Leveraging Experience & Expertise, Part 1

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There are many biopharmaceutical CMOs in the industry who would gladly take your promising molecule and develop it to the best of their ability. But when your company's future is dependent on getting that molecule through testing, scale-up, regulatory filings and production as quickly and efficiently as possible – there are only two things that matter when choosing a biopharm CMO for your product – experience and expertise.

This is where a CMO like Laureate Biopharma in Princeton, NJ can provide the qualities needed to bring your biopharmaceutical product to market with the assurances only an experienced player in this market can provide.

Background & Overview

"We've always been in the biopharmaceutical space," says Michiel Ultee, Ph.D., the company's Chief Scientific Officer who has been with company for most of its 30 year history. "We are particularly adept at recombinant production of mammalian cell produced proteins, and over the years we've added different capabilities enhancing our analytical capabilities, our purification capabilities and added larger bioreactors."

Laureate's range of services for biopharmaceutical customers begins right after the discovery phase. "Pure research or discovery is not our area," says Ultee. "However, we do enable the companies that provide these services to turn their R&D into a product. We do all the additional development, the scale-up, the cGMP production and testing required before it's suitable for a safe and effective product. All we need to know is the identity of the protein and we can produce a cell line and take it from there."

For companies that are further along the road to production, Laureate can transfer that product into their facility, including products that are ready for final filling.

Laureate views this tech-transfer process as critical to ensure success. “It’s a critical process, “says Ultee. “We have to understand their molecule very well – they have to understand our process – there is a lot of exchange of information and collaboration between scientists.” To ensure that all Requests for Proposals (RFPs) from potential clients are handled in a timely and comprehensive manner, the company follows up all RFP’s with a technical call with the new customer’s scientists to make sure all parties involved understand the project’s scope, parameters and goals. A project management group is brought in as early as possible to detail the expected timeline, project activities, and responsible subject matter experts and map out what needs to be done when.

The Quest for Quality

For any biopharmaceutical CMO implementing the right systems and strategies to ensure a quality product is paramount to success. At Laureate, discussions with customers related to quality systems and strategies are really dependent on the project’s current stage.

Lisa Cozza, Laureate’s Vice President of Business Development explains that since every customer is unique and projects come to Laureate at different stages – the quality systems discussion can take many different forms. “With companies where the goal is to get into the clinic or animal studies, the focus is on the immediate technical challenges of the protein and its production, and less on quality systems. In other scenarios, we have clients that might already have their bulk drug substance and are looking for fill/finish, or they are looking for process improvements at larger scale or to launch

out of our facility. In those cases, the quality conversation starts right away – and a quality audit is done by the potential customer early on to vet our facilities and capabilities."

"Pretty much all of our customers do a quality audit," says Ultee. "They want to be sure that when they develop a product with us it will be done under GMP and will meet regulatory approval for their clinical testing program."

A Complex World

With biopharmaceuticals growing in importance not only to the financial health of the pharmaceutical industry but also to the health of consumers - one might think that the complexity of making biopharmaceuticals has increased over the years.

"I don't know if it has become more complex," says Ultee. "I think it has become more rigorous, as people have come to understand proteins better, we have come to know what matters more and what matters less. We have evolved from the process making the product to the product being sufficiently well-defined and characterized that process changes can be accommodated. There is a lot of analytical testing that is done now which is a change from the early days of biopharmaceutical development – where you had a process and you couldn't change it because the process defined the product."

"It is definitely not what it was 20 years ago" says Cozza. "The expectations of the regulatory agencies have become so comprehensive – that although it may be easy, physically, to go out there and make some product, the additional hurdles of regulatory, analytical comparability and reporting make for a much tougher assignment. This has evolved the talent pool as well. Today it has become easier to find manufacturing talent – where in the past it wasn't easy – but meeting the tougher analytical and technical reporting requirements require a different talent pool."

Please tune into tomorrow's Chem.Insider Daily *for part two of this two-part series.*