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

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ECOPRIME TWIN - CAPTURESMB* TO THE PROCESS SCALE

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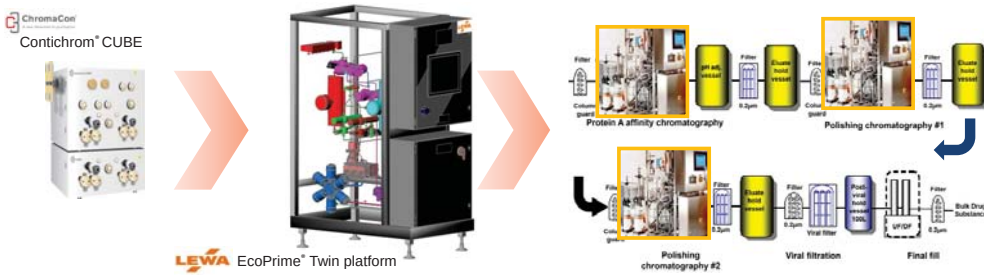
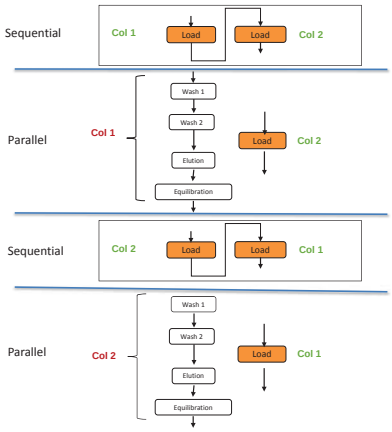
OBJECTIVES: Lab-Scale - Pilot/Production-Scale (GMP) - Integrated Continuous DSP

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

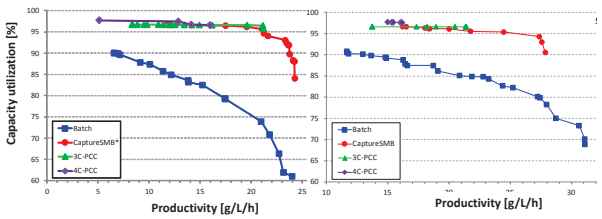


Parallel and Sequential loading: splitting into 2 columns, capacity utilization maximized, typically > 90% of SBC.
→ Faster loading flow rates can be used

Performance Parameters:

$$CU = \frac{A+B}{Q_{SAT} \cdot n \cdot V_{col}} \qquad \text{Prod} = \frac{m_{mAb,eluate,cycle}}{n \cdot V_{col} \cdot t_{cycle}}$$

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

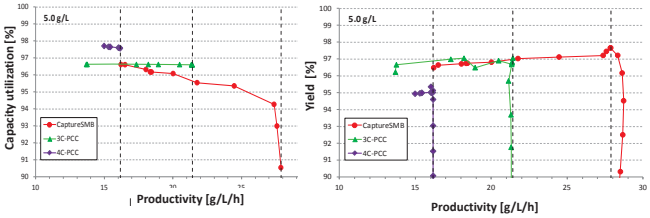


Multicolumn has resin utilization with higher production rates than batch processes (blue)

Capacity utilization > 90% and 5.0 g/L titer

4C-PCC	3C-PCC	CaptureSMB*
100%	130%	175% productivity
16 g/L/h	21 g/L/h	28 g/L/h

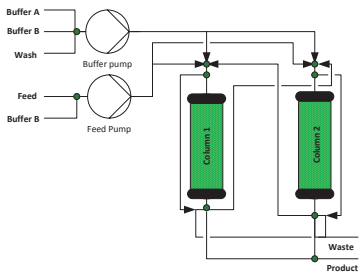
Sudden yield decrease for 3C-PCC and 4C-PCC when attempting to increase productivity
CaptureSMB* yield remains stable



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

* Patented

EcoPrime Twin Design

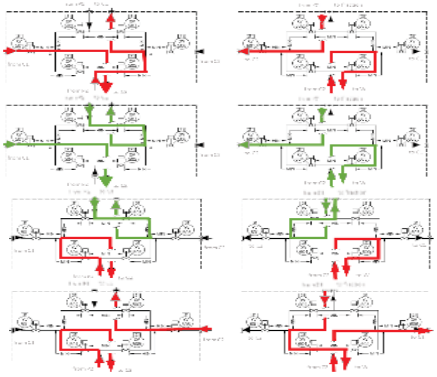


Hygienic metering pumps with LEWA intellidrive technology
- Feed pump
- Recovery pump for wash, elution, regeneration, and equilibration
- Option: 4 pumps (MCSGP)

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 complaint

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 !

ICB Institute for Chemical and Bioengineering
ChromaCon A new dimension in purification
LEWA