Leveraging Experience & Expertise, Part 2

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This is part two of a two-part piece. Part one can be found here *[1].* [1]

The Impact of Technology

Laureate's history in the biopharmaceutical manufacturing business has given them a unique insight as to how technology has changed over the years and also how vendors of biopharmaceutical manufacturing equipment have improved their products.

"We have close relationships with the equipment and materials vendors we work with," says Ultee. "Improvements in bioreactor design, cell-line construction, cell-culture media and feed solutions, have resulted in dramatic increases in cell-culture titers. These have allowed us to ensure that the cells both grow well and produce well."

"On the downstream side – we have seen a tremendous shift in purification strategies that have transformed from overnight slow processes in cold rooms many years ago to the current high-speed, synced, two- or three-step a day processes – that produce a much purer product. This is the result of advances in separation sciences."

Perhaps the greatest development in biopharmaceutical manufacturing has been the advent of single-use/disposable technologies.

"Disposables have advanced," says Ultee. "The early things that were disposable – pipettes and roller bottles – were good because it eliminated the need to wash them. Shake flasks are disposable and bioreactors are now disposable – and pre-packed chromatography matrices that allow us to work very rapidly – they are not necessarily disposable - but they offer a lot of advantages."

"The use of disposable flow paths, where you do not have to worry about product changeover, is really ideally suited to CMOs." says Cozza.

Laureate has been using single-use disposable fluid paths in their fill/finish area for the last 12 years, citing reduced changeover times and elimination of carryover from one product to another as two of the main benefits of this technology. In addition to using disposables in their fill/finish operations Laureate also employs the technology in its bioreactors. In fact the company regularly does beta testing on the newest single-use bioreactor designs in order to stay current.

“We want to stay current and innovate and keep up with latest technology because it makes for a faster and a more robust process,” says Ultee.

Biosimilars & Biobetters

In the biopharmaceutical industry there is perhaps no hotter topic than that of biosimilars and biobetters.

With a vested interest in the race to develop and produce biosimilars and biobetters, Laureate is keeping a watchful eye on this rapidly developing topic.

“The production of biosimilars is taking up a lot of capacity,” says Cozza. “There are a lot companies and CMOs collaborating on these programs. At the same time" Cozza continues, “the acceptance of using CMOs to get bulk drug products developed and launched is growing.”

Cozza says that Laureate is getting a lot of interest from “virtual” companies who would never consider building a facility – and therefore must rely on the experience and expertise of a company like Laureate.

“I think with biosimilars you are going to see the same thing that happened with small molecule production – a lot of it will eventually go to CMOs,” says Cozza. “The biosimilars race is going to be very similar to the generics race.”

“I have a very optimistic view on biosimilars and biobetters," says Ultee. “In the clinical space – there are a lot people trying and they will come to CMOs like us to try out their product. I also think it will focus interest in good analytical capabilities – which we have added in the last few years – we have doubled the size of our analytical team. We have put a lot of focus on that in part because of the advent of biosimilars – and the related molecules – biobetters. I’m more interested biobetters because, like biosimilars, I think the indication for the drug is already known, but you just don’t have to make it match precisely to the innovator drug. There are therefore improvements you can introduce to provide for higher potency, longer half-life, etc. You can make improvements that maybe the innovator had also thought of but didn’t do because the drug in its present form was doing well.”

Future

With a well-established reputation as being a leader in biopharmaceutical manufacturing, Laureate is looking towards the future with an eye on growth and to continue to supply the level of service and quality it has become known for in the industry.

Speaking to the company's current and future capabilities, Cozza has this to offer, "We are a stand-alone CMO that can provide services across the entire CMC chain. You can come to us with a protein and we will help you file your IND or BLA with the material we generate and data we supply. The fill/finish and regulatory services we provide sets us apart. A lot of CMOs have some of the same things – we all have process development and tanks of various sizes – but what we've done, including investments in our analytical capabilities, quality systems and our facility, enable our scientists to stay on the leading edge of new and challenging products. This keeps us unique."

"I see us as being one of the top tier CMOs in five years due to our investments and growth. Our leadership has pushed the envelope toward growth and has made a lot changes and innovations," says Ultee.

At the end of the day, what really matters to companies looking for a CMO is if they can get the job done - at Laureate it's an everyday occurrence.

"I believe our science sets us apart," says Ultee. "We have a reputation for tackling difficult proteins."

"Clients come to us with big challenges," concludes Cozza, "and we help them succeed."

To read part one of this two-part series, please click here. *[1]*

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