Pharmaceutical sciences

SRI offers a full suite of pharmaceutical product capabilities from drug formulation to manufacturing of final drug product under current Good Manufacturing Practices (cGMP) regulations.

We also offer all of the analytical chemistry capabilities required to support early formulation activities through to cGMP product release and long-term stability testing. We offer a variety of state-of-the art techniques for preformulation, formulation, manufacturing and analytical chemistry that can be applied to your particular product development needs from Preclinical through Phase 1/ Phase 2 clinical trials.

SRI has more than 30 years of experience solving challenging problems in formulation, drug delivery, manufacturing, and analytical chemistry. Our direct, hands-on experience in product development has led to the advancement of over 225 products into clinical trials and approximately 25 to the market. Our unique capabilities include robotic systems for rapid identification of optimal solvents; in vitro intestinal penetration models; a proven track record in enhancing absorption of poorly bioavailable or short half-life drugs; manufacturing of a range of dosage forms including topical, oral, sterile, and spray-dried formulations; and extensive stability testing conditions.

Preformulation studies

SRI specializes in conquering "problem" compounds – those with poor solubility, low bioavailability, short half-life, and/or gastric intolerability. We conduct preformulation studies to guide the formulation strategy for your drug candidate. Typical preformulation characterization studies offered include determination of:

- Physicochemical properties
- Aqueous and pH solubility, organic solvent solubility
- Crystallinity by x-ray
- Hygroscopicity and lipophilicity
- pKa, partition coefficients, and tissue distribution coefficients
- Thermal properties (DSC, TGA)
- Moisture content
- Particle size and morphology
- Drug-excipient compatibility

Every drug formulation is customized to enhance the physicochemical properties of your drug candidate.

Stability studies

SRI offers stability storage and testing that adheres to ICH guidelines. Our standard storage conditions include frozen (ultracold and -20°C), refrigerated (5°C), ambient (25°C/60% RH), intermediate (30°C/65% RH), and accelerated (40°C/75% RH). Custom storage conditions and specialized climatic zone considerations can also be accommodated upon request. In addition to long-term drug substance and drug product stability studies to support ongoing clinical trials, we routinely incorporate short-term stability studies in the evaluation of candidate formulations. We also perform photostability and temperature cycle studies.

Our stability study evaluations are preceded by forced degradation studies to develop sensitive and specific analytical methods so that impurities and degradation products can be tracked and quantified. Our in-house analytical and synthetic chemists can identify impurities through various structure elucidation techniques and synthesize reference standards of the active ingredient and degradation products to support ongoing stability assessments.

To ensure the quality and security of your drug substance and drug products, our stability storage program features:

- Storage units with validated conditions of temperature, humidity, and light (visible and UV)
- Validated computerized system for continuous monitoring of temperature, humidity, and light, with cumulative reports
- Emergency power back-up for chambers and computer monitoring systems
- Local audible alarms and an automatic notification system to 24/7 on-site security personnel with protocols for notifying facility engineers and technical staff
- A double-lock system to access chambers

Stability study failures can be prevented or controlled by formulation development.

Dosage form manufacturing: R&D, GLP, and cGMP

SRI's dosage form manufacturing facilities are designed to provide you with a single, high quality resource for the manufacture and packaging of oral, topical, and parenteral products for nonclinical and clinical studies. These activities are supported by our Quality Control and Quality Assurance Units which inspect, test, and release the products in full compliance with the FDA GLP and cGMP regulations and international regulatory agencies.

Our R&D, GLP, and cGMP facilities and equipment are designed to support early development through Phase 2 clinical supplies manufacturing. The low volume batches needed for safety evaluations and early clinical trials present unique challenges, and we are ready to work with you to overcome limited bulk drug supplies and tight turnaround times.

Our extensive collection of equipment provides the capabilities needed to produce R&D, pilot, and clinical-scale batch sizes including:

Liquid/sterile dosage forms

- Fill/finish capability for small and large molecules
- Liquid capsule filler
- Lyophilizer

Solid dosage forms

- Capsule filling
- Capsule bander
- Capsule polisher
- Capsule sorter
- Tablet press

Topical/transmucosal dosage forms

- Semi-solid filler
- Franz diffusion cells
- In-line permeation cells
- Unguator™

Sterile spray drying

- Aqueous and organic based
- Containment option for steroids/potent drug

Mixing and blending

- Liquid mixing bag system
- Planetary mixers
- V-Blenders
- Emulsifiers

Milling

- Low speed mills
- High speed mills

Granulation

- Roller compactor
- Granulator/oscillator
- Extrusion-spheronization
- Fluid-bed granulator

Coating

- Pan coater
- Spray coater

Packaging

- Induction sealer
- Blister pack sealer
- Heat sealer
- Laminated tube sealer
- Vial capper

Sterilization

- Autoclave
- Depyrogenation
- Sterile filtration

Other

- Fiberoptic dynamic dissolution
- DLS particle size analyzer
- Microfluidizers
- Texture analyzer
- Viscometer

We can customize our manufacturing capabilities to produce the dosage form and batch size you need.

Formulation development

At SRI, we have the experience and expertise to solve challenging formulation and drug delivery problems. We address the cost parameters and regulatory requirements for formulating new drugs, and we look for simple, economical solutions to dosage design challenges. Protection of proprietary information is routinely incorporated into our procedures.

Parenteral (Solution, lyophilized, nanosuspension)

- Intravenous
- Intramuscular
- Rapid Onset Injectables
- Long-Acting Injectables (LAI)
- Subcutaneous

Oral (Immediate-release)

- Powder-in-bottle
- Solution/Suspension/ Emulsion
- Capsules
- Tablets
- Spray-Dried Dispersion (SDD)
- Self-emulsifying drug delivery system (SEDDS)
- Orally disintegrating tablets

Oral (Sustained-release)

- Extended-release capsules and tablets
- Multi-particulate Systems (MUPS)
- Microspheres

Topical & transdermal

- Cream
- Gels
- Ointments
- Film/Patch

Formulated drug products are more effective than their individual components used singly.

Alternative drug delivery systems

Drug delivery technologies can modify drug release, absorption, distribution, and elimination profiles to improve product efficacy and safety, as well as patient convenience and compliance. Oral and parenteral are the most common routes of drug delivery, but alternative routes of administration are preferred in many situations. SRI has expertise in the development of these specialized drug delivery systems:

- Buccal films, tablets
- Vaginal films, gels, inserts, bioadhesives
- Nasal
- Biodegradable Implants
- Pediatric dosage forms
  - Syrups
  - Solutions
  - Suspensions
- Modified release dosage forms
- Nanoparticles/ nanosuspension
- Liposomes
- Bioadhesive/ mucoadhesive topicals

SRI has been working on formulation and delivery approaches to enable currently approved drugs to be delivered in a more economical and practical manner in an approach sometimes referred to as “IV to PO.” We have had great success in reformulating IV drug products into oral dosage forms.

Analytical chemistry

SRI has state-of-the-art technology and experienced scientists offering a broad range of analytical method development and validation, and quality control analyses of small molecules and biologics. We work closely with drug development scientists in medicinal chemistry, formulations, pharmacokinetics, toxicology, and manufacturing to identify, quantify, and characterize materials to meet R&D needs and be in full compliance with FDA GLP and cGMP requirements. Our analytical team contributes the following:

- Pharmaceutical analysis
  - Reference standard characterization and Certificate of Analysis
  - Bulk pharmaceutical ingredients
  - Excipient testing according to official monographs
  - Structure elucidation of intermediates, impurities, and degradants
- Methods development and validation
  - In-house use
  - Method transfer in and out
  - Validation levels tailored to phase of development
- Analytical support for preformulation and formulation development
  - Efficient immediate feedback to formulators
  - Short-term stability studies
  - Planning for final product methods
- Dose verification for in vivo and in vitro GLP studies
  - Dose concentrations and homogeneity in vehicle media or device
  - Short-term dose stability under conditions of use
  - Test article characterization and stability
- Quality control activities and cGMP clinical trial materials
  - Quarantine, testing, and release or rejection of materials and products
  - In-process testing
  - Cleaning validation
  - Stability studies per ICH guidelines for drug substances and products

We have decades of experience working with hundreds of drugs.

Clinical Manufacturing Unit (CMU)

SRI's Clinical Manufacturing Unit (CMU) is a versatile, multi-purpose, multi-product GMP facility, designed to support the production of clinical trial materials for Phase I, and II studies. As a non-profit organization we do not conduct commercial manufacturing in-house, but we specialize in tech transfer and managing manufacturing activities at CDMO/CMO sites The SCMU encompasses a 2,400 square-foot space, meticulously divided to optimize functionality and maintain the integrity of all processes:

900 ft²

Pilot laboratory
Facilitates scale-up activities for a range of pharmaceutical products.

1200 ft²

Clinical manufacturing suites
Dedicated to the production of clinical trial materials, with capabilities to handle various dosage forms including solids, liquids, injectables, and semisolids.

300 ft²

Support area
Provides space for material staging, packaging, labeling, and carton loading.

400 ft²

Sterile fill/ finish clean room
The CMU features an advanced sterile fill/finish clean room, operated and maintained according to ISO 14644-2 standards. The clean room suite includes Class 10,000 Sterile Gowning Room, Class 1,000 Anteroom, Class 100 Aseptic Processing Area.

SRI Biosciences, a division of SRI International, integrates basic biomedical research with drug and diagnostics discovery and preclinical and clinical development.

SRI is an independent nonprofit research instituteheadquartered in Menlo Park, Calif., with a rich history of supporting government and industry. We create and deliver world-changing solutions for a safer, healthier, and more sustainable future. For more than 75 years, we have collaborated across technical and scientific disciplines to discover and develop groundbreaking products and technologies and bring innovations and ideas to the marketplace.

Learn more at www.sri.com.

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