AGC Biologics

Global CDMO Services for Biologics and Cell & Gene Therapies

AGC Biologics Company Introduction

AGC Life Science Company

Our Purpose

Cardiovascular Diseases

Pediatric Metachromatic Leukodystrophy

Febrile Neutropenia

Arthritis, Spondylitis

COVID-19

Refractory Acute Myeloid Leukemia

Homocystinuria

Systemic Lupus Erythematosus

*Our purpose is to **bring hope to life** by enabling life-changing therapies for patients around the globe, creating a healthier and happier tomorrow.*

Prostate Cancer

Anemia

Soft-Tissue Sarcoma

Treatment of Solid Tumors

Diabetes

Rheumatoid Arthritis

Fibrosis and Inflammatory Disease

Malignant lymphoma

Crohn's Disease

Pulmonary Arterial Hypertension (PAH)

AGC Life Science Company

AGC Biologics

Our Core Values

KNOWLEDGE – We possess strong scientific and technical expertise

TRUST – We create positive experiences that our customers can rely on

QUALITY – We strive for excellence in our people, products and services

INGENUITY – We find creative solutions to difficult challenges

ACCOUNTABILITY – We follow through on our commitments

TEAMWORK – We put the success of the team above our own personal goals

Our Mission

To work side by side with our customers in order to **improve patients' lives** by bringing new biopharmaceuticals to market.

Mammalian

Microbial

pDNA

Viral Vector

Cell Therapy

mRNA

Our Services — *from Pre-Clinical to Commercial*

Tech Transfer

Our collaborative approach ensures an efficient & successful transfer process

Analytical Development

Our methods ensure your product's identity, safety, purity, and potency

Process Validation

We help deliver a robust and cost-effective supply for commercial approval

Process Development

We can apply existing processes or develop new, innovative processes

Formulation Development

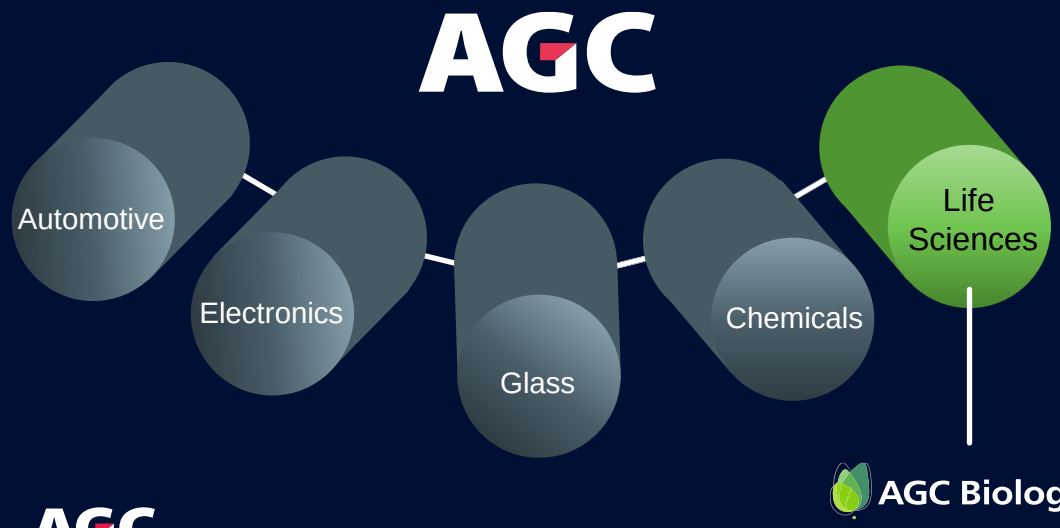
We provide innovative solutions to the specific challenges posed by your individual protein or therapy

cGMP Manufacturing

We offer capacity and technological ingenuity you can rely on at every stage, from clinical to commercial

AGC Biologics is Part of AGC, Inc.

- Founded in 1907
- Headquarters in Tokyo, Japan
- Net FY sales: 2,036 B Yen (~14.1 B USD)
- 57,000+ employees globally
- Strategic businesses driving revenue and future growth:



Benefits for AGC Biologics Customers

Financial stability and backing of a global organization

Long-term vision and strategic plan for AGC Biologics

Access to capital to expand global capabilities and capacity

AGC
Life Science Company

Our History

1907 — **Asahi Glass Co. (AGC) Founded**

Pictured above:
AGC Inc. HQ located in Tokyo, Japan

1973 — **AGC Inc, Life Science Team established**

1993 — **Biomeva Founded**

2001 — **CMC Biologics Founded**

2007 — **CMC Biologics Acquired ICOS**

2008 — **AGC Inc, Chiba facility started CDMO business**

2016 — **AGC Inc. Acquired Biomeva**

2017 — **AGC Inc. Acquired CMC Biologics**

2018 — **AGC Biologics Formed (Biomeva + CMC + AGC Biosciences)**

Pictured above:
AGC Biologics HQ located in Bothell, WA

2020 — **Acquired Facility in Boulder, CO and MolMed in Milan, Italy**

2021 — **Acquired Facility in Longmont, CO**

Pictured above:
Main entrance of Longmont Campus

AGC Life Science Company

AGC Biologics

What Makes Us Unique

Customer-Centric Culture

- Partnering on a mission to impact and save lives
- Unparalleled culture of communication
- Ability to scale with our customers' evolving needs

Technical Innovation

- Backed by 25 years of industry-leading experience
- Forefront of development
- Significant investments in innovation for our customers' current and future needs

Global Facilities Network

- Seven world-class cGMP facilities across three continents
- Over 2,500 talented employees
- Continuous expansion

Our Global Network

7	2,500+	175+
FACILITIES	EMPLOYEES	CUSTOMERS SERVED

AGC
Life Science Company

AGC Biologics

Our Global Network

Seattle

Seattle

Washington, USA

Mammalian

Microbial

Regulatory Approvals: FDA, PMDA FMA Acquired

- Mammalian manufacturing scale from 100 L to 12,000 L, including Bioreactor 6Pack™ technology
- Upstream, downstream and analytical development
- Center of Excellence for formulation
- Fed-batch and perfusion manufacturing processes
- Expansion completed on the installation of 24,000 L added mammalian capacity and a 1,500 L microbial production facility

Our Global Network

Longmont

Longmont
Colorado, USA

Regulatory Approvals: FDA Registered

Cell Therapy

Viral Vector

- 100+ GMP commercialization batches produced without failure
- Analytical and process development for viral vector and cell therapy
- Multi-product viral vector manufacturing and fill / finish (AAV, LVV, RVV)
- Adherent: 24 L / 48 L cell factories, 200 L fixed-bed bioreactor (iCELLis500)
- Suspension: bioreactors ranging 50 L, 200 L, 500 L, 2,000 L
- iCELLis500 bioreactors ranging 200 L, 500 L, 2,000 L
- Multiple new cell therapy processing suites
- Automated fill and finish for viral vectors in early 2024

Our Global Network

Boulder

Boulder

Colorado, USA

Mammalian

Regulatory Approvals: FDA Registered

- State-of-the-art large-scale commercial mammalian manufacturing, featuring 2 x 20,000 L vessels (17,000 working volume)
- Designed for high titer DSP processes (up to 10 g/l)
- Large scale volume + high titers = tremendous cost savings
- Ability to expand by two to four 20,000 L vessels

AGC Life Science Company

AGC Biologics

Our Global Network

Copenhagen
Denmark

Mammalian

Microbial

Regulatory Approvals: FDA, EMA, HC, PMDA, ANVISA

- Mammalian manufacturing scale from 100 L to 12,000 L, including the Bioreactor 6Pack™ technology
- Three independent mammalian lines with fed-batch and perfusion capabilities
- Microbial manufacturing at 2 x 1,500 L
- Upstream, downstream and analytical development
- New facility adding 8 x 2,000 L single-use bioreactors coming online early 2024

Copenhagen

AGC Life Science Company

AGC Biologics

Our Global Network

Heidelberg
Germany

Microbial | pDNA | mRNA

Regulatory Approvals: FDA, EMA, PMDA FMA Acquired

- Center of Excellence for plasmid DNA, with commercial manufacturing experience
- Offering pDNA supply in all grades and quantities
- mRNA supply in various quantities (R&D / GMP grade)
- Microbial manufacturing scale from 100 L to 1,000 L
- Upstream, downstream and analytical development
- Freedom-to-Operate and RNAse free processes

Our Global Network

Milan

Milan

Italy

Cell Therapy

Viral Vector

Regulatory Approvals: EMA, TFDA

- 25+ years of industry-leading expertise and 3 commercially approved products
- Cell therapy and viral vector clinical and commercial capabilities with large GMP capacity
- AAV / LVV / RVV manufacturing and Fill / Finish
- Adherent: 24 L / 48 L cell factories, 200 - 500 L fixed-bed bioreactor (iCELLis500)
- Suspension: 50 L, 200 L and 1,000 L bioreactors
- Cell therapy: 10+ suites performing open and closed processes for both autologous and allogeneic products
- Processes and capabilities for virtually any cell type, $CD34^{+}$HSC, T-Cells, NK Cells, hMSCs and more.
- 160+ in-house analytical tests ensures fast turnaround

Our Global Network

Chiba

Japan

Regulatory Approvals: PMDA, MFDS

Mammalian

Microbial

pDNA

- Microbial manufacturing scale up to 3,000 L
- Mammalian manufacturing scale from 500 L to 2,000 L
- Upstream, downstream and analytical development
- Only CDMO in Japan with microbial and mammalian capabilities backed by a global resources network
- pDNA development up to 20 L, stainless steel fermenter
- High-Quality and GMP plasmid manufacturing scale from 100 L to 150 L, stainless steel fermenters

Chiba

AGC Life Science Company

AGC Biologics

Seven Sites, One Quality System

Environment, Health & Safety (EHS) is a Top Priority

Regulatory requirements are consistently monitored to ensure compliance.

Established processes help identify potential EHS hazards related to our operations.

EHS Management System ensures a strong focus on ongoing improvement projects.

Process controls in place reduce potential of negative EHS impact by day-to-day operations.

Formal evaluations assess potential EHS impact by new projects and other changes.

Continuous efforts in sustainability development help ensure a bright future for our planet.

Gold Sustainability Rating (CPH)

14001:2015 Environmental (CPH, HDB, SEA)

45001:2018 Health & Safety (CPH, SEA)

50001:2018 Energy (CPH)

WA State, U.S. Safety & Health (SEA)

AGC Life Science Company

AGC Biologics

Current Programs & Track Record

Current Programs

48+
Mammalian

36+
Microbial

15+
Cell Therapies

20+
Viral Vectors

Track Record

6
Commercial Mammalian Products

8
Commercial Microbial Products

4
Commercial Viral Vectors

2
Commercial Plasmid DNA

3
Commercial Cell Therapies

150+
Mammalian Cell Culture-based Products

100+
Microbial Processes & Products

400+
Manufactured Viral Vector GMP Batches

550+
C&GT Treated Patients (autologous)

30+
C&GT Clinical Trials Supplied in EU and US

Experienced Leadership

Patricio Massera
Chief Executive Officer
MERCK · CMC Biologics · Intervet Schering-Plough Animal Health

Kasper Møller, Ph.D.
Chief Technical Officer & Exec. VP, EU & Japan Regions
CMC Biologics · DTU Technical University of Denmark

Tomoko Miyagawa
Executive VP, Corporate Development
AGC

Luis Velez
Executive VP, USA Region
teva · AMGEN · Baxter

Greg Shelton
Executive VP, People & Culture, General Counsel
stryker · Medtronic

Carrie Mygatt
Executive VP, Finance
Honeywell · CORNING · stryker

Akira Nakamura
Senior VP, Corporate & Strategic Planning
AGC

Wendy Laderach
Senior VP, Corporate Quality
AMGEN

Andrea Porchia
General Manager, Copenhagen
symphogen, a Servier Company

Dieter Kramer
General Manager, Heidelberg
SANDOZ A Novartis Division · NOVARTIS

Jun Takami
General Manager, Chiba
Roche · CHUGAI

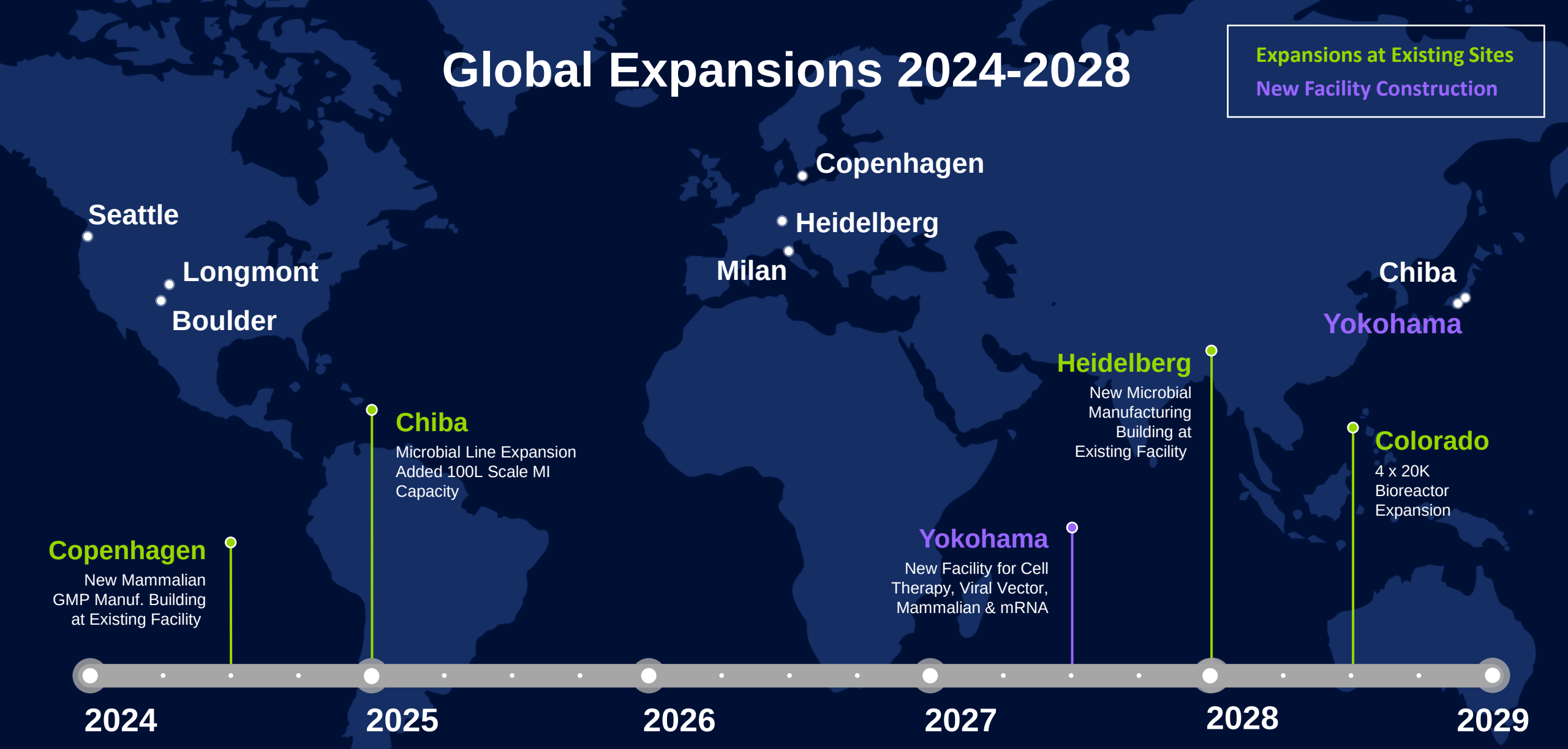
Luca Alberici
General Manager, Milan
MOLMED · Sanford Burnham Prebys

Whitney Sandberg
General Manager, Colorado
ThermoFisher SCIENTIFIC · Mallinckrodt Pharmaceuticals

Mike Tranmer
General Manager, Seattle
Pfizer · PAR PHARMACEUTICAL

Global Expansions 2024-2028

Expansions at Existing Sites
New Facility Construction



This timeline reflects current plans for expansion from 2024 through 2028 and is subject to change.

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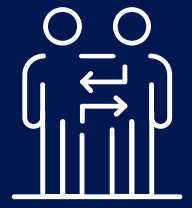
A Partnership You Can Rely On



Customer-Centric Culture

We work side-by-side with you — collaborating, problem solving and being great partners to each other.

Technical Innovation

We are driven by flexible thinking, continuous innovation and technical creativity.

Global Facilities Network

Our globally aligned network of sites in the U.S., Europe and Asia provides a consistent and seamless experience.

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Thank You

Learn more at agcbio.com

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