Secrets to Successful Development for Emerging Biotechs

Source: Singota Solutions

Emerging biotechs are behind many of the pharma industry's latest therapeutic innovations. And while many CDMOs are eager to work with these companies, they must learn to accommodate the specific needs of an early-phase biotech. Often, biotechs receive funding that is dependent on reaching specific milestones in development, resulting in high pressure to uphold challenging timelines. To help successfully tread this tightrope, a CDMO must provide access to reliable technology, robust equipment and facilities, and experienced development teams.

In a recent webinar hosted by Singota Solutions, William Powers, Singota's Senior Director of Business Development and Manufacturing, highlighted some of the common characteristics of early-phase biotechs, including pain points like limited API and regulatory experience. To conquer these challenges, Powers illuminated some key approaches to enhance a CDMO's ability to support an emerging biotech and build a pathway to success. In the following Q&A, Powers provides feedback to webinar attendees on how CDMOs can adapt to the needs of different drug sponsors and maintain rapid timelines.

Q: Can you provide an example of how to address and mitigate some of the unknowns encountered during development?

William Powers: One example is a drug's exposure to freeze-thaw cycles, which could have an unfortunate effect on a drug substance. Should an issue arise during manufacturing where filling must be stopped for a period, necessitating that the drug substance be re-frozen and thawed again, it is important to know whether this will adversely affect the product. Testing for the potential impact of an additional freeze-thaw cycle early on can help avoid the potential loss of a batch. A study or test can be devised using a small sample exposed to a freeze-thaw cycle and then evaluated for degradation using a robust method.

Q: How can a CDMO offer flexibility in their fill schedules?

Powers: If a CDMO specializes in development and offers equipment dedicated to development services, they're going to have some scheduling flexibility. Small batches don't require the large blocks of time for formulation or filling that commercial batches do; thus, a manufacturing schedule can be adjusted to accommodate multiple client projects. A CDMO should let clients know upfront about schedule flexibility and prepare to adapt if client schedules shift.
At Singota, we know the clients' desired lead times based on their clinical trial dates and will adjust manufacturing slots based on the project lead time projections. It is important to note that actual project lead times are driven by the activities leading up to a manufacturing run. We must factor in how long these activities will take and account for the possibility that their outcomes may require additional tests and research.

Q: Clients may have very different GMP expectations from CDMOs and one client's requirements may not fit with another's. How do CDMOs balance requirements from different clients?

Powers: It takes a lot of upfront discussion with clients to understand their requirements and ensure that these requirements align with a thoughtful regulatory strategy. This is why recruiting regulatory experts to a CDMO team is important. Not everyone's requirements are going to be the same, and CDMOs must thoughtfully distinguish these basic requirements. Phase 1 clinical trial efforts require a successful batch and control strategy. If clients wish to include additional tasks or approaches in the project, CDMOs should attempt to accommodate them while properly conveying any potential risks.
The knowledge that emerges from development effort should be a guiding principle. Sometimes a client may insist that a certain test or approach be conducted in a manner at odds with the CDMO's recommendation; this is where staff knowledge can be especially helpful. Third party experts could also provide consultation in terms of what has been done previously and how it is relevant to your API.

Q: What does it look like to transfer a potential product from another CDMO?
Powers: The process is the same. If another CDMO has previously worked with a particular drug product and now wants to transfer that work to a new CDMO, you, as the client, should have access to that information. When we start discussing the gap assessment, i.e., what we know and what we don't know, that information should be made available. We will also ask, Why the transfer? What about the project with the previous CDMO went well? What went wrong? We work to build an honest and collaborative environment and need a clear understanding of what has worked in the past and what hasn't.

Q: When considering a rough timeline for that type of transfer, does it depend on the client and the product?
Powers: Yes. Gap assessments are conducted in person, rather than back-and-forth via email. If a CDMO can get a client team into their facility to discuss the project, they'll gain greater insight into how something worked, how long it took, how complicated it is, and how much additional investigation is needed. Three to four weeks would be a typical timeline.

Q: What is the typical lead time for filling in a Phase 1 clinical trial?
Powers: That is the key question. Lead times are constantly changing and affected by resource capacity utilization at a CDMO. No CDMO has access to an infinite number of technical resources. Plus, there are varying amounts of risk reduction required. If a project is relatively straightforward — a sponsor has ample experience with the drug product, previous scale ups, and material compatibility — it comes down to how quickly we can get a batch record written and testing qualified. With a project like this, a typical timeline is 8 to 10 weeks.

If a project requires an extensive amount of configuration and/or lacks robust methods, this could take 38 weeks or longer. Most commonly though, the timeline falls somewhere in the middle: 20 to 26 weeks. This depends on the size of the staff and the capability of the client to provide proper background information.

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