

• SEATTLE
• LONGMONT
• BOULDER

COPENHAGEN •

• HEIDELBERG

• MILAN

CHIBA
YOKOHAMA

Modalities at this site:

Mammalian

Microbial



COPENHAGEN CAMPUS

An EU Biologics CDMO Hub

Our **AGC Biologics Copenhagen site** is one of the largest and most active facilities in our global network. The core teams of scientists have **25+ years of expertise** in development and manufacturing, including **six commercial products** brought to market. This means your product is being managed by some of the best in the business.

Microbial and Mammalian Production Systems

We operate multiple cGMP lines at a variety of scales. The facility also offers a great depth of innovation, and uses the latest single-use and stainless steel technology and systems.

Copenhagen, Denmark

MAMMALIAN CAPABILITIES

cGMP single-use manufacturing

3 x 500 L production bioreactors

7 x 2,000 L bioreactors

NEW line in 2024: 8 x 2,000 L expansion

MICROBIAL CAPABILITIES

cGMP manufacturing

2 x 1,500 L fermenter, stainless steel

150 L fermenter, stainless steel





Process Development

- Successful development and transfer of 100+ customer projects over 25+ years
- 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, 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

Microbial Manufacturing

- 2 x 1,500 L fermentor, stainless steel
- Extensive cGMP manufacturing experience, from *E. coli* to yeasts
- High cell density fermentation

Mammalian Manufacturing

- Three independent mammalian lines with fed-batch and perfusion capabilities
- 3 x 500 L single-use bioreactors
- 7 x 2,000 L single-use bioreactors, supported by our 6Pack System™ system
- Flexible capacity and technological systems

Globally Aligned Quality System

- 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

New Expansion More Than Doubles Mammalian Cell Culture Capacity

- Ready for use in 2024
- 18,000 m² distributed across manufacturing, quality control laboratories and technical and warehouse areas.
- 8 x 2,000 L single-use bioreactor production line, supported by our 6Pack System™ system - greatly extending available capacity.
- 1 x 500 L perfusion bioreactor
- Genetically modified organisms, biosafety level 1, in single-use technology in cleanrooms.
- Two downstream purification lines
- **Do not miss out!** We are actively taking meetings now to fill immediate capacity needs for active biologics projects.

*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



Certified:
Environmental
Health and Safety
Energy