

testing services for controlled environments

WuXi 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.



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.

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

Testing Services

You follow your own protocol/test plan for selection of sites and collection of the samples, which are shipped to us 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. You follow the established sampling plan, then ship the samples to us for incubation, enumeration, and characterization/identification. We analyze the data and provide a formalized final report that includes the test results and recommendations for establishing Alert and Action levels.

Supplemental Services

• On-site assessment & monitoring • ID of environmental isolates • Tracking of isolates • 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

Talk to us and find out how our controlled environment testing 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