

CONSIDERATIONS WHEN SELECTING A CMO FOR GMP MANUFACTURING

By Anna Gilbert

It's an exciting time for a new biopharmaceutical when process transfer starts, and the product moves into GMP manufacturing. Many small firms don't have their own in-house manufacturing capabilities and must turn to a contract manufacturing organization (CMO) to produce GMP product. While a CMO must have the requisite technical capabilities, there are many other considerations that will help to make your manufacturing experience successful.

Here are some practical considerations that should be part of the CMO decision process:

- ▶ **Project Management Team** – a great project manager at the CMO can drive the success of your project; ask about how the project management team is structured. Review the project manager job description and ask to meet potential project manager candidates. Once the contract is in place don't be afraid to ask for a new project manager if things aren't working out.
- ▶ **Supporting Areas** – while it is obvious to evaluate process development, manufacturing and QC during the selection process, it is critical to ensure supporting departments are robust. For example, if the warehouse does not have strong receipt and tracking processes, there may not be materials available for production and you may lose a scheduled manufacturing slot.
- ▶ **CMO Culture** – does the CMO communication style match yours? Are they nimble and flexible? If you are a small client at a large CMO, it can be difficult to get the attention you require. Large firms typically have mature processes that can be rigid and hard to modify; and even if you can make changes, there may be significant monetary and timeline implications. The flip side is that large and established CMOs may have a strong global network to allow for manufacturing and distribution in other jurisdictions.
- ▶ **Success Rate** – ask what the manufacturing success rate is; 90% or better is good; 70-80% is not so good and will increase cost and impact timeline.

- ▶ **Availability** – you may have found the perfect CMO but if they don't have a manufacturing slot until next year and you need material this year, it's not going to work.
- ▶ **Local Talent Pool** – a CMO in Churchill, Manitoba may have a difficult time recruiting and maintaining talent. It's worth looking to see if there are area colleges/universities with relevant programs where they can recruit employees.
- ▶ **Flexibility** – some CMOs will manufacture on a campaign basis that allows for flexibility; other CMOs may require a suite reservation fee with monthly suite payments. The latter is appropriate for later phase clinical trials where you have a need for large amounts of material but is expensive for small, early phase trials.
- ▶ **Global footprint** – if you are planning to expand outside of the US, evaluate a CMO to ensure they have sites in other countries to facilitate easier tech transfer.
- ▶ **Regulatory History** – have they been successfully inspected by the FDA or other regulatory jurisdictions? Do they have warning letters or other red flags?
- ▶ **Financial Stability** – perform a review of their financial history. The perfect CMO isn't helpful if it goes out of business.

If you plan to use a CMO to manufacture a GMP autologous cell therapy product, consider adding the following considerations to the list above.

- ▶ **Chain of Identity** – does the CMO have experience in tracking each lot from apheresis to patient infusion? If so, is it a paper system or an electronic system?
- ▶ **Transportation** – is the CMO in an area with good air and ground transportation options? For example, the greater LA area has several airports and many ground route options, so receipt of incoming apheresis and outgoing product is more likely to be successful.

Choosing a CMO for GMP manufacture of your product is an extremely important step, especially for companies with one or several drug candidates. Looking at more than just the technical capabilities of a CMO can make the difference between success and failure when making the transition into GMP manufacturing. Take time to map out the questions you have and make sure they are answered to your satisfaction. Once you sign your contract, it is time consuming and expensive to change course. Consultants at BPTG have extensive experience assisting companies in evaluating CMOs and preparing the contractual documents necessary for a successful CMO working relationship.

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