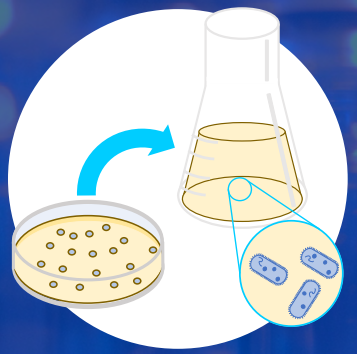
Biopharmaceutical Process & Product Development

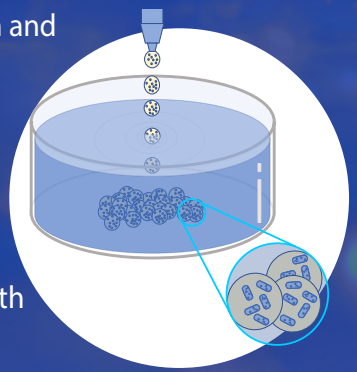
Formulation & Process Development

- 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

SwRI®

SOUTHWEST RESEARCH INSTITUTE

Chemistry Manufacturing & Controls

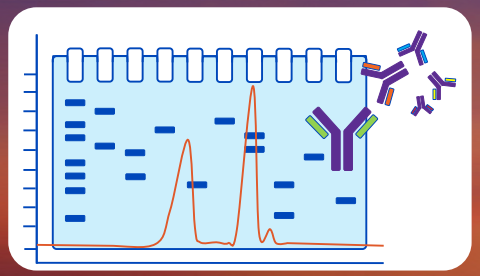
- Confirm reproducibility with developmental batches
- Generate and test batches to support GLP toxicity
- Generate materials under CGMP for Phase I and Phase II clinical trials
- Provide oversight for the manufacture and testing of engineering and GMP batches
- Assist with CMC regulatory submissions

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

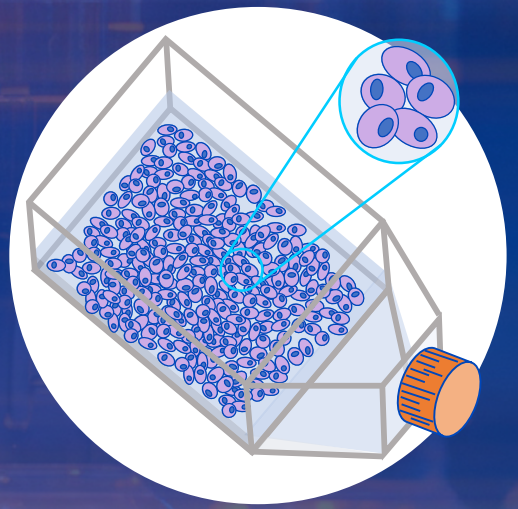


API & Formulation Testing

- 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
In silico modeling, screening	Analytical transfer, development, & characterization including custom assays		
Drug substance and drug product development Formulation, analytical and process development			
	Development/manufacturing under GMP/GLP Monitored stability storage Analytical method transfer and validation		Program management & regulatory submissions Support for CMC of IND