

• SEATTLE
• LONGMONT
• BOULDER

COPENHAGEN •

• HEIDELBERG
• MILAN

CHIBA
YOKOHAMA

Modalities at this site:

Microbial

pDNA

mRNA



HEIDELBERG FACILITY

An EU Microbial CDMO Hub

Our AGC Biologics Heidelberg site serves as a hub for microbial systems and services in the European market with **over 40 years of experience**. Located in the hot spot of life sciences in Germany, the site has scientists with several decades of protein expression experience. This enabled AGC Biologics to establish a **center for custom pDNA services and a growing mRNA service line** here. The facility's segregated line design allows for capacity and technological flexibility while ensuring compliance with current global guidelines required for cGMP compliance.

Microbial Manufacturing Services

- Stainless steel fermenters with working volumes of 10 L, 100 L, and 1,000 L
- Single-use fermenter 50-100 L working volume
- Segregated lab with 10 L glass fermenters and downstream equipment for HQ plasmid DNA production
- Continuous centrifugation harvest
- Experience with *E. coli*, *P. pastoris*, and other microbial expression systems
- Production as secreted proteins, soluble intracellular proteins, or inclusion bodies
- Quality control release and stability testing





Microbial Fermentation Capacity

- 1 L multi-fermenter system
- 5 & 10 L fermentation, non GMP
- GMP production fermenters - 100 & 1,000 L stainless steel, 50-100 L single-use
- 1,000 L, 2,000 L and 5,000 L stainless steel tanks for protein refolding
- Insoluble proteins via Inclusion bodies
- Secreted proteins, intracellular soluble proteins
- Downstream processing up to 3,000 L of protein solution
- Raw material analytics (GMP), microbial analytics (GMP)
- Protein Analytics (GMP), IPC & release testing

mRNA

- GMP production line 10 to 50 L
- Available mRNA and host systems
- Customized process development based on your specific mRNA and hosting system
- Extensive technical expertise in fermentation, purification, and analytics
- mRNA drug substance compliant to EMA & US FDA standards

pDNA

- Production of therapeutic proteins and DNA plasmids
- We have been manufacturing pDNA for more than 10 years
- Experience in both clinical and commercial pDNA manufacturing
- Expanded capabilities in extending services in hosts and plasmids (low and high copy pDNA expression systems) in process development with scales of 1 L to 10 L for pDNA
- Processes can be scaled up to 50 L, 100 L, 500 L or 1,000 L cGMP manufacturing
- Fast platform approach for smaller pDNA amounts via a small-scale line, with scales of 10 L to 50 L
- Beneficial for producing transfer plasmids for in-house applications, starting material for AAV and LVV applications, and as linearized starting material for Messenger RNA (mRNA) manufacturing

Globally Aligned Quality Systems

- 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



ISO Certified:
Environmental