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# Scale-up of Continuous Multicolumn Chromatography for the Protein A capture step: from Bench to Clinical Manufacturing

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## Highlights

- Seamless upscaling of continuous protein A capture chromatography
- Consistent product quality and comparable to batch mode
- Productivity is increased by 400-500%
- Smooth performance of hardware and software during a ten day non-stop run

## Abstract

The awareness about implementing continuous processing for biopharmaceutical products has significantly increased throughout the recent years not only at developmental scale but also for phase I supply in clinical trial manufacturing. In this study, we focused on upscaling continuous protein A chromatography from lab to pilot scale using the Cadence™ BioSMB PD and the Cadence™ BioSMB Process 80 system, respectively. Additionally, we evaluated hardware and software capability whilst running the system for 10 days non-stop using feed from a perfusion bioreactor. In terms of product quality and removal of impurities, comparable data was obtained regarding lab scale and production scale. Compared to batch mode, productivity was increased by 400 to 500%. Furthermore, the system worked accurately during the whole trial, proving its potential for the implementation into a hybrid or an end-to-end continuous process.

Keywords: Multi-column chromatography Downstream processing Continuous chromatography Upscale

## 1. Introduction

Continuous processing for the production of pharmaceuticals is expected to become more established compared to conventional batch processing in the future, exhibiting

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