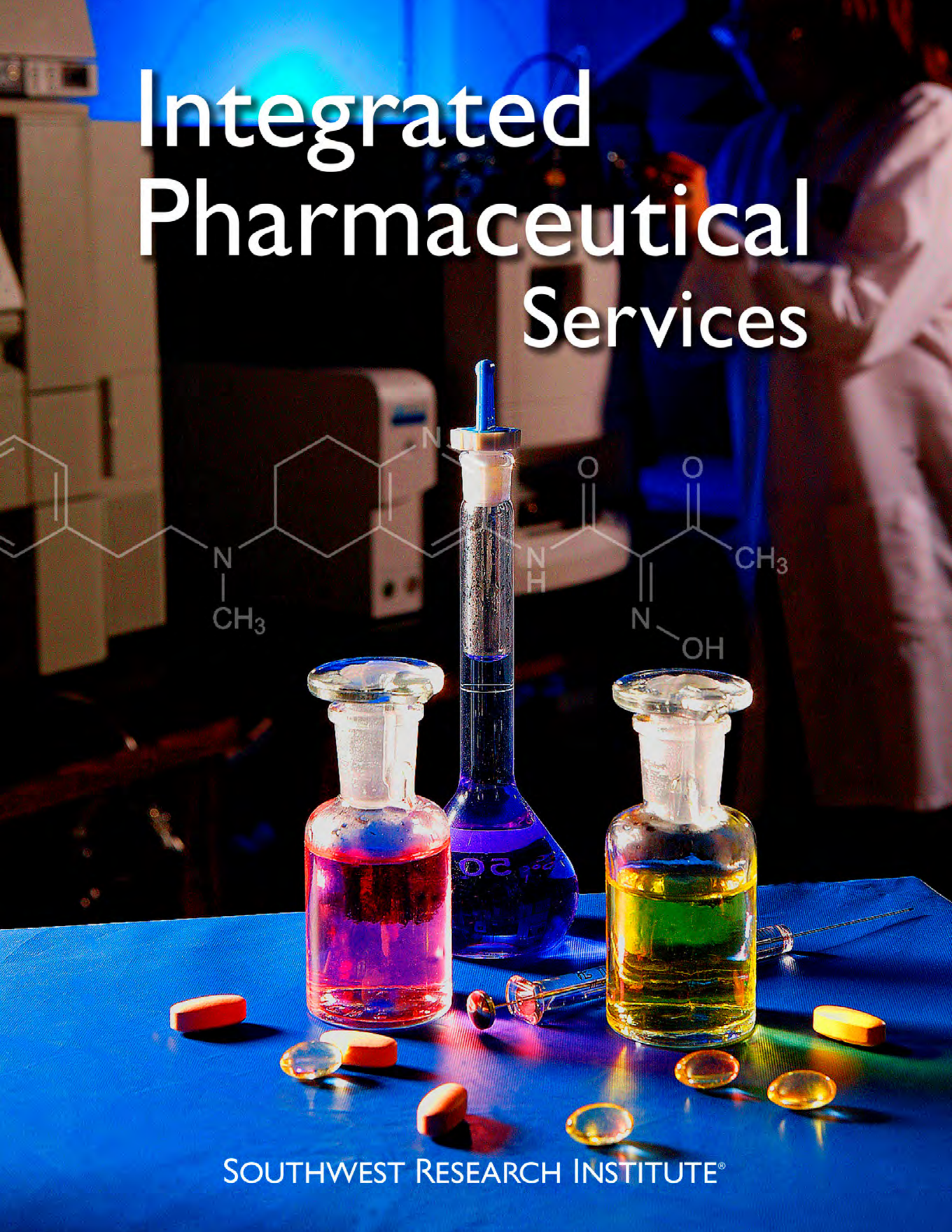
Integrated Pharmaceutical Services



SOUTHWEST RESEARCH INSTITUTE®

Southwest Research Institute® (SwRI®) is a nonprofit contract research and development organization offering comprehensive services spanning drug design and discovery through Current Good Manufacturing Practice (cGMP) drug substance and drug product supply for clinical trials. Integrated program management, consulting, technical writing, and preparation of regulatory applications services are also available.

Drug Discovery → **Biochemistry** → **Drug Substance Development** → **Drug Product Development** → **cGMP Manufacturing** → **Program Management & Regulatory Submissions**

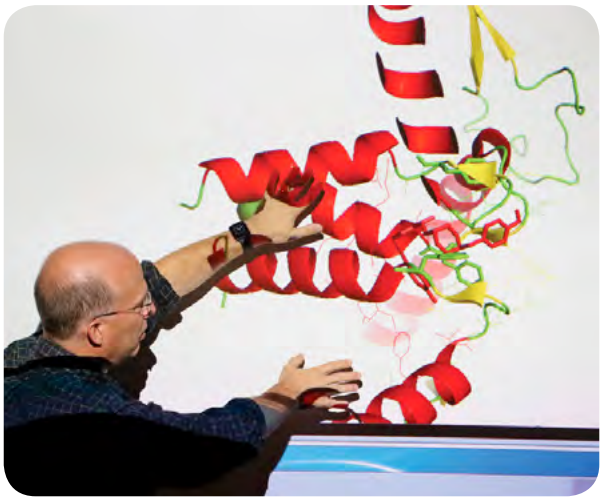
Southwest Research Institute®

Founded in 1947 as an independent, nonprofit research and development organization, Southwest Research Institute provides significant research, engineering, and evaluation resources for industry, business, and government. With nine technical divisions and state-of-the-art laboratories, the Institute uses a multidisciplinary, integrated approach to solving complex problems in science and applied technology. Subject to the client's wishes, programs are kept confidential. As part of a long-held tradition, patent rights arising from sponsored research at the Institute are often assigned to the client. SwRI generally retains the rights to Institute-funded advancements.

Drug Discovery

Biostructure-based drug design with proprietary Rhodium™ docking platform

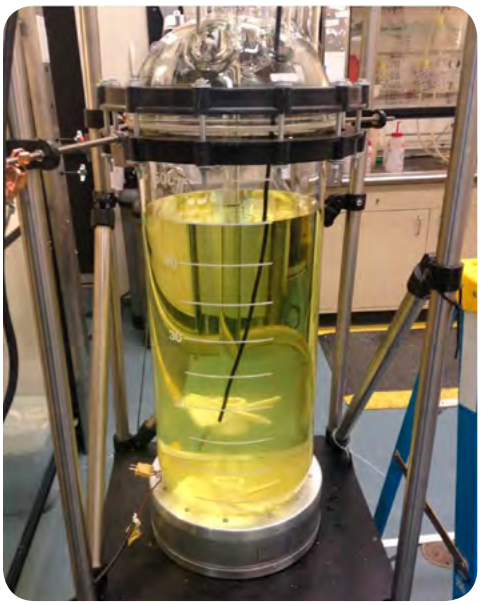
- QSAR services — pharmacophore modeling, PCA, homology models
- Screening library synthesis
- *In vitro* assay development
- Hit to lead optimization
- Physicochemical properties determination and salt screening
- Scale-up for *in vivo* studies



Biochemistry

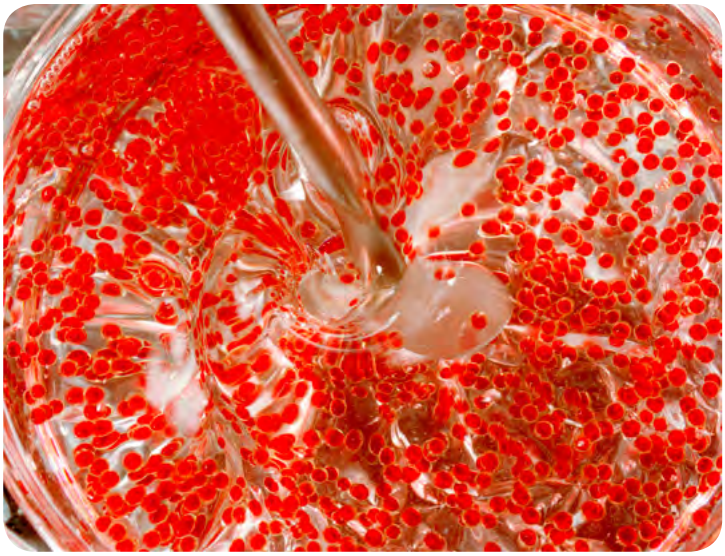
- Tissue culture, microbiology, molecular biology, antibodies
- Protein expression, purification, characterization
- Protein engineering (activity, stability, stereoselectivity)
- Enzyme kinetics, calorimetry, UV/Vis/fluorescent spectroscopy
- Cell based assays, ELISA
- Viral expression and characterization

Drug Substance (API)



- Technology transfer and evaluation of existing process
- *De novo* process development
- Isolation and characterization of process impurities
- Process optimization and parametric studies (design space)
- High potency drugs
- Controlled substances — schedule II-V
- Specialized needs (chromatography, flow chemistry, others)
- Physicochemical properties and salt screening
- Analytical methods development and qualification or validation
- ICH stability studies
- Forced degradation
- Reference standard qualification
- Specifications development

Drug Product (Formulation)

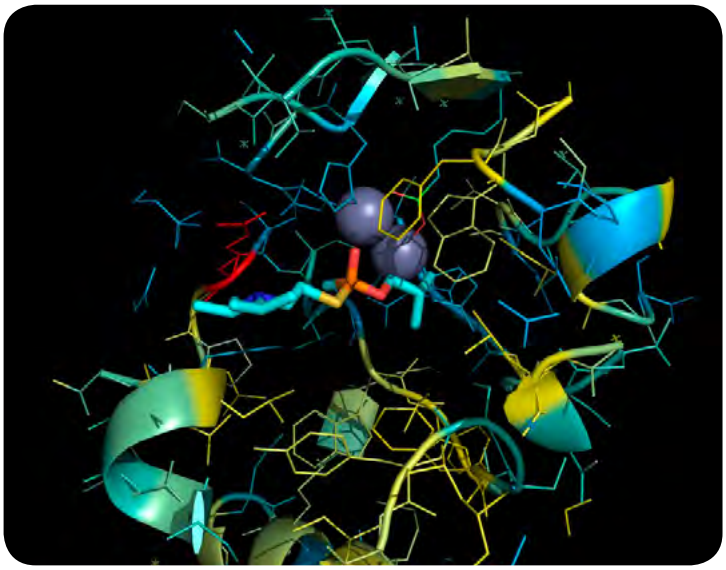


- Pre-formulation/formulation development for small and large molecules, controlled substances, potent compounds, toxins
- Oral, parenteral dosage forms
- Scale-up and technology transfer
- Microencapsulation — extrusion, fluidized bed, spray drying, liposomes, micelles
- Milling (hammer mill, ball mill, jet mill, bead mill)
- Granulation (fluidized bed coater, spray dryer, pan coater, extrusion)
- Emulsion/suspension (homogenizer, polymerization, pickering emulsion)
- Specialized dosage forms (implantable delivery systems, sustained release, particle size reduction, protein conjugates and targeted delivery systems)
- Particle engineering — granulation, emulsions, suspensions, electrospinning, core shell particles, polymerization, morphology design
- Engineering and consulting – custom equipment design and demonstration
- Analytical methods development and validation/qualification

cGMP Manufacturing (Drug Substance and Drug Product)

- Gram to kilogram scale manufacturing (drug substance, drug product)
- Technology transfer
- FDA inspected facility
- ISO 9001:2008 quality system
- cGMP chromatography services
- High potency and controlled substances
- Specialized processes
- Release testing for drug substance and drug product

Rhodium™ — New Dimension in Protein Docking



- Unbiased comprehensive *in silico* docking on protein structures
- Extremely high throughput
- Demonstrated efficacy in multiple druggable targets
- Superior selectivity for selection of true ligands
- Superior accuracy in predicting binding poses
- Ideal for allosteric sites and protein-protein interactions
- Available as a service — no contracts or licenses required

Founded in 1947 as an independent, nonprofit research and development organization, Southwest Research Institute serves as a significant resource for research, engineering, and testing services for industry and government. With nine technical divisions, the Institute uses a multidisciplinary, integrated approach to solving complex problems in science and applied technology. The Institute occupies more than 1,200 acres and provides more than 2 million square feet of laboratories, test facilities, workshops, and offices for nearly 2,700 employees who perform contract work for industry and government clients.

We welcome your inquiries.
For additional information, please contact:

SwRI®

Advanced science. Applied technology.

Joe McDonough, Ph.D., Director
(210) 522-3670
joe.mcdonough@swri.org

Pharmaceuticals and Engineering Department
Chemistry and Chemical Engineering Division
Southwest Research Institute
6220 Culebra Road • P.O. Drawer 28510
San Antonio, Texas 78228-051

pharmdev.swri.org

The Chemistry and Chemical Engineering Division of Southwest Research Institute has achieved certification to ISO 9001:2008, an internationally recognized quality standard.

Find us on

Designed & printed by SwRI MPS

01-0217-2 JCN256466 bl