PHARMACEUTICAL TOXICOLOGY

Pharmaceutical and Biotech Product Safety Toxicology Support

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 PhD and board-certified or equivalent toxicologists who provide technical services required to meet product safety needs of the pharmaceutical and biotechnology industries for liability prevention purposes and to meet FDA, EMA and other regulatory compliance requirements. Services provided include the following:

1. **Permitted Daily Exposure (PDE) for Cleaning Limits/ Cross-Contamination Protection –** SafeBridge toxicologists set permitted or acceptable daily exposure (PDE/ADE) values for active pharmaceutical ingredients (APIs) as a means for setting quantitative cleaning limits for cleaning validation programs. In these cases, limits are developed to measure surface or rinsate levels in order to prevent potential cross-contamination in a multi-purpose plant operation. SafeBridge employs either the guidance of the International Society of Pharmaceutical Engineering (ISPE) under Risk-MaPP, the EMA guidance on cross-contamination and ICH quality guidelines.
2. **Leachables and Extractables Toxicology Risk Assessments –** The rubber and plastic components used in medical products and devices have received increased scrutiny for potential leachables and extractables that may come into contact with drug products. SafeBridge toxicologists set PDE values for these materials as a means for setting quantitative analytical targets for detecting potential leachables and extractables in drug products. SafeBridge has assisted companies seeking to evaluate product safety for Orally Inhaled Nasal Drug Products (OINDP), medical devices, injectable/parenteral products and other routes of administration by developing robust and scientifically defensible risk assessments consistent with regulatory guidance.
3. **Genotoxic Impurity Toxicological Risk Assessments –** SafeBridge can assist in the toxicological assessment of potential genotoxic impurities that may appear in the active pharmaceutical ingredient (API) or drug product. Scientifically-supportable risk assessment methodologies and the ICH M7 guidance on genotoxic impurities are employed. These assessments have included assessing chemical synthetic processes, as well as potential degradants from stability testing. These evaluations have included use of in silico predictive software for determining genotoxic potential as well as recommending, coordinating and interpreting genetic toxicology testing.
4. **Impurity, Contaminant and Degradation Toxicological Evaluation –** As with potential genotoxic impurities, product quality may be affected by an impurity, contaminant or degradant that may appear in the active pharmaceutical ingredient (API) or drug product. Scientifically-supportable risk assessment methodologies and development of PDEs are employed to protect patients that may take the drug product.
5. **Nitrosamines –** SafeBridge can qualitatively assess synthetic processes, APIs and drug products for the formation of nitrosamines and produce assessments to meet regulatory guidelines.

The SafeBridge "advantage" is that these services are not produced "in a vacuum." All expert reports are peer-reviewed by another toxicologist. They are integrated and receive support as needed from other experts (e.g., analytical, plastic chemistry and other chemists) to provide practical and comprehensive solutions for our clients.

CONTACT OUR TEAM!

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

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