Safety Evaluations for Infusion Pumps

Prove the safety of your device with expert testing and risk assessments.
safety evaluations: the process

Risk Evaluation

Testing

Risk Assessment

Scalable Programs • Proven Performance

**TRAINING**
Team training and cross-training to maximize flexibility and meet project timing.

**OPERATIONS**
Performance metrics to ensure best practices and consistency.

**CAPACITY**
Proactive planning to achieve program goals.
safety evaluations: our testing programs

WuXi AppTec offers biological safety testing programs designed specifically to provide proof of safety for your infusion pump.

**infection control**
- Disinfection Validation
- Cleaning/Re-Processing Validation
- Antimicrobial Efficacy
- Biofilm Potential

**sterilization management**
- Sterilization Validation
- Dose Audit/Lot Release

**materials characterization**
- Residual Cleaning Study
- Influence on Drug Stability
- Extractables
- Leachables (overall and specific drug product)

**toxicity**
- Biocompatibility (in vitro and in vivo)
- Genotoxicity
- Risk Assessment
safety evaluations for infusion pumps

**PROGRAM FEATURES**

- ISO 17025 accreditation
- Experienced staff
- Service on ISO Technical Advisory Groups
- In-house surgeons and veterinarians
- On-site histopathology
- On-site clinical pathology, including hematology, clinical chemistry, urine analysis & coagulation
- Specialized programs in sterilization and reprocessing validations, including dose reminder programs and submission-ready validation report manuals
- Comprehensive services, with testing to meet regulatory expectations worldwide
- Expert guidance in designing product-specific testing plans for successful submissions

**PRODUCT EXPERIENCE**

With 25 years of experience, WuXi AppTec is a recognized leader in safety testing for a variety of devices/combination products, including:

- Device & Drug / Biologic / Tissue Combinations
- Permanent Implants
- Single-Use and Reusable Devices
- Hemostasis / Wound Healing
- Orthopedic Devices
- Cardiovascular Devices
- Laparoscopic / Endoscopic Devices
- Neurostimulation Devices
- Surgical Devices
- Dental Devices