

TOXICOLOGY STUDY MANAGEMENT

Scientific & Regulatory Consulting

Toxicology studies are often an essential regulatory requirement for new food ingredients. Our highly experienced Registered Toxicologists can represent you as an independent study monitor and provide a full toxicology study management service, which includes selection of CROs, study design assistance and protocol review, overseeing testing phases, and critical review and interpretation of data, to ensure that your studies are designed appropriately and your reports are presented in the best possible manner.



Toxicology Studies

Toxicology studies can be a major financial investment for businesses, so it is vital that these studies are well-designed and well-executed to achieve success. Our expertise will help ensure that the correct studies are conducted in the correct way.

At Intertek we have several Registered Toxicologists with a wealth of experience in managing toxicology studies specifically conducted with food ingredients. We have also established good working relationships with renowned CROs over many years, and we draw upon those contacts to understand the most efficient way to conduct the required toxicology studies.

Risks and Challenges

Good management of toxicology studies can be time- and resource-consuming, requiring experience and attention to detail. We can take this resource burden from you and give you the peace of mind that your studies will be designed and reported appropriately for your needs.

Study Design and Protocol Review:

International testing guidelines are available for many toxicology studies; however, these guidelines are not "one size fits all." They can be open to interpretation and include many optional or case-specific endpoints. Expert scientific judgment is essential to ensure the studies are designed and conducted appropriately for your specific regulatory needs. In some instances, investigative studies, for which testing guidelines are not available, may be required. With our expertise across a broad range of toxicology subdisciplines, we can provide the necessary guidance to ensure that these studies are properly designed and executed.

Dose Selection:

In the case of repeated dose studies, appropriate dose selection is especially important. These doses are often used to define the daily amounts of the ingredient you will be authorized to use. Finding a dose high enough for a sufficient margin of safety, but not so high as to cause excessive toxicity, requires a fine balance, and is difficult to achieve without relevant knowledge and experience. Our experts are well-accustomed to dealing with this issue.

Overseeing Testing Phases:

Monitoring a study throughout the testing phase is crucial to ensure the study is being conducted correctly and according to protocol. This is particularly important for larger and more complex studies, which have lots of moving parts and high costs. Our understanding of the experimental procedures involved is extremely beneficial when monitoring a study, to help ensure its scientific quality and integrity is maintained throughout.

Data Interpretation and Reporting:

The final report is the one output from the study that the regulatory agency assesses; therefore, experience with toxicology studies conducted on food ingredients is important for interpretation of findings and completion of the report. Although CROs do have study experience, this experience is often from a pharmaceutical or chemical background, both of which have subtle but essential differences in how to conduct studies and interpret data. Our specialization in toxicology studies specifically conducted on food ingredients is critical for ensuring your study is reported in the appropriate way.

Regional Toxicological Requirements

Our experts are well-versed in navigating the various complex tiered approaches to toxicology testing across all major jurisdictions, including the European Union and the United Kingdom, the United States, and China. We will help you ensure you only conduct the studies that are needed for your jurisdiction(s) of choice, and, in cases when multiple studies may be required, that they are designed to minimize cost, and time, without jeopardizing the overall outcome of the program.

The Intertek Advantage

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Total Quality. Assured.

FOR MORE INFORMATION

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