

## Continuous Purification Technology

### Peptides, Oligos, ADC's, RNA, DNA and similar drug products

Abstracts & links for MCSGP enabled HPLC series of Learning Webinars below.

Simply go to YouTube ["YMC Process Technologies"](#) channel to view them all.

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

#### [Process & economics for continuous purification by MCSGP enabled HPLC \(peptides / oligo yield & purity\)](#) by Thomas Müller-Späth, Ph.D.

Technology to increase yield by 2 to 3-fold while reducing solvent usage by up to 70% while maintaining purity targets is presented in this 30-minute presentation. Animations illustrate the technique and quickly provide the viewer of how the process mimics conventional HPLC purification - but with internal, automated recycling of side fractions.

Economics of the process as applied to oligonucleotides are illustrated by the impact of incorporating the patented MCSGP process on **plant productivity and cost-out** (and we explain what the heck "MCSGP" stands for!). This same MCSGP process can be applied to peptides and other difficult to purify or highly potent molecules such as ADC's.

#### [Design features of GMP scale MCSGP enabled HPLC](#) by Dr.-Ing. Kathleen Mihlbachler & Mr. Matt Bui

Now being applied at production scale, HPLC enabled with MCSGP (Multi-column Counter-current Solvent Gradient Purification) technology has the **unique ability to not only achieve difficult separations but is a continuous process that delivers up to 60% more yield** at target purity and operates with up to 10-fold higher productivity than batch. Solvent savings approach 70% in many cases.

This 25 minute mini-webinar will give the viewer a close look at design features of the GMP scale systems. It is recommended that attendees first view the (30 minute) webinar titled: "[Process & economics for continuous purification by MCSGP enabled HPLC](#)" which details how MCSGP works.

The presentation will spend time on the P&ID and call out some **unique design features that differentiate this from a batch HPLC** (software, fast acting valves and multi-column functionality).

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## [UV-based dynamic process control of HPLC twin-column MCSGP enabled system \(Mcontrol / AutoPeak\)](#)

by Thomas Müller-Späth, Ph.D.

This ~20-minute seminar presents the unique (patented) control for processes using MCSGP found on YMC Contichrom systems. Performing **M**ulticolumn **C**ountercurrent **S**olvent **G**radient **P**urification (MCSGP), operation with **MControl significantly reduces effects on product quality caused by temperature, solvent quality, conductivity, pH and/or column variability** (bed height, aging, packing quality...).

MControl compensates for peak shifts by adjusting the fractionation start: Same product fraction position, same product quality, increased robustness of continuous process operation.

MControl (which may also be referred to as AutoPeak) is a companion control mechanism to "AutomAb" which is employed in systems operating the patented CaptureSMB process found in twin-column systems in the capture (Protein A) step. AutomAb is presented in a webinar titled: [UV-based dynamic process control of twin-column LPLC system \(AutomAb\)](#).

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## [The Contichrom CUBE bench FPLC tool – features and applications for large and small molecule process development](#)

by Thomas Müller-Späth, Ph.D.

The Contichrom systems are multi-purpose bench-top chromatography system for proteins, oligos and peptides. Contichrom CUBE bench-top systems allow exploring the world of continuous chromatography processes offering process capabilities for capture (CaptureSMB), polishing (MCSGP) and side compound enrichment (N-Rich). The operating software ChromIQ facilitates transition from single column chromatography to continuous chromatography in a few minutes. This presentation details the CUBE instrument hardware, functionalities, case studies of process design and operation of the Contichrom system.

A companion webinar specifically covering the operating software (ChromIQ) will give deeper insights into the operating and control platform. It can be viewed here: [Novel benchtop FLPC \(Contichrom® CUBE unit\) ChromIQ software](#).

## [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.

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## [Novel benchtop FLPC \(Contichrom® CUBE unit\) ChromIQ software - unique features for design, operation and evaluation of continuous chromatography](#)

by **Thomas Müller-Späth, Ph.D.**

The Contichrom platform are multi-purpose chromatography system for proteins, oligos and peptides. The Contichrom CUBE bench-top system is controlled by the user through the ChromIQ operating software. **ChromIQ comes with unique features that make it particularly useful** when designing, running and evaluation, including wizards for rapid process design and performance estimation based on single column chromatography, active buffer management, graphical tools to determine steady state and evaluation tools for buffer consumption calculation. The presentation will provide an **overview of the software features and application cases**. A companion webinar overviewing the hardware and functionality of the CUBE unit is recommended viewing for higher level understanding of this lab instrument. View here: [The Contichrom CUBE bench FPLC tool – features and applications for large and small molecule process development](#).

## [YMC – chromatography analytical to prep scale tools – leveraging YMC technology](#)

by Gerard Gach, Jeff Kakaley & Ann Rousek

**Chromatography columns, packing media, resins, LPLC and HPLC bench and GMP scale systems** are just a few of the best-in-class lab and GMP scale process solutions for the bio & pharmaceutical industry by the 40 year-old life sciences company, YMC.

This 25 Minute webinar introduces the attendees to the **technologies and services pioneered and offered by YMC** – a toolbox of pioneering, proven and forward-looking purification products.

YMC is a Life Science technology company with offices and factories in North America, Asia, India, and Europe. Founded in 1980, and headquartered in Kyoto, Japan, YMC employs over 500 employees.