

CONTINUOUS DOWNSTREAM PROCESS DEVELOPMENT FOLLOWING QUALITY BY DESIGN PHILOSOPHY

Marc Bisschops, Pall Biotech, Netherlands
marc_bisschops@pall.com
Denis Kole, Pall Biotech, Netherlands

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Continuous process technologies are available for essentially every step in a fully integrated continuous downstream processing platform. Most of these technologies have a significantly higher throughput and specific productivity than their batch equivalent process steps. The consequence is that the amount of material required to run experiments during continuous process development work is significantly higher than in batch process development.

High throughput experimentation platforms have been established for performing design of experiments studies for many batch downstream processing steps, but for the equivalent continuous bioprocessing technologies this doesn't exist. This limits the amount of different process variations that can be tested as part of the process characterization studies.

In this presentation, we will analyze a continuous monoclonal antibody purification platform, using the Quality by Design approach to identify the key process parameters and critical process parameters. Based on the process knowledge and process design information available for the various continuous bioprocessing technologies, we will analyze how these critical process parameters translate into a continuous bioprocessing platform for monoclonal antibodies.