

GMP PROTEIN MANUFACTURING SERVICES

Put our GMP expertise to work for you.



Our expertise with protein-based therapies extends from the discovery of IL-2 and covers over 30 years of GMP manufacturing support for biopharmaceutical companies and US government clients. ABL supports industry, academic and government clients developing

- Monoclonal antibodies
- Glycoproteins
- Virus-like particles (VLPs)
- Fusion proteins
- Immunotherapeutics
- Critical reagents for diagnostic assays
- Other cutting edge recombinant protein therapies

Every protein product brings a unique set of challenges during development and manufacturing scale-up to reach the clinic. From the initial technology transfer discussion to the shipment of vialled product, ABL's scientific and operations staff are focused on developing a robust, reproducible, GMP-compliant process that delivers high quality material at maximum expression and recovery yields. We can work with clients to optimize specific unit operations during process transfer, or create a comprehensive product development plan (PDP) outlining each step of development and scale-up, highlighting technical, regulatory and schedule risks.

Services

- Cell line development
- GMP master/working cell banks (MCB/WCB)
- Transient transfection scale-up
- Upstream cell culture development
- Downstream purification development
- Manufacture of toxicology material
- GMP manufacture of drug substance (DS)
- Aseptic fill/finish of drug product (DP)
- Analytical development and qualification
- Release and stability testing

Capabilities

- Mammalian Cell Culture Process Focus
- Multiple Sartorius BIOSTAT® STR Single-Use Bioreactors – 50L, 200L, 400L
- Column Chromatography – Multiple GE AKTA Systems – Explorer, Pure, Ready, Process
- TFF – UF/DF
- Multiple GMP cleanroom manufacturing suites with dedicated HVAC, airlocks and access control
- CMC/Regulatory support
- Aseptic Fill/Finish
 - Up to 10,000 vials/batch

Experience

- Monoclonal antibodies
- Glycoproteins
- Virus-like particles (VLPs)
- Fusion proteins
- Enzymes
- Other recombinant proteins

Quality Systems

ABL's U.S. location adheres to Good Manufacturing Practices (GMP) standards and is ISO 9001 accredited.

ABL welcomes client audits and keeps a permanent audit record detailing each audit performed, results, corrective actions taken, and follow up verification of the final outcome.

Contact Us Today



ABL AWARDED 3-YEAR PROGRAM EXTENSION

ABL Awarded 3-Year Program Extension as the Biologics Production Facility for NHLBI's SMARTT Program.

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ABL RECOGNIZED FOR SUPPORT

ABL Recognized for Supporting Fill-Finish of Novavax's Zaire Ebolavirus Glycoprotein Nanoparticle Vaccine

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Download ABL's brochure describing government partnering services

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