

Therapeutic proteins are a fast growing segment of the pharmaceutical industry. These include native proteins, recombinant and fusion proteins, peptides and antibody fragments, many of which are manufactured through

# Therapeutic Proteins - Development and Manufacture Through Fermentation Technology



- Class 100,000 (ISO 8) Manufacturing suite:
- Fermentors - 100 L / 1,000 L / 4,000 L
  - Continuous disc stack centrifuge
  - Automatic piston discharge high-speed centrifuge
  - High-pressure homogenizer
  - Temperature-controlled, stirred processing tanks up to 4,000 L



- † Class 10,000 (ISO 7) segregated purification suites:
  - GE Uniflux™ tangential flow ultra/diafiltration, Unicorn™ software
  - Millipore® Liquid BioChromatography production and pilot-scale systems
  - BPG QuickScale high-performance columns
- † Lyofast 5 pharmaceutical freeze dryer (Lyophilizer)



## Quality Management

- Dedicated Quality Assurance (QA) and Regulatory Affairs personnel are in place to handle:
- † Document review and approval (e.g. MMF, SOPs, batch records, product release)
  - † Equipment qualification including 21CFR part 11 compliance
  - † Validation of manufacturing processes and cleaning procedures
  - † Investigation of non-conformances
  - † Change control implementation
  - † Corrective And Preventive Action (CAPA)
  - † Personnel training and Qualification program
  - † Drug Master File (CTD-DMF) filing with the regulatory agencies (e.g. FDA, EMEA)

## Analytical Services

Therapeutic proteins analytical tests are compliant with Pharmacopoeia (EP/USP) methods and ICH guidelines. Managed via a validated Informatics System for Quality Control (QC) analytical data (SAP-QM), our services include:

- † Analytical methods development and validation
- † Testing of raw materials, in-process control, and final product release
- † Stability testing
- † Cleaning efficiency testing
- † Selected protein analysis tests:

Test	Methods
Protein concentration	Biuret, Lowry, UV ( $A_{280}$ ), W/C, Bradford
Molecular mass	ESI-MS
Protein identity	Western blot, LC-MS (Peptide mapping), Amino acid analysis
Protein purity	RP-HPLC, TLC, SDS-PAGE
Immunoassay	ELISA, Radioimmunoassay, Immunofluorescence
Potency/Activity	Bio assays (Enzymatic, Affinity, Attachment, Lytic )
Impurities	Heavy metals, Water (KF)
Residuals	qPCR (DNA), LC-MS/MS (Kanamycin), HPLC (IPTG)
Endotoxin	LAL
Microbial load	Bio-burden, Sterility



SAFC Pharma can support your fermentation derived therapeutic protein needs from the pre-clinical to commercialization

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Inspiring Science

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