

CONTINUOUS INTEGRATED BIOLOGICS MANUFACTURING

John Welsh, Pall Biotech
john_welsh@europe.pall.com
Louise Taylor, CPI Ltd
Spyridon Gerontas, Allergan Biologics Ltd
Martyn Hulley, Astra Zeneca Ltd
Richard Krucia-Tran, GlaxoSmithKline Ltd
Daniele Messina, CPI Ltd
Tibor Nagy FujiFilm Diosynth Biotechnologies Ltd
Ferran Sanchez, Sciex Ltd

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Biosimilars and patent expiry are forcing the biopharma industry to find new ways to maintain competitiveness by ensuring affordability, quality, and delivery performance. Despite great improvements in upstream processing (USP) efficiency, higher titres create downstream processing (DSP) bottlenecks and facility fit issues: Equipment reaches its physical and capacity limits thereby increasing processing time, material consumption and overall cost. Continuous processes have been proposed as a solution to many of these issues as they offer higher productivity while reducing cycle times, buffer/resin usage and required footprint.

A consortium of UK based biopharmaceutical companies, suppliers and not for profit research organisations, funded by an Innovate UK grant, has been created and will investigate how such an integrated, continuous downstream process system can be realised. The system has been constructed and is currently operating at the Centre for Process Innovation at Darlington, UK. The project combines and condenses multiple DSP unit operations to function as one uninterrupted system with integrated analytics and overarching automated control. The aim is to create an operationally-efficient, multi-product platform which replicates the functionality of a larger plant processing 100 L feedstock per day (independent of product titre).

The integrated unit will be tested on several biologic processes demonstrating the system's potential to enable product changeover, increased facility flexibility and productivity. Significant focus will be given to process validation procedures and the use of low level control to achieve process stability (steady state) and maintain acceptable product quality. This work will lay the foundation for real-time release strategies and replace drug substance release testing.

This presentation will provide an overview of the project and show recently-acquired data from the automated purification of industry-relevant monoclonal antibodies. In doing so, this will highlight the applicability and demonstrate the real-world potential for integrated continuous processing to advance the manufacturing of biopharmaceuticals.