

EXPERIENCE UNRIVALED

MICROBIAL FERMENTATION SERVICES

AbbVie Contract Manufacturing offers world-class fermentation capabilities

based on more than 60 years' leadership in fermentation. Your project will benefit from AbbVie's scientific expertise as a leading developer and manufacturer of fermentation processes at our 180-acre facility in North Chicago, Illinois. We bring the same degree of expertise and passion to your project as we do with our own – supporting you from strain improvement through to large-scale manufacturing.

DEVELOPMENT SERVICES

- › Strain improvement via classical and recombinant methods
 - Bacterial (actinomycetes, recombinant)
 - Fungal (molds and yeasts)
- › Preparation of master and working cell banks
- › Inoculum process development
- › Process development and characterization at pilot scale (10 L – 750 L), including process validation
- › Method development
 - Analytical, Cleaning, Microbial

CAPABILITIES

- › GMO and non-GMO organisms
 - Actinomycetes, *E.coli*, Fungi, *Bacillus*, Yeast, GLSP or BSL-1 organisms
- › On-site anaerobic and aerobic waste treatment
- › Solvent storage and recovery
- › Able to meet pharma and food GMO, Halal and Kosher requirements

COMMERCIAL SERVICES

- › Over 3000 m³ fermentation capability
 - Scale 10,000 L – 100,000 L working volume
- › Batch and continuous sterilization
- › Dedicated cell bank preparation facility and maintenance with redundant equipment and controls
- › Broad range of downstream unit operations
 - Broth separation via scroll decanters, microfold disk stack centrifuges, belt filter
 - Liquid extraction
 - Concentration via reverse osmosis, thin film evaporation, flash evaporation, mechanic vapor recompression
 - Purification via chromatography, ion exchange, ultrafiltration, carbon decolorization, crystallization
 - Reactions for semi-synthetic products
 - Product isolation via cartridge and depth filtration, filter press, basket centrifuge and filter pot
 - Drying and bulk packaging via blender dryers, fluid bed dryers, tray dryers, filter dryers, milling and dry blending

CONTRACT MANUFACTURING

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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

ANALYTICAL SERVICES

Chemistry

- › 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

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