Article | November 10, 2022

10 Ways to Improve Your CDMO Partnerships

By Joyce Lifland, PhD, Senior Sales Executive, Apprentice

In 2021, the pharmaceutical Contract Development and Manufacturing (CDMO) market size was valued at $186.62 billion, and is expected to grow to a whopping $289.64 by 2027 — representing a compound annual growth rate of 7.29%.

Although the market is poised for rapid growth, various challenges related to the pandemic (including a massive uptick in demand) have resulted in long CDMO lead times, supply shortages, and visibility issues.

In this article, we'll explore what CDMOs are, why they're necessary, and ten ways pharma companies can improve their partnerships — regardless of market conditions.

CDMOs: An Overview

What are CDMOs?

Contract development and manufacturing organizations(CDMOs) are companies that offer a wide range of services related to drug development and manufacturing. CDMOs do everything from R&D to clinical manufacturing and commercial production.

Pharma companies partner with CDMOs to accelerate innovation by outsourcing some (or all) of their development and manufacturing needs. It's a mutually beneficial relationship that saves pharma companies valuable time while also reducing infrastructure costs such as those associated with equipment, facilities, and labor.

Most importantly, pharma companies can remain agile and respond quickly to changing market conditions — which is crucial to maintaining a healthy bottom line and competitive advantage.

"CDMOs are a crucial piece in the pharmaceutical industry that helps bring treatments to patients faster. They provide manufacturing capacity and development expertise to early startups with innovative drugs. They also help free up manufacturing capital in large pharmaceutical companies so they can invest in new pipelines."

CDMO vs CMO: What's the difference?

Although you may hear people use CDMO and CMO interchangeably, these organizations serve different purposes.

A CDMO is an organization that provides everything needed to successfully develop and manufacture new and existing products, from start to finish. Think of it as a full-service solution that can meet you wherever you are in the drug innovation or production lifecycle.

In contrast, a CMO focuses solely on the manufacturing aspect of drug production. Pharma companies tend to leverage CMOs to save on equipment costs associated with mass production, especially during the earlier phases when approval isn't a guarantee.

Why are CDMOs necessary?

To understand why CDMOs are necessary, it's important to start with the brass tacks: drug manufacturing is a time-consuming, costly, arduous process. Only one in every 5,000 drugs screened will eventually make it to market. And this process takes about 12 years on average and can cost billions.

The bottom line? If you work in pharmaceutical manufacturing, the odds aren't in your favor.
However, CDMOs act as a safeguard. These organizations eat a lot of the typical risks associated with drug production because they have ready-to-go facilities, are staffed with seasoned experts, and can provide a level of agility and responsiveness that pharma companies need to navigate changing market conditions.

Common challenges to working with CDMOs

There are a number of issues that organizations may face when partnering with CDMOs.
These challenges include:

- Data delays and visibility issues
- Restrictions on imports and exports
- Communication across multiple platforms
- Supply demand versus availability

Left unaddressed, these challenges may create a ripple effect in the drug production lifecycle, resulting in costly delays and resource waste.

"The two main challenges can be summarized as supplies and speed. Demand for critical supplies remains high from manufacturing, healthcare, and other essential businesses and nations continue to ramp up stockpiling measures."

"For CDMOs, the pandemic levels of activity continue. Disruption sets a new bar and becomes the norm. At the same time, we have to move at extraordinary speed and the needs change quickly, demanding extreme agility."

In the next section, we'll walk you through 10 ways you can proactively address these challenges to ensure a harmonious partnership with your CDMO.

10 Ways to Improve CDMO Communications

Tip #1: Have a "Partner-First" Mentality

The right CDMO will act as your co-pilot. It will help you navigate the various ebbs and flows of drug development and manufacturing, even when market conditions are uncertain.

As such, it's important to maintain a partner-first mentality. This means, you know exactly what your partner's needs are (and vice versa), and you deliver. In the case of drug manufacturing, a good starting point is with your tech transfer (TT) package.

Tech transfer is the process of sharing information between organizations. This information may include manufacturing methods, knowledge, software, intellectual property, technologies, skills, or other data.

In pharma, tech transfer refers to the process of sharing pharmaceutical manufacturing data and knowledge across stages, sites, and teams. To ensure a successful tech transfer with your CDMO, consider their most pressing needs so you can prioritize addressing the knowledge gaps that will be the most crucial to their success.

If you aren't sure where to begin, check out this article, which outlines our top 10 recommendations for optimizing your TT process.

Tip #2: Connect Key People

When it comes to successfully manufacturing new drugs through a CDMO, it's crucial that the right people get connected (and stay connected), at the right time. Any lapses can result in costly errors for both organizations.

To avoid unnecessary issues and downtime, supply your CDMO's team with the contact information for the key people, such as project managers, who are associated with each initiative. This should include the names, phone numbers, email addresses, and any other insights pertinent to the project. In conjunction, request the same information from your CDMO team to ensure you have a direct line to the people involved.

Also, make sure to carve out time to make a formal introduction on both sides. A little facetime goes a long way (be it virtually or in real life), and allows stakeholders to build the rapport necessary to navigate future challenges or setbacks.

Tip #3: Be Transparent

As with anything in business, communication is key.

Be transparent throughout the drug manufacturing process to ensure everyone gets on — and stays on — the same page. If there are any issues that arise throughout (on either side), make sure to address them proactively.

Ultimately, the clearer you are about your expectations, the easier it will be to communicate discrepancies.

When planning communications with your CDMO, consider cloud-based solutions that can provide real-time data transfer and visibility. This will ensure everyone stays on the same page and can allow multiple organizations to work as one team from anywhere, at any time.

Better yet, find a collaboration platform that's purpose-built for the life sciences to ensure compliance with clean-room and regulatory standards.

Tip #4: Digitize

Paper-based legacy systems aren't the most reliable sources when it comes to transcribing, capturing, and sharing important information — especially as it relates to pharma.

In fact, paper records lead to 62% of data breaches in companies with 500+ employees, which is bad news for your intangible assets (which make up 90% of the value of S&P 500 companies).

That's why forward-thinking pharma companies are adopting smart, AI-powered technologies. Not only do these systems allow these organizations to automate processes, maintain compliance, and reduce the likelihood of errors, but they also provide a detailed digital "paper" trail that can be shared across sites and teams.

"Using paper systems for CDMO manufacturing is inefficient because your capacity and capability is limited by your human capital. The manual model is not scalable, and you will be left behind by your competitors who can deliver faster and provide more transparency to their clients."

Tip #5: Outline Your Goals

You partnered with a CDMO for specific reasons; make sure those reasons are clearly communicated from the get-go.

This is important not only for alignment purposes, but also because CDMOs balance many clients at once. For example, there may be discrepancies between how you capture and transcribe deviation reports, versus how your CDMO does. And not all CDMO organizations have the ability or bandwidth to adapt their workflows and processes to mirror those of their clients.

Tip #6: Have an IP Agreement in Place

Intellectual property (IP) like trade secrets and patent-protected innovations and processes can be a sticky subject — especially when the findings occur externally. That's why we recommend creating a legally binding agreement that outlines who owns the IP.

In some cases, the IP may be co-owned, while in other cases the pharma company will maintain full ownership. Clarity is key because it means you'll mitigate the risk of costly legal battles in the future.

Tip #7: Review Failures; Restrategize as Needed

In pharmaceutical manufacturing, failures are bound to happen.

Oftentimes, failure is a good thing because it allows life science professionals to understand what's working versus what isn't, and tweak their approach based on these findings. However, sometimes failures are avoidable, and are the result of CGMP deviations, data capture, or quality issues.

Be proactive and review failures with your CDMO team, and work together to find a solution. Depending on the scope and complexity of your project, you may want to schedule a recurring monthly meeting, or approach this ad hoc, on an "as needed" basis.

Tip #8: Navigate Audit Processes Together

Regulatory bodies like the Food and Drug Administration (FDA) routinely inspect regulated facilities, such as drug manufacturers. This auditing process involves reviewing the systems, documents, and processes to ensure human and animal safety is protected.

As such, make sure you work with your CDMO to determine how you want to collectively tackle the auditing process. Not sure where you begin? Start with this article. It outlines a three-step process for surviving an FDA audit (and make sure you share it with your CDMO team too!).

Tip #9: Outline Regulatory Action Responses

When the FDA determines conditions violate the Food and Drug Cosmetic (FD&C) Act, it issues a Form 483. This form details the violations and objectionable conditions found during inspection.

It also requires a response. Failure to respond in a timely manner can result in pending applications getting denied or the revocation of distribution rights for existing products.

Save yourself the headache by outlining regulatory action responses in the event you or your CDMO is served with a Form 483. This will allow you to respond quickly and take corrective action sooner, rather than later.

Tip #10: Ask Questions

If you're uncertain about something, don't make assumptions. Be direct and ask questions. Chances are if you lack clarity, other stakeholders from your team or CDMO do too.

Drug manufacturing is a complex, multifaceted process — especially when key people are separated by time and distance. Keep the lines of communication open by asking questions as they arise.

Closing Thoughts: Connected Communication Is Key

Monitoring information on the status of a procedure, test method, or batch on paper requires operators to manually document every step.

This means that resource usage and records can only be reviewed periodically — and often post-completion. This is further exacerbated when the process is done through a CDMO, with status updates typically only being available through calls, emails, and meetings.

To counteract these challenges, you can leverage the real-time connectivity of digital solutions to build trust and transparency between your teams.

"Trust is critical to CDMO and their clients. Today, most pharmaceutical companies still feel like working with CDMO is like a black box because there's no transparency between the two.

Being able to build trust with your new clients faster and maintain the level of trust with your existing clients is the key to success for CDMOs."

Lack of real-time visibility into the production lifecycle results in costly delays, production deviations, and other issues. But it doesn't have to be this way. Instead, pharma companies can leverage smart technologies.

Tempo is specifically designed for multi-enterprise communications. It connects your organization to your CDMO partners so that every step of production is executed in concert, regardless of who owns it.

CDMO Comms: Point of View

"The pharmaceutical CDMO market focus has been shifting from small molecule to large molecule and CGT manufacturing. The balance is going to tilt even more towards large molecules and CGT with the recent advancement in personalized medicines.

To stay ahead of the game, CDMOs should invest and innovate now before it's too late. In the words of an old Chinese proverb: "The best time to plant a tree was 20 years ago; the second best time is now."

References

1. *Center for Drug Evaluation and Research. (2020, September 21). Current Good Manufacturing Practice (CGMP) Regulations.* U.S. Food and Drug Administration. https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations
2. *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs.* (2016). ScienceDirect. https://www.sciencedirect.com/science/article/pii/S2452302X1600036X

3. *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018.* (2020, March). NIH | National Library of Medicine. https://pubmed.ncbi.nlm.nih.gov/32125404/
4. Muenz, R. (2021, September 8). *Challenges and Solutions for Pharma CDMOs.* Lab Manager. https://www.labmanager.com/big-picture/pharmaceutical-development-solutions/challenges-and-solutions-for-pharma-cdmos-26407
5. *What Does It Mean to Be a Full-Service CDMO?* (2015). American Pharmaceutical Review. https://www.americanpharmaceuticalreview.com/Featured-Articles/180425-What-Does-It-Mean-to-Be-A-Full-service-Cdmo/

Source

10 Ways To Improve Your CDMO Partnerships (pharmaceuticalonline.com)