



**AGC Biologics**

Right. On Time.

- CELL LINE DEVELOPMENT
- CLONE SELECTION
- PROCESS DEVELOPMENT
- MANUFACTURING

ONCOLOGY  
IMMUNOTHERAPY  
PATHWAYS



# STEM Alliance Meeting

AGC Biologics

# AGC Bioscience, Biomeva GmbH, and CMC Biologics Have Converged to Form AGC Biologics

**AGC**

Bioscience

+



**BIOMEVA**  
MANUFACTURING

+



**CMC**  
biologics

*are now*

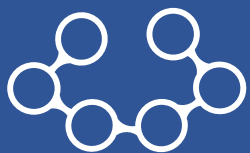


**AGC Biologics**



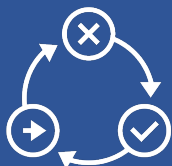
# Comprehensive Drug Substance Service Offering

## Cell Line Development



Microbial and mammalian cell lines;  
CHEF1® and ASPEX proprietary  
expression technology platforms

## Process Development



Upstream, downstream, process  
characterization & validation;  
High-throughput technologies

## Analytical Testing



Analytical development,  
characterization, stability studies,  
and bioassays

## Formulation Development



API and drug-product  
formulation development  
(both liquid and freeze-dried)

## Clinical Manufacturing



Tox and Phase I / II / III product  
according to  
EMA / FDA / JP / ICH guidelines

## Commercial Manufacturing



Market supply under  
EMA, FDA, and  
PMDA requirements

## Quality Services



QC testing, stability testing,  
QP release,  
and regulatory support

# Global Network of cGMP Facilities

- = current clients
- ★ = 6Pack locations



# Diverse, Long-Standing Customer Base

Mix of large, mid-size and small / **virtual pharma and biotech companies**

**Projects** originating in the **US, EU, Asia, South America and the Middle East**

**12 of the top 20** pharmaceutical companies

**Over 50%** of our projects are in **late-phase or commercial stage**



# Proven Mammalian Experience

Specialty in orphan / fast-track / breakthrough biologics

GMP cell culture capacities between 100L and 12000L

150+ mammalian biologics developed

- mAbs
- complex proteins
- coagulation factors
- fusion proteins
- Antibody-like formats (bi- and tri-specifics)

Full process and analytical development capabilities



# Excellence in Microbial Fermentation

- Extensive microbial network, with cGMP facilities in Denmark, Germany and Japan
- Flexible development capabilities and manufacturing scales with capacities from 100L to 4500L
- Capabilities to work with many different bacterial and yeast systems
- ASPEX™ proprietary expression platform
- More than 50 microbial products developed
- Experience with cytokines, hormones, receptors, antigens, nanobodies, Fabs and fusion proteins of novel and biosimilar products





# Focus on Advanced and Specialized Technologies

- Extensive use of single-use technology to enable portability and scalability of process
- Deep technical expertise to address specialized formulation and handling needs of next-generation molecules
- Adoption of multi-column chromatography technology to reduce manufacturing costs through improved resin utilization
- Implementation of high-throughput technologies to accelerate timelines and lower costs
  - **ambr<sup>®</sup> 250**
    - Fully-automated bioreactor system for parallel processing using 100-250mL single-use bioreactors controlled by an automated liquid handling platform
  - **Octet<sup>®</sup> HTX**
    - Monitors up to 96 biosensors simultaneously, enabling label-free detection for protein quantification and kinetic characterization at unmatched speed



**Commitment to continuously invest in innovative technologies to improve the efficiency, productivity, safety and quality of our operations**

# New HQs Bothell



# New Capabilities

## Recently implemented

New 6Pack in Copenhagen, Denmark since October 2018

R&D Center in Bothell since January 2019

## Under implementation

New QC and PD laboratories in Heidelberg, Germany from May 2019

Mammalian facility in Chiba, Japan from October 2019

New Microbial facility in Bothell from Q2 2020

New Mammalian expansion facility (2 new 6Pack) in Bothell from Q2 2020

# Key Success Factor

## Highly Specialized PEOPLE

- Currently Employing 350 people in Bothell.
- Our expansion plans will require 150 more in the next 2 years.

Currently AGC Biologics is working in more than 50 projects worldwide.

Life Science is experiencing the biggest growth in history.

Talent is highly required.

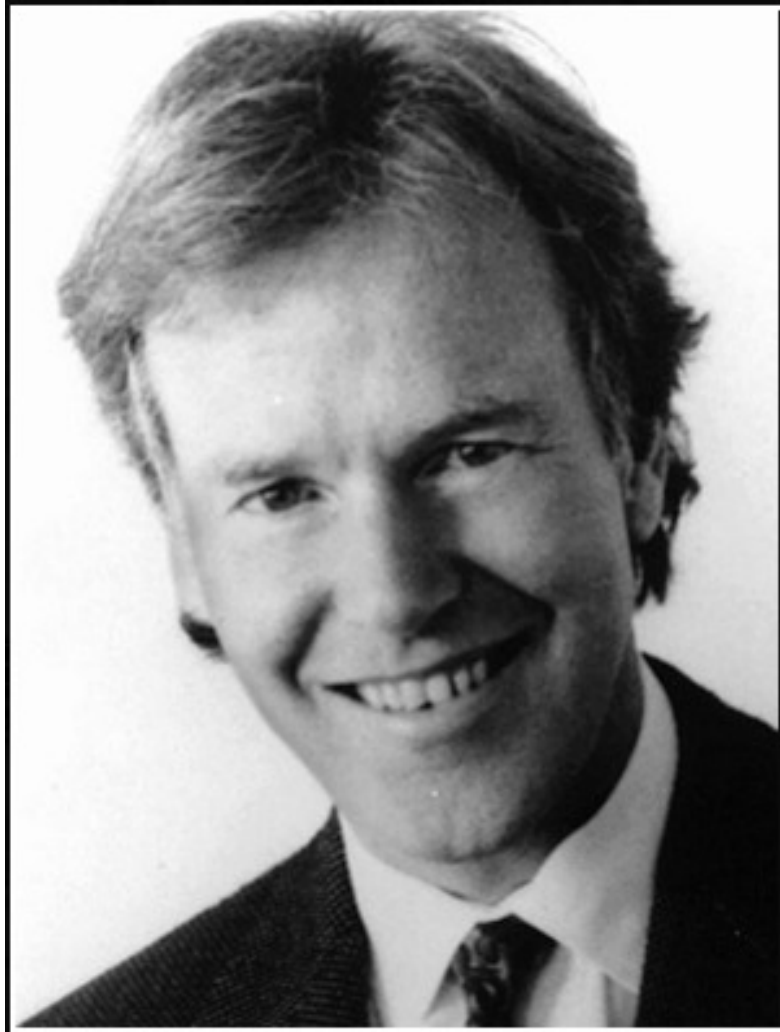


# Developing new Employees

## Options to bring Talent are:

- Importing from other States/Countries.
- Hiring from other Companies in the area.
- Developing new employees:
  - High School. Project BioPath.
  - Collaboration with local Colleges.
  - Building a Training Center.





Sharing knowledge is not about giving people something, or getting something from them. That is only valid for information sharing. Sharing knowledge occurs when people are genuinely interested in helping one another develop new capacities for action; it is about creating learning processes.

— *Peter Senge* —

**AZ QUOTES**



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**Thank You**

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