



Vaccine Development Program

Vaccines continue to be the most effective method of controlling infectious disease. In recent years vaccines are being used for other uses as well, including as a therapy for cancers; autoimmune diseases, substance addiction and many other purposes. From developing a formulation to designing clinical protocols, our experienced staff works together with our clients to ensure that we provide all the vaccine-related services that they might need. Key to our vaccine development effort is our 10,000-square-foot animal facility with separate surgical suites and complete pathology capability. In addition, SRI houses 12,000-square-foot of cell biology and microbiology laboratories complete with BSL-3 capabilities and CDC select agent clearance.

SRI's experience and resources cover various types of vaccines (DNA, subunit protein, live virus, peptide and modified toxins) for conditions including infectious disease, toxins and cancer. Our Vaccine Development Program also has full capabilities to carry out assay development and assess vaccine performance. These services include GCP immunogenicity assays for samples from human clinical trials and GMP product quality assays (characterization and release assays, potency assays and stability assays).

In addition to our extensive array of laboratory services, SRI offers expert consultation on vaccine development strategies and writes detailed product development plans. During the latter stages of the preclinical phase, a full package of regulatory services is available to prepare, assemble, review, deliver and follow up on IND submissions.



Bridging the drug development gap

Services

IMMUNOGENICITY MEASUREMENT

- Antibody titers:
 - ELISA
 - Toxin, viral, and microbial neutralization assays
 - ADCC activity
- Cell mediated immune assays for T cell activation and function
 - ELISPOT for single cell activities
 - Cytometric flow for multiple cytokines
 - CD4 antigen driven proliferation
 - CD8 cytotoxic activity
 - Chemokine analysis

EFFICACY STUDIES

- In vitro models (BSL-3 as necessary)
- In animal models (BSL-2)

ASSIST WITH PRODUCTION OF GMP VACCINE

- Identify, qualify and manage subcontractors
- Develop a formulation
- Formulate, fill and finish
- Conduct analytical characterization and stability studies
- Develop and perform potency assays
- Make antibody against manufacturing cell proteins required for release assay

PRECLINICAL SAFETY TESTING IN ANIMALS

- Consult on study design
- Perform GLP toxicology and safety testing
- Perform GLP biodistribution and integration studies as required
- Perform GLP reproductive toxicology studies as required

REGULATORY SUPPORT

Throughout each project, SRI provides complete and comprehensive regulatory support for its clients:

- Consultation on strategy and management of FDA interactions
- Submission of all meetings and follow-up documentation (e.g. preIND)
- Staff training for FDA meeting presentations
- Clinical Protocol design and conduct of Animal Rule efficacy studies for biothreat agents
- Preparation and submission of all FDA documentation, including INDs, Clinical Investigators' Brochure and Master Files

You Make the Call

For further information, contact our Client Services Team:

Toll Free: (866) 451-5998

Phone: (650) 859-3000

Fax: (650) 859-3041

Email: biosciences@sri.com

<http://www.sri.com/biosciences>