AGC Biologics

Microbial Capabilities

Our microbial CDMO services are backed by our **30 years** of scientific expertise and a global resource network on 3 continents. We provide microbial manufacturing and development services at our Seattle, Copenhagen, Heidelberg, and Chiba facilities.

Our microbial services range from cell-line development and process development to clinical and commercial manufacturing. Our expertise includes experience with E. coli, Pichia pastoris with or without methanol induction, Pseudomonas Fluorescens (PFEnex system), Bacillus (non-sporulating), L. casei, and more.

TRACK RECORD

8 commerical microbial products

100+ microbial processes and products

Our quality systems, GMP manufacturing scale, as well as regulatory qualification allow us to meet demand at any phase.

We offer a variety of flexible stainless steel and single-use bioreactors for GMP manufacturing, with capacity as large as **3.000 L**.

Strain Development & Cell Banking

- Fully licensed freedom-to-operate (FTO) capabilities for strain development
- Multiple modes of expression - including secretion (yeast), periplasmic secretion, soluble intracellular expression, and inclusion bodies
- Full strain development for *E. coli* (multiple strains available)
- Experience with other expression system host cells including *Pichia pastoris* with or without methanol induction, *Pseudomonas fluorescens* (PFEnex system), *Bacillus* (non-sporulating), *L. casei*
- Production of master cell banks (MCB) and working cell banks (WCB)
- Microbial cell banking including creation, characterization and storage (with redundant cell banks at different sites)
- FDA approved cell banking

Process Development

- Flexible development scales up to 10 L
- AMBR® and DASGIP® bioreactor systems
- ÄKTA purification technology
- Pilot runs up to 20 L to demonstrate reputability and performance
- Proprietary pDNA and mRNA manufacturing platforms in-house
- Tangential flow filtration (TFF) using AGC Biologics standard membrane
- Enhanced upstream process, reliable chromatography for purification, endotoxin and host cell protein removal, and high cell density fermentation
- Methanol feeding, oxygen enrichment, continuous centrifugation, and high-pressure homogenization capabilities

Molecule types we work with:	
scFv-Antibodies	Fab-Fragments
Enzymes	Peptides
FC-Fusion Proteins	Plasmid DNA
Recombinant Protein & Enzymes	Multi-Specific Modalities
Conjugated & PEGylated Proteins	Virus-Like Particles (VLP)
Antibody Fragments	Nanobody
Growth Factors	Cytokines

Host cells:
E. coli
P. pastoris
P. fluorescens
L. Casei
Bacillus **(non-sporulating)**

GMP Manufacturing

- Manufacturing at scales from 50 L to 3,000 L with potential to scale to 5,000 L
- Standard industry systems, including batch and fed-batch methods
- Stainless steel and single-use bioreactors
- 8 commercial products produced

Comprehensive Analytical Capabilities In-House

- Broad variety of in-house methods help ensure dependable project timelines
- Core competency in developing, transferring and validating analytical methods
- From early clinical methods through in-process control and release methods
- State-of-the-art methods: UPLC, LC/MS, SEC, SDS-PAGE,UV, ELISA, cell-based bio assays and many more

Quality Assurance

- Fully licensed freedom-to-operate (FTO) capabilites
- Support with regulatory submissions
- Comprehensive, global quality system
- Regulatory compliance and validation expertise
- History of successful client audits and regulatory inspections

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