Cell-Free Protein Synthesis Scale-Up and GMP Production of Protein Biotherapeutics for Clinical Trials

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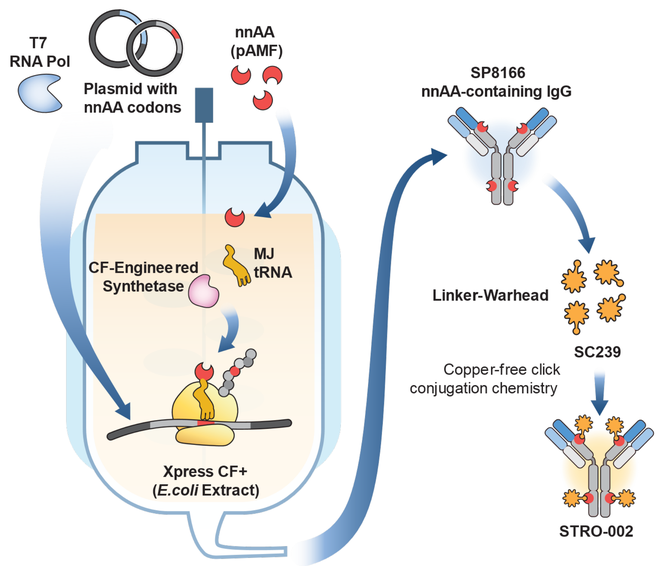
BACKGROUND

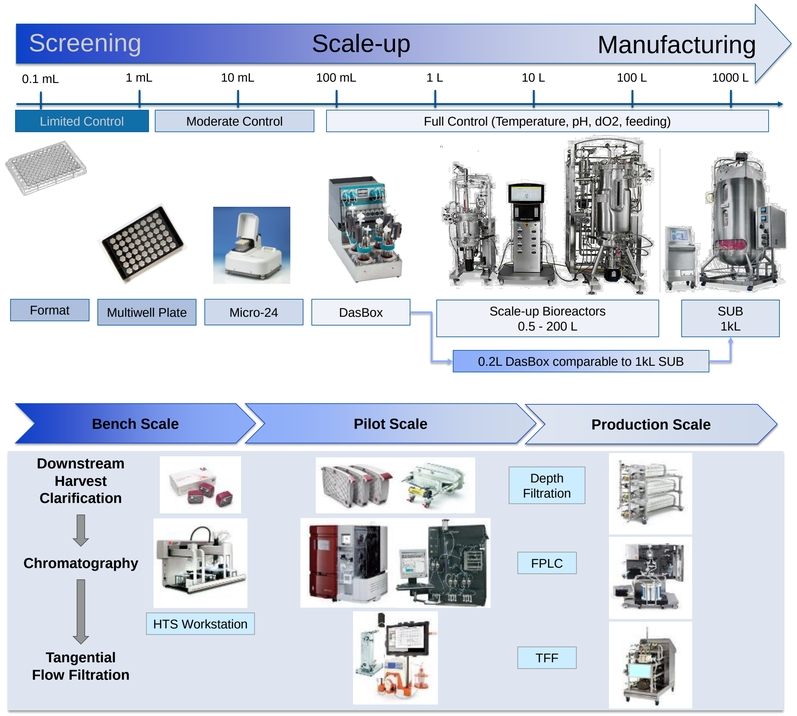
- Traditional expression systems require several days or weeks for each process cycle. This slows down process development and increases the time to clinic for new product candidates
- In addition, these systems are limited to the 20 canonical amino acids which constrains the ability to produce next-generation therapeutics like antibody-drug conjugates
- Sutro Biopharma has developed a cell-free protein synthesis process, XpressCF+™, that capitalizes on the speed and flexibility of cell-free systems to accelerate product and process development
- XpressCF+™ further enables GMP production of non-natural amino acid containing antibodies at a clinically relevant scale



Schematic of clinical candidate STRO-002 production by XpressCF+™. The incorporation of the non-natural amino acid (pAMF) enables site-specific conjugation of the linker-warhead payload.

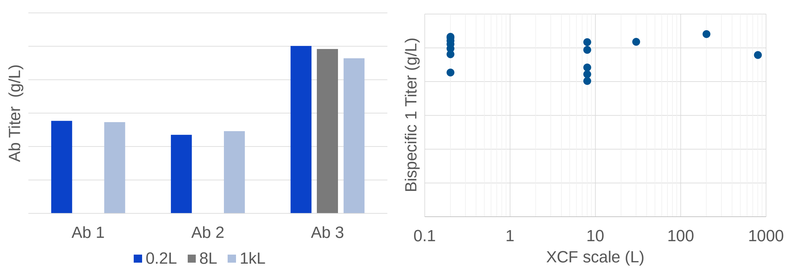
RAPID PROCESS DEVELOPMENT

- XpressCF+™ expression is complete in <24 hours
- Uses standard bioreactors and downstream processing
- Less than 12 months from product lead to GMP manufacture (several months faster than a CHO process)



CONSISTENT AND SCALABLE UPSTREAM

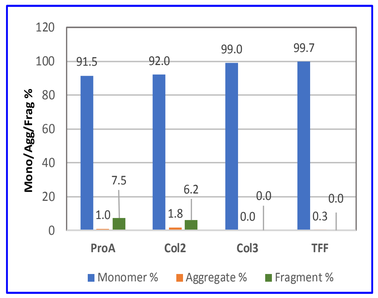
- Titer is reproducible and consistent from 0.2L to 1kL for both monospecific and bispecific antibodies



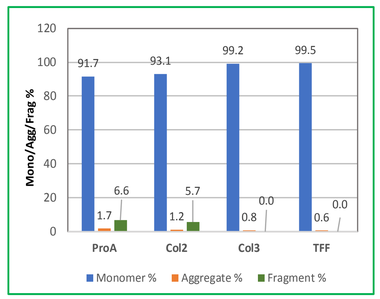
CONSISTENT AND SCALABLE DOWNSTREAM

- Conventional downstream processing consistently delivers appropriate product purity
- Process-related impurities (HCP & endo) are efficiently removed

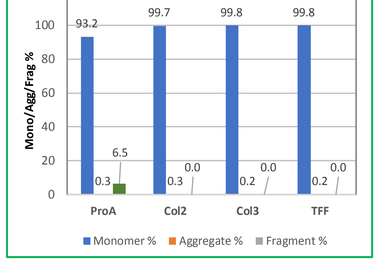
25 L

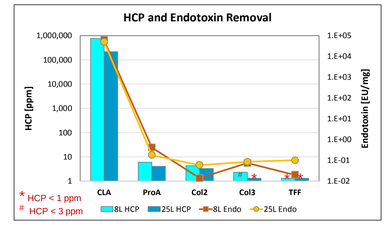


600L



1kL

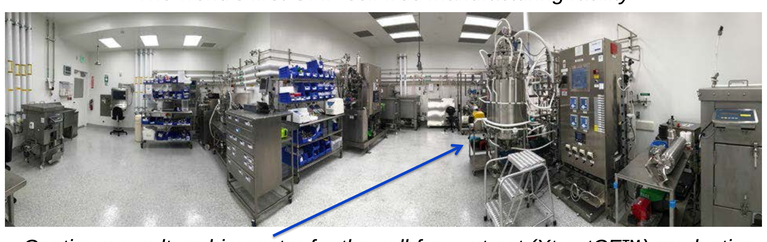




SUMMARY

- Sutro Biopharma's XpressCF+™ technology brings the power of cell-free processing to clinical manufacturing
- Multiple XpressCF+™ produced ADC's are currently in clinical trials
- For more info: www.sutrobio.com

The world's first GMP cell-free manufacturing facility



Continuous culture bioreactor for the cell-free extract (XtractCF™) production