

# 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



# Aseptic Filling and Lyophilization Services

## 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

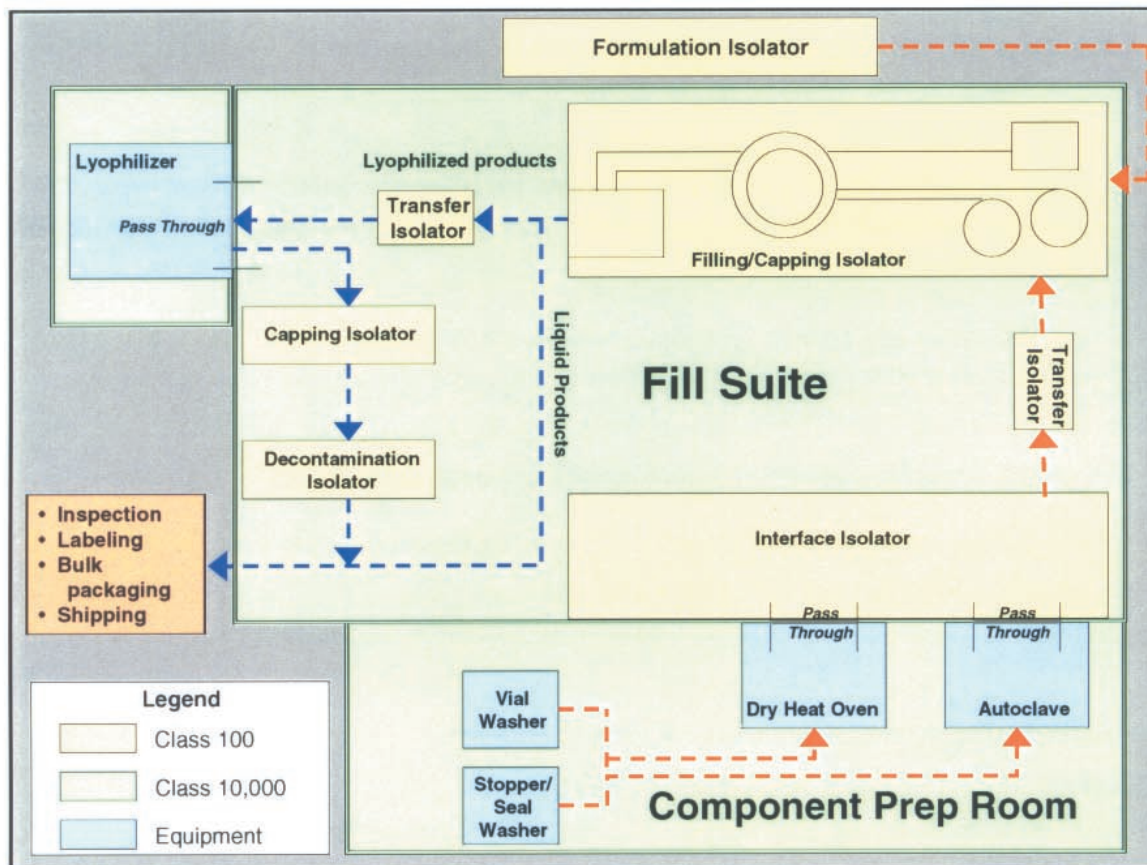
### Lyophilization

- 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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