



Research Triangle Park, NC, USA Facilities

Dedicated facilities for cGMP biopharmaceutical contract manufacturing services of monoclonal antibodies, vaccines and recombinant proteins

- Process development laboratories (30,000 ft² / 2,800 m²)
- cGMP manufacturing facility (110,000 ft² / 10,000 m²)
- Successfully completed EMEA, FDA (CBER and CDER) and Health Canada inspections

cGMP Manufacturing

FERMENTATION (Bacteria and Yeast)

- Two inoculum preparation suites with 30 L seed fermentors
- Dedicated small-scale production areas with two x 140 L fermentors
- Two separate intermediate-scale suites:
 - One 150 L and 3 x 2,000 L production fermentors
- Capability to process high density cultures with high cooling demands
- In-line mass spec gas analysis process control

FERMENTATION - Harvest and Recovery

- One small-scale and two intermediate-scale recovery suites with:
 - Holding tanks
 - Centrifuges (disc stack, nozzle discharge)
 - Two Homogenizers – up to 1,000 bar
 - Recovery vessels – up to 3,000 L
- Refold suite

CELL CULTURE (Mammalian and Insect Cells)

- Two cell culture inoculum preparation suites with 20 L seed bioreactors
- Dedicated small-scale production areas with two x 110 L bioreactors
- Intermediate-scale production train:
 - 150, 650 and 2,000 L production cell culture bioreactor train
- Dedicated buffer and media preparation areas

CELL CULTURE - Harvest and Recovery

- Dedicated harvest suite
- 2,000 L harvest vessel
- Microfiltration equipment – up to 200 ft²
- Centrifuges / homogenizers

PURIFICATION (Cell Culture and Fermentation)

- Four Class 100,000 small-scale purification suites
- Three Class 10,000 intermediate-scale purification suites
- Two solution preparation suites – up to 3,000 L
- Chromatography skids – up to 1,000 L/h
- Column sizes up to 100 cm diameter

- Full range of chromatographic methods (SEC, IEX, HIC, HCIC, affinity and expanded bed)
- Ultrafiltration / diafiltration skids (filter area 5-200 ft²)
- Two small-scale and intermediate-scale bulk filling suites with Class 100 areas
- Class 10,000 small-scale Final Formulation suite

MISCELLANEOUS

- Molecular biology and cell line development using MARtech® or DHFR amplification
- Suite for cell-based assays
- Dedicated glass wash preparation area
- Small-scale freeze drying capacity (up to 24 L bulk volume)



