

#### FACILITY DESIGN FOR EFFICIENCY AND NEXT-GEN PROCESSING

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### Agenda

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- Upstream and Downstream Technologies
  - Facility Design
  - Next Generation Processing
  - Single Use Technology
  - Process Economics

















# Dynamic Control of Perfusion Rates Challenge: Perfusion process can consume large volumes of media, driving up cost Evaluation of titers in Day 10 (High Density Fed-Batch) to Day 14 (Fed-Batch) across five cell lines / process



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N	Aulticolu	umn Co	ntinuous	Capture -	- Protei	n A Co	st Model	Example	3
	20 cm-	70.7 L Total cost in 60 cm	Protein A resin: \$883,750 diameter	10 cm -	15.9 L Pri Total cost in res <b>67</b> Total resi <b>5</b>	rotein A sin: \$198,750 % capacity u n savings: \$ 5% cost dec	15.9 L Pro Total cost in res utilization increa 486,000 (per ca crease per bate	otein A in: \$198,750 ase ampaign) ch	
		Column Volume (L)	Total Resin Cost (\$12,500/L)	Capacity Utilization %	Total Time (hr)	# of Cycles Needed	Material Processed per Cycle (kg)	Productivity (g/L/hr)	
	Current Gen	70.7	\$883,750	55%	11	3	3.2	12	
	Next Gen Scenario #1	31.8	\$397,500	92%	13	4	2.8	23	
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## Chromatography Skid – CIP Header (Closing Open Connections)

Knowledge

#### CHALLENGE

Chromatography skids have standard open TC . connectors.

#### **OUR SOLUTION**

- Skid designed with a single sanitization inlet used to clean all flow paths.
- Lynx connector combined with standard aseptic connectors are installed on inlets and outlets prior to sanitization.
- All open connections are made prior to sanitization.
- After sanitization, Lynx connector is activated by quick twist to create open flow path through the skid



TOM BEOGRAPHY SKICI INIERS NaOH Inlet Closed Open



- Standardizes dispense rate, dose volume, and maximum and minimum wait times for viral inactivation and neutralization
- Reduces operator error and overshooting



Facility	Area of facility	Process Metrics Assumptions	~ Annual Output (metric tons/year)
<b>Current State (SUF 1)</b> 3 x 2000L Bioreactors	36,400 sq. ft.	Lots = 66 (5 day cadence) Titer = 6 g/L DSP yield = 70%	0.56
Next Generation Manufacturing (SUF 2) 3 x 2000L Bioreactors	20,120 sq. ft.	Lots = 90 (3-4 day cadence) Titer = ~10 g/L DSP yield = 70-80%	1.24
<b>Goal of new suite</b> : footprint and shorte	Increase the ining proces	nroughput, while decreasing mar sing durations	nufacturing

