Contichrom® Twin-column FPLC Chromatography
Integrated and Continuous Manufacturing
Trends: to continuous manufacturing

Continuous = no defacto market leaders, high interest, high risk & high reward

- **Today:** Batch Processes
- **Emerging:** Integrated Processes
- **Tomorrow:** Continuous Processes

- Continuous manufacturing is gaining interest due to its potential to reduce costs and increase efficiency.
- The transition from batch to continuous processes is leading to a shift in market dynamics.
- This trend is accompanied by high risk and high reward, as companies invest in new technologies and processes to maintain a competitive edge.
Contichrom® for Continuous Biomanufacturing

Cell Factory
For production of therapeutic protein

Biochromatography
→ rate limiting and most expensive

Production
Perfusion Culture

Isolation
CaptureSMB

Purification
MCSGP

Polishing
AIX/Virus Filter

Final cleaning and drug formulation
The Three Pillars of Continuous Chromatography

Continuous Downstream

PILLAR 1
Continuous Capture

CaptureSMB®
2C-PCC

PILLAR 2
Continuous Polish

MCSGP

PILLAR 3
Process Control

AutomAb®

New Regulatory Structure Based on Three Pillars
2C-PCC suited for long-term continuous operation

USP & DSP Integrated

25 day operation
With varying feed titer

Perfusion
Harvest rate: 1RV/day

Viable cell density

Capture SMB
- Columns: 2 x 1 ml
- Cycle time adjusted to feed concentration

2C-PCC (CaptureSMB): 25 day operation

Contichrom CUBE Combined or Lab-10 equipment

From: M. Morbidelli, Nov 2015, Integrated Continuous Manufacturing Conference, Berkeley, CA
Combining two CUBE system modules allows operating a downstream chromatographic purification train fully continuously. The system can be directly docked to an upstream perfusion reactor and serve an integrated USP/DSP continuous manufacturing process development tool with DSP under control of the ChromIQ operating software.

Contichrom® for Integrated Manufacturing
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• Combining two purification steps in one continuous process

Protein A elution + inline dilution = CIEX load

Protein A regen., CIEX elution

Protein A Load. CIEX regeneration

Blue – UV 1
Red – UV 2
Gray – cond 2

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Combining CUBE units for fully continuous manufacturing

- Integrated batch,
- cyclic and continuous processes for single process steps

Fully continuous integrated process

Clarified harvest

Protein A CaptureSMB

Pool surge vessel

MCSGP CIEX

Tandem AIEX FT mode

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