Sterile Solutions: How to Choose the Right CDMO?

How do you know if you have chosen the right CDMO? Do you just wait to have the answer when your product is out on the market?

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The correct choice of a contract development manufacturing organization (CDMO) involves detailed analysis of the options available. This type of analysis requires financial resources and time. The first aspect to consider is the project you are going to outsource, which determines the type of CDMO and whether to choose a transactional, tactical, or strategic CDMO. So what´s the difference between one and the other?

A *transactional partner* is an indirect partner. This type of transaction-based relationship provides little loyalty between both parties. As soon as the transaction is no longer attractive, the contracting organization moves on to another supplier or vendor.

A *tactical partner* is one that has some common business interest, but different expectations. This kind of relationship can evolve to a more strategic alliance when mutual success and trust come into play.

A *strategic partner* is a long-term business relationship where both parties expect to grow together with similar expectations about products and markets. Both parties are involved in the global management of the product lifecycle. Risks and milestones are shared and business objectives must be aligned. A global, full-service CDMO can identify potential opportunities lying in the sponsor products and suggest some innovative solutions. A limited number of sponsor–CDMO relationships, however, are able to progress to strong strategic alliances.

What to look for in a strategic partner?

There are some key points to consider in guaranteeing a successful strategic partnership:

- In a strategic alliance, both partners should obtain greater benefits than they would from working alone, because the objectives of both parties are aligned. Sharing certain resources can result in saving time and investments, especially for smaller companies that do not have the capital to build new equipment or new manufacturing lines.
- There is a balanced expectation from both sides; this case is especially relevant when the sponsor and CDMO have different sizes. A relationship between a small CDMO and a large pharmaceutical company can be extremely successful if based on mutual trust and common objectives.
- The amount of time invested in finding the right partner can be rather long and it comes with experience. The process involves an accurate evaluation, understanding of the objectives, aligning different cultures, and performing audits, which all involve time and consume resources. For this reason, it is crucial to define exactly the type of relationship you are expecting from your CDMO to minimize risks and obtain maximum efficiency. The best recommendation would be to start with companies you already know. While this approach could save time, it is also important to ensure that the current partner can offer the services you need for the new project. For those without any prior experience with a CDMO, a short visit to the contract manufacturer is mandatory. Looking at the facilities and equipment, as well as talking to the people at the potential CDMO, will give you an idea of the CDMO's capabilities. These first impressions provide more information than you can imagine.

Less tangible factors to consider in CDMO selection

Don't think of your product as merely an item; behind each product, there is a patient, and it is important not to forget this aspect.

Both the manufacturer and sponsor are responsible for product quality, from the early stages to the final step of the process. The manufacturing company, however, holds the ultimate responsibility. A valuable attribute for any CDMO is, therefore, its integrity.

Product quality is considered the most crucial success factor for pharmaceutical contract manufacturing in injectable products, and quality remains the greatest challenge when the sponsor works with a CDMO.

Alignment of top management between sponsor and CDMO is another factor to take into consideration. Creating synergies between both parties requires more than an objective and a strategy. It involves optimal coordination

Image is courtesy of Grifols.

between teams and a global framework to provide the best solution for needs and process requirements.

The responsiveness of the CDMO should also be taken into account. Throughout the project, the sponsor and the CDMO will deal with unexpected events that can disrupt the schedule of the project. During the development phase and earliest stages particularly, the chance of problems arising is greater. Therefore, a fast and effective decision-making process is an important asset to keep the project moving. As a sponsor, you are contracting a service but you should let your CDMO suggest improvements related with the process, methods, and product.

Another factor to consider is the CDMO´s attitude when faced with a risk. Does the CDMO adopt a positive attitude? Or does the CDMO refuse to assume any risks due to a lack of knowledge? Take time to answer these questions in depth because it will help to determine if this company is the right CDMO for your project.

Many reports show communication as the top challenge of the sponsor-contract service, especially if both partners have different cultures. Communication must be team-based with individuals that are capable of building winning relationships based on honesty. Good communication can help a project to move along quickly, but poor communication can lead to delaying the launch and even affect the availability of the product on the market. Both parties must share all the information because a lack of transparency will hinder the progress of the project. Sharing, even if it means sharing mistakes, can streamline the next steps. For a CDMO, It is acceptable if a project is not awarded to your facility due to technical reasons; however, don't let poor communication be the reason for losing a project.

Four attributes to consider when choosing a CDMO—tenacity, credibility, flexibility, and simplicity

Tenacity. Be open to new challenges even if it means making some mistakes; this attitude will convert the CDMO company into a more competitive organization.

Credibility. While it is often easy to talk about how well a CDMO works, it is much better to show the results. The best promotional campaign for a CDMO is not an advertisement; the best campaign is what customers tell you.

Flexibility. The CDMO should be flexible enough to adapt to sponsor requirements but maintain its own identity without losing the values of the company.

Simplicity. A project can have different approaches and points of view but the main goal is always the same (i.e., to try and make the job as simple as possible and to be fully committed).

Complexity of sterile manufacturing and outsourcing trends

Injectable dose formulations have experienced strong growth despite the dominance of solid-dose formulations. The current trend is to work with CDMOs that offer full service capabilities from formulation to commercial production. This trend is expected to continue in the next few years, driven by the following key factors and requirements:

- Highly sterile and aseptic manufacturing conditions. Access to technology and equipment requires high levels of investment.
- Parenteral manufacturing requires a high level of automation to minimize human interaction with the product and avoid contamination risks, as well as to detect the presence of particles using automatic controlling processes.
- Skilled and experienced personnel
- Pharma and biotech companies are switching to prefilled syringes for existing and new products, and also to ready-to-use (RTU) containers to minimize potential risks of contamination, which is a result of less manipulation. The RTU formulas are a top market trend in the lifecycle management to add value to a product that has been on the market for a long time.

The emerging markets are more favourable to outsourcing solid dosage forms than injectable products that involve a more challenging formulation, a complex manufacturing process, and high quality assurance requirements.

Lifecycle management for injectable products

A viable product lifecycle management strategy is a key tool that can help injectable drug companies stay competitive in the marketplace. One of the current trends in the injectable field is to move from a vial (concentrated) to a pre-mixed solution (ready-to-use formula). The advantages of a pre-mixed solution compared to a vial include:

- Less manipulation of the container, which consequently minimizes contamination and medical errors
- Increased patient safety as a result of minimizing the risk of receiving an incorrect dose
- More safety for physicians because the use of needles for preparation is avoided and there is less contact with cytotoxic drugs.

Reformulations are also used to improve efficacy or for reducing the frequency of injection. The CDMO's experience and knowledge are key factors to take into consideration when selecting the manufacturer for such a project.

The approach is to select a CDMO that can offer development and manufacturing from vial containers to premixed solution. This approach allows the sponsor to establish a long-term relationship with the CDMO and work together as strategic partners, taking into consideration the requirements for manufacturing capacity, regulatory issues, potential investments, and launch schedules. Working with the same CDMO means saving time and money and being able to rely on someone you trust. Given that the pharmaceutical contract manufacturing market is expected to grow, choosing the right CDMO can determine the future success of your company. PTE