

Aseptic Filling and Lyophilization Services

BioReliance Corporation uses the latest aseptic filling technologies, operated by an experienced and dedicated team of scientists and process engineers. The result is efficient, cGMP-compliant production of your virus or protein therapeutic into the final dosage form, without the significant investment for in-house facilities and personnel.



All filling and component assembly takes place in a state-of-the-art class 100 barrier isolator system.

- Virtually eliminates operator-introduced contamination
- Gives you greater assurance of product safety and purity

We can accommodate a wide range of vial and lot sizes, utilizing manual and automated filling systems.

- Provides the flexibility and capacity to grow with your product needs
- Offers the advantage of working with one contractor from development to commercialization



BioReliance technical support services include formulation development, lot release testing and analytical stability studies. In addition, we offer guidance in regulatory issues.

- Provides the convenience of a multiservice vendor
- Offers a cost-effective alternative to qualifying multiple contractors

Our staff has 30+ years of combined experience in filling parenteral liquid and lyophilized biologics.

- Results in efficient technology transfer of your process
- Ensures the timely and high-quality production of your product



Products Filled

- Gene therapy products
- Viral/bacterial vaccines
- Monoclonal antibodies
- Recombinant protein therapeutics
- Microbial products
- Diluents/buffer

Services

- Formulation development of liquid/lyophilized virus- and protein-based therapeutics
- Manual and automated cGMP filling of parenteral drugs
- Lyophilization process development
- cGMP lyophilization

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Capabilities

Final Fill

- Fully automated filling
 - Up to 50,000 vials per lot
 - Up to 7,000 units per hour
- Manual/semi-automated filling
 - Up to 1,500 vials
- Validated for 2,3,5 and 10 ml glass vials

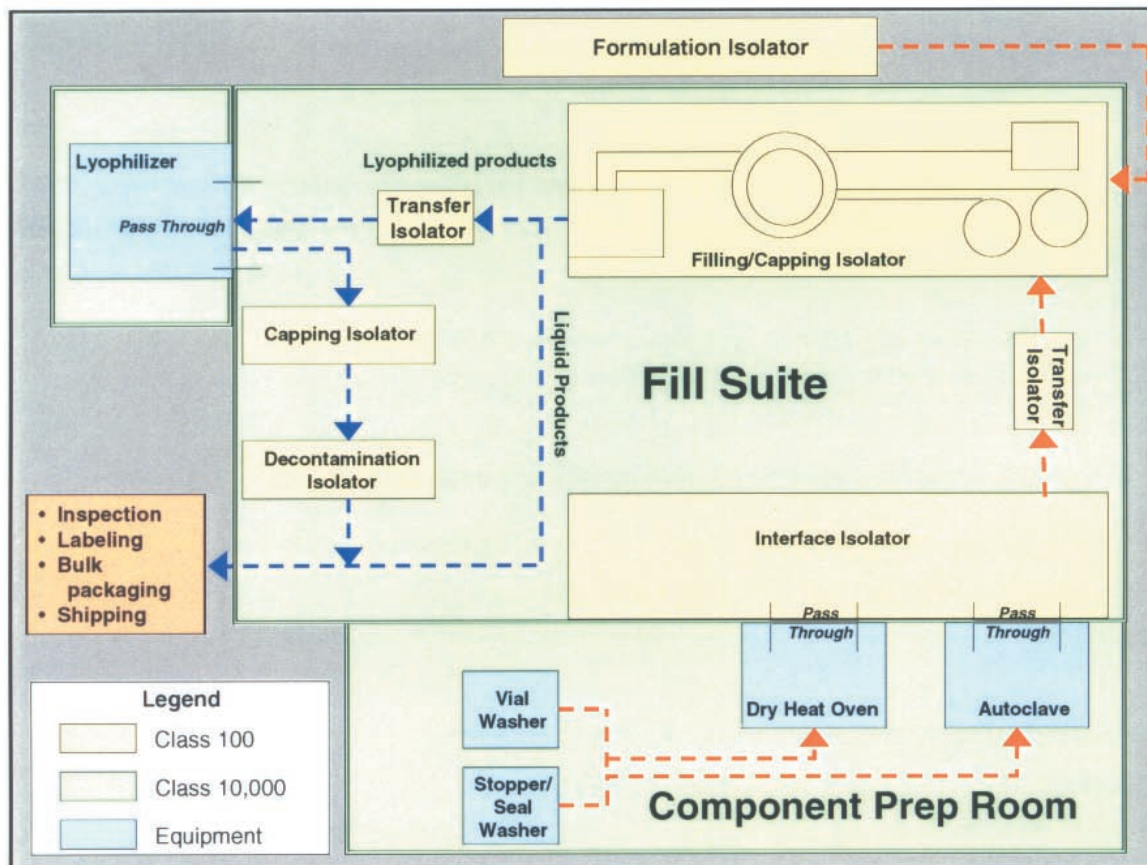
Lyophilization

- Lyophilization development up to 2,000 vials per lot
- Large-scale lyophilization up to 30,000 vials per lot (available 2003)

Facility Highlights

- Class 100 barrier isolator system within a class 10,000 room
- Class 10,000 component prep room with a class 1,000 air shower zone
- BL-2 classification
- Vapor-phase hydrogen peroxide sterilization
- Large-scale cGMP lyophilization facilities (available 2003)

cGMP Fill Suite Layout and Process



Quality, Science and Services You Can Trust

Comprehensive Services Available from BioReliance:

Cell Line Characterization
Viral Clearance Validation
Lot Release Testing
cGMP Manufacturing of Viral-Based Therapeutics
Analytical Testing
Genetic and Mammalian Toxicology Testing
Laboratory Animal Diagnostic Services

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