



Fermentation Manufacturing Capabilities

www.abbottcontractmfg.com

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An Industry Leader

Abbott Fermentation, centrally located in North Chicago, Illinois, offers you the manufacturing expertise that comes from being the industry leader in pharmaceutical Fermentation for over 50 years. From strain development through large scale manufacturing, Abbott is committed to manufacturing excellence in support of your most important projects. Our facility has a proven record of success in these areas:

- High standards for quality and compliance in a safe work environment
- Class-A certified operation, focused on low-cost processing and delivering on commitments
- Culture of continuous improvement
- Pollution prevention and resource conservation

Manufacturing Services

Abbott performs small and large scale Fermentation of conventional and recombinant organisms with the following support systems:

- Dedicated inoculum preparation facility
- Non-GMP fermentors from 10L to 750L for your pilot scale needs
- GMP capable fermentors from 10,000L to 100,000L for your clinical and commercial projects
- Batch and continuous sterilization
- Nutrient feed systems
- Process Analytical Technology (PAT) and process control systems
- Computerized data acquisition
- Foreign growth identification and management program

Downstream, you have access to a wide variety of validated recovery equipment. Abbott will provide the know-how to design and implement a practical and efficient recovery process.

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| • Ion exchange | • Chromatography |
| • Liquid-liquid separation | • Ultrafiltration |
| • Solid-liquid separation | • Crystallization |
| • Other separation processes | • Drying (fluid bed, blender, tray) |

Technical Services

Abbott's depth of technical expertise can support your unique and challenging Fermentation requirements. The disciplines within Abbott's development organization include microbiology, molecular biology, chemistry, biochemistry, chemical and biochemical engineering. Our technical core competencies encompass the following areas of concentration:

- Strain development and culture improvement (classical and recombinant)
 - Bacterial (actinomycetes, recombinant)
 - Fungal (molds and yeasts)
 - Documented transfer of culture assets and inoculum technology
 - Robust inoculum procedures for commercial manufacturing
 - Seamless transfer to the manufacturing inoculum facility
- Process development and justification/characterization
 - Laboratory scale
 - Pilot scale (55 L and 750 L)
- Process scale-up and optimization
- Process justification/characterization
- Process validation
- Analytical method development and validation

Facilities and Utilities

Our 70-acre site is supported by the following systems:

- Distributed Control Systems (DCS)
- Class 10,000 rooms and USP-purified water for downstream processing
- Effluent management and waste treatment
- Controlled temperature storage for bulk solids and liquids

Support Systems and Services

We treat your product with the same care and attention as our own products and keep you informed of the details as we execute your project. Our highly skilled resources and proven systems will support your project, in the areas of:

- Project management
- Quality assurance
- Process and cleaning validation
- Environmental, health and safety programs

Quality Control and Analytical Capabilities

Manufacturing is supported by 24-hour on-site quality control laboratories equipped with state of the art instrumentation for chemical and microbiological analysis performed by trained and experienced quality control staff, with the following capabilities:

- BET: kinetic and gel clot
- Microbial limits testing
- Specific organism detection
- Heat shock
- Water activity testing
- Microbial identification
- Bioburden
- Automated bioassay for potency
- Process biomapping
- HPLC (reverse phase, normal phase, ion exchange, gradient and isocratic methods, pulsed amperometric detection)
- X-ray analysis
- ICP analysis
- Particle-size analysis
- Atomic absorption analysis
- Spectrophotometry (FT-IR, UV-Vis)
- Wet chemistry (titrations, limit tests, LOD, color, flame, pH, heavy metals)
- Total organic carbon testing
- Thin layer chromatography
- GC (FID and TCD detection, capillary and glass columns, headspace and residual solvent analysis)

In addition to in-process and release testing, the QC laboratories also perform stability testing with on-site stability chambers spanning conditions required by ICH Q1A climatic zones I – IV, including refrigerated and freezer conditions, as well as photostability and cycling studies. Abbott's expert stability program administration ensures compliance with global regulations by providing protocol creation, managing storage, dispensing and testing of samples, trending analysis of results and authoring annual stability reports.
