

In-Life Services: Custom Medical Device & Materials Testing

Frequently medical devices require testing beyond the standard ISO/FDA 10993 testing methods. These tests may be performed to better understand material performance, device performance and design, implant methodologies and implant training. Analysis may be performed on devices at all stages of development, however for materials biocompatibility, material performance and implant technique development, it is strongly recommended that tests should be conducted with final sterilized product or representative samples according to objectives of the testing.

WuXi AppTec is capable of supporting GLP, Non-GLP and R&D device and material testing. Because of the diversity of medical device design and usage, WuXi AppTec recognizes that each device and situation be evaluated with the customer and a systematic approach be developed that meets all requirements for successful project completion. This analysis may include:

- Model Identification
- Model Evaluation or Development
- Study Scheduling
- Regulatory Consultation
- Device Performance and Evaluation
- Histopathology

Complete toxicology and biocompatibility/safety testing services are also available.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biologics 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.

**WX
LISTED
NYSE**

WuXi AppTec Capabilities

Acute Implantation

- Small and Large Animal Implants
 - Subcutaneous
 - Intramuscular
 - Intraperitoneal
 - Thoracic and Abdominal
 - Vascular

Chronic Implantation

- Small and Large Animal Implants
 - Subcutaneous
 - Intramuscular
 - Intraperitoneal
 - Thoracic and Abdominal
 - Vascular

Variety of Animal Models

- | | |
|------------|-------|
| Mice | Dog |
| Rat | Pig |
| Guinea Pig | Goat |
| Rabbit | Sheep |

Custom Research Protocols

- Protocol Research
- Protocol Development
- Protocol Review & IACUC Approval
- GLP, Non-GLP and R&D Studies

Study Conduction

- Optimum Animal Model / Test Selections
- Scheduling
- Study Direction
- Protocol and Regulatory Compliance
- Data Collection, Analysis & Archiving

WuXi AppTec Services

- Surgical Expertise
- Necropsy and Tissue Collection
- Pharmacokinetic Analysis
- Animal Care and Veterinary Services
- Histopathology / Immunochemistry
- Clinical Pathology
 - Chemistry – 18 Test Parameters
 - Hematology – 14 Test Parameters

WuXi AppTec Expertise

- Device/Drug Combinations
- Device/Tissue Combinations
- Device Implants
- Single-Use Device Evaluations
- Hemostasis / Wound Healing
- Orthopedic Devices
 - Bone Defect Studies
 - Bone Stabilization Implants
 - Induction Studies
- Cardiology Devices
 - Catheters and Coronary Stents
 - Atherectomy Devices
 - Pacing and Defibrillation Leads
 - Chronic Sensors
 - Fabrics and Vascular Grafts
- Research Devices and Materials
 - Monoclonal Antibodies
 - Drug Metabolism
 - Allograft, Autograft & Xenograft Implantation
 - Thrombogenicity
 - Neuro Stimulation and Device Placement
 - Bacterial Challenge of a Device Implant

**For more information on
WuXi AppTec's services
please contact:**

U.S.
+1 (651) 675-2000 • +1 (888) 794-0077
info@wuxiapptec.com

WE ARE DETERMINED TO SERVE YOU BETTER®

www.wuxiapptec.com