

• COPENHAGEN
• HEIDELBERG
• MILAN

CHIBA
YOKOHAMA

SEATTLE
LONGMONT
BOULDER

Modalities at this site:

Mammalian

Microbial

pDNA



CHIBA FACILITY

The only CDMO site in Japan with a global resource network

High-Quality Resources & Support in Asia

This multipurpose, highly-efficient facility is **the only CDMO site in Japan** offering access to microbial, mammalian and plasmid DNA services with a strong international supply chain network of resources to help bring these products to market. The facility's core structure and gravity-based design enable it to guarantee flexibility and high quality clinical and commercial products.

Mammalian, Microbial, & pDNA Services

The Chiba teams has experience in cGMP microbial manufacturing for numerous projects, ranging from *E. coli* to yeasts. The site's mammalian offering guarantees capacity and technological flexibility, thanks to the extensive adoption of the latest **single-use technology** systems. This facility can also manufacture plasmid for both non-GMP and GMP uses such as DNA vaccines or starting material.

Chiba, Japan

cGMP MAMMALIAN CAPABILITIES

2,000 L single-use production bioreactor
500 L single-use production bioreactor

cGMP MICROBIAL CAPABILITIES

3,000 L fermenter, stainless steel
150 L fermenter, stainless steel

cGMP PLASMID DNA CAPABILITIES

20 L to 150 L fermenters, stainless steel





Process Development

- Over 15 years of experience and 30+ process development projects completed with various expression systems
- Inclusion bodies & secreted to periplasm
- Full development service from lab development to commercial production
- Rapid & robust process establishment using AGC Biologics' Mammalian platform method
- Reliable transfer, verification & optimization of customer's process
- Extensive experience with various resins & membranes
- Upstream development including 50 L single-use bioreactor for mammalian processes
- Upstream development for plasmid DNA up to 20 L stainless steel fermenter
- Seed train from 500 ml up to 180 L for microbial
- Downstream development services
- Analytical development services

Microbial Manufacturing

- 3,000 L fermenter, stainless steel
- 150 L fermenter, stainless steel
- Extensive cGMP manufacturing experience, from *E. coli* to Yeasts
- High cell density fermentation

Mammalian Manufacturing

- 2,000 L single-use bioreactor
- 500 L single-use bioreactor
- Flexible capacity and technological systems
- Chromatography and membrane purification
- Fully single-use technology and closed approach

Plasmid DNA Manufacturing

- High-Quality and GMP-grade plasmid manufacturing
- 150 L, stainless steel fermenter
- pDNA supply in different qualities for non-GMP or GMP purposes to be used as: DNA vaccine or starting material for gene therapy (LVV, AAV, and other viral vectors), RNA drugs, or cell-free protein production

Globally Aligned Quality System

- Documentation, policies, procedures
- Regulatory approval expertise
- Site-specific procedures, specifications and records
- Seven global sister sites sharing best practices
- What happens here in Chiba, happens at other sites across the globe - we share best practices to meet clinical and commercial needs