

Continuous Purification Technology

mAbs, rProteins, vaccines and other biomolecule products

Abstracts & links for CaptureSMB focused series of Learning Webinars below.

The basics of CaptureSMB twin-column purification – how does it work and case studies

[CaptureSMB; How does it work – twin-column capture \(2-PCC\) LPLC technology and practical application](#)

by Thomas Müller-Späth, Ph.D.

Technology to **increase productivity in the capture chromatography step** during the purification of bio-molecules (e.g. mAb) by 2 to 3-fold while **reducing Protein A and buffer usage by up to 50%** is presented in this 30 minute presentation.

Animations to illustrate the technique will quickly provide the webinar attendee with insight of **how the process mimics conventional batch LPLC purification – but allows continuous chromatography**. Economics of the process as applied to mAbs illustrate the impact of incorporating the patented CaptureSMB process on plant productivity and cost-reduction. **Information on scale-up and GMP scale equipment** presently in use at multiple biopharmaceutical companies will be shown.

[Case studies – customer data from CaptureSMB experiences of twin column system](#)

by Dr.-Ing. Kathleen Mihlbachler

Experience of multiple end-users employing GMP scale pilot systems using twin-column continuous capture and sequential batch (polishing) chromatography **on actual mAb feed-stock is presented in this data-based presentation**. Economics as modeled by end-users is also shown.

During this 30 minute webinar a number of **case studies showing the successful operation of a twin-column capture process (CaptureSMB) for monoclonal antibodies in GMP pilot scale** are reviewed. Compared to traditional batch chromatography, specific productivity and resin capacity utilization by up to 2-3 fold and 30-60%, respectively.

[Automation of twin-column chromatography - insights on how the system controls enable users' easy operation](#)

by Dr.-Ing. Kathleen Mihlbachler

Twin column chromatography greatly extends the productivity in the manufacture of protein therapies such as mAbs, vaccines, ADC's, peptides and such. **The automation of a twin-column chromatography system has similarities to batch LPLC's and HPLC's however the industrial, GMP compliant controls platform on a YMC Contichrom Twin System has enhancements** and format that is uniquely user friendly. This 40 presentation is intended to provide the **highlights of this automation platform**.

[Recipes, Reports & Trending tools for Contichrom \(2-PCC\) TWIN / LPLC](#)

by Hanna Froebe

While similar in many respects to **reporting and recipes** to batch chromatography, twin-column (continuous) chromatography has more and richer data and methods. This 35 minute webinar provides insights into **reporting, recipes and trends** and how the display format can be adjusted: ranges, colors, style, number of signals and tags, live or static, or layered like a standard batch LPLC.

Recipes that use **configurable sequence templates** (up to 20) are illustrated and how parallel sequences and interconnected sequences are re-used. The presenter will cover how recipes can have different states; Development, production or archived and **compliance to CFR 21 Part 11**.

This seminar is presented in brief to give potential users a high level overview of automation and attendees can request a one-on-one live demonstration or hands-on experience to delve deeper into this user friendly control and reporting platform.

[UV-based dynamic process control of twin-column \(2-PCC\) LPLC system \(AutomAb\)](#)

by Thomas Müller-Späth, Ph.D.

For robust operation in clinical and commercial manufacturing, continuous processes benefit greatly from dynamic process monitoring. This presentation deals with the **dynamic UV-**

based control of twin-column capture (CaptureSMB). For the capture process, the “AutomAb” control **accounts for changes in resin capacity, titer and adjusts the operating parameters** such that load and yield are kept constantly at the set point. This presentation elucidates the working principles of this patented dynamic process control method and provides **case studies** for capture applications.

**More than just continuous capture-
this system can perform multiple downstream functions**

**[Multi-functionality elements of twin-column LPLC systems:
Continuous capture, BID, Sequential polish...](#)**

by Mr. Wayne Nettnay

The webinar expands on additional functionality available in YMC's twin-column LPLC chromatography design and its process control. The presentation reviews the **continuous capture** (Protein A) capture of mAbs, at the GMP production scale and then overviews additional features that provide multi-functionality on a single system; traditional **batch** chromatography, **sequential batch (polishing)** operation, where two orthogonal chromatographic steps, such as different IEX or HIC chromatography, are run consecutively on the Contichrom TWIN Capture system. Additionally, the systems' can have incorporated **in-line dilution** functionality that allows the direct usage of concentrated buffers. Finally, some examples of these functions are presented.

[Sequential \(orthogonal\) polishing chromatography; a "pool-less" two-column connected process & how it works](#)

by Thomas Müller-Späth, Ph.D.

In this brief (~15 minute) webinar, we focus on one unique functionality of the multi-functional Contichrom TWIN Capture LPLC: the **sequential batch ("pool-less") polishing operation**. Our twin-column system allows the **sequential purification of two orthogonal chromatographic modes where the purified product of the first column is directly loaded onto the second column** without any storage tanks in between. This sequential operation can be applied when connecting a capture step with a sequential polishing step or two polishing steps.

Three combinations of chromatographic operations are introduced: (1) flow-through and flow-through, (2) flow-through and bind & elute, and (3) bind & elute and flow-through.

Case studies will be presented that highlight the advances of the sequential operation, such as increased productivity, buffer savings, and reductions in OpEX and CapEx.

[Process characterization and validation for continuous chromatography systems](#)

by **Thomas Müller-Späth, Ph.D.**

Continuous downstream processing is increasingly evaluated and implemented in the biopharmaceutical industry. For the capture of monoclonal antibodies using protein A affinity chromatography, periodic countercurrent processes have been described. While general process principles have been fully understood, the focus has shifted to important manufacturing-related aspects such as scale-up, control and validation.

As part of a process validation procedure, this ~30 minute seminar **presents an outline of a risk-based model-assisted process characterization approach for the twin column capture process** CaptureSMB. The basic procedure uses process description, risk analysis and ranking, parameter testing and statistical analysis as main elements. It is shown **how modeling can be used to significantly lower the experimental burden** of twin column capture process validation and find optimal process operating ranges.

[Virus clearance and carryover study on twin-column \(continuous chromatography\) system](#)

by **Thomas Müller-Späth, Ph.D.**

On its pathway to clinical and commercial scale multi-column capture chromatography requires development of scalable models for virus validation studies. In this study, **retro- (X-MuLV) and parvo-virus (MVM) clearance in twin-column continuous capture chromatography (CaptureSMB) was investigated and a surrogate model was developed using standard batch mode chromatography.** The results showed that the log reduction values (LRVs) achieved during CaptureSMB were also comparable to the LRVs obtained using standard batch capture chromatography and that virus carryover could be well controlled. Further this presentation also shows assessments of the **impact of resin cleaning strategy and the duration of clean-in-place solution exposure on virus carryover.**

This is a ~20 minute presentation after which an audience Q&A session ensues.

Single use interface on twin-column systems; hybrid design use in lower classification cleanrooms

by Wayne Nettnay

This Webinar illustrates how YMC have adapted their stainless steel twin-column chromatography systems to **operate within a single use facility**. Graphics and discussions will include the enabling single use devices which allow the aseptic handshake between gamma irradiated, single use feed, buffer, and collection vessels/tubing, to a durable stainless system which has been sanitized using NaOH. Included is **information on the automated sequences and piping design that ensures complete sanitization of all SS wetted surfaces**. There is also some forward looking information on other methods of sanitization using ozone gas and the advantages this might have over caustic.