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INTELLIGENT & STREAMLINED DRUG PRODUCT MANUFACTURING: ASSURE SCALABILITY, OVERCOME REGULATORY HURDLES & SPEED TIME TO CLINIC

The influx of drug products to the market has remained constant over the past decade. However, the speed and quantity at which novel vaccines, therapeutics, and candidates are currently entering into clinical development is unparalleled. Capacity for manufacturing these products is in high demand.

Clinical timelines in general are usually very fast. The world needs these life-saving therapeutics - and the development and manufacturing industry must be proactively adapting to meet this accelerated demand. The increasing necessity for capacity is intensifying the difficulty for biotech and pharmaceutical companies to identify agile, high-quality services that can deliver as if the world depends on it.

Due to this ever-changing landscape, it is more important than ever to partner with a CDMO that is proactive with how they plan, resource, and execute programs. Reacting to supply chain and general product development challenges as they surface can cost invaluable time, money, and, most importantly, human lives.

THE POWER TO MAKE®

The CDMO industry prides itself on being flexible, adaptable, and responsive to changing customer needs. Helping drug developers address the challenges their programs may encounter and adapting to their needs is at the core of a successful CDMO sponsor relationship. When partnering with a CDMO, it is important to dive deeper into their manufacturing programs to get the specifics.

Look at what the CDMO is publishing, like thought leadership content or peer-reviewed papers in scientific journals. Scroll through trusted industry resources where editors with real industry experience manage the content to serve biotech and pharma readers. Review what their experts are talking about or case studies that may parallel your own situation.

DEVELOPING AN INTELLIGENT MANUFACTURING PLATFORM

Every step and aspect of the manufacturing process should be examined to define the full-service offering. This allows for a high level of support, ensuring a successful tech transfer or design of the clinical program from start to finish.

There are some program details that tend to have a bigger impact on the timeline for tech transfer to a CDMO than others. Often, drug developers rely on input from consultants or historical precedent to dictate program decisions on critical factors from components and method qualification to excipients and more.

An intelligent manufacturing program is streamlined and proactive. The platform is built from expertise and combines years of experience into each standard process. Highly structured, this platform can then be tailored to each drug developer and introduce fewer variables, thereby

speeding up the timeline and minimizing the need for third-party support.

FOCUSED TECH TRANSFER

Tech transfer activities for bringing a new product or process into the facility are usually rate-limited by analytical method transfers, availability of components, and formulation specifics. Especially in early stage novel therapeutics, there are often gaps between the state of the methods for in-process control and product analysis and what is suitable for cGMP operations.

Likewise, with the formulation process, these early stage programs have been performed on a bench top with inadequate attention paid to the scale and process characterization needed to ensure a successful cGMP operation. Many times this is an education process between both the customer and the CDMO, with the rate-limiting terms needing clarification to be in place prior to a run. A clinical-to-commercial program typically involves fewer unknowns, but includes long lead time activities that may or may not propose a risk to a customer's timeline depending on the quality of the process characterization activities that the customer and CDMO focused on during clinical development.

Leveraging a CDMO's experience to ensure the best fit for the product and the facilities, the time to manufacturing is greatly reduced, and many of the challenges that typically occur can be planned for or altogether avoided.

Late-stage development also has time and cost hurdles that can be circumvented by designing these early stage programs in such a way as to leverage as much information as possible in late-stage and decrease the scope of work needed to get from clinical to commercial scale.

TAILORED DRUG PRODUCT MANUFACTURING

Once tech transfer activities are finalized, drug product manufacturing can bring its own challenges to work through. These challenges range from batch record completion and engineering studies to fill line availability, which individually or together can slow programs down.

To overcome these hurdles and reduce variables, a platform could offer several areas to gain time-savings. For example, there is the potential to skip engineering studies prior to cGMP operations (dependent on the product), using an existing library of mixing and product contact parts to minimize compatibility studies. Flexibility within the fill line can be a benefit for available capacity.

Extensive experience in manufacturing a wide variety of drug products and working together on these program considerations can significantly cut down the manufacturing timeline.

Well-designed product quality and analytical programs are critical to ensure a successful final product. On-site laboratories are key and can enable scientists to employ a full range of methodologies and techniques to characterize clients' products, or to develop test methods to validate a product's quality through its life cycle.

An intelligent platform can offer time-savings for analytical services by sustaining product quality with concurrent and in parallel reviews and method verifications. An advanced platform for analytical services can also minimize the analytical transfer scope – or provide satellite ID samples for bulk drug substance lots that send reports back to the drug substance manufacturer to decrease the cost and time associated with method transfer.

EFFICIENT PACKAGING & SHIPPING

In order to support a product's clinical performance and market success, in-house labeling and

packaging solutions can provide greater safety and efficiency for your supply chain. The platform should be Drug Supply Chain Security Act compliant and utilize a track and trace service.

On-site storage and distribution services minimize supply chain risk inherent to third party sites, and makes the supplier management process simple.

An ideal platform partner would provide the ability to choose from an existing library of packaging and labeling components, plus use validated shipping configurations and preferred couriers. The CDMO personnel would schedule the shipments and have drug product lots shipped under quarantine (if the situation permits). Shipping could be one less task the drug developer would have to handle.

REGULATORY PARTNERSHIP

Partnering with a CDMO whose regulatory team that has experience with programs that require prompt attention and a strong regulatory strategy, can help expedite regulatory review and approval. A CDMO's team should be available to assist with and contribute to clinical and marketing application submissions. The regulatory team should help with regulatory submissions, clinical filings, and commercial launches.

Partnering with a CDMO who has expertise in Emergency Use Authorization (EUA) product requirements, an established FDA e-submission policy, a CMC section authoring program, and concurrent batch documentation review, will advocate for your program with regulatory agencies, and provide guidance and support to navigate obstacles and progress programs to clinics.

REMOTE ACCESS MONITORING

The ability to observe the manufacturing process is something that varies among CDMOs. In today's world, a personalized, secure, and remote viewing platform to monitor the process provides assurance and value. The ability to monitor operations in real time and stay connected to the product when developers cannot be physically present provides confidence and value.

Remote auditing procedures would provide additional value to support live, interactive conversation and interviews, guided walk-through of operational areas, and the ability to review documents and data.

DESIGNED FOR SPEED

An intelligently designed platform built specifically to cater to the drug developer could offer a unique opportunity to capitalize on regulatory and manufacturing expertise. Leading CDMOs can help clients can move from signature to filling in as little as 6 weeks.

Ajinomoto Bio-Pharma Services' designed and planned their AJILITY platform to intelligently manufacture your drug product allowing you to partner with a CDMO that will prioritize your program and drive it to completion.

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