

The production and storage of biologics is expensive, thus accurate forecasting is critical. Overestimating supply will waste resources, while underestimating could create empty pipelines for several months.

While no CDMO has a “crystal ball,” partners like Thermo Fisher Scientific can leverage standardized platform processes and platform analytics for a variety of products, making forecasting faster and more predictable. In addition, strong supplier relationships will enable critical materials to be secured quickly and expedited to meet demand, while still maintaining the necessary testing, characterization and any other supporting data required.

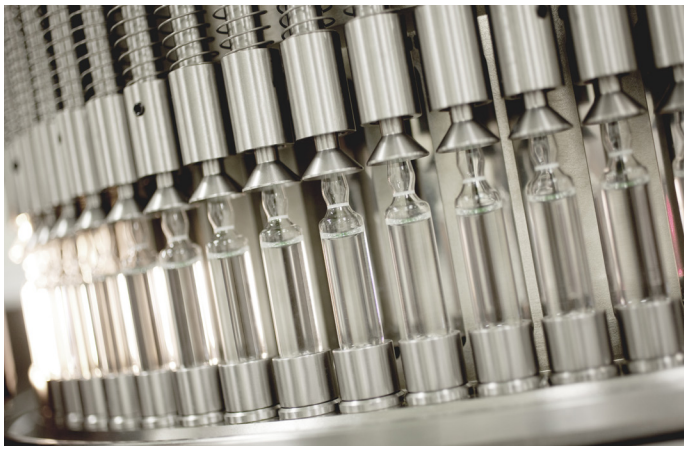
Your partner misses/pushes back deadlines.

Timing is critical at each stage of the development and commercial launch processes. Several activities must align for the optimal timing of clinical studies, regulatory filing dates and commercial launch dates. Moreover, hitting development milestones is often tied to securing funding from investors for smaller biopharmaceutical companies.

While delays due to unforeseen events are sometimes unavoidable, using an experienced CDMO can lead to fewer timeline slips because they can anticipate challenges and be proactive rather than reactive. Moreover, committing to a timeline and working with a project management team is extremely helpful for risk mitigation. When a deadline is missed, experienced teams will work together to deliver the best solution for the CDMO and the customer.

Your partner cannot accommodate timeline changes.

It's important to mitigate risks in processing and bioprocessing as much as possible, but it's equally important for CDMOs to quickly rework their schedule to accommodate customer needs. Such flexibility starts with having good communication between the client and CDMO partner in addition to a central project management team handling (and working to condense) timelines and eliminating redundant activities among drug substance and drug product teams.



Your current CDMO can't manage your product at the next scale or clinical phase.

Having the ability to stay with the same CDMO for small-scale work and high-volume production—and all activities in between—is a big advantage in a competitive market. When a small CDMO only has small-scale equipment and cannot produce drug substance or drug product at larger quantities, clients risk having to extend timelines as they identify a new partner, coordinate transfers and wait for an open fill slot.

Likewise, CDMOs that specialize in small-scale work or high-volume products may lack mid-scale equipment that is often needed to develop and launch orphan and rare drugs. Having access to a full breadth of end-to-end services can pay dividends as clients seek to get to market quickly and efficiently.

Your vendor only works with their own proprietary technology.

Many CDMOs will only consider fitting client projects into their rigid proprietary technologies. When CDMOs offer no flexibility in important areas such as cell lines, formulations and manufacturing technology, the customer must consider the risks of unnecessary process changes, potential impact to product quality or increased costs from royalties and licensing fees. When clients are not bound by one choice of platform (whether it's a cell line or piece of equipment), developers can customize an approach that's right for the project and the molecule, and not just the CDMO.

Having access to a full breadth of end-to-end services can pay dividends as clients seek to get to market quickly and efficiently.

Experienced and knowledgeable partners will be able to draw on their experience and network to create flexible solutions for every project, whether it is choosing from among various cell lines to optimize development, or condensing timelines with single-use bioreactors. A good partner can pivot and shift to accommodate the customer's needs.

The breadth of analytical services is limited.

Some CDMO customers utilize third-party vendors for their analytical needs, often because their production or development site does not have strong analytical development capabilities. This can lead to other issues that include shipping errors, delays at the testing site or difficulty in remediating when errors occur. Using third-party services can also compound inefficiency.

Most vendors will not have every assay or test that the client requires, forcing the client to use multiple third-party analytical labs. Conversely, Thermo Fisher Scientific has strong analytical and formulation development capabilities as well as quality control labs to support process development and drug substance/drug product manufacturing needs, greatly minimizing the need for third-party testing.

Leveraging multiple vendors to manage the analytical requirements for a biologic development and manufacturing project could potentially add months to the timeline.CDMO cannot meet your expectations.

The choice of CDMO may well be one of the more important factors in ensuring a project efficiently and cost-effectively progresses to commercialization.

Projects can fail as a result of poor communication and lack of transparency between a CDMO and the client. Clients must be honest with themselves as they evaluate their relationship with their CDMO. Is your CDMO transparent about challenges? Does your partner escalate problems appropriately and efficiently?

Does the CDMO drive communication about the project's timeline and ensure milestones are met? Do they deliver a high-quality product? Is your project manager accessible? Are you functioning as one team striving to meet a common goal? If the CDMO is over-promising and under-delivering in any of these areas, it is time for the client to move on to another partner.

Summary

The choice of CDMO may well be one of the more important factors in ensuring a project efficiently and cost-effectively progresses to commercialization. When activities align, as in the Quick to Care and Quick to Clinic programs, efficiency is gained from better communication among drug substance and drug product teams, fewer redundant activities, project manager-controlled timelines, overlapping scheduling of drug substance and drug product groups efforts, a seamless transition between groups and more.

Moreover, when CDMOs have significant experience with late-stage work—and a diverse toolkit for accommodating a wide variety of projects of varying scale—they can better anticipate and avoid issues that could be problematic for scale up and approval. And as commercial demand changes over time, CDMOs should be able to support added demand and even build redundancy across the network. Ultimately, the biopharmaceutical development process is filled with risk and has many potential areas for issues to surface; your CDMO should not be among these challenges.

References

1. Chi Heem Wong, Kien Wei Siah, Andrew W Lo, Estimation of clinical trial success rates and related parameters, Biostatistics, Volume 20, Issue 2, April 2019, Pages 273–286, https://doi.org/10.1093 biostatistics/kxx069

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

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Christy Eatmon supports the Global Sales and Business Development teams in providing technical support, designing strategies and supporting new business opportunities for Thermo Fisher's sterile manufacturing business. Christy has more than 15 years of experience in the pharmaceutical industry with an emphasis on process engineering, product development, aseptic manufacturing and filling. She has working knowledge of all phases from drug discovery to sterile product commercial manufacturing with expertise in small and large molecule sterile formulation. Previously, Christy supported the Greenville, North Carolina, site as a Senior Principal Scientist in the Commercial Operations and Pharmaceutical Development Services areas.

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Frank Ritacco has a PhD in Microbiology and Molecular Genetics from Rutgers University, and over 20 years of experience in the pharmaceutical industry. Prior to joining Thermo Fisher Scientific, Frank has worked at Bristol-Myers Squibb, Unigene Laboratories and Wyeth Research. His areas of expertise include mammalian cell culture, microbial fermentation, cell line development, media development and optimization, process development, scale-up, tech transfer, and clinical manufacturing. In his current role at Thermo Fisher, Frank oversees new technology development in the Bioprocess and manufacturing sciences, driving scientific innovation and collaboration between internal and external partners, and also serves as a technical subject matter expert and point of contact, interfacing with customers and the biopharmaceutical community.

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