

services for processed tissue and tissue-based products

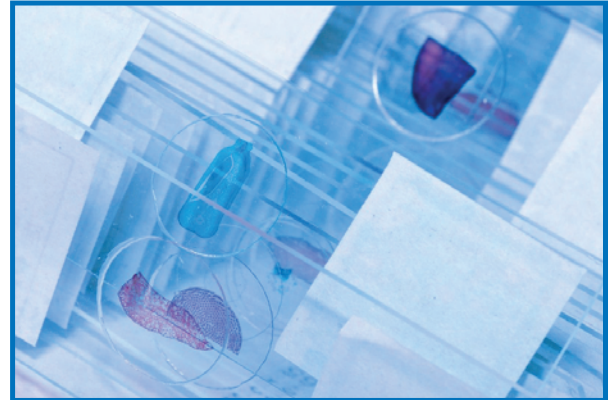


Comprehensive
services to
support the
success of
tissue products

specialized services with unequaled expertise

WuXi AppTec offers the industry's most comprehensive program of services for processed tissue and tissue-based products — built on our unequalled experience and expertise.

Our facilities are FDA registered, with additional qualifications that include FDA registration for HCT/Ps, ISO certification, and accreditation by AAALAC and the American Association of Tissue Banks (AATB).



testing

DBM Lot Release Assays (cGMP)

Osteoinductivity (in vitro)

In-vitro assays can be used to estimate the potential osteo-inductivity of demineralized bone matrix (DBM) as a screening tool for raw materials and final product or as an alternative to animal testing. Two platforms are available: the alkaline phosphatase assay and the BMP (bone morphogenic protein, -2, -4 or -7) ELISA assays.

Osteoinductivity (in vivo)

In-vivo assays in nude mice or rats are used to definitively prove the ability of a DBM product to induce ectopic bone formation. The study is performed by intra- or inter-muscular implantation of product followed by histopathology.

Endotoxin (LAL)

The kinetic chromogenic LAL method provides direct quantification of detected endotoxin levels to determine existing level of endotoxin on the product or endotoxin reduction of a production process.

Quality Testing

WuXi AppTec has a wide range of expertise in all areas of quality testing used for processed tissue and tissue-based products. Test offerings include:

- Bioburden
- Endotoxin (LAL)
- Sterility
- Residual Moisture
- Environmental Monitoring
- Water Quality
- Package Testing
- Accelerated Aging

Custom Assays

Validation of Sterilization Procedures

Validation of Decontamination Procedures

Process Change Validations

Other Custom Services

Additional customized studies that complement a tissue testing program, including biocompatibility testing and cell-based potency assays.



aseptic processing

cGMP CONTRACT SERVICES FOR DEVICE,
COMBINATION AND TISSUE PRODUCTS

WuXi AppTec offers unique cGMP processing services for device, combination, and tissue products that require processing in a controlled environment. Our exceptional expertise, combined with our advanced facility and highly trained staff, ensures that we can provide comprehensive capabilities – from proof of concept to scale-up for product release.

Capabilities

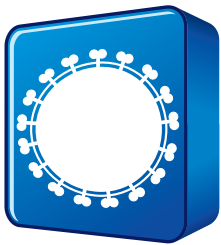
- Aseptic processing
- Assembly and final packaging
- Method optimization
- Commercial-scale production
- Feasibility / Pilot projects

Program Features

- Exacting technology transfer
- Complete, documented process control
- Highly trained, experienced staff
- Reliable, consistent on-time delivery
- Established quality systems / quality controls
- QA inspection and release

The WuXi AppTec Facility

Processing is conducted in ISO Class 7 (Class 10,000) laboratories operating under strict GMP compliance in positive-pressure suites. Laboratories are HEPA filtered, continuously monitored and alarmed. Validated systems and procedures ensure the highest product quality.



viral clearance studies

Processes Experience

Our experience spans a broad range of different processes, including:

For nearly 25 years, WuXi AppTec has provided proven performance at all levels of viral clearance studies. Our extensive expertise, unparalleled suite capacity, comprehensive database mining and collection of ultra-pure, high-titer virus stocks make us the clear industry leader.

INACTIVATION

- Heat / Pasteurization
- Low and high pH
- Solvent / Detergent
- Irradiation
- Sterilization
- High-energy light
- Alcohols
- Disinfectants
- Liquid chemical sterilization
- Gas / Plasma / CO₂ processes

CLEANING

- Kinetics of inactivation
- Coupon studies



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PROGRAM FEATURES

Full range of services – from testing to processing
– to meet regulatory expectations worldwide.

Experienced staff

Expert guidance in designing product-specific
testing plans for successful submissions.

State-of –the-art facilities

FDA registered

ISO certified

FDA HCT/P registered

AAALAC accredited

American Association of Tissue Banks (AATB)
accredited.

PROVEN EXPERTISE

Over 25 years experience with tissue and tissue-
based product testing.

Over 10 years providing aseptic processing
services.

Experience developing successful programs for
human and animal tissue, including: bone, skin,
ligaments, collagen and heart valves.



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