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Proceedings

Fall 11-2-2015

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Recommended Citation

Atul Mohindra, "Integrated and single use continuous manufacturing" in "Integrated Continuous Biomanufacturing II", Chetan Goudar, Amgen Inc. Suzanne Farid, University College London Christopher Hwang, Genzyme-Sanofi Karol Lacki, Novo Nordisk Eds, ECI Symposium Series, (2015). http://dc.engconfintl.org/biomanufact_ii/107

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Integrated and Single Use Continuous Manufacturing

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Continuous processing for biopharmaceutical production is attracting considerable interest within the industry. The concept of continuous processing is not new and the value of continuous manufacturing has been well documented for decades across the steel, chemicals and food industries. Despite the vast differences between product types, the advantages of continuous over batch production remain consistent and include steady state operation, high volumetric productivity, streamlined process flow and reduced capital costs.

Over the past decade, significant investments have already been made with continuous bio-manufacturing development. The need for the biopharmaceutical industry to follow suit is being influenced by a number of business drivers including:

- accelerated development times for continuously operated steps
- reducing overall costs
- maintaining stringent quality/regulatory requirements
- flexibility to match changing product demands

At present, contract manufacturing organisations often need to flexibly accommodate large-, mid- and small-volume drugs (e.g., therapeutic proteins, niche or orphan drugs), preferably within the same manufacturing facilities. Furthermore, the ability to rapidly adjust production capacity to accommodate fluctuating and/or mis-forecasted demands is also needed. In order to ensure that Lonza maintains the required level of flexibility, our vision is to put in place even more flexible production capabilities utilising both continuous and batch processes whilst lowering the risks associated during process execution and process transfers.

Over the past decade, we have focussed on developing simplified, efficient and robust mammalian cell culture/purification platform processes. More recent activities have focussed on taking advantage of new and converging single use technologies as well as ensuring that we use state of the art analytical tools at the right time and at the right place in our processes. We are now looking to move one step further by integrating the single use unit operations which will allow for processes to be operated in a continuous mode.

This poster will outline Lonza's approach to establish continuous flexible manufacturing facilities using single use technologies.