

Contract Services for Biopharmaceuticals

Technical Bulletin

cGMP MANUFACTURING

Our 57,000 sq.ft. facility in Princeton, New Jersey includes development laboratories and manufacturing areas that house both stirred-tank and hollow-fiber bioreactors ranging from 10 to 2500 liters in size. Critical equipment and processes have been validated for the production of biopharmaceuticals, and our facilities have been routinely inspected by regulatory agencies. Our senior staff has successfully manufactured both clinical trial size material as well as commercial product for over 10 years.



EXPERIENCE

- **Extensive experience working with biopharmaceutical products**
 - **Monoclonal antibodies**
 - **Recombinant proteins**

FACILITIES

- **Validated cGMP biopharmaceutical manufacturing facility in Princeton, New Jersey**

cGMP SERVICES

- **Cell line development and optimization**
- **Process development and validation**
- **Formulation development**
- **Analytical development and assay validation**
- **Protein production in mammalian cell bioreactors**
 - Stirred tank bioreactors
 - AcuSyst Xcell™ hollow fiber bioreactors
 - Wave bioreactors
- **Purification and downstream processing**
- **Aseptic filling**
- **Stability testing**
- **Quality control testing**
- **Protein conjugations**
- **Radiopharmaceutical test labeling**

