



USP <797> <800> STERILE COMPOUNDING

Key Elements of a Compliant Environmental Sampling Plan

AN ENVIRONMENTAL SAMPLING PLAN CONFIRMS THE EFFECTIVENESS OF:

- Personnel and Material Work Flows
- Cleaning
- Deviation and Corrective Actions
- Engineering Controls
- Personnel Training
- Quality Assurance System



TYPICAL ENVIRONMENTAL TESTS

- Chemo Wipe Testing
- Differential Pressure*
- Non-Viable Air (total particulates)
- Temperature/Relative Humidity*
- Viable Air (no settle plates)
- Viable Surface



* <797> Revision requires continuous monitoring devices



KEYS TO A SUCCESSFUL SAMPLING PLAN

- Robust policies and procedures that define sample interval, sample locations, acceptance criteria, data review and approval and trending
- Dedicated and trained staff
- Quality System is seamlessly integrated into operations
- Microbial identification when over limits
- Training and on-going assessments



COMMON CHALLENGES FOR IN-HOUSE TESTING

- Availability of equipment
- Deviation investigation and corrective action
- Documentation management
- Evaluation of the effectiveness of cleaning/ disinfection agents and cleaning processes
- Maintenance, calibration and repair
- Plate inventory and management
- Time



COMMON CAUSES FOR EXCURSIONS

- Facility design and engineering controls
- Flow of Materials and Personnel
 - Lines of demarcation
 - Ineffective gowning
 - Materials not wiped down
- Incomplete training
- Lack of on-going assessments



QUALITY ASSURANCE PROGRAM



HOW QUALITY SOLUTIONS CAN HELP



**Certification &
Environmental
Testing**



**Environmental
Monitoring (EM)
Kits**



**Facility Design
and Assessment**



**Personnel
Training &
Assessment
Support**

Quality System and Compliance Consulting



EM KITS

- Provide Kits and Reports to self perform routine environmental sampling
- Support your in-house testing with incubation and enumeration of test samples





ENSURING A RETURN ON THE COST OF QUALITY

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