



# Aseptic Processing

## cGMP CONTRACT SERVICES FOR DEVICE, COMBINATION AND TISSUE PRODUCTS

*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**

### Testing Services Also Available

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

### The 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.*

### Consultation

*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

*All AppTec facilities are FDA registered. Additional qualifications include ISO certification, AAALAC accreditation, FDA registration for HCT/Ps and medical devices, and AATB accreditation.*

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