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.

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

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

- 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

<table>
<thead>
<tr>
<th>Hosts</th>
<th>E. coli, yeast, etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture tank</td>
<td>4,500 L</td>
</tr>
<tr>
<td>Separation</td>
<td>UF &amp; MF system, Centrifuge, High-pressure homogenizer</td>
</tr>
<tr>
<td>Purification</td>
<td>UF &amp; MF system</td>
</tr>
<tr>
<td></td>
<td>Chromatography system (maximum column size Ø 1,000 mm)</td>
</tr>
<tr>
<td></td>
<td>HPLC system (maximum column size Ø 650 mm)</td>
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</tbody>
</table>

**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.
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.

<table>
<thead>
<tr>
<th>Hosts</th>
<th>E. coli, yeast, etc.</th>
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</thead>
<tbody>
<tr>
<td>Culture tank</td>
<td>300 L / 400 L</td>
</tr>
<tr>
<td>Purification</td>
<td>UF &amp; IMF system</td>
</tr>
<tr>
<td></td>
<td>Chromatography system (maximum column size ø 450 mm)</td>
</tr>
<tr>
<td></td>
<td>HPLC system (maximum column size ø 350 mm)</td>
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