



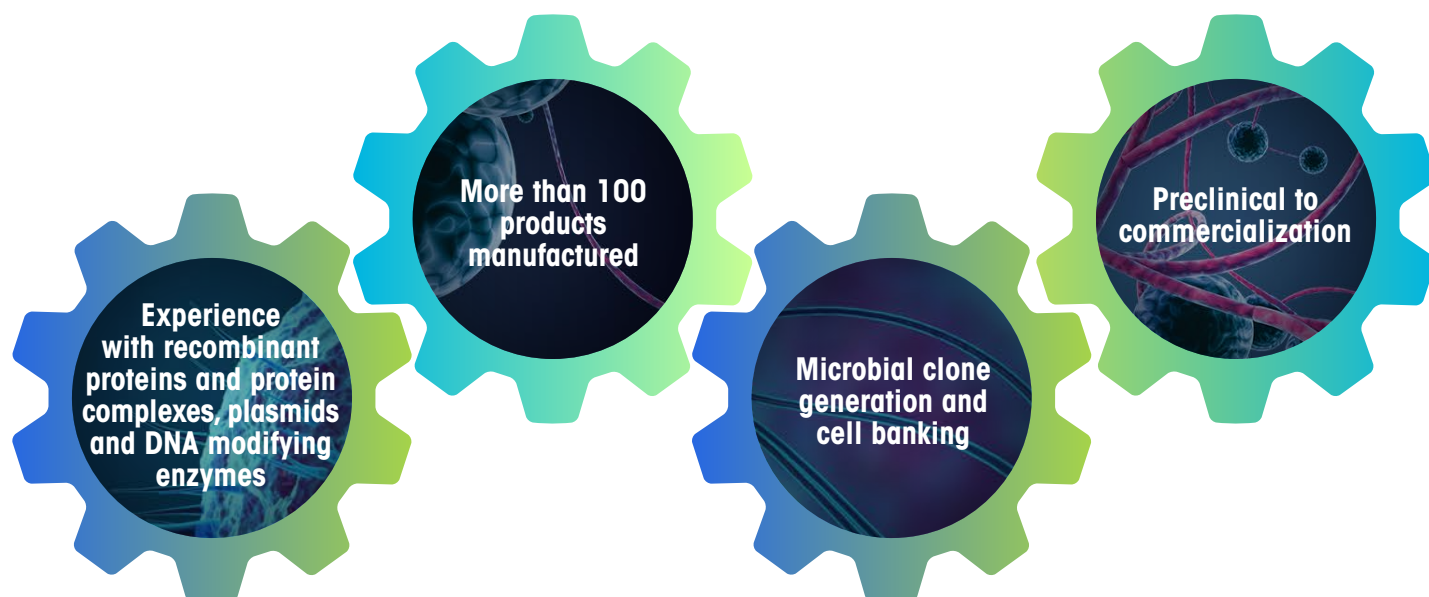
CDMO SERVICES FOR  
BIOPHARMACEUTICALS

## DEVELOPING MICROBIAL BIOPRODUCTION PROCESSES OVER THE LAST 40 YEARS

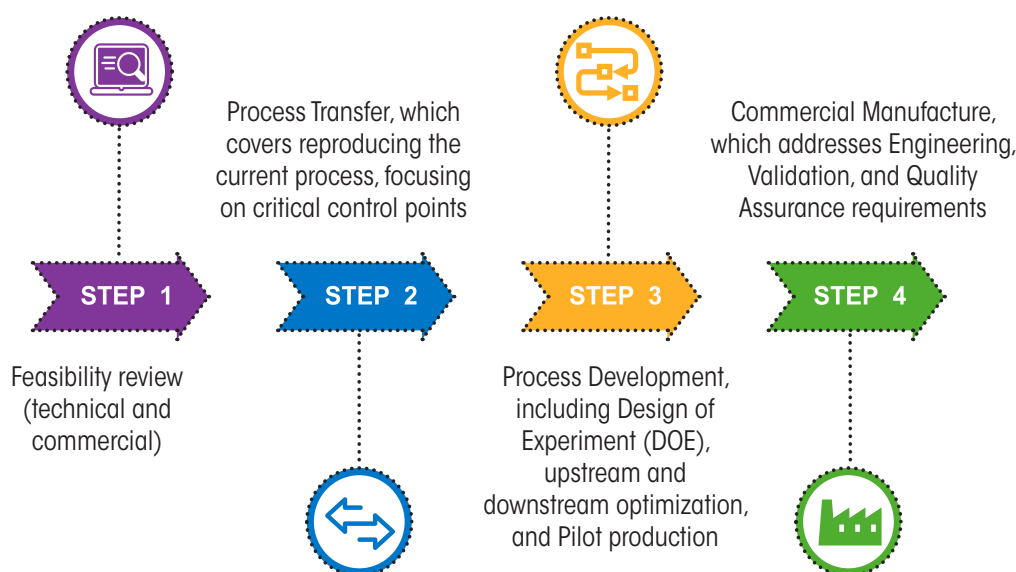
By leveraging our microbial fermentation expertise, SEKISUI can develop and manufacture your recombinant protein and other biopharmaceuticals

BiProduction  
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> <li>- Chromatography scale from 1L–200L</li> </ul> </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
- ✓ Class D pharma grade facility with an ISO 7 clean room
- ✓ GMP regulations as specified in quality agreement
- ✓ Expanded cGMP microbial Production available from end of year 2023
- ✓ ISO13485 plus other controlled processes (suitable for biopharma processing)
- ✓ OHSAS 18001 safety management system and ISO 14001 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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