PHARMACEUTICAL TOXICOLOGY

Quality Assurance Services

Trinity Consultants is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Trinity has the technical expertise and acute industry knowledge to provide optimal solutions to highly complex pharmaceutical development, process, safety, and facility design challenges.

SafeBridge, a Trinity Consultants team, has an experienced staff of registered quality assurance professionals (RQAP-GLP) to provide comprehensive study auditing, training, and regulatory compliance services.

Services provided include the following:

- **Quality Assurance (QA) Training and Program Design:** SafeBridge provides clients (including both Sponsors and CROs) with expert guidance for compliance with EPA, FDA, and OECD Good Laboratory Practices (GLPs) as well as FDA Good Clinical Practices (GCPs). Customized training documents and presentation materials are prepared to meet the Client's objectives. Common training topics include: basic GLP and GCP principles; test article documentation and chain of custody; preparation and maintenance of Standard Operating Procedures (SOPs); study auditing procedures; documentation procedures and data management; multisite study compliance; FDA/EPA regulatory inspection preparation.
- **Pre-Qualification Site Visits and Facility Inspections:** SafeBridge performs independent GLP and GCP facility inspections on behalf of Sponsors and CROs. For contracted testing programs, SafeBridge evaluates GLP or GCP compliance of candidate testing facilities via remote assessment or on-site facility inspection prior to program initiation. The following areas are evaluated: organization and personnel; Quality Assurance Unit; SOPs; facilities and equipment; data and sample collection and storage; Archives.
- **Protocol Reviews for Testing Guideline Compliance:** SafeBridge QA personnel review draft study protocols to ensure that scientific and technical aspects of the study design are compliant with applicable testing guidelines of EPA, FDA and/or OECD. GLP or GCP compliance of the study protocol is also assessed (see Study Audits). SafeBridge protocol reviews ensure that potential testing guideline deviations are identified and addressed prior to study initiation.
- **Study Audits:** SafeBridge provides QA auditing services for toxicology, chemistry, human clinical, and environmental fate and effects study designs. The following aspects of the study are inspected by QA personnel to assure that applicable regulatory requirements (GLP or GCP) are satisfied: study protocol; test article chain of custody, receipt, usage, and disposition; critical (in-process) study phases and procedures; draft report; raw data; final report; study archival. SafeBridge study audits ensure that potential documentation errors, protocol deviations, and/or compliance violations are identified and addressed prior to regulatory submission of a completed study.
- **Technical Review of Study Reports:** The following items are included in the technical report review performed by SafeBridge QA personnel: the experimental design and procedures used in the study are presented in a clear and concise manner; data transformation and calculations are correct; the results presented in the text accurately reflect the data presented in the tables and/or figures; the results of the study are discussed clearly and appropriately. SafeBridge report reviews facilitate the regulatory review process for submitted studies.

Quality Assurance services are provided on a time and materials basis.

CONTACT OUR TEAM!

For more information about how we can help your organization, please contact us.

Trinity Consultants | SafeBridge
P 650.961.4820 / *info@safebridge.com*

SCAN THE QR CODE TO LEARN MORE

HEADQUARTERS 12700 Park Central Dr, Ste 600, Dallas, TX 75251
P +1 800.229.6655 / P +1 972.661.8100

trinityconsultants.com/life-sciences