

Microbiology & Package Testing



HOW TO

**Navigate your product from
development to delivery**

 WuXi AppTec

The Leader in Combination Product Services

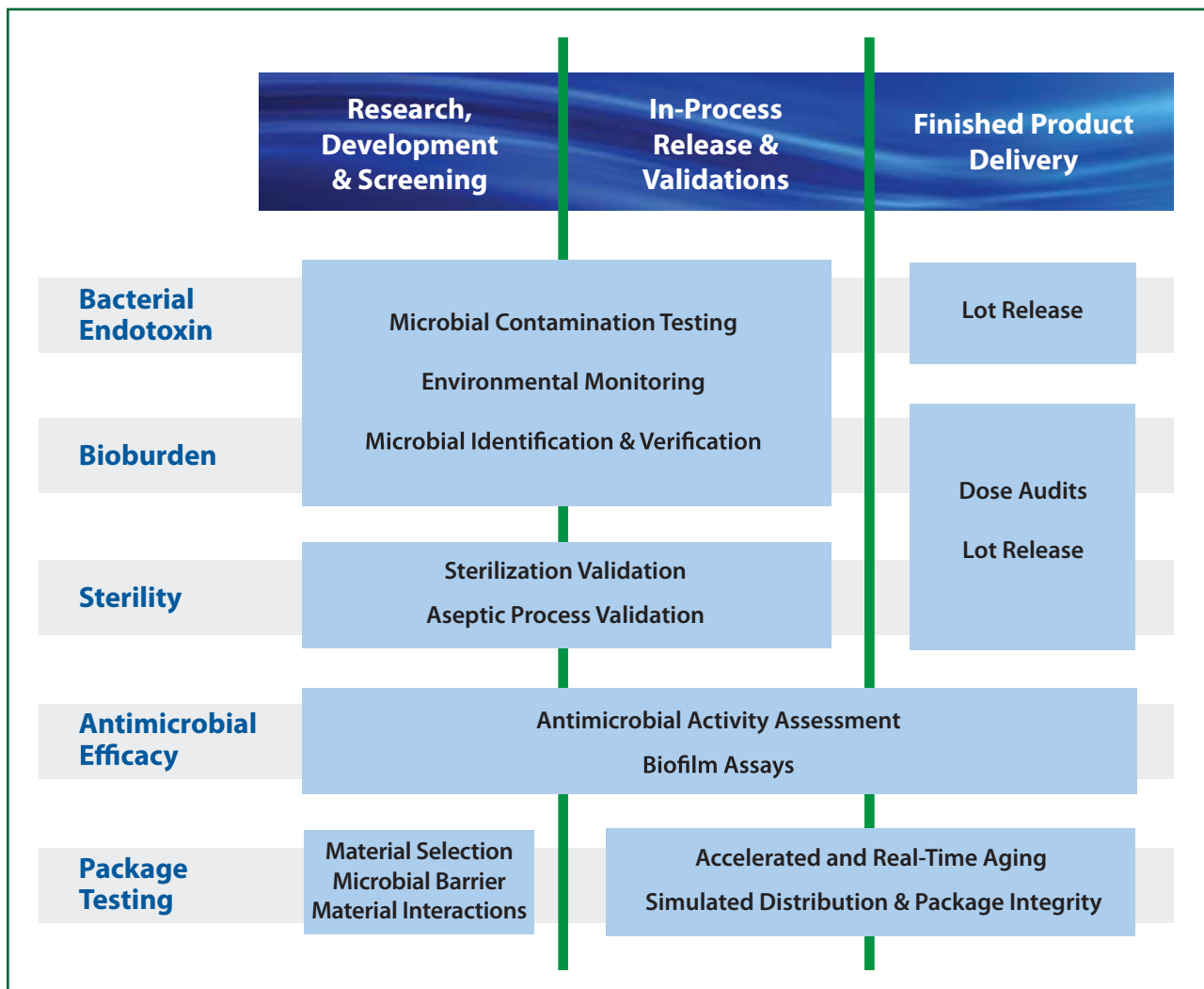


Microbiology & Package Testing

Expert guidance and comprehensive testing services – from development to delivery of your product

At WuXi AppTec, we know the challenges you face in complying with the wide range of evolving testing standards related to your devices/combination products. Well-developed test plans and coordinated implementation are essential for addressing these challenges.

With unparalleled expertise and experience, WuXi AppTec can guide you in the development of your critical testing programs and provide you with a comprehensive menu of testing to ensure requirements are met as you navigate your product from development to delivery.





Testing Services & Their Applications

Bioburden

Materials Acceptance
Process Evaluation
Sterilization Validation
Change Control
Environmental Monitoring

Sterility

Component Screening
Lot Release
Sterilization Validation
Aseptic Process Validation

Endotoxin

Materials Screening
Lot Release
Process Validation

Package Testing

Accelerated Aging
Package / Seal Integrity
Simulated Distribution
Shelf Life / Stability Determination

Chemistry

EO Residuals / Process Residuals
Physicochemistry
Materials Characterization

Microbial Assays

Antimicrobial Effectiveness
Cleaning / Disinfection / Sterilization Efficacy
Biofilm Evaluation

Representative Sample Case Study

Aseptically packaged kit of devices with biologic component (orthobio putty kit)

While every product offers a unique set of challenges, the following "case study" demonstrates how WuXi AppTec has developed and performed successful testing programs in support of regulatory submissions.

D = Device Component(s) B = Biologic Component(s) F = Final Product

Development/Screening Phase

- D:* • Bioburden on spatula, mixing container and syringe (includes Microbial IDs)
 - Sterility screening of purchased saline solution
- B:* • USP Microbial Enumeration of putty raw material
 - USP Test for Specified Microorganisms of putty raw material
 - Bacterial Endotoxin screening for putty raw material

In-Process Phase

- D:* • Radiation sterilization validation of spatula, mixing container, and syringe
 - Validation of aseptic fill of saline in syringe
- B:* • Validation of disinfection step for putty processing (bacterial/viral clearance)
- F:* • Validation of aseptic assembly of all components into kit
 - Package validation on final tray configuration (post sterilization)
 - Accelerated aging package validation on tray configuration

Finished Product Phase

- D:* • Quarterly radiation sterilization dose audits of device components
- F:* • 21 CFR 610.12 / USP Sterility test for batch release of kit
 - Bacterial Endotoxins test for batch release of kit
 - Real time aging study on final packaged tray



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EXPERTISE

► Products

Medical Devices
Combination Products
Tissues
Biopharmaceuticals
Pharmaceuticals

► Registrations / Certifications

ISO 17025
FDA
ISTA

► Industry Leadership

Leaders and members of industry committees
AAMI Sterilization Standards
IEST Contamination Control
ASTM Microbiology and Packaging
AATB Scientific & Technical Affairs

Expert members on international committees
ISO Microbiological Methods
ISO Radiation Sterilization
ISO Washer-Disinfector
ISO Liquid Chemical Sterilization

Recognized industry experts in sterilization validation

TESTING FEATURES

► Comprehensive services

► Specialized programs

Sterilization Validation
Reusable Device Cleaning / Resterilization Validation
Simulation Distribution Shipping Validation
Environmental Monitoring Validation
Package Integrity / Aging Validation

► Customized studies

A dedicated laboratory performs antimicrobial/efficacy custom studies for:

- drug or biological substances
- medical devices
- preservatives
- textiles
- tissue (human and animal)
- variety of bacteria, yeast and filamentous fungi

► Experienced staff

► Technical experts

► Protocols on file

► Programs to meet regulations worldwide

► Online ordering

► Rapid reporting



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Contact us to learn more about navigating your product from development to delivery:
(1) 651-675-2000 / 888-794-0077 • www.wuxiapptec.com • www.comboproducts.com