

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.

Testing Services Also Available

With many years of experience in testing medical devices and biologicals, WuXi AppTec is able to offer clients the additional convenience of comprehensive testing services for their products, including anti-microbial efficacy studies, biocompatibility studies, materials characterization, microbiological testing, viral/bacterial inactivation validation, environmental monitoring, and package testing. A full menu of toxicology, custom implant, and histopathology services is also available.

Consultation

WuXi AppTec scientists are experts in conducting aseptic processing programs, as well as assisting in the development of client-specific testing programs to meet particular needs.

Qualifications

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

Talk to us and find out how our aseptic processing services can work for you.

Contact a WuXi AppTec Account Manager at
651-675-2000 or email: info@wuxiapptec.com



Expert Solutions for Product Development