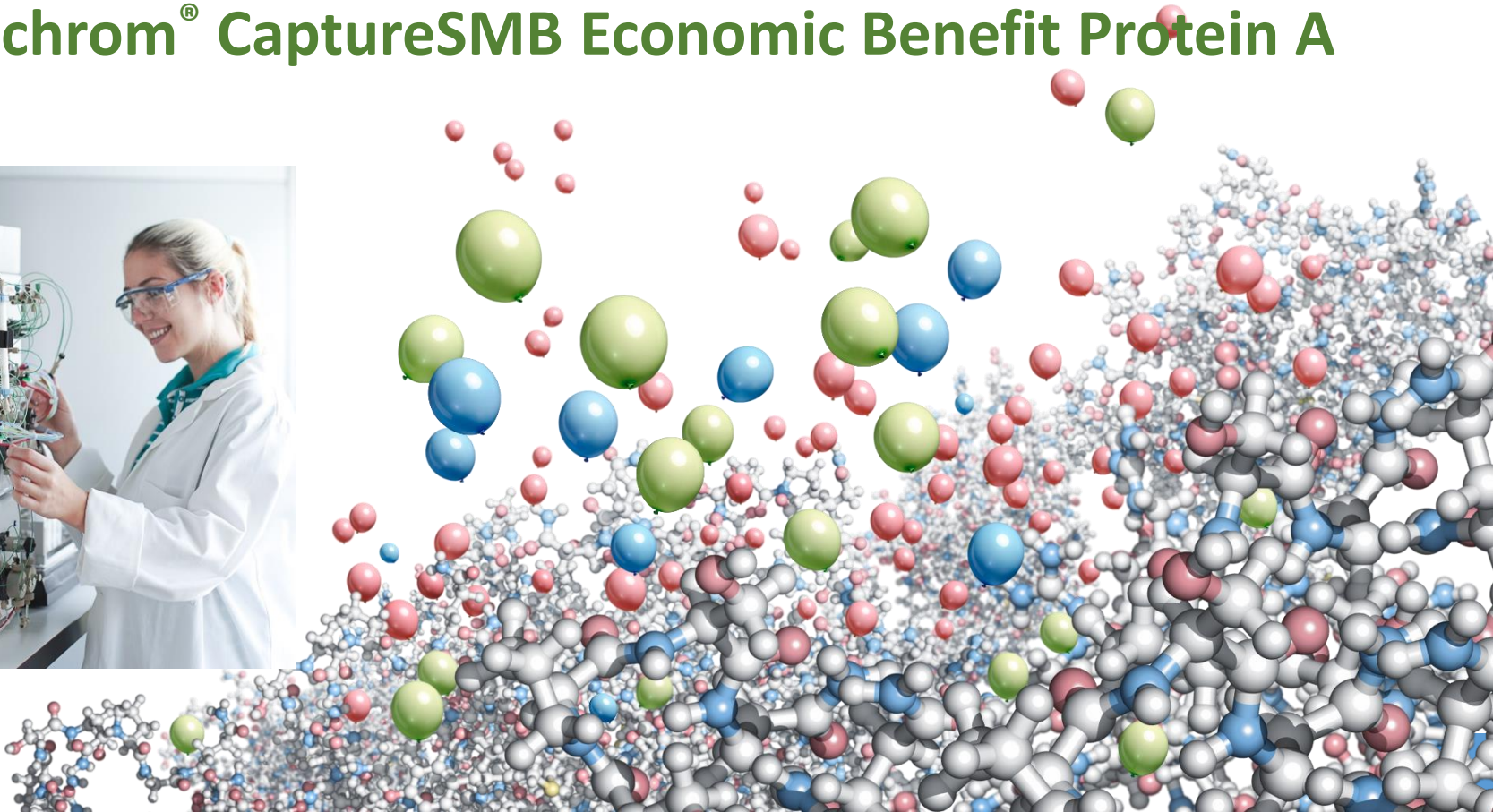




Contichrom[®] Twin-column FPLC Chromatography

Contichrom[®] CaptureSMB Economic Benefit Protein A



Economic Evaluation of CaptureSMB (2C-PCC) CMO / CMC scenario

- Clinical manufacturing of small batches
- Scenario assumptions:
 - Production geared towards minimizing resin costs
 - Production of monoclonal antibody
 - 2000 L fermenters
 - 2 g/L titer
 - 4 kg mAb / batch
 - 20 batches per year
 - Protein A lifetime: 200 cycles but new resin has to be used for each batch
 - Process Performance:
 - Load CaptureSMB 40 g mAb/L resin
 - Load Batch 25 g mAb/L resin



Evaluation of CaptureSMB (2C-PCC), CMO / CMC scenario

- Minimizing Protein A resin costs and buffer consumption

Annual performance		CMO / CMC Scale Batch	CMO / CMC Scale CaptureSMB
Protein A resin volume	Liters	80	2 x 33
Column diameter	cm	72	2 x 47
Buffer consumption	Liters	90,900	57,000
Resin costs	US\$	1.04 Mio	0.43 Mio
Resin cost savings	US\$	/	0.6 Mio / 60%
Buffer Savings	Liters	/	35,000 / 40%

→ Significant OPEX reduction through use of CaptureSMB



Economic Evaluation of CaptureSMB (2C-PCC)

Commercial scale scenario

- After clinical manufacturing phase I-III and product registration material is produced at commercial scale for market supply.
- Scenario assumptions:
 - Production geared towards minimizing resin costs
 - Production of monoclonal antibody
 - 5000 L fermenters
 - 3 g/L titer
 - Annual product output: 300 kg monoclonal antibody
 - 20 harvests per year
 - Protein A lifetime: 200 cycles
 - Process Performance:
 - Load CaptureSMB 40 g mAb/L resin
 - Load Batch 25 g mAb/L resin



Evaluation of CaptureSMB (2C-PCC), Commercial scale

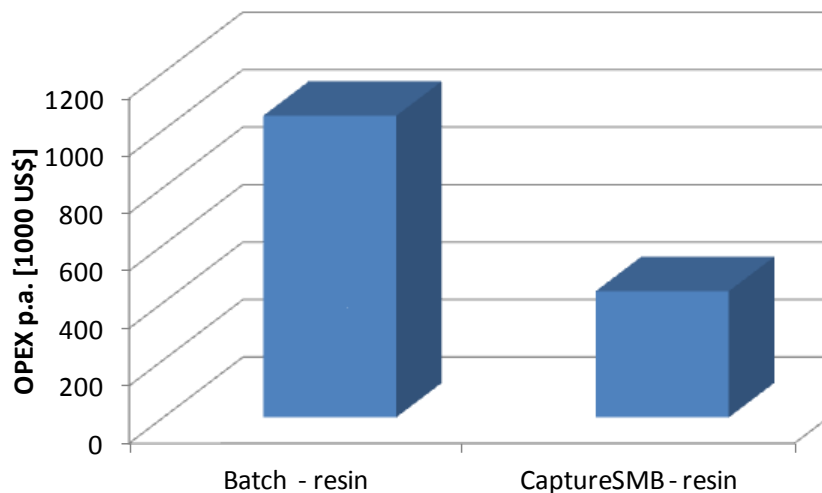
- Minimizing Protein A resin costs and buffer consumption

Annual performance		Commercial Scale Batch	Commercial Scale CaptureSMB
Protein A resin volume	Liters	200	2 x 47
Column diameter	cm	113	2 x 78
Buffer consumption	Liters	340,000	210,000
Resin costs	US\$	2.6 Mio	1.2 Mio
Resin cost savings	US\$	/	1.4 Mio / 54%
Buffer Savings	Liters	/	130,000 / 40%

→ Significant OPEX reduction through use of CaptureSMB

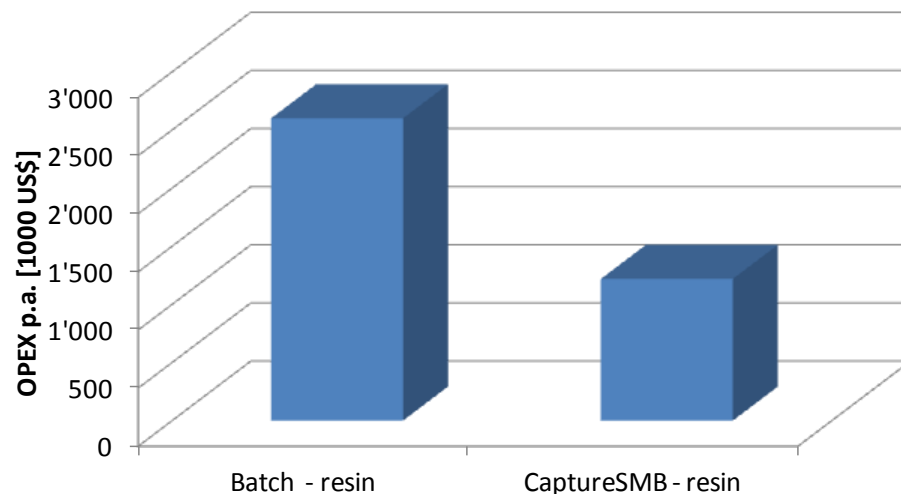
CaptureSMB (2C-PCC) Economic Benefit Protein A

Minimizing OPEX by using CaptureSMB
- affinity capture step - CMC / CMO scenario



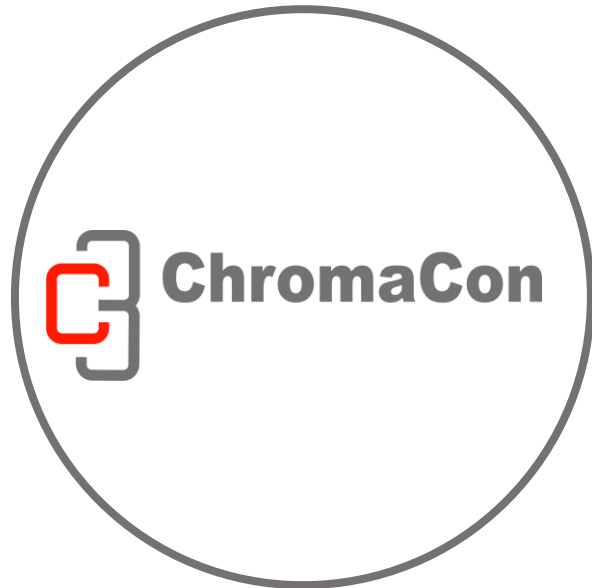
Saving 60% Protein A annual resin costs of 0.6 mio USD p.a. for an output of 20 batches

Minimizing OPEX by using CaptureSMB
- affinity capture step - Commercial scenario



Saving > 50% Protein A annual resin costs to more than 1 mio USD p.a. for a standard mAb process (200kg/p.a.)

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