



CDMO SERVICES FOR  
BIOPHARMACEUTICALS

## DEVELOPING MICROBIAL BIOPRODUCTION PROCESSES OVER THE LAST 40 YEARS

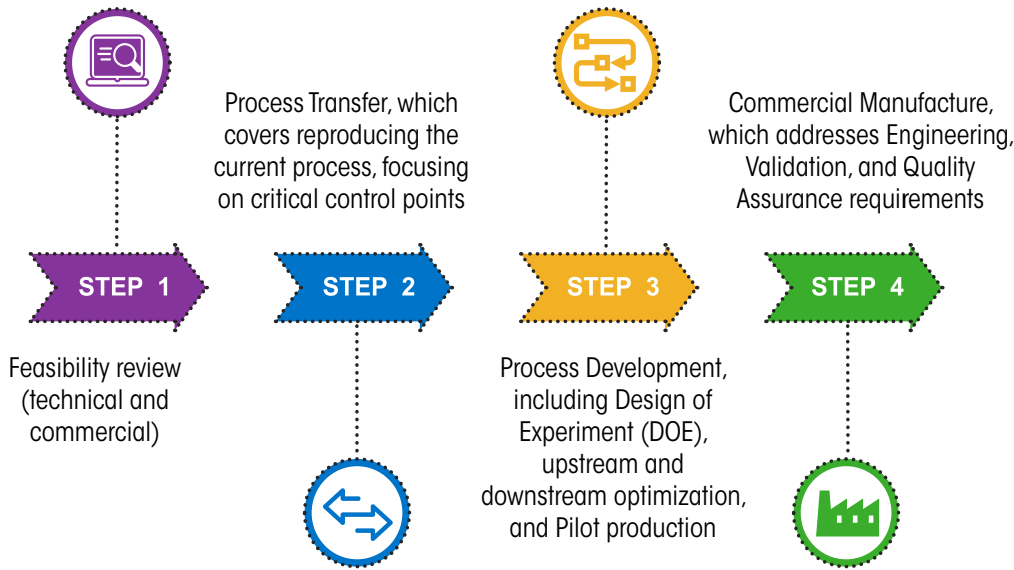
By leveraging our microbial fermentation expertise, SEKISUI can develop and manufacture your recombinant protein and other biopharmaceuticals

BioProduction  
by **SEKISUI**

SEKISUI has vast experience with projects from pre-clinical to commercial, including but not limited to recombinant systems such as *Escherichia coli* and *Pichia pastoris*, and associated purification and analytical technologies. Our primary expertise lies in the production of enzymes; however, our capabilities are also suitable for plasmids, antibody fragments, DNA modifying enzymes, and other protein production.



PROCESS  
DEVELOPMENT  
AND  
TRANSFER



CORE COMPETENCIES	EXPERIENCE WITH A WIDE RANGE OF MICROORGANISMS	CAPABILITIES
<ul style="list-style-type: none"><li>• Microbial fermentation</li><li>• Plant tissue extraction</li><li>• Protein purification</li><li>• Bioprocessing</li><li>• Bulk formulation</li><li>• Lyophilization</li></ul>	<ul style="list-style-type: none"><li>• <i>Escherichia coli</i></li><li>• <i>Bacillus</i></li><li>• <i>Streptococcus</i></li><li>• <i>Streptomyces</i></li><li>• Fungi</li><li>• Yeasts</li><li>• Facility designed to handle organisms up to ACDP and BSL Category 2</li></ul>	<ul style="list-style-type: none"><li>• 2L, 5L, 10L, 50L development fermenters</li><li>• 20L, 50L, 70L, 120L, 500L and 5,000L fermenters</li><li>• Chromatography<ul style="list-style-type: none"><li>- Ion exchange</li><li>- Hydrophobic</li><li>- Mixed Mode</li><li>- Affinity</li></ul></li><li>- Chromatography scale from 1L-200L</li><li>• Freeze drying up to 80L scale, bulk powder, or vials</li></ul>

ANALYTICAL SERVICES

Analytical testing and analytical method development are central to SEKISUI expert services. Quality control tests, such as tests for sterility, bioburden, and endotoxin, are routinely performed in-house. Product-specific QC tests are developed and validated, as SEKISUI has a team with profound knowledge of pharmaceutical method development and validation.

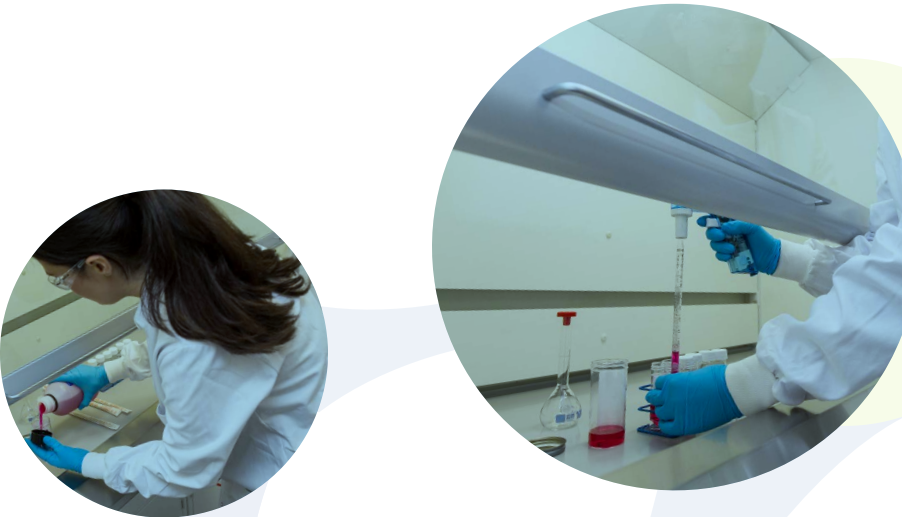
Examples of Analysis:

- Automated enzymatic activity assays
- Capillary and gel electrophoresis
- HPLC
- ELISA
- qPCR
- Nuclease testing
- Host cell protein and DNA
- Endotoxin and bioburden
- Binding affinity

Our facilities and expertise include world-class fermentation-based manufacturing and fully integrated research and development, quality, and engineering.

QUALITY STANDARDS

- ✓ Operations certified to ISO 9001
- ✓ ISO 8 clean rooms
- ✓ Aspects of cGMP as specified in quality agreement
- ✓ Expanded cGMP microbial Production (Class C) available from 2025
- ✓ OHSAS 18001 safety management system and ISO14001 environmental management system



## PARTNER WITH EXPERTS IN MICROBIAL FERMENTATION BIOPRODUCTION BY SEKISUI ADVANTAGE:



### SEKISUI'S other businesses:

**SEKISUI**  
**DIAGNOSTICS**

*Because every result matters™*

[SEKISUIDIAGNOSTICS.COM](https://www.sekisuidiagnostics.com)

Diagnostic materials, tests, and  
Contract Manufacturing

**SEKISUI**

SEKISUI MEDICAL CO.,LTD.

[SEKISUIMEDICAL.JP](https://www.sekisui-medical.jp)

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Pharmaceutical Contract Manufacturing

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