INDUSTRIAL HYGIENE & EHS

Environmental Assessment Services for Pharmaceuticals/Medicines

Trinity Consultants SafeBridge

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, can help you evaluate and prepare environmental assessments of pharmaceuticals/medicines to meet regulatory requirements in the United States, Europe, and Canada. Our experts can help you navigate the process from start to finish or step in to assist at any point along the way including:

Environmental Risk Assessments (ERAs)

SafeBridge's knowledgeable scientists can evaluate physical chemical properties, and mammalian and aquatic toxicity data to prepare environmental risk assessments:

US FDA

Prepare the Request for categorical exclusion (RCE) for your new drug application submissions (NDA) to FDA

- Evaluate for extraordinary circumstances [e.g. endocrine, androgen and thyroid (EAT) activity]
- Prepare full Environmental Assessments (EA) for environmental introduction concentrations (EIC) or exceeding the criteria or if extraordinary circumstances are present

EU EMA

Conduct Tier I and II environmental risk assessments (ERAs), as appropriate.

- Tier 1 ERA: including evaluation of fate and effects data, determination of predicted environmental concentration (PEC), screen for persistence, bioaccumulation, and toxicity (PBT), and specific toxicity profile (e.g., endocrine active substances), and provide recommendations for Tier 2 Assessment if required
- Tier 2 ERA: including interpreting and reporting of fate and effects studies according to EMA Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (2024).
- Study monitoring of recommended fate and effects studies according to OECD guidelines
- Preparation of Tier II ERA to include appropriate fate and effects data and determining risk in surface water, sediment or sewage treatment plant

Regulatory Scoping and Assessment

SafeBridge's team of experts will evaluate your regulatory objectives to define the requirements and provide clear, comprehensive guidance for complying with environmental assessments required by the US Food Drug Administration (FDA) and European Medicines Agency (EMA). As stated above SafeBridge can prepare the submission packages to meet regulatory requirements.

Studying Monitoring

SafeBridge's qualified expert toxicologists, environmental scientists, and registered quality assurance professionals (RQAP-GLP) are available to provide comprehensive study monitoring services for Good Laboratory Practice (GLP)-compliant studies intended for regulatory submission.

Studying monitoring services includes:

- **Project Management:** In cases, where additional environmental data need to be developed for compliance with US FDA, Health Canada or and EU EMA environmental assessments, SafeBridge's dedicated team can provide high quality project management services to assist with the identification and qualification of contract testing laboratories with requisite expertise and experience. SafeBridge project managers will help define and manage the testing program scope, budget, and timeline, as well as provide clear guidance for initiating the program including documentation, procurement, and characterization requirements of the ingredient.
- **Expert Scientific Guidance:** Provide guidance to the client and coordinate and monitor the scientific aspects of studies with the testing facility such as:
  - Oversee study protocol development and finalization to ensure compliance with applicable testing guidelines and scientific objectives;
  - Address pertinent activities and procedures of studies with key laboratory personnel;
  - Answer technical/scientific questions that arise during the course of the studies.
- **Interpretive Review of Study Data:** Conduct timely study monitoring including: identifying any atypical results due to uncontrolled variables and recommend corrective actions; evaluating study findings in order to select definitive study dose levels based on range-finding test results.
- **Scientific and Technical Report Review:** Conduct timely reviews of study reports to ensure clear and concise presentation of experimental design and procedures and demonstrate results accurately reflect the data; 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; ensure that the report and study conduct are compliant with applicable GLPs.

CONTACT OUR TEAM!

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

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