De-risk and accelerate the drug development process for gene therapy

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In today's challenging financial environment, it is more important than ever to get key biotech business decisions right first time. One of the most important and topical of these is the choice of CDMO partner. Here, Dr. Kim Watanabe, General Manager and Site Head for Patheon Translational Services, a part of the Thermo Fisher Scientific pharma services contract development and manufacturing organizational arm, shares her advice and insights into optimizing outsourcing strategy.

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WHAT ARE THE KEY HIGH-LEVEL TRENDS IN THE GENE THERAPY SECTOR THAT ARE IMPACTING BIOTECH DECISION-MAKING AROUND OUTSOURCING?

Lack of harmonization in manufacturing, supply chain continuity issues, a shortage of technical personnel with appropriate experience, and limited regulatory support are all key bottlenecks that most biotech companies looking to outsource are facing. Contract development manufacturing organizations (CDMOs) can offer immediate access to standardized manufacturing processes and analytics, technical expertise and cGMP facilities, regulatory knowledge, and support with scalability.

In our recent experience of the COVID-19 pandemic where the macroeconomy came to a grinding halt, we learned new lessons in drug development. Drug developers are now putting more weight on logistics and raw material inventory management as part of their decision-making process. We will see a greater emphasis on partnering with CDMOs that can offer a true end-to-end solution for support, as a one-stop-shop.

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WHEN SHOULD SMALL BIOTECHS ENGAGE WITH CDMOS?

Early engagement and working in collaboration with an experienced CDMO that can support end-to-end manufacturing is key.

Our advice is to engage with an expert CDMO, that have th potential to support customers all along the drug development value chain, including lead candidate screening and selection, process development and cGMP clinical through commercial manufacturing. While screening for a CDMO partner, ask questions on how they can help accelerate the path to cGMP manufacturing.

WHAT CAN CDMOS DO TO PROVIDE SUPPORT TO BIOTECH UNTIL THEY ARE READY?

CDMOs can play a consultative role by asking the right questions upfront to understand the ultimate clinical trial goals and work backwards to design the program.

An experienced CDMO partner can play a consultative role from the beginning at the ideation stage and mitigate the pitfalls found at critical junctions of the drug development process. Qualified CDMOs have gone through this process many times before, for other molecules, so they can ask the right set of questions in moving a drug from concept to clinic ensuring that the manufacturing process can support the intended clinical design. The design of the chemistry, manufacturing, and controls (CMC) strategy works in close conjunction with the manufacturing process and the intended clinical application.

HOW ARE CDMOS HELPING BIOTECHS SOLVE THE CHALLENGES OF DOING BUSINESS TODAY AND ADDRESSING CONCERNS OF THE FUTURE?

CDMOs and small biotechs can develop symbiotic relationships together – 78% of CDMO businesses are made of small emerging biotechs.

As a CDMO, we are hoping to control critical supplies, align the manufacturing platform and analytics from lead identification stage and simplify business terms such as contracts and licensing agreements – all of which should translate to time and cost savings.

WHAT SHOULD BE CONSIDERED WHEN CHOOSING A CDMO PARTNER?

When selecting a CDMO, it is pivotal to focus on a multidisciplinary CDMO, that has technical bioprocessing, regulatory and quality expertise, transparency and flexibility, and access to raw materials to accelerate drug development.

Some CDMOs offer flexibility in process development and analytics to accommodate unique needs of biotech organizations, while others may also provide a standardized platform approach. It is important to understand your biotech's fundamental needs and assess for a good technological fit. If there is limited time and budget available, perhaps there could be an opportunity to partner with a CDMO early to test drive standardized platform technologies without heavy upfront investment in process development.

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