

# Toxicology Implant Studies



**HOW TO**

**Keep up with changing standards  
and stay ahead of the game.**



** WuXi AppTec**

**The Leader in Combination Product Services**

# Toxicology + Implant (TI) Studies

## TI EXPERIENCE

WuXi AppTec has many years of experience performing both toxicology and implant studies. For combination products/leachables, in particular, performing the toxicology and implant testing within one study is faster, more robust and more cost effective. Plus the combined study meets ISO 10993 Part 6 *and* Part 11, providing valid data for submission to the FDA and other regulatory agencies.

- Approaching 50 completed TI studies.
- More than two dozen different companies have contracted with WuXi AppTec for these studies.
- Multiple products have already received regulatory approval.

## PROGRAM FEATURES

- Testing is custom designed with the sponsor for each test article.
- Program results meet all ISO/FDA requirements and have been internationally accepted.
- Senior staff have extensive experience in the area of medical device tissue responses and toxicology.
- In-house resources include board-certified pathologist and toxicologist dedicated to the program.
- Regulatory and consulting services available to support sponsors.



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Contact WuXi AppTec for your next Toxicology + Implant study:

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