



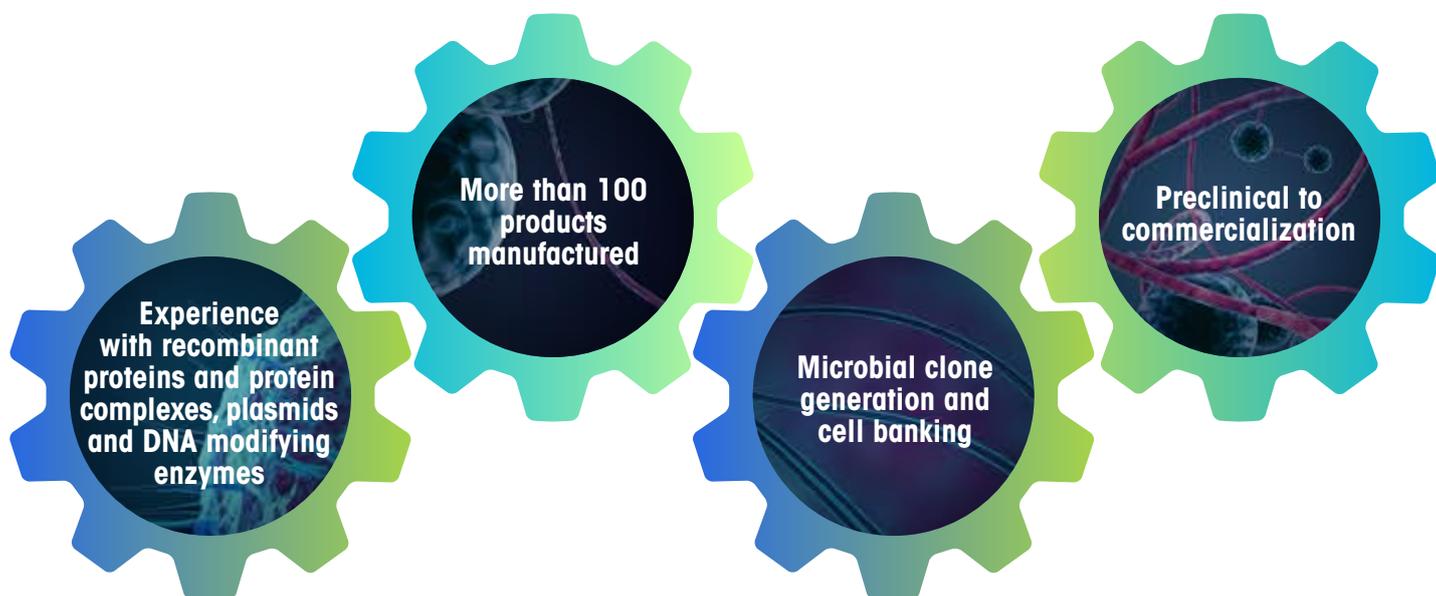
CDMO SERVICES FOR  
BIOPHARMACEUTICALS

## DEVELOPING MICROBIAL BIOPRODUCTION PROCESSES OVER THE LAST 40 YEARS

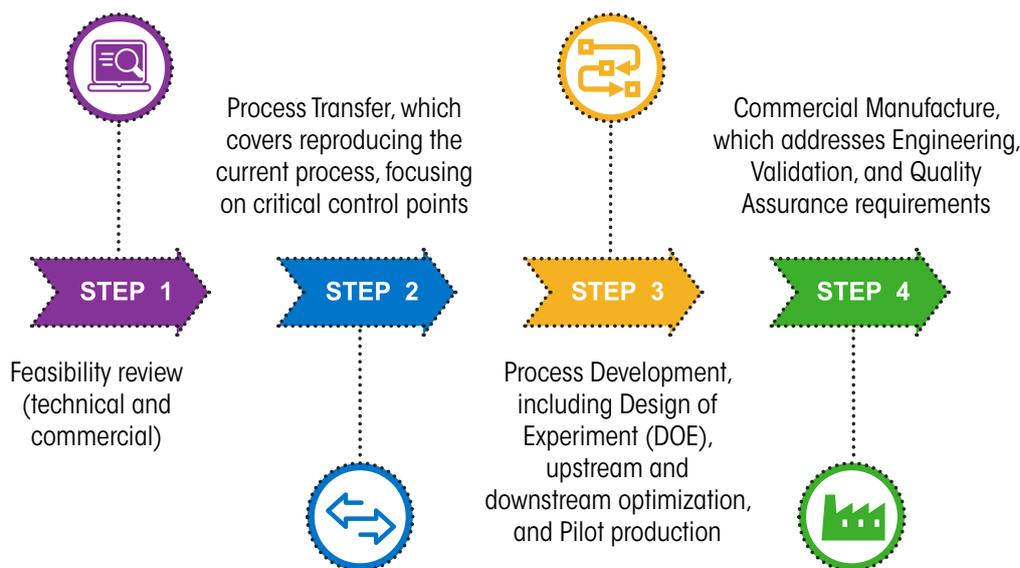
By leveraging our microbial fermentation expertise, SEKISUI can develop and manufacture your recombinant protein and other biopharmaceuticals

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> <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
- ✓ Aspects of cGMP as specified in quality agreement
- ✓ cGMP microbial production (Class C) facility under expansion to enhance production capacity and capabilities.
- ✓ 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](http://SEKISUIDIAGNOSTICS.COM)

Diagnostic materials, tests, and Contract Manufacturing

**SEKISUI**

SEKISUI MEDICAL CO.,LTD.

[SEKISUIMEDICAL.JP](http://SEKISUIMEDICAL.JP)

Drug Development Services and Pharmaceutical Contract Manufacturing

**SEKISUI Diagnostics (UK) Limited**  
Liphook Way, Allington Maidstone,  
Kent, ME16 0LQ, UK  
Phone: +44 1622 607800  
Fax: +44 1622 607801

[BIOPRODUCTION-SEKISUI.COM](http://BIOPRODUCTION-SEKISUI.COM)