### **GMP BIOMANUFACTURING SERVICES**

# GMP Manufacture of Virus-Based and Protein-Based Products

- Virus-Based Products
- Protein-Based Products
- Aseptic Filling Operations



The path to market for new medicines is often fraught with highly technical challenges, not the least of which is development of a robust, scalable manufacturing process producing safe and effective product that meets global regulatory requirements.

Many different facets of product development must come together to create a successful manufacturing strategy. At ABL, our clients benefit from our 30-year history of GMP production. With facilities located in the U.S. (Rockville, MD) and Europe (Strasbourg, France), we offer a comprehensive list of services for translating promising research into GMP supply. ABL is capable of manufacturing preclinical and clinical material.



ABL is focused on providing quality contract manufacturing services for biologics production of vaccines, gene therapies, oncolytics, and monoclonal antibodies and other therapeutic proteins. Using single-use bioreactor technology and other disposable systems, ABL reduces client expenses by decreasing time in suite, mitigating the risk of product carryover, and minimizing the need for expensive cleaning validation studies.

Contact ABL today to discuss how we can put our expertise and capabilities to work for the advancement of your product into the clinic and beyond.

#### Services

- GMP production of vaccines / gene therapies / oncolytic products
- GMP production of monoclonal antibodies/therapeutic proteins
- GMP aseptic fill/finish of drug product
- Process development
- Analytical development, qualification, validation
- Lot release and stability testing
- Master and working cell banks
- Master and working viral seed stocks
- CMC and regulatory services

## Quality Systems

ABL's U.S. location adheres to Good Manufacturing Practices (GMP) standards and is ISO 9001 accredited. ABL Europe's facility is regularly inspected by the French regulatory authorities (ANSM) and is a GMP licensed site for the manufacture of drug substance and aseptically prepared small volume liquid (drug product) viral products in accordance with EMA regulations..

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.

# NAJÍT TECHNOLOGIES PARTNERS WITH ABL FOR DEVELOPMENT OF NOVEL VACCINE PLATFORM

ABL is working with Najít Technologies, Inc. to advance the development of Najít's novel HydroVax™ vaccine platform.

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Contact Us Today

# ABL EUROPE AND SILLAJEN EXPAND STRATEGIC MANUFACTURING COLLABORATION FOR ONCOLYTIC VIRUS THERAPIES

SillaJen, Inc., a clinical-stage, biotherapeutics company focused on the development of oncolytic immunotherapy products for cancer, and ABL Europe, an ABL, Inc. company providing dedicated viral vector GMP services for gene therapy, oncolytic products and vaccines for all stages of clinical supply, have expanded their strategic manufacturing collaboration.

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#### PROTEIN MANUFACTURING BROCHURE

Download ABL's brochure describing government partnering services.

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## GMP VACCINE & VIRAL VECTOR PRODUCTION

Download ABL's brochure describing virus manufacturing services

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