Outsourcing Your Parenteral Manufacturing – Choosing the Optimal CDMO

When a drug substance requires a parenteral formulation to administer it, there are key factors to consider when choosing the ideal CDMO partner.

Ronald Aungst, Jr., Ph.D.
Vice President
Portfolio and Sourcing for Drug Product
Curia

Track records, product handling limitations, and cost are all factors to consider when outsourcing parenteral manufacturing. Choosing the right CDMO partner is not an easy task, but Curia has resources to make the decision easier. To learn more, Pharmaceutical Technology sat down with Dr. Ronald Aungst [Vice President, Portfolio and Sourcing for Drug Product, Curia] to discuss what CDMOs have to offer and how these partnerships can improve tech transfers and drug product development.

PHARMTECH: What is the most important question to consider when choosing a parental manufacturing partner?
AUNGST: I would say probably the regulatory track record of not only the facility, but also the overall company when you're looking at new CDMOs [contract research, development, and manufacturing organizations] to engage for your manufacturing partner. Quite honestly, the track record really is going to represent the aseptic processing capabilities or technologies that are being used to ensure the sterility of your final product.

PHARMTECH: What other major factors play into a client's decision when making that choice?
AUNGST: There are a number of additional factors that you can take into consideration, one being: what are their abilities with regards to product handling limitations, such as high potent products, biologics, or BSL [biosafety level] limitations that they have? Other things, such as technical expertise in process engineering, allow you to ensure successful process validation [and] capacity to meet the downstream demand that you have for your product. Also, timelines to get into the commercial state of readiness, quite honestly. Lastly, I'd probably say the ability to assure good supply chain continuity when it comes to components and consumables, such as filters and vials and stoppers.

PHARMTECH: Should pricing be a major driver in the overall decision?
AUNGST: It's always a consideration for clients, of course, but given the likely low impact versus other factors that I noted earlier, I typically don't believe that clients make that the major decision point for them.

PHARMTECH: What is a typical timeline for tech transfers to a commercial manufacturing facility?
AUNGST: It's highly dependent upon the product needs or the equipment and consumable lead times. But typically, I would say 12 to 18 months is normal, from contracting signature to commercial manufacturing readiness, although we've had some programs that have moved much faster, especially when supporting the battle against the COVID-19 pandemic.

There are definitely a number of CDMOs across the industry that can support formulation development in clinical manufacturing, but there are only a few that can really support the full breadth of a client's drug product development through commercial manufacturing.

PHARMTECH: What if a client needs help on developing the formulation to assure long-term stability? Are there CDMOs that can provide the full offering from formulation development through commercial manufacturing of injectables?

AUNGST: There are definitely a number of CDMOs across the industry that can support formulation development in clinical manufacturing, but there are only a few that can really support the full breadth of a client's drug product development through commercial manufacturing, our company being one of those.

PHARMTECH: At what stage should a biotech or pharma start to consider the downstream activity of a tech transfer?

AUNGST: The earlier, the better. Typically, you want to have your phase three clinical batches run out of the intended commercial facility. Vetting a commercial manufacturing CDMO that can support your product likely needs to occur as the phase two clinical batches are being manufactured. Additionally, since not all manufacturing facilities are identical, engaging the commercial CDMO early on in the process development stage provides a significant opportunity to ensure a smooth tech transfer, with a process developed to meet the needs of the downstream commercial manufacturing facility itself.

PHARMTECH: What makes Curia unique? Why should pharma companies choose Curia over other CDMOs that offer similar capabilities?

AUNGST: We are a comprehensive, one-stop shop that offers curiosity-to-cure solutions. Apart from that, what makes us unique is our employees who operationalize our mission and vision to deliver life-changing treatments in our day-to-day activities. This makes Curia better positioned to serve our customers with that same passion. Also, our ability to better serve emerging biopharma companies with more close-knit partnerships, better communication, and evolving with their program needs.

Engaging the commercial CDMO early on in the process development stage provides a significant opportunity to ensure a smooth tech transfer, with a process developed to meet the needs of the downstream commercial manufacturing facility itself.