

Testing Services for Controlled Environments



AppTec provides manufacturers with testing services designed to help validate, monitor, and ensure the integrity of GMP/controlled environments – from laboratory counters to cleanrooms to entire manufacturing facilities. With our many years of microbiological testing for medical product industries, plus our experience in operating our own in-house manufacturing facilities, we have the expertise to advise you in designing a custom testing program to fit your particular needs.

AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

Environmental Monitoring

An environmental monitoring program can be used to assess the microbial levels of critical areas and evaluate the effectiveness of various manufacturing controls, including cleanliness, HEPA filtration, disinfection, gowning, and aseptic handling procedures. Monitoring of products used during manufacturing, such as water, cleaning solutions and gases, can also be helpful in demonstrating and maintaining environmental control.

The experts at AppTec can help you design and implement such a program. A variety of service options are offered:

Testing Services

You follow your own protocol or test plan for selection of sites and collection of the samples, which are shipped to AppTec for incubation, enumeration, and characterization/identification. We provide you with test results for your analysis.

Comprehensive Services

We consult with you to develop an appropriate protocol and sampling plan by reviewing schematics or by on-site evaluation of controlled areas. You follow the established sampling plan and return the samples to us for incubation, enumeration, and characterization/identification. We analyze the data and provide a formalized final report with the test results and recommendations for establishing Alert and Action levels.

Supplemental Services

- On-site assessment and monitoring
- ID of environmental isolates
- Tracking of isolates (using RiboPrinter® system)
- Annual trending of results
- Training of your personnel for sample collection
- Rental of an RCS air sampler
- Culture media for sampling purposes (e.g., RODAC plates, exposure plates, RCS air strips).

Disinfection Process Efficacy

This type of study is used to evaluate the log reduction of a disinfection or antimicrobial process used on products or materials. It evaluates specific disinfection agents, alone or in combination, and is typically conducted with a variety of microorganisms – a panel of organisms typically used for efficacy testing; those organisms that are of the most concern to product integrity or application; or environmental/product isolates.

Efficacy of Sanitizers / Surface Cleaning Validation

This type of study is used to determine the efficacy of sanitizing agents on various inanimate surfaces (such as counters, floors, and other areas/materials that are routinely cleaned). It is typically conducted with variety of microorganisms, most often those that are of concern in the environment or product application.

NOTE: Standard methods (ASTM, AOAC, USP, ISO, etc.) can be modified, expanded or otherwise customized to provide specialized challenges or fulfill particular requirements.

ADDITIONAL SERVICES

- Microbial Identification
- Water Testing / TOC
- Chemical / Analytical Testing
- Custom Protocols
- Consultation Services



For more information about our wide range of services, contact an AppTec Account Manager at 888.794.0077.

www.apptec-usa.com