Trinity Consultants

SafeBridge® Regulatory & Life Sciences Group

Extractables and Leachables Support

Trinity Consultants' SafeBridge Regulatory and Life Sciences Group, along with our subcontractor, Material Needs Consulting, provides testing, toxicology, and expert consulting support for extractables and leachables (E&L) for biotechnology and pharmaceutical product development.

Testing and Regulatory Submission Support

- E&L Testing Support
  - Conduct an assessment of appropriate testing conditions based on route of administration, product contact surfaces, drug formulation and other factors
  - Qualify laboratories for testing
  - Project management of entire E&L program
  - E&L study protocol review, study management and monitoring
  - Biocompatibility testing protocol review, study management and monitoring
    - USP <87>, <88>, <661>, <381>, and ISO-10993
  - Quality assurance review of E&L testing results and reports
- Material Selection for Devices and Packaging
  - Consult with product development teams to ensure the best selection of plastics and elastomers
  - Recommend stabilizer and additive systems
  - Assist companies in dealing with unexpected changes to the polymer or additives used in marketed products
- Supply Chain Management
  - Qualify vendors of materials and establish specifications
  - Implement quality control programs
  - Change control management
  - Design release testing programs
- Regulatory Consulting
  - Regulatory submission on E&L results for CMC section of submissions
- Training
  - Customized training programs on E&L

Toxicology Support

For each chemical or class of chemicals above the Analytical Evaluation Threshold (AET), SafeBridge will develop a Permitted Daily Exposure (PDE) value. A PDE is a health-based limit and represents a dose (either oral, intravenous (IV), or otherwise specified) that is unlikely to cause an adverse effect if an individual is exposed by that route, at or below this dose every day for a lifetime.

SafeBridge will review the relevant and available information on each compound. Data provided by Client and through an independent literature search of electronic databases will be considered. Pertinent information includes pharmacological activity in laboratory animals and humans, pharmacokinetics, non-clinical (toxicological) studies in laboratory animals, human clinical experience, and adverse reaction reports in humans. The most relevant study or studies on which to base a PDE will be identified. If needed or deemed appropriate, SafeBridge will use in silico or “read across” approaches for assessing the toxicity of these compounds.

SafeBridge will provide a monograph documenting the scientific rationale for these values. The monograph will include a summary of relevant pharmacological and toxicological information and relevant human clinical experience, as well as the PDE calculation.

The PDE for each compound will be compared to the exposure levels from the potential exposure to determine the margin of safety of these leachables in the use of packaging system of the drug product, and a rationale will be provided for inclusion or exclusion of each compound. The summary report will be focused on the health-based risk assessment methodology currently required by regulatory authorities. The rationale for excluding or not of compounds identified in the E&L testing will also be provided.

For more information on how SafeBridge can help you with extractables and leachables support, contact us today at info@safebridge.com.