

# Therapeutic Proteins

ABL's expertise with protein-based therapies began with the discovery of IL-2 and has spanned over 25 years of cGMP manufacturing for industry and government clients. In addition to providing comprehensive process development and manufacturing services for microbial and mammalian processes, ABL offers *in vivo* and *in vitro* preclinical testing for optimal integration of discovery, preclinical and clinical activities.



## HIGHLIGHTS

- State-of-the-art cGMP manufacturing facility validated and put into service in 2011
- Multiple production platforms
- Small scale adherent to bioreactor-based processes
- Experienced Project Management

### Experience

- Antibodies, Recombinant Proteins, Cytokines, Immunotoxins, and Diagnostic Proteins and Kits

### Manufacturing Services

- Cell Line Development
- Upstream and Downstream Process Development
- cGMP Cell Banking - Mammalian & Microbial
- cGMP Bulk Production
- Aseptic Fill/Finish (Liquid Fills)
- Analytical Method Development and Qualification

### Manufacturing Capabilities

- Mammalian Cell Culture up to 400 L
- Microbial Fermentation up to 40 L
- Aseptic Fill/Finish up to 3,000 Vials

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## cGMP Cell Banking

A critical step early in the development of a biological therapeutic or vaccine is the establishment of Master and Working cell banks produced in compliance with current Good Manufacturing Practices (cGMPs) and characterized as outlined in the FDA Points to Consider Document on the Characterization of Cell Lines used to Produce Biologicals. Our development and manufacturing teams will work with you to establish a clonal cell line that stably produces your product, and meets all regulatory requirements to support clinical and commercial production.

The ABL team has many years of experience producing cell banks for clinical programs. Let us work with you, utilizing our expertise, to generate a cost-effective strategy to meet your cell banking requirements: from cell line development and optimization to manufacture and inventory management.

### Non-GMP Development

- Cell line Construction and Optimization
- Animal Origin-Free Adaptation
- Mammalian and Microbial Research Banks

### cGMP Cell Bank Manufacture

- Mammalian (e.g., CHO, HEK 293, Vero, MDCK)
- Microbial (e.g., E. coli)
- Master and Working Cell Banks
- Freeze-Thaw Viability Testing

### Support Services

- Preclinical Testing (Nonhuman Primates, Rodents, Rabbits)
- Analytical Development & Qualification
- Regulatory Affairs

### Fully Integrated Project Management

- Project Team Leadership
- Budget and Schedule Tracking
- Third Party Vendor Management as Needed



ABL is a leading contract research and manufacturing organization, partnering with our clients to *advance* their vaccine and therapeutic development programs.

To inquire about services and other opportunities,  
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