

Toxicology Implant Studies for Medical Devices – ISO 10993

WuXi AppTec offers custom toxicology implant studies designed to meet the combined requirements of ISO 10993 – Part 6 and Part 11 that focus on the evaluation of implantable materials and coatings. Candidate test articles include devices such as bioresorbable/biodegradable implants as well as combination products.

These studies can provide critical information demonstrating the length of time for implant resorption, the remodeling characteristics, and the toxicologically important intermediates of bioresorbable/biodegradable implants.

For combination products, toxicology implant studies help provide a determination of both local tissue reaction and systemic reaction – key information for a regulatory submission. This data can be used in a toxicological safety evaluation, a GAP analysis for an existing product, or a GAP analysis for an existing product being submitted to a new regulatory agency.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

Primary Benefits

As combination products and medical device designs advance, alternate testing strategies leveraging implant toxicology – such as models developed by WuXi AppTec – are increasingly recognized for providing benefits not offered by traditional extract studies.

Avoidance of Destructive Extracts

The toxicology implant testing models evaluate results collected from device implantation rather than submitting test samples to exaggerated heat and potentially destructive solvents in the attempt to create a representative extract. This process can introduce artifacts that would not normally occur in the clinical situation.

Clinically Relevant Results

Directly implanting the material/device facilitates observation of the physical interface of the material with the tissue, which is recognized as producing the closest clinically relevant results from a preclinical model.

Consolidated Testing

The toxicology implant model can replace at least three 10993 tests (for example, two extract studies + one implant study). Consolidated testing offers better utilization of animals, facilitates result interpretation, and can streamline test panel planning and timelines.

Study Options

Given the specialized nature of toxicology implant studies, each study is unique. From the available options – such as the examples shown below – studies for particular test articles are designed to provide the most clinically relevant results.

Animal Model: Rat, rabbit, dog, pig

Sex: male, female

Duration: 1 week to multi-year

Implant Sites: Subcutaneous, intramuscular or relevant clinical site (*Ex:* intraperitoneal, bone, spine, calvaria)

Common Endpoints: Histopathology, Clinical Chemistry, Coagulation, Hemocompatibility

Study Considerations

When designing the appropriate toxicology implant study for your specific needs, we take into consideration many factors to match clinical applications as closely as possible. Considerations include:

- What are the current applications of the constituent components?
- How will the combination product's application differ from the consistent parts' original intended use?
- What is the new product's route of administration?
- How long will the product be implanted in the patient?
- What are the issues regarding sample preparation and delivery to the test system?

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