FAQs
risk assessment programs

Why are risk assessments needed?
ISO 10993-1 requires a biological evaluation to be performed with consideration of physical, biological and chemical properties of a medical device. A risk assessment can be a key component of this evaluation to determine the appropriate biological testing strategy and to support the biological safety of a medical device. Risk assessments may be performed at different stages of the product lifecycle and for differing reasons, such as evaluating a vendor or material change or to determine equivalence to an existing device.

Who should write risk assessments?
According to ISO 10993-17: " These allowable limits are intended to be derived, using this part of ISO 10993, by toxicologists or other knowledgeable and experienced individuals, capable of making informed decisions based upon scientific data and a knowledge of medical devices."

Can risk assessment be done as a replacement for biological testing?
In general, a risk assessment is not a replacement for biological testing, though in some cases a risk assessment could be used to demonstrate toxicological equivalence of a device to a predicate device or to a post-process or material change. Further, with minor changes such as switching to a different vendor, simple chemical evaluations may be performed to limit biological testing, in addition to an assessment of the similarities of the data. In other cases, a risk assessment can be used in addition to biological test data to address carcinogenicity. Risk assessments should be used to frame the choices of the biological test program, to ensure that all of the critical endpoints for a safety assessment are evaluated.

How long does a risk assessment take?
The duration of a risk assessment will vary with the complexity of the device and the materials used in its construction, including additives and colorants, and the total number of extractable/leachable chemicals that are evaluated. Additional factors such as processing aids and machining lubricants must be considered in the overall evaluation as well. The more factors to be researched and addressed, the longer the risk assessment process will take. Furthermore, uncommon chemicals will take longer to research than those that are routinely found in medical device materials.

Why does it take so long to get my report?
WuXi AppTec has a rigorous review process as is required by ISO 10993-17. First, the toxicologists must thoroughly research all of the materials involved in the product. Then, they must write a cohesive and understandable assessment of their findings. Some of these finding may require consultation with you to clarify intended use and application of the product. Last, each report draft is reviewed by a second person to ensure that it meets our standards before the final report is issued.

Are there specific cutoffs for safe levels of chemicals?
At this point, there is no single cut-off value for every chemical to be determined as safe. The level of contact, extent of exposure, and duration of exposure are all factors that dramatically impact the toxicological profile of chemicals. Each of these factors must be considered for the device under review. Concepts like the Threshold of Toxicological Concern (TTC) and Tolerable Intake (TI) can be helpful in setting limits but must be evaluated separately in each case.

Is there a central source for medical device toxicology data?
Because medical devices incorporate so many different types of materials, and there is a wide range regarding the nature and duration of biological contact, there is no single source of toxicology data. Often materials data is kept confidential, or if publicly available, may not include all of the information needed to make complete assessments. This is one of the reasons why materials characterization and biological testing is often necessary.

Can you do a risk assessment based on other laboratories' data?
It is possible to review data from other laboratories to perform a risk assessment. However, to ensure complete understanding of the work, WuXi AppTec toxicologists must have access to the raw data, not simply summary reports. In some cases, information may not be complete enough or analytical methods may not have been robust enough for our toxicologists to render an opinion. Prior to starting a project, we can make a brief, initial review to determine if we can proceed with the risk assessment.

What is the process to get a risk assessment done?
Because each product is unique, the risk assessment process is started with an initial consultation with WuXi AppTec experts to understand the product and your project goals. Then, our toxicologists review the available data and formulate a plan for deeper research of technical journals and toxicology databases. A draft report is produced that discusses the available data (including what can be found in publicly available data sources) and renders an opinion as to the potential for patient risk. This draft is provided to the client for a preliminary review to ensure that the overall project goals have been met. Once the draft has been accepted, a final report is provided.

What is the deliverable from a risk assessment?
For most risk assessments, we will deliver to you a complete, descriptive report that explains all of the factors known about the device, the research approach, the data found on the chemical entities of interest, and an overall assessment of the device. For evaluation of extractable/leachable chemicals, the margins of safety for each chemical will be used to assess the overall health risk to the patient should the chemical be released during clinical use.

WuXi AppTec has many years of experience and unmatched expertise regarding risk assessment. Our toxicologists are highly familiar with ISO 10993-17 requirements and will perform an initial consultation, conduct thorough research and deliver a final report ready for regulatory submission.

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WuXi AppTec

To learn more about our risk assessment programs, contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com