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

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Multi-Column Continuous Chromatography enables Integrated Continuous DSP
• higher productivity
• size reduction
• elimination of hold tanks

technical and process challenges; business and regulatory drivers

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

CaptureSMB* - Process Optimization and Comparison

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

Capacity utilization > 90% and 5.0 g/L titer

Performance Parameters:
- $CU = \frac{t_{out}}{t_{in}}$ - Productivity $[g/L/h]$
- $Y = \frac{m_{prod}}{m_{in}}$ - Yield $[%]$

EcoPrime Twin Design

Hygienic metering pumps with LEWA intellidrive technology
- 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

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 leaking 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!