



Regulatory Support and Services

SRI International provides expert assistance in the assessment and implementation of Food and Drug Administration (FDA) regulations and protocols. Our clients require strict adherence to current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP) regulations. We work with universities, pharmaceutical, and biotechnology companies, ranging in size from start-up to multinational. SRI also provides assistance for the preparation, assembly, review, delivery, and follow-up of documentation required for Sponsor's pre-IND and IND submissions.

SRI has unmatched quality for a Contract Research Organization. In over 55 years of providing FDA-compliant studies for its clients, SRI has never had a study rejected by the FDA.

Pre-IND and IND Support

- Prepare and submit all necessary documents for pre-IND meeting
- Obtain and review preclinical and clinical information needed for the IND
- Prepare or update the Investigator's Brochure (IB) as described in the Code of Federal Regulations, Title 21 Section 312.23
- Prepare or assist in the writing of a Master File or amend as necessary
- Collect and submit documentation required for key IND sections
- Assemble IND study protocol and provide information relative to the four basic sections of the clinical aspect (clinical protocol, investigator data, facility data, and IRB data)
- Assemble, edit, and index the IND for submission to the FDA
- Obtain any necessary authorization for cross-filing of information and obtain lot release protocols as well as required investigator brochures prepared by the manufacturer or appropriate organization
- Participate in discussions with the FDA during pre-IND and IND meetings



Bridging the drug development gap

Regulatory Compliance Consulting

ASSESSMENT

- SRI audits cGMP/GLP compliance to state and federal regulations
- We provide detailed written reports and recommendations
- We review and evaluate Standard Operating Procedures and Regulatory Protocols
- We review methods of documentation and data integrity

PLANNING

- Inspect facilities, computer systems, equipment, and qualification plans
- Coordinate investigational new drug (IND) FDA meetings and correspondence
- Review quality assurance plans, quality control specifications, and test methods
- Provide regulatory recommendations
- Provide manufacturing, production, and testing support
- Qualify contract manufacturers and testing vendors
- Provide overall project management

IMPLEMENTATION

- Provide employee education and training
- Provide ongoing oversight and auditing for compliance
- Coordinate document preparation, project protocols, and Master Production Records
- Provide method development and analytical validation
- Provide stability testing and storage programs

Quality Control Services

Analytical chemistry is an integral component of the entire drug development process. SRI uses its years of experience and state-of-the-art technology to provide a broad range of custom and quality control analyses to our clients. We can help you identify, quantify, and characterize drug substances and products in full compliance with FDA requirements.

- Pharmaceutical analysis (reference standard characterization, excipients, active pharmaceutical ingredient)
- Analytical method development and validation
- Dose verification for GLP studies (concentration, homogeneity stability)

- Quality control activities for cGMP clinical trial materials

- Stability studies and storage (ICH and custom conditions, photostability)

Available capabilities include chromatography (HPLC,GC), spectroscopy (FTIR, UV, NMR, ICP, FAA), and electrophoresis and immunoassays (CE, SDS PAGE, western blot, ELISA) as well as LC/MS/MS, dissolution and disintegration testing, Karl Fischer analysis, polarimetry, wet chemistry, viscosity, and other compendial testing.

You Make the Call

For further information, contact our Client Services Team:

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