

# Microbial Fermentation Services

AbbVie Contract Manufacturing offers world-class fermentation capabilities based on more than 60 years of leadership in fermentation. Your project will benefit from AbbVie's scientific expertise as a leading development and manufacturer of fermentation processes at our 180-acre facility in Chicago, Illinois. We bring the same degree of expertise and passion to your project as we do with our own, supporting you from cell bank development through large-scale manufacturing.

## Types of Products

- Small molecule API's to be administered orally or as an injectable
- Large molecule API's to be administered orally
- Bulk food ingredients
- Agrochemical active ingredients
- Semi-synthetic products

## Types of Organisms

- GMO & non-GMO manufactured under GLSP (good large scale practice)
- Experience with:
  - Actinomycetes
  - *E. coli*
  - Fungi
  - *Bacillus*
  - Yeast

## Development Manufacturing (Non-GMP)

- Strain improvement via classical and recombinant methods
- Preparation of R&D, master and working cell banks
- Inoculum process development
- Fermentation and downstream process development and characterization including:
  - 55–500L fermenters in pilot plant
  - Track key parameters including pH, DO, temperature, agitation and off-gas
  - Recovery operations that are representative of commercial scale
- Method development and transfer for analytical, microbial and cleaning methods

## Clinical and Commercial Manufacturing

- Over 3000 m<sup>3</sup> fermentation capacity
- Fermenter working volumes from 10,000L–100,000L
- Batch and continuous sterilization of media
- Dedicated facility for cell bank preparation and storage with redundant equipment and controls
- Broad range of downstream capabilities including:
 

- Microfiltration	- Chromatography
- Centrifugation	- Crystallization
- Liquid / Liquid extraction	- Fluid bed drying
- Ultrafiltration	- Filter drying
- Evaporation	
- Packaging liquids into presterilized totes or tanker trucks and dried solids into drums

## Contract Manufacturing

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### Analytical Services

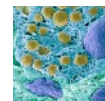
- High Performance Liquid Chromatography (HPLC) – reverse phase, normal phase, etc.
- ICP-OES and ICP-MS
- Gas Chromatography (GC) analysis
- GC-MS and LC-MS
- Reference standard & purity characterization
- Spectrophotometry (FT-IR, UV-Vis, GC Mass Spec)
- Wet chemistry (titrations, LOD, pH, heavy metals, etc.)
- Biopotency
- Turn-key stability testing service
- Cleaning method development via LC and TOC
- X-ray diffraction, TGA and DSC
- Optical and electron microscopy
- Surface area and particle size analysis on site
- Specific organism detection
- Microbial identification and limits testing
- Bioburden (AMC / Endotoxin – LAL)
- Environmental testing

### Manufacturing Excellence

- Class-A certified operation, focused on efficient processing
- Key Performance Index (KPI) monitoring
- Environmental Health and Safety (EH&S) programs to ensure pollution prevention and resource conservation
- Process Analytical Technology (PAT) and process control systems
- Distributed Control Systems (DCS)
- Continuous improvement

### Client Commitment

- Reliable supply through established supply and operations planning (S&OP) processes
- Dedicated project management
- New product introduction business process
- Global Chemical Manufacturing Control (CMC) filing support
- Information confidentiality and security via cyber and physical controls



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Vision. Expertise. Success.