From Conception to Manufacturing: Accelerating Therapies With Curia

How partnering with a CDMO can make drug development easier, and what to know to ensure a successful collaboration

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During drug development, biotech companies must navigate several steps in which bottlenecks commonly present themselves. Partnering with a contract development and manufacturing organization (CDMO) can help biotechs keep development on track. To learn more, *BioPharm International* sat down with Scott Alderucci, Director of Process Development at Curia Global, Inc., to discuss the advantages of partnering with a CDMO throughout a molecule's journey from conception to clinical trials, as well as what these companies need to know to ensure a successful partnership.

BIOPHARM INTERNATIONAL: When in the development process should a pharmaceutical or biotech company engage with a CDMO?
ALDERUCCI: We feel engagement should begin as early as possible once a company has identified a molecule it wants to move forward with for development. Contacting the CDMO early provides benefits for both parties. This is because the drug company can screen and identify a partner CDMO. that it is confident in using by learning and understanding the technical processes CDMOs have for properly developing a program suitable for good manufacturing practice (GMP) production and the steps needed to advance the program. It also gives the CDMO time to properly schedule and slate in the necessary work, as well as advance of any activities. Many drug companies, large or small, need guidance at this early point to properly time and schedule for activities, milestones, and financing to ensure a seamless process from start to finish. This is where the multidisciplinary expertise of CDMOs becomes a real advantage to clients; we specialize in areas of the path to GMP production and have proven expertise in investigational new drug (IND) filings. This includes areas that are needed at early stages for documentation, required testing, method qualification, and sourcing of materials of the correct grade to move forward.

BIOPHARM INTERNATIONAL: What do these companies need to have ready on their end to successfully collaborate with a CDMO?
ALDERUCCI: Our experience shows that most pertinent paths to success are through trust and transparency. Both parties need to understand that this is a partnership, with each party's measure of success dependent on efficient transfer of knowledge and data. In most cases, there is work that has to be performed and learned information that can be transferred to accelerate the process development from the beginning. It is pertinent that there is a relationship of trust, and that all information is utilized to meet and exceed goals established early in the program. The same is applicable as we go forward through the program. We find it important to have routine exchanges of data as to what is performed, as well as results obtained regardless of outcome because the data helps drive the process and decisions that are mutually discussed.

BIOPHARM INTERNATIONAL: Let's say I need more resources but don't have a finalized molecule picked. What support could I get in that early stage?
ALDERUCCI: Curia, with experience in early-stage development, has taken programs from inception to realization and is an excellent partner for progressing a molecule to development. I've been involved with multiple partners that lacked the time, resources, or personnel to move a program forward and came to us for that need. I can give an example of a privately funded organization that had no lab space but was pushing an academic program to clinical phase and wanted to do it quickly. We took everything compiled, which was minimal process knowledge and experimental testing, and started from the molecular sequence optimization through transfection and production optimization in only a few months. That program wound up being used in manufacturing in about a year from initiation and eventually was used in Phase I studies. That's a great example of taking an idea to a therapy where all the process quality and regulatory needs are done with experienced scientists, specialists, and innovators to make what was a concept a reality.

BIOPHARM INTERNATIONAL: On the other side of that previous question, let's say I have a molecule and want to be in Phase I trials of my drug as soon as possible. What can the biologics division of Curia provide?
ALDERUCCI: I like that question because we have some recent history of this type of scenario. We were approached by a potential partner that had a very tight timeline and most of the required preliminary work for development for production and analytics already worked out. However, due to certain circumstances, they saw an imperative need to be in clinic in only three to four months. This is a tight timeline for any business in that kind of predicament. We rapidly executed all proposals and initiated documentation and tech transfer prior to all agreements being signed to have a workflow and set of discussions going to facilitate a quick start of operations. Execution began immediately, and with a rapid scale up to focus on some of these conditions to our equipment platform parameters, we were able to outperform the results we were hoping to match. Confirmation was achieved in a few weeks, verifying the outline we were given. Unique-to-program materials were rapidly acquired in batch records and required reagents were made in parallel with little risks. While processes were enacted, we processed and released ahead of schedule and supported all the documentation transfer while enacting the stability studies. This project was a challenge, but we were very satisfied that, even under pressure and inspiring probability of outcome, we helped this client meet their request.

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BIOPHARM INTERNATIONAL: Focusing on large molecules, what resources can you provide?
ALDERUCCI: We have pushed hundreds of programs from gene to protein, so we have a wide working range of types synthesized and produced for multiple levels of production. We have a dedicated site that can perform all molecular biology, including design through implementation. Then, our team can perform initial protein scouting either in-house or provide materials for the partner to test. We have an additional team able to do all cell line development and optimization for research cell banking, as well as a purification team that can come up with a scheme that optimizes the recovery and purity of the molecule suitable for clinical trials. We also have a dedicated process development lab that can scale this up to hundreds of liters for initial toxicology and proof of concept for manufacturing. In the same facility, we can implement all necessary protocols and documentation needed to execute manufacturing scales up to multiple kilogram amounts of protein or antibody for phase trials. We also support our partners in the initial scope for IND filings with all of our operations.

BIOPHARM INTERNATIONAL: Can you share some success stories from your recent work?
ALDERUCCI: Speaking to some of our statistics on programs, the Curia proprietary CHO-GSN platform has been used in over 150 cell line development campaigns. Of those that have completed, nine are currently being used in clinical trials as far as Phase III. Curia has generated 46 more CHO-GSN cell lines that were used in GMP and IND enabling tox studies. We have several in the queue at any time at multiple stages, from still in planning design to undergoing manufacturing, so it is always imperative to plan well in advance to ensure a slot suitable for a program's timeline.