

# Biopharmaceutical CMO Service

GMP Manufacturing (300 – 4500 L)

Process Development

Recombinant Protein Expression System (ASPEX)



# Biopharmaceutical CMO Service



We can help you find the shortest way from your idea to the finished product.

The pharmaceutical development process is fraught with obstacles. Whether our customers need help constructing expression systems, establishing industrial processes, or performing large-scale commercial production, we at AGC can provide the optimal solution at all times, drawing upon the combined strength of our original technologies, experience, and facilities. We can cut down the development period for pharmaceuticals while our more efficient processes reduce costs.

CMO: Contract Manufacturing Organization



# Biopharmaceuticals – Fast to market

Support for Drug  
Approval Applications

## GMP Manufacturing

AGC provides materials that meet a wide range of needs from non-clinical to clinical trials and commercial production.

300 L  
to  
4500 L

## Process Development

AGC contributes to establishing reliable manufacturing processes with its wealth of development experience.

20 L  
to  
300 L

## Recombinant Protein Expression System

AGC supports the construction of the high-yield recombinants based on *S. pombe* (ASPEX).

# GMP Manufacturing (4500 L)



AGC is a CMO that supports the manufacture of pharmaceuticals.

AGC is a leading CMO that pioneered the contract manufacture of biopharmaceuticals in Japan. We provide a wide range of solutions from expression systems to process development and on through commercial production based on a wealth of experience.



A GMP manufacturing base equipped with a 4500 L culture tank.

## ASPEX Bio Plant

Hosts	<i>E. coli</i> , yeast, etc.
Culture tank	4,500 L
Separation	UF & MF system, Centrifuge, High-pressure homogenizer
Purification	UF & MF system Chromatography system (maximum column size $\phi$ 1,000 mm) HPLC system (maximum column size $\phi$ 650 mm)

- Core structure ensuring high cleanliness
- Simple design employing gravitational flow
- Highly flexible for various needs and processes
- High efficiency by repetitive manufacturing
- Licensed drug manufacturing facility

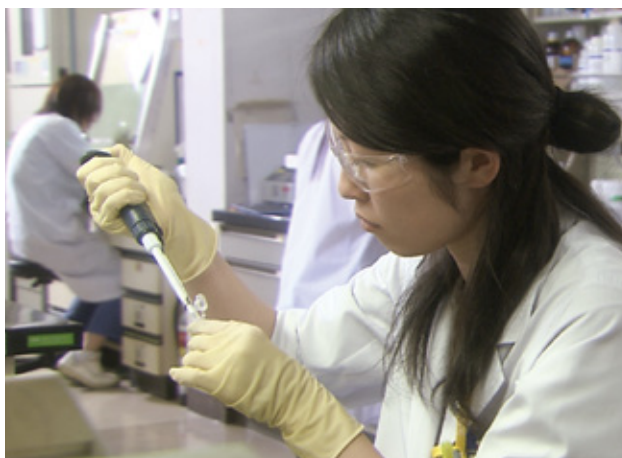


## Quality Control Quality Assurance

**AGC has established a reliable quality assurance system through diligent quality control.**

We provide contract services from the development of analytical methods through release testing with an appropriate turnaround time and costs, thereby adequately reflecting your needs.

We also provide support for drug approval applications.



# Process Development Service Protein Expression Service (ASPEX)

AGC *Schizosaccharomyces pombe* Expression system

ASPEX is an expression system developed  
by AGC.

We provide the best solutions for gene expression with cutting-edge technology using fission yeast, *S. pombe*.

*S. pombe* expressing GFP

# Process Equals Quality

## Process Development Services

**We promote development within an integrated management system.**

A project management system is incorporated from the earliest stage of development. Our experienced expert staff provides ideal development management based on the wealth of experience that our CMO brings to every project.



## Protein Expression Service

**Creation of high-yield recombinants**

We provide high-quality, high-yield production systems through an optimal combination of expression vector systems with the improved *S. pombe* hosts that best suit the characteristics of the target protein.



## Development Center

**We cover all phases from process construction through scale increases and GMP manufacturing.**

- Two independent culture/purification systems.
- A wealth of experience in process development and manufacturing.

Hosts	<i>E. coli</i> , yeast, etc.
Culture tank	300 L / 400 L
Purification	UF & MF system
	Chromatography system (maximum column size $\phi$ 450 mm)
	HPLC system (maximum column size $\phi$ 350 mm)



**AGC ASAHI GLASS CO., LTD.**  
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