

• SEATTLE
• LONGMONT
• BOULDER

COPENHAGEN •

• HEIDELBERG

• MILAN

CHIBA •

Modalities at this site:

Mammalian

Microbial



SEATTLE CAMPUS

A Multifaceted N. American Manufacturing Site

The Seattle campus serves as our headquarters and has been **producing biologics products for 30 years**. This site operates multiple cGMP manufacturing lines and a variety of scales for mammalian and microbial biologics at our site. With a uni-flow design, the campus offers capacity and technological flexibility, including extensive adoption of single-use systems, while ensuring compliance with current ICH guidelines required for cGMP compliance. This location also serves as our **center of excellence for formulation** and employs the latest fed-batch and perfusion manufacturing processes.

Global AGC Biologics R&D Center

- The Seattle site houses AGC Biologics' global research and development center, where our scientists focus on modernizing and advancing our development and manufacturing capabilities worldwide
- Responsible for developing and implementing procedures that improve titers/yields, cell line development successes and more.





Process Development

- Full development service from lab development to commercial production
- Microbial and mammalian based processes including insect cells
- Reliable transfer, verification and optimization of customer's process
- Cell line development services, including creation of new cell lines, cloning, cell banking, and seamless process transfer to GMP manufacturing
- Upstream emphasizing bench scale development and production, using high throughput systems and pilot plant bioreactors
- Downstream development services utilizing chromatographic and TFF systems
- Process characterization and process validation supportive studies
- Full analytical development services
- Raw material analytics (GMP), microbial analytics (GMP)

Mammalian Manufacturing

- Mammalian manufacturing scale from 100 L to 12,000 L, including stainless steel lines and single-use technology based systems
- 2 x 3,000 L stainless steel lines
- 18 x 2,000 L single-use bioreactors, supported by our 6Pack System™ system lines (36,000 L total capacity)
- Fed-batch and perfusion manufacturing processes

Microbial Fermentation Manufacturing

- 1 x 1,500 L Microbial Line, room for expansion to 5,000 L
- Insoluble proteins via Inclusion bodies
- Secreted proteins, intracellular soluble proteins
- Protein Analytics (GMP), IPC & release testing

Expanded Warehouse Space

- AGC Biologics completed expanded warehouse space to further safeguard product and materials; 67,750 square feet, fully segregated
- Facility has unique entry/access, (no shared access points)
- No shared utilities; all unique fire suppression, HVAC, and electrical utilities
- 10 exclusive loading docks
- Facility maintained at controlled room temperature (15-25 C) *including largescale freezing
- Bulk DS and intermediates

Globally Aligned Quality Systems

- Full QC Services: Release Testing, DS and DP Stability
- Thorough documentation, policies, procedures
- Site-specific processes, specifications, and records
- Backed by a network of seven sites with decades of biologics expertise sharing best practices to meet clinical and commercial requirements
- Regulatory approval expertise

*6Pack System™ lines can be run as a single 2,000 L run or in groups of 2, 3, 4, or 6 x 2,000 L simultaneously, sequentially or staggered. Designed for maximum scalability and flexibility - The 6Pack System™ is AGC Biologics' proprietary solution for large-scale mammalian manufacturing, using single-use technology



ISO Certified:
Environmental,
Health & Safety



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