



 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.