

TOXICOLOGICAL RISK & SAFETY ASSESSMENTS

Intertek Assuris can help you to assess potential risks associated with the presence of a given substance in your product, providing scientific rationales to identify areas of concern or justify the establishment of specification limits.



Manufacturers use a variety of measures to ensure that their products meet necessary quality levels; these measures include ensuring that each produced batch or lot meets established release specifications and ensuring that known or suspected hazardous substances are not present at levels of concern in the products. However, the potential toxicity of these known or suspected hazardous substances (residual solvents, process impurities, leachables and/or extractables, contaminants, degradants, and excipients) and the acceptability of their specification levels may not be certain. Toxicological risk assessments can be conducted either proactively or reactively in order to address the risks associated with exposure to these substances.

Your Challenge

The production of high quality products such as drugs, biologics, or medical devices is a process involving constant checks and controls. The sources for unwanted/unknown substances in such products can be myriad, and an understanding of the impact of the presence of such materials as process or product impurities, extractable/leachable compounds, and residual solvents is paramount to the establishment of acceptable levels (e.g., specification limits, needs for product recalls, etc.). But how do you know whether certain compounds or substances might represent a safety concern? How can the acceptability of the presence of specific levels of potentially dangerous compounds be established? What happens when a specification limit needs to be changed (e.g., during scaleup)? What happens when a contaminant is found? Identification of known or suspected hazardous substances requires an assessment of the risks associated with exposure to these substances. Proactive risk assessments can establish specification

limits to identify a level of a substance in the finished product or the active ingredient that is considered suitable given the product's intended use. Reactive risk assessments can generate a safety profile of a previously un-addressed, potentially hazardous substance in order to provide an evaluation of the risks associated with exposure to this substance.

Our Solutions

Intertek Assuris works with clients to understand the nature of the potential concern, whether it be due to leachables from a medical device, the presence of a suspected genotoxic impurity in an oral capsule in production, degradants of the active ingredient in a drug product, or a contaminant in a batch of product. Our scientists then conduct literaturebased evaluations of the toxicological potentials of known or suspected hazardous substances with considerations being given to the following factors:

- Toxicological endpoints
- Pharmacokinetic and/or physicochemical data
- Route of exposure
- Exposure scenario for the intended patient population

The acquired information is used to generate a scientifically defensible approach, whether proactive or reactive, that addresses the risks of exposure to potentially hazardous substances and that can help establish specification limits, resolve contamination issues, and improve product quality.

The Intertek Advantage

Our team of experts have been providing clients with study protocol development and placement of non-clinical toxicology and related testing programs for decades. We have extensive and hands-on experience

monitoring safety and efficacy studies. We work closely with clients to design and monitor studies and to audit testing facilities to ensure protocol consistency and compliance with Good Laboratory Practice (GLP).

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.

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