



# Global cGMP Manufacturing

**A global manufacturing network using the latest technology and processes to support drug substance production at all major clinical and commercial stages.**

We're committed to helping you achieve your project goals and timelines with the highest standard of service and quality.

Our expertise includes protein-based mammalian and microbial systems, plasmid DNA (pDNA), messenger RNA (mRNA), viral vectors and cell therapy. Our services support the full lifecycle of your product, from pre-clinical phases through commercial manufacturing. We have successfully produced **250+ biologics, 400+ batches of GMP viral vectors** and supplied materials for **30+ CGT clinical trials**.

## Regulatory Track Record

Our global cGMP facilities are designed to optimize capacity and maintain compliance with global pharmaceutical regulations. We maintain an **excellent regulatory track record**, including inspections, certifications and registrations with the US Food and Drug Administration (FDA), European Medicines Agency (EMA), Health Canada (HC), Taiwan Food and Drug Administration (TFDA), Ministry of Food and Drug Safety (MFDS), Pharmaceuticals and Medical Devices Agency (PMDA), and the Brazilian Health Regulatory Agency (ANVISA).

## Commercial Products Track Record

**6** Mammalian | **8** Microbial | **4** Viral Vectors | **2** Plasmid DNA | **3** Cell Therapies



## Seattle, Washington

### MAMMALIAN CAPABILITIES

- 2 x 3,000 L stainless steel production bioreactors
- 18 x 2,000 L single-use bioreactors (three 6Pack System™ lines\*)
- Perfusion capacity up to 1,000 L/day

### MICROBIAL CAPABILITIES

- 1,500 L stainless steel fermenter

## Boulder, Colorado

### MAMMALIAN CAPABILITIES

- 2 x 20,000 L stainless steel tanks (17,000 L working volume)
- Expansion capabilities for additional 20,000 L bioreactors, based on client needs

## Longmont, Colorado

### VIRAL VECTOR CAPABILITIES

- 48 L Cell Factory System (adherent)
- 7 x iCELLis® 500 bioreactors (adherent)
- 50 L, 200 L, 500 L and 2,000 L single-use bioreactors (suspension)
- Fill & finish in vials and bags of different format

### CELL THERAPY CAPABILITIES

- Flexible development and manufacturing space using autologous and allogeneic processes
- 3 x Grade-C/B cell therapy suites
- Technology: CliniMACS Prodigy, CliniMACS Plus, G-Rex (100, 500 ml), Xuri, LOVO, Sepax

## Chiba, Japan

### MAMMALIAN CAPABILITIES

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

### MICROBIAL CAPABILITIES

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

### PLASMID DNA CAPABILITIES

- HQ & GMP manufacturing: 150 L stainless steel fermenter

## Copenhagen, Denmark

### MAMMALIAN CAPABILITIES

- 15 x 2,000 L (including a 6Pack System™ line\*) single-use bioreactors
- 2 x 500 L single-use bioreactors
- Perfusion capacity up to 1,000 L/day

### MICROBIAL CAPABILITIES

- 2 x 1,500 L stainless steel fermenter

## Heidelberg, Germany

### MICROBIAL CAPABILITIES

- 1,000 L stainless steel fermenter
- 100 L single-use fermenter
- 100 L stainless steel fermenter

### PLASMID DNA CAPABILITIES

- **pDNA supply in High-Quality and GMP-grade for:**
  - DNA vaccine
  - Starting material for gene therapy (LVV, AAV and other viral vectors)
  - Starting material for RNA drugs
  - Starting material for cell-free protein production
- **Development scales**
  - 1 L up to 10 L
- **Manufacturing scales**
  - 1,000 L stainless steel bioreactor
  - 100 L single-use bioreactor
  - 100 L stainless steel bioreactor

### MESSENGER RNA CAPABILITIES

- **mRNA supply in different qualities:**
  - R&D grade scale: 10 ml - 1 L glass or single-use
  - GMP grade scale: 500 ml - 10 L wavebag

## Milan, Italy

### VIRAL VECTOR CAPABILITIES

- 48 L Cell Factory System (adherent)
- 50 L, 2 x 200 L and 2 x 1,000 L single-use bioreactors (suspension)
- iCELLis® 500 bioreactor (adherent) with room for expansion to meet additional GMP demand
- Fill & finish in vials and bags of different format

### CELL THERAPY CAPABILITIES

- 10 x Grade-B cell therapy suites
- Suites of different size and different equipment for autologous and allogeneic products
- Technology: CliniMACS Prodigy, CliniMACS Plus, LOVO, Xuri, Rotea, Sepax, Biostat RM, G-Rex

All volumes are working volumes unless otherwise noted

\*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