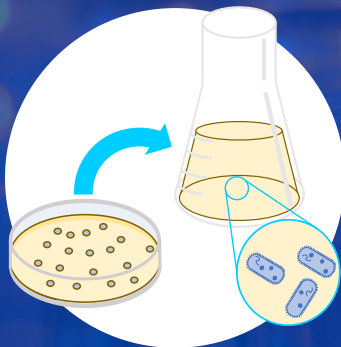


# Biopharmaceutical Process & Product Development

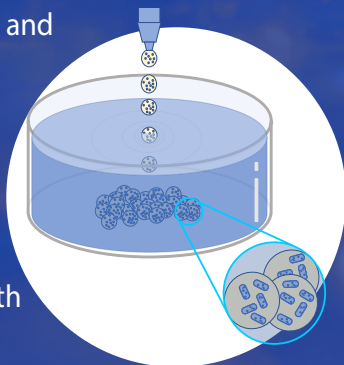
## Formulation & Process Development

- Identify critical process parameters and explore quality attributes for crucial drug product specifications
- Enhance shelf stability, bioavailability, handleability, and targeted delivery through microencapsulation and formulation



## Tech Transfer, Scale-Up & Manufacturing

- Transfer production and analytical methods
- Develop or modify new and existing methods
- Maintain jacketed stainless steel growth vessels up to 150 L



SwRI has expertise ranging throughout the full drug development process. This includes in silico discovery and proof-of-concept studies, which lead to process development and scale-up, and the development and transfer of manufacturing processes for CGMP production.

SwRI maintains certifications in FDA, CGLP, and CGMP. SwRI is an ISO 9001 and ISO 13485 compliant facility.

**We welcome your inquiries.**  
**For more information, please contact:**

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# Biological Services



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## Chemistry Manufacturing & Controls

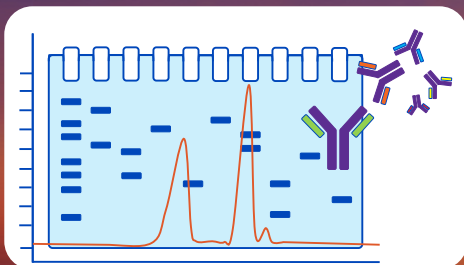
- Confirm reproducibility with developmental batches
- Generate and test batches to support GLP toxicity
- Generate materials under CGMP for Phase I and Phase II clinical trials
- Provide oversight for the manufacture and testing of engineering and GMP batches
- Assist with CMC regulatory submissions

## Bioassay Development & Screening

- Transfer or develop robust bioassays to evaluate the potency of drug payload
- Develop a workflow to screen large numbers of variables to support formulation and process development

## Analytical Instrumentation

- FPLC
- Multi-mode plate reader
- SDS-PAGE and blotting
- ELISA
- RT-qPCR analytical capabilities
- Cell-based assays
- Microcalorimetry

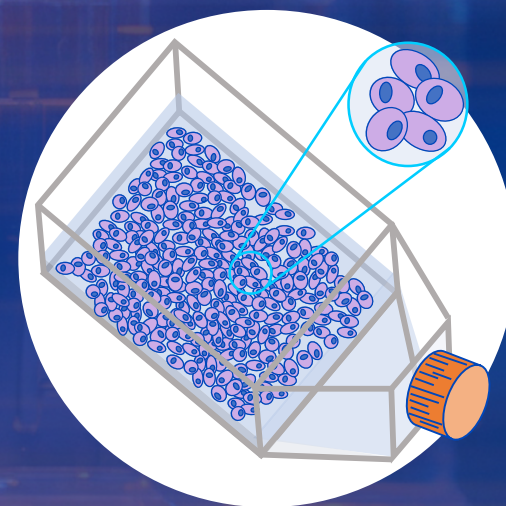


## API & Formulation Testing

- Particle size distribution (PDI), size determination by dynamic light scattering
- Osmolality
- Water activity
- Viscosity measurement
- Zeta-potential
- Encapsulation efficiency
- Total drug substance content
- Viability or activity assessment
- In vitro potency
- Stability/forced degradation
- Residual solvents
- Solubility
- Trace impurity analysis
- LC-MS/MS

## Drug Carriers

- Microspheres
- Microcapsules
- Lipid nanoparticles
- Liposomes
- Polymer nanoparticles
- Emulsions/suspensions
- Exosomes



Discovery	Early Development	Clinical R&D	Approval
<b>In silico modeling, screening</b>  Drug substance and drug product development Formulation, analytical and process development	<b>Analytical transfer, development, &amp; characterization including custom assays</b>  Development/manufacturing under GMP/GLP Monitored stability storage Analytical method transfer and validation		Program management & regulatory submissions Support for CMC of IND