



Biologics Manufacturing Capabilities

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Building on Experience and Accomplishment

Abbott will manufacture your product in full cGMP compliance. Our existing in-house systems free your organization to focus on your pieces of the product development puzzle.

- Change control (quality systems, engineering and procedural)
- GMP training
- Equipment and facility validation
- Cleaning validation
- Preventive maintenance and calibration
- Environmental monitoring
- Product changeover
- Multiproduct facility

You bypass the time it takes to develop GMP systems, leaving cGMP compliance to our experienced and trained staff. Numerous regulatory inspections and customer audits have probed and improved these systems over the years, paving the way for successful implementation of your project.

Quality and regulatory staff work with you to develop your regulatory strategies and filings. A Type V Drug Master File covering all aspects of the facilities and its operation is on file with the FDA for your reference in early filings.

Process Equipment

Extensive installed and validated process equipment minimizes the lead time to bring your product into production. Existing systems are covered by current SOPs.

- Mammalian cell culture vessels systems (3000 L and 6000 L)
- Disposable bioreactor GMP suite (500 L)
- Automated, fixed process tanks (200 L to 6000 L)
- Mobile process tanks (100 L to 1500 L)
- Disk stack centrifuges (Alfa Laval)
- Cross-flow filtration skids (10 to 100 LPH)
- Chromatography columns up to 1-meter diameter
- Chromatography skids (3 to 1571 LPH)
- Cartridge filter housings (1- to 6-round, 10 to 30 inches high)
- Incubators (carbon dioxide and temperature controlled)

Our process equipment reduces your project time and eliminates your production-related capital investment. In-house process engineering and process controls capabilities handle any required customization.

Utilities

Reliable, modern utility systems provide ample capacity to support your process requirements. These systems are continuously monitored.

- USP purified water
- Water for injection
- Clean steam
- Plant steam
- Chilled water
- Compressed air
- Compressed gases (oxygen, nitrogen, carbon dioxide)
- Effluent neutralization
- Effluent decontamination
- Distributed control systems

Your process fits best here because we have the services where you need them.

Support Equipment

Extensive support equipment meets a broad range of project and process needs.

- Clean-in-place skids
- Automated glass washers
- Depyrogenation oven
- Autoclaves
- Refrigerators
- Freezers (-20, -40, -80, -140°C)
- Bench-top analytical instrumentation (pH, conductivity, weight, UV)
- HVAC

Our flexibility in addressing your process configuration and hold-time requirements builds on these calibrated and validated systems.

Facilities

Our state-of-the-art facilities are flexibly configured to accommodate your process requirements. 84,000 square feet of cGMP manufacturing space provides four Class 100,000 fermentation suites, five Class 10,000 purification suites, Class 100 filling hoods and appropriate facilities for all supporting operations, such as material storage, buffer preparation, media preparation and glass wash.

Designed and operated with personnel, product and equipment flow paths geared to regulatory compliance, our facility gives your product the protection it needs.

Temperatures in our purification cold rooms can be adjusted up to room temperature to fit your process requirements.

Continuous monitoring by our building management system and continual environmental testing ensure that your environmental requirements are met.

Process Development/Optimization

Our process development equipment and personnel are capable of supporting early development needs to commercial product launch.

- Cell line development
 - Analytical method development
 - Cell culture process development
 - Purification process development
 - Viral clearance studies
 - Process scale-up lab (300 L)
 - Extended product characterization
 - Process characterization
 - Process validation
 - Manufacturing support
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Quality Control and Analytical Capabilities

Quality control laboratories are equipped with a broad range of state-of-the-art instrumentation for chemical and microbiological analysis.

- HPLC (SEC, ion exchange, affinity, reverse phase)
- Electrophoresis (CE, IEF, SDS-PAGE)
- ELISA
- Microbial identification
- DNA quantification (threshold)
- DNA identification (PCR)
- Endotoxin
- Spectrophotometry (FT-IR, UV-VIS)
- TOC
- Oligosaccharide analysis
- Peptide structure determination (LC/MS/MS)
- Host-cell protein
- Bioburden

Trained and experienced quality control staff will transfer, validate and apply your assays to meet even the most aggressive in-process control and release requirements.
