PHARMACEUTICAL TOXICOLOGY

Study Monitoring 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, Regulatory has an experienced staff of toxicologists and registered quality assurance professionals (RQAP-GLP) to provide comprehensive testing program management and study monitoring services for toxicology, chemistry, and environmental fate and effects study designs. Services provided include the following:

- **Design of Testing Programs:** SafeBridge evaluates regulatory data requirements or recommendations and assesses data gaps to define appropriate testing programs. SafeBridge also uses published literature or prepares data waiver requests to reduce the scope of testing programs when scientifically justified.
- **Laboratory Selection and Pre-Qualification Audits:** SafeBridge prepares Requests for Proposals and coordinates the bidding process among candidate testing facilities. The selected laboratory can be evaluated for regulatory compliance (GLP or GCP) via remote assessment or on-site facility inspection.
- **Scientific Guidance:** SafeBridge guidance on the scientific aspects of studies is provided to the client and testing facility by senior scientists:
  - Overseeing study design and protocol development to ensure compliance with applicable testing guidelines and scientific objectives;
  - Discussing pertinent activities and procedures of studies with key laboratory personnel to determine when guidance is needed;
  - Answering questions that arise during the course of the studies; and
  - Consulting with the client or other scientists in order to address scientific issues that arise during the course of the studies.
- **Monitoring Study Conduct:** SafeBridge staff monitor the following as appropriate: performance of protocol specified activities and/or key study procedures; timeliness and adequacy associated with the performance of all study activities; overall study time frames in accordance with data development package requirements.
- **Quality Assurance Audits:** SafeBridge QA personnel inspect testing facilities prior to initiation of testing programs to assure compliance with applicable regulatory requirements (GLP or GCP). In addition, during the conduct of studies the following are audited/reviewed: study protocols; test article chain of custody, receipt, usage, and disposition; critical (in-process) study phases and procedures; draft report; raw data; final report; and study archives.
- **Interpretive Review of Study Data:** SafeBridge conducts timely periodic reviews of data during studies to: assure expected effects are being observed; identify any unexpected treatment-related effects; identify any effects due to uncontrolled variables and recommend corrective actions; select definitive study dose levels based on range-finding test results.
- **Scientific and Technical Report Review:** SafeBridge ensures clear and concise presentation of experimental design and procedures; results accurately reflect the data presented in tables and/or figures; results of the study are evaluated scientifically and are discussed clearly and appropriately; conclusions made for the study are scientifically valid and consistent with the study's objectives.

Study Monitoring services are provided on a time and materials basis depending on the study type, testing facility, and client approved scope of work.

CONTACT OUR TEAM!

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

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SCAN THE QR CODE TO LEARN MORE

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