Striving for Clinical Trial Success?

It Starts with One Crucial Choice

Complex drug formulations, stringent regulatory standards, and a tough capital landscape are creating pressure for drug developers as they approach clinical trials. At this stage, a wrong decision could mean significant delays to a product's timeline, increased costs, and even jeopardise the success of years of research.

More than ever, drug developers need strategic thinking and expert support to begin their in-human trials. During this critical early development stage, the right Contract Development and Manufacturing Organisation (CDMO) can be more than a valuable service provider—they can be a vital partner.

As Director Supply Chain and Project Management at Vetter, my colleagues and I have successfully partnered with various customers from large pharma to start-ups to bring their new molecules through the process of clinical manufacturing for their in-human trials. Up to this point, Vetter has successfully conducted over 1,000 batch fills at its two clinical sites in the U.S. and Austria. In this article, I will outline how drug developers can focus on their key competencies but also what they have to consider to start the challenging path through early clinical phases.

Begin by Finding the Right Outsourcing Partner

Most pharmaceutical and biotechnology firms have expertise in drug development but may lack the necessary infrastructure, specialised knowledge, experience, or resources to manufacture clinical trial materials (CTM) at scale. This critical step of drug product development requires precise formulation, packaging know-how, and regulatory documentation, all of which are essential to manage the integrity of the in-human trial.

Fill and finish CDMOs focus on providing the CTM, such as filled vials or syringes, in accordance with regulatory standards. The drug products and accompanying documentation are then provided to the drug developers, who use them in their clinical studies. The global clinical trial supplies market size was estimated at USD 2.58 billion in 2023 and is anticipated to grow at a compound annual growth rate (CAGR) of 6.5% from 2024 to 2030.[1] As this market grows, selecting the right filling CDMO becomes even more critical for supporting a successful clinical trial. Here are some steps drug developers can take to evaluate and select the best partner for their unique molecule:

Step 1: Conduct Comprehensive Research

Before starting the search for an outsourcing partner, it's critical to thoroughly research potential partners that align with your criteria. Leverage resources such as online databases, industry publications, peer recommendations, and testimonials to gather insights. Check for important credentials like regulatory compliance. Gain an understanding of the different niches of potential partners, as some may have specific core competencies.

Step 2: Set Clear Objectives and Expectations

Having a solid understanding of your needs will help streamline the selection process and effectively communicate key requirements. Knowing your objective ahead of time will allow a potential partner to understand your needs.

Additionally, consider critical expectations regarding quality, timelines, budget, and deliverables. The ability of a manufacturing partner to meet the quality and scale requirements of a project is paramount. Biopharma companies benefit from working with experienced service providers who are familiar with a variety of molecules. This expertise enables the effective handling and manufacture of a wide range of compounds.

Step 3: Assess Fit and Compatibility

After narrowing down your options, evaluate the compatibility of potential partners with your needs. This can be achieved through consultants, interviews, site visits, reference checks or even audits. It's important to confirm that the partner's culture, values, and vision align with your own.

Long-term partnerships are built on early alignment and strong relationships. We currently work with a wide range of customers from over 20 different countries. These include the global big pharma and biotech companies, as well as start-ups developing their first compound. Looking more closely at our early clinical business, around 70% of our clients have less than 200 employees. Each customer and their molecule require a different approach, making each project unique.

Pay attention to their communication style, transparency, and how they manage feedback and change. Trust, respect, and collaboration should also be key factors in your decision-making process. Even if they are a top-performing service provider, they may not be the right fit for every drug development company. There is no harm in passing on a five-star partner if they're not suited for your specific needs. When exploring partnership options, remember to think beyond current requirements. Look for a CDMO that can help meet the immediate milestones and support throughout the entire product life cycle. Even better, look for a partner that is making investments in capacity now to allow room for expansion in the future.

Next, Build a Plan with Your Selected Partner

Once the right partner is in place, it's time to focus on execution. For injectable drug products, the transition from preclinical to clinical manufacturing is a vital development step – and one that involves much more than simply scaling production of an active pharmaceutical ingredient. The planning process should carefully consider timelines, batch sizes, packaging material, testing protocols, and supply chain. Think of this as a detailed onboarding process. The more that both partners can share openly at the onset, the better suited the CDMO will be to develop a filling process to get the first clinical trial batch right.

Successfully navigating the process takes experience and careful planning. Here are some of the key ways a CDMO for clinical development can help support that success through a comprehensive partnership strategy:

Identifying Development Needs

The right CDMO for your clinical trials will assess the progress made so far, identify the next necessary steps, and establish realistic timelines for CTM that meet the

stringent requirements for human use. They provide essential expertise in scaling up production, interpreting analytical methods, and maintaining regulatory compliance for injectable drugs. For example, if the primary packaging will play a role in the injectables' efficacy, a strong partner will address the time and supply chain considerations at the onset to proactively address potential hurdles before a timeline is agreed upon.

Mapping the Regulatory Pathway

CDMOs with experience manufacturing CTM possess a deep understanding of regulatory expectations for different drug substances, delivery formats, and more. A knowledgeable partner can offer valuable insights that help maintain proactive compliance with evolving regulatory standards, like the most recent revisions to Annex 1. Annex 1, which governs the manufacture of sterile products in Europe, has introduced stricter guidelines on aseptic processing, environmental monitoring, and contamination control.

Proper interpretation of these standards is critical, as missteps in compliance can lead to costly delays or, worse, failures in regulatory approval. A CDMO with engrained expertise in interpreting and implementing these updates helps maintain that the first clinical batch adheres to all the necessary protocols, minimising risks and positioning your drug for successful regulatory review.

Evaluating the API

CDMOs evaluate the API to determine its suitability for CTM production, including formulation support, handling requirements, and sourcing. They maintain that the compound is processed correctly to manage product integrity. Service providers with specialised experience developing CTM can accurately determine the required amount of API for the target quantity of CTM, while also checking that the API is properly handled, stored, and protected during clinical manufacturing based on detailed information provided by the customer.

Selecting an Optimal Container

A CDMO helps choose the right container for your drug product, considering factors like patient needs, product efficacy and market trends. They guide decisions on whether to use vials or syringes and plan for future responsibilities and licensing requirements. An understanding that clinical trial packaging may have different requirements than commercial packaging is important to get the first CTM batch right and achieve the desired outcome.

Transferring and Adapting Analytical Methods

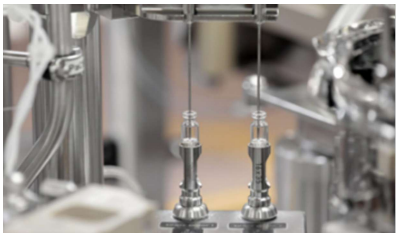
CDMOs support the evaluation of methods and adoption of Standard Operating Procedures (SOPs) for clinical scale production. They maintain that quality attributes and process parameters are aligned with regulatory standards and that testing methods are effective.

In the pharmaceutical industry, method transfer is a critical element of quality control in the drug development process. Close collaboration with our customers is essential to transfer their product-specific and with phase appropriate qualification to our manufacturing environment. With a wide range of services and methods, our analytical experts have the flexibility to perform transfers of a variety of analytical methods."

Building a Project Timeline

Collaborating with an experienced manufacturing partner allows drug developers to create a well-informed, strategic and realistic timeline for their CTM project, which is essential for accurate scheduling and budgeting.

Thorough planning often can make all the difference as the decisions you make early in the process can have a significant downstream impact on your product's development. It is also important to have all the necessary information about your drug substance and address potential logistic, technical and regulatory hurdles proactively.



Finish With Clinical Trial Success

Outsourcing clinical trial material manufacturing is a complex decision with long-lasting implications on the path to clinical development. Be sure to select a CDMO partner that prioritises quality, has the necessary experience, demonstrates flexibility, and understands the urgency of your timeline.

A successful partnership with the right CDMO could mean the difference between a smooth transition from preclinical to clinical and successful path through early-stage development and costly delays, so make sure to evaluate all potential partners carefully and with the above considerations top of mind.

REFERENCE

1. Clinical trial supplies market size and share report, 2030. https://www.grandviewresearch.com/industry-analysis/clinical-trial-supplies-market

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Mark Rauckhorst, Director Supply Chain & Project Management, Vetter, joined Vetter Development Services USA in 2013 as a Project Manager, focusing on early phase clinical projects at Vetter's first U.S. site in Chicago. In 2022, he was promoted to Director Supply Chain and Project Management. Prior to joining Vetter, Mark was a Project Manager at Regis Technologies where he managed custom synthesis manufacturing projects with the focus on process research development, non-cGMP manufacturing, and cGMP production of Phase I & II clinical trial materials.