Antimicrobial and Specialty Chemical Regulatory 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 toxicologists and registered quality assurance professionals (RQAP-GLP) to assists clients with the regulatory approvals of antimicrobial ingredients, biocides, disinfectants, and specialty chemicals by providing expert guidance and project management throughout all phases of the process of registration in the US, Canada, and Europe. Our extensive experience and highly organized program management enables us to shorten the timeframe typically associated with regulatory approvals, often compressing time to market. Of critical importance, we have a track record of constructive interface with regulatory agency contacts in the U.S., Canada, and Europe, and other countries on scientific and technical issues that benefit our clients. We are especially effective building novel and successful strategies to ensure that our clients are in the strongest regulatory and safety positions possible. In many cases, our guidance and/or interaction with regulatory agencies has resulted in the most effective use of resources for ingredient approval or product registration.

Our team's extensive expertise in toxicology and safety assessment is invaluable in addressing regulatory interactions and the issues needed for ingredient approvals, providing services that include:

Regulatory Scoping and Strategy

SafeBridge performs data gap analysis for state, US and international regulatory frameworks, interfaces with regulatory agencies on behalf of clients, and designs data development strategies to meet clients' specific regulatory objectives.

Data Development/Testing Program Management

SafeBridge oversees the design, implementation and management of efficacy, toxicology, product chemistry, and environmental testing programs conducted according to Good Laboratory Practice (GLP) standards, provides quality assurance oversight of GLP testing programs including test guideline compliance, study audits, and scientific/technical reviews of study reports, and prepares waiving and bridging justifications for data requirements.



Regulatory Submission Support

SafeBridge prepares Robust Study Summaries for regulatory submission, prepares technical dossiers for active ingredient and product registrations (state, federal and international), and interfaces with regulatory authorities pre- andpost- submission, including client representation at technical meetings.

Scientific and Regulatory Affairs

SafeBridge scientists provide understanding of safety and regulatory risks associated with finished products, ingredients, or product constituents of interest and direct engagement with regulatory authorities.

CONTACT OUR TEAM!

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

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