biological evaluations

WuXi AppTec provides a full program of biological evaluation solutions – led by a highly experienced team of scientists – to help ensure you meet critical regulatory requirements for evaluating the safety and efficacy of your product.

Strong biological evaluations have *7* core characteristics:

- Materials characterization performed on final product.
- Biological test selection driven by chemical characterization.
- Test plans and final analysis directed by bio-availability.
- Biological testing performed in compliance with GLPs.
- Cohesive report package including all necessary data.
- Impact of changes to materials, processes or product configuration considered.
- Comprehensive evaluation made from all available and applicable sources.

Services scaled to fit your needs.

Our program offers you the flexibility of selecting individual services or opting for a cohesive program of linked services that results in a complete package for your agency submissions.

Consultation Services
Leveraging the strength of our team to answer your regulatory questions

Gap Analysis Report
Systematic evaluation of gaps in your testing program files/records

Biological Evaluation Test Strategy
Detailed plan and rationale for your testing program

Summary of chemistry and/or biocompatibility data
Executive summary report outlining available data

Toxicological Risk Assessment (Initial)
Following materials characterization, a report based on literature reviews and preliminary product information

Residual Chemical Analysis
Evaluation of residual chemical in a finished product including analysis of tolerable intake levels.

Toxicological Risk Assessment
Thorough evaluation assessing the toxicological potential of the product based on chemistry data

Biological Evaluation Report
Overall assessment of all materials characterization, toxicology and biocompatibility data – written by a toxicologist

Talk to us and find out how our biological evaluation program can work for you.

Contact a WuXi AppTec Account Manager at 651-675-2000 or email: info@wuxiapptec.com

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WuXi AppTec
Expert Solutions for Product Development

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regulatory considerations for biological evaluations

Regulatory complexity and a tightening market have made getting medical devices and combination products to market increasingly difficult. Not only have there been changes in the official guidances, but also a *philosophical* change when it comes to biological evaluations. Designing your product's testing program as a cohesive package is important – the ISO documents are supporting this approach.

With over 20 years of experience in testing a wide variety products, and with so many of our experts serving on the regulatory standards committees / working groups, WuXi AppTec has critical insight regarding these issues and trends. Count on us to provide knowledgeable expertise that will help you meet regulatory expectations – working with you from program design to final risk assessment or any step along the way.

Excerpts from:

ANSI/AAMI/ISO 10993-1:2009

Biological evaluation of medical devices –
Part 1: Evaluation and testing within a risk management process

From Section 4:
General principles applying to biological evaluation of medical devices

4.1 The biological evaluation of any material or medical device intended for use in humans shall form part of a structured biological evaluation program within a risk management process… The biological evaluation shall be planned, carried out, and documented by knowledgeable and experienced professionals.

4.4 The choice of tests and the data required in a biological evaluation, and their interpretation, shall take into account the chemical composition of the materials, including the conditions of exposure as well as the nature, degree, frequency and duration of exposure of the medical device…

From Section 7:
Interpretation of biological evaluation data and overall biological safety assessment

Expert assessors who have the necessary knowledge and experience shall determine and document:

a) the strategy and program content for the biological evaluation of the medical device;

b) the criteria for determining the acceptability of the material for the intended purpose, in line with the risk management plan;

c) the adequacy of the material characterization;

d) the rationale for selection and/or waiving of tests;

e) the interpretation of existing data and results of testing;

f) the need for any additional data to complete the biological evaluation;

g) overall biological safety conclusions for the medical device.

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