



a strategic
PARTNERSHIP

**Comprehensive
Environmental Health,
Occupational
& Pharmaceutical
Regulatory Support**

STRATEGIC REGULATORY CONSULTING



&
TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT



Comprehensive Environmental Health, Occupational & Pharmaceutical Regulatory Support

A STRATEGIC PARTNERSHIP:

Strategic Regulatory Consulting (SRC) &
Toxicology Excellence for Risk Assessment (TERA)

flexible solutions for your business needs

ABOUT SRC

- Ohio based company assisting drug and device companies since 1987.
- A team of highly experienced, industry professionals with over 200 total years in product development, clinical, and regulatory expertise in the drug, biologic and medical device areas.
- We promise our clients a high level of expertise, quality and cost effectiveness.

ABOUT TERA

- Ohio based independent non-profit corporation founded in 1995.
- Mission to protect public health and the environment through dedication to the best use of toxicology data for risk assessment.
- We have provided support for large pharma. And we help industry, government and non-governmental organizations (NGOs) to find common ground through the application of good science to risk assessment.

TOGETHER WE CAN PROVIDE SUPPORT
FOR YOUR SMALL TO MEDIUM SIZE
BIOTECH AND PHARMA COMPANY

SRC AREAS OF EXPERTISE

Our experienced team has extensive industry experience and covers every aspect of drug and device development, from conception to FDA approval.

- Regulatory Strategic Planning (Fastest Track)
- FDA Meeting Management (Pre-IND, Pre-IDE, End of Phase 2)
- Gap Analysis (manufacturing, preclinical & clinical)
- GMP, QA, QC Audits
- Toxicology Program Design and Management
- Study and Protocol Design
- Clinical Trial Design
- Clinical Project Management
- Regulatory Writing (Final Reports, IND, ANDA, NDA, IDE, 510k, PMA)
- Literature Reviews & White Papers

TERA AREAS OF EXPERTISE

Our team provides independent and objective risk and toxicological science.

- Hazard Identification Screening
- MSDS Development
- Occupational Exposure Limit Development
- Hazard Assessment of API, impurities, intermediates and leachates
- Hazard Banding
- Health and Safety Clearance of Chemicals
- Dose-response modeling
- Physiologically Based Pharmacokinetic (PBPK) Modeling
- Cleaning Limit Determination & Validation
- Full Occupational & Environmental Risk Assessments



WE'VE WORKED WITH A DIVERSE CUSTOMER BASE. HOW CAN WE HELP YOU?

www.tera.org

www.srcteam.com

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