ASEPTIC FILLING OPERATIONS

GMP Aseptic Fill/Finish Services

Flexible, responsive scheduling. Quality product.

 With aseptic filling operations in the U.S. and Europe, ABL provides our clients with the scheduling and logistical responsiveness needed to support global trials. Whether as part of a comprehensive development and GMP production program or to address drug product filling on a stand-alone basis, we integrate vialing, inspection, labeling, testing, and storage and distribution activities to meet the often demanding timelines for the provision of clinical trial materials.

ABL maintains an isolator-based line specifically designed to fill live virus products in Strasbourg, France. Our Rockville site also supports filling of live virus in addition to filling therapeutic proteins and other biological products for clinical trials.

Services

- GMP aseptic fill/finish of drug product into vials and ampoules
- 100% visual inspection and AQL procedures
- Labeling and packaging on lot basis
- Management of drug product release and stability testing
- Adjuvant mixing studies
- Multiple temperatures for the storage of drug product storage under GMP:
    - Ambient (+15°C to +25°C)
    - Refrigerated (+2°C to +8°C)
    - Frozen (-25°C to -15°C)
    - Ultra Low Frozen (-80°C to -60°C)

Capabilities

- GMP aseptic filling of protein therapeutics up to 10,000 vials per lot
- GMP aseptic filling of vaccines, gene therapies and other virus products up to 10,000 vials per lot
- Ampoules filling up to 10,000 units per lot
- Vial sizes from 2 mL – 10 mL vials
- FDA and EU compliant operations
- Experienced Quality (QA/QC) teams

- Dedicated Regulatory Affairs staff
- Strong Project Management Support

Types of Products

- Monoclonal antibodies and other recombinant proteins
- Vaccines
- Gene therapy vectors
- Oncolytics
- Immunotherapies
- DNA/RNA oligonucleotides
- Peptides
- Placebo and diluent lots

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.

Contact Us Today

 **ABL RECOGNIZED FOR SUPPORT**

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

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 **OUR NEW STATE-OF-THE-ART, FULLY AUTOMATED VIAL FILLING LINE**

ABL Increases Aseptic Fill/Finish Capacity

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