sartorius stedim biotech

Single-use process platforms help biomanufacturers reduce costs

White Paper

turning science into solutions

Single-use process platforms help biomanufacturers reduce costs

By Miriam Monge

There are many new challenges facing those involved in the manufacture of biopharmaceuticals. Whereas in the past, overall process efficiency was sometimes treated as an afterthought as companies tried to get to market as quickly as possible, the production costs of biopharmaceuticals are now, receiving greater attention which is spurring interest in continuous bioprocessing. The loss of patent protection from blockbuster drugs is creating a market for biosimilars in which being able to compete effectively requires low prices underpinned by low manufacturing costs.

Enhanced flexibility and reduced operating costs are being achieved through the widespread adoption of single-use technology either as part of completely single-use processes or as hybrid solutions. However, questions around suitable standards for product contact plastics continue to be debated within industry forums. Greater assurance can be provided to regulators that products are manufactured by well controlled and characterized processes due to advances in process analytical technologies and enhanced QbD regulatory submissions.

While bioprocess engineers must now apply themselves to addressing these issues they can at least be thankful that the collective experience within the industry is now sufficiently great that many of the original challenges faced by teams in the first few decade of the industry have now been resolved. Unless a particular project requires the entire process to be reimagined there need be no reason for designing individual bioprocesses from scratch. Fortunately we are able to stand on the shoulders of bioprocessing giants.

Platform processes that are capable of being used to manufacture different biologics from the same class are arguably the physical embodiment of this collective knowhow. The platform approach can be applied to classes of biopharmaceuticals such as Monoclonal Antibodies, Antibody-Drug Conjugates and Vaccines. Process platforms allow tremendous efficiencies to be gained as they utilize the same equipment, supply chain for consumables, documentation and training. Learning acquired from the operation of one process can be applied to other processes within the platform and data can sometimes even be shared between processes during regulatory submissions.

For these reasons companies that have a pipeline of similar molecules have adopted the process platform approach to increase the efficiency of process development and increase standardization within operations. Contract Manufacturing Organizations often make great use of process platforms because of their need to perform rapid process transfers and operate many different processes. Cost and time savings can be gained wherever it is possible use common equipment, methods and raw materials.

In this era in which organizations can be virtual and often increasingly without borders, a new trend is emerging whereby biopharmaceutical companies are collaborating with capable suppliers who can provide entire platform bioprocesses to their partners. Based upon the supplier's experience of working on many development and engineering projects with multiple clients their accumulated expertise can be leveraged by biopharmaceutical companies seeking to rapidly install new production capabilities. These may be smaller companies whose focus has previously been on drug development but wish to develop a manufacturing competency or larger companies that want to outsource bioprocess innovation to a partner.

Entire single-use bioprocess platforms for the production of monoclonal antibodies, for example, can be obtained from suppliers such as Sartorius Stedim Biotech (ref 1). These are complete end-to-end production platforms, suitable for commercial manufacturing up to 2000 L Single-use bioreactor scale and comprise a cell line, a seed train, the production bioreactor, harvest and purification steps, cell culture media and buffers with the associated equipment required to produce them. Sartorius, indeed, is going beyond providing just the single-use equipment but is in addition able to provide cell lines, media optimization services and product Bioanalytical and Biosafety testing (ref 2). By adopting process platforms the engineering burden is considerably reduced, lowering the cost and speed of implementation even in the event that the platform must be adapted to their specific requirements and will subsequently enable firms to reach the clinic sooner.

To be successful the implementation of process platforms must be adequately supported by the selected partner. Purchasing the tool without having a full understanding of how to use it effectively will prevent the full benefits from being realised. The necessary support may include process development tools, process simulation and cost of goods modelling, engineering and regulatory consultancy services. Access to this considerable expertise from suppliers providing fully integrated solutions can help biopharmaceutical companies save time and reduce their own costs for not having to develop these fully fledged competencies in-house.

The collaboration between the biomanufacturer and its supplier becomes sufficiently deep that the relationship requires management focus. They can be facilitated by working with partners who designate a single point of contact to the collaboration by bioprocess leaders with an in-depth knowledge of the platform and associated services able to make timely recommendations to their clients whilst also knowing who and when to call upon more specialist expertise when required.

The resources that are saved by working with suppliers to deliver process platforms can be conserved altogether resulting in higher profitability or a reduced need to raise finance to fund operations. Alternatively the resource can be channelled back into the organization and used to address those significant and specific challenges that are difficult to outsource. Collaborations with suppliers of process platforms looks set to change the way biopharmaceutical companies are structured operate and compete as the biopharmaceutical industry reaches maturity.

Ref 1: https://www.sartorius.com/en/mab/
Ref 2: http://www.biooutsource.com/

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