

## Engineering Conferences International ECI Digital Archives

---

Integrated Continuous Biomanufacturing II

Proceedings

---

Fall 11-2-2015

# EcoPrime twin – Scale-up of CaptureSMB to the process scale

Kathleen Mihlbachler

*LEWA Process Technologies*, [kmihlbachler@lewapt.com](mailto:kmihlbachler@lewapt.com)

Thomas Muller-Spath

*ChromaCon AG*

Lars Auman

*ChromaCon AG*

Michael Bavand

*ChromaCon AG*

Rick Langone

*LEWA Process Technologies*

*See next page for additional authors*

Follow this and additional works at: [http://dc.engconfintl.org/biomanufact\\_ii](http://dc.engconfintl.org/biomanufact_ii)

 Part of the [Biomedical Engineering and Bioengineering Commons](http://dc.engconfintl.org/biomanufact_ii)

---

### Recommended Citation

Kathleen Mihlbachler, Thomas Muller-Spath, Lars Auman, Michael Bavand, Rick Langone, and Gerard Gach, "EcoPrime twin – Scale-up of CaptureSMB to the process scale" in "Integrated Continuous Biomanufacturing II", Chetan Goudar, Amgen Inc. Suzanne Farid, University College London Christopher Hwang, Genzyme-Sanofi Karol Lacki, Novo Nordisk Eds, ECI Symposium Series, (2015). [http://dc.engconfintl.org/biomanufact\\_ii/116](http://dc.engconfintl.org/biomanufact_ii/116)

This Conference Proceeding is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Integrated Continuous Biomanufacturing II by an authorized administrator of ECI Digital Archives. For more information, please contact [franco@bepress.com](mailto:franco@bepress.com).

---

**Authors**

Kathleen Mihlbachler, Thomas Muller-Spath, Lars Auman, Michael Bavand, Rick Langone, and Gerard Gach

# ECOPRIME TWIN - CAPTURESMB\* TO THE PROCESS SCALE

Kathleen Mihlbachler<sup>1</sup>, Daniel Baur<sup>2</sup>, Thomas Müller-Späh<sup>3</sup>, Gerard Gach<sup>1</sup>, Massimo Morbidelli<sup>2</sup>

<sup>1</sup> LEWA Process Technologies, Devens, USA

<sup>2</sup> Institute for Chemical and Bioengineering, ETH Zurich, Zurich, Switzerland

<sup>3</sup> ChromaCon AG, Zurich, Switzerland

OBJECTIVES:

Lab-Scale

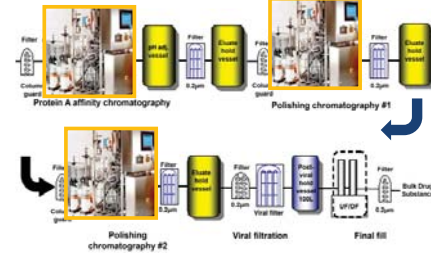
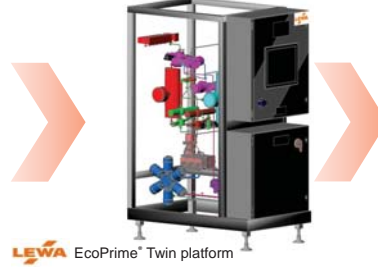
- Pilot/Production-Scale (GMP)

- Integrated Continuous DSP

Multi-Column Continuous Chromatography enables Integrated Continuous DSP

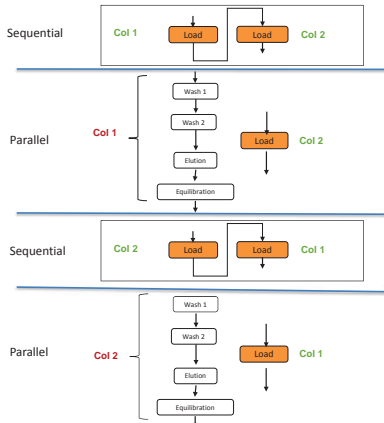
- higher productivity
- size reduction
- elimination of hold tanks

technical and process challenges;  
business and regulatory drivers



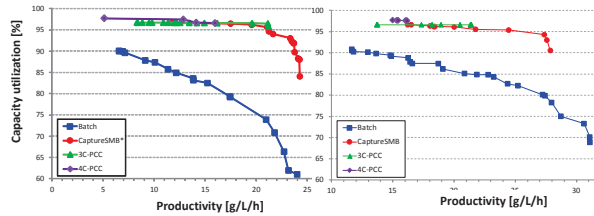
## CaptureSMB\* - Process Optimization and Comparison

Feed titer of 2.5 g/L and 5 g/L



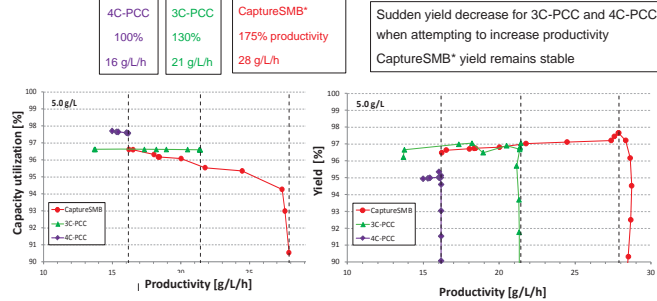
Parallel and Sequential loading: splitting into 2 columns, capacity utilization maximized, typically > 90% of SBC.  
→ Faster loading flow rates can be used

Performance Parameters:  $CU = \frac{A+B}{Q_{SMB} \cdot n \cdot V_{col}}$   $Prod = \frac{m_{Ab} \cdot chuate_{cycle}}{n \cdot V_{col} \cdot t_{cycle}}$



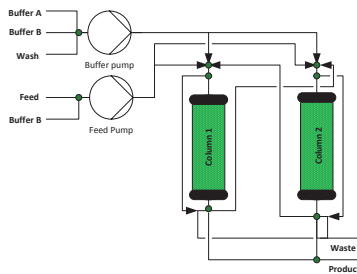
Multicolumn has resin utilization with higher production rates than batch processes (blue)

Capacity utilization > 90% and 5.0 g/L titer



2-column CaptureSMB\* highest productivity by retaining CU and yield

## EcoPrime Twin Design



Hygienic metering pumps with LEWA intellidrive technology

Feed pump

Recovery pump for wash, elution, regeneration, and equilibration

Option: 4 pumps (MCSGP)

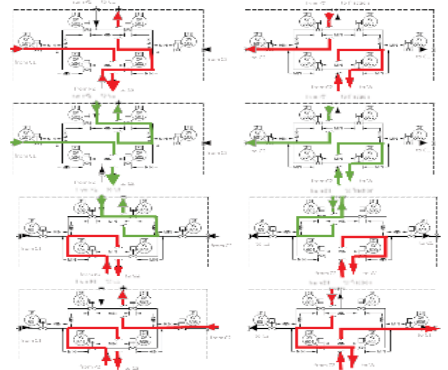
Single diaphragm valves and valve blocks

Design Specs:

- Min volumes within valve blocks
- Capable to carry out the process flow charts without any cross-contamination
- Reduce system volume with min piping length between the columns and the valve blocks but also before and after the blocks; but comparable to CaptureSMB.

- GMP equipment build on the EcoPrime LPLC platform: all parts compliant
- User-friendly automation software that is GAMP5 compliant

Flow charts: Inlet and outlet blocks



## Risk Assessment

For skid design and its parts to ensure the safety of the process, operation, and ultimately to the patient:

- Compliant with regulation (GMP, GAMP 5, 21CFR part 11 ...)
- Alarm and event logs, access control
- Avoiding any cross-contamination and dead legs
- Cleanability of all wetted parts
- Mechanical and chemical stability of the parts
- No leaching or extractable
- No effect of the skid onto the process and of the parts onto the mechanical and chemical stability of the molecules

## Conclusion

1. Smaller column ID ⇒ higher efficiency ⇒ better resin utilization ⇒ **Cost out**
2. Shorter columns ⇒ higher flow rates ⇒ **Productivity**
3. Reduced buffer consumption ⇒ **Cost out and Space reduction**
4. Less process complexity ⇒ **Robust operations**
5. Fewer hardware components (pumps, valves, piping) ⇒ **Less risk**

Lower capex investment and smaller footprint!