

USP <797>/<800> Sterile Compounding

Key Elements of a Compliant Environmental Sampling Plan

An Environmental Sampling Plan Confirms the Effectiveness of:



Cleaning

Deviation and Corrective Actions

Engineering Controls

Personnel Training

Quality Assurance System

Typical Environmental Tests



Chemo Wipe Testing

Differential Pressure*

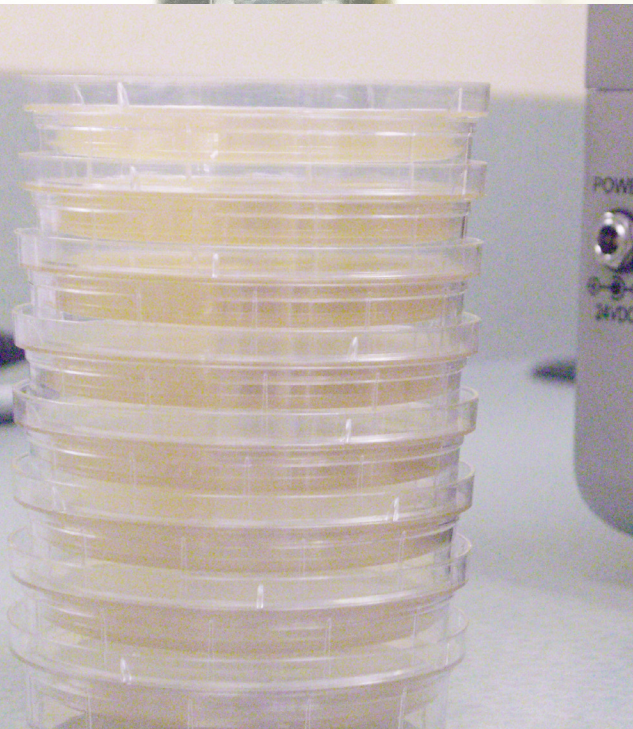
Non-Viable Air (total particulates)

Temperature/Relative Humidity*

Viable Air (no settle plates)

Viable Surface

* <797> Revision requires continuous monitoring devices



Keys to a Successful Sampling Plan



Change control

Dedicated staff

Quality System is seamlessly integrated into operations

Robust policies and procedures that define sample interval, sample locations, acceptance criteria, data review & approval

Microbial identification

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 of Excursions



Facility design and engineering controls

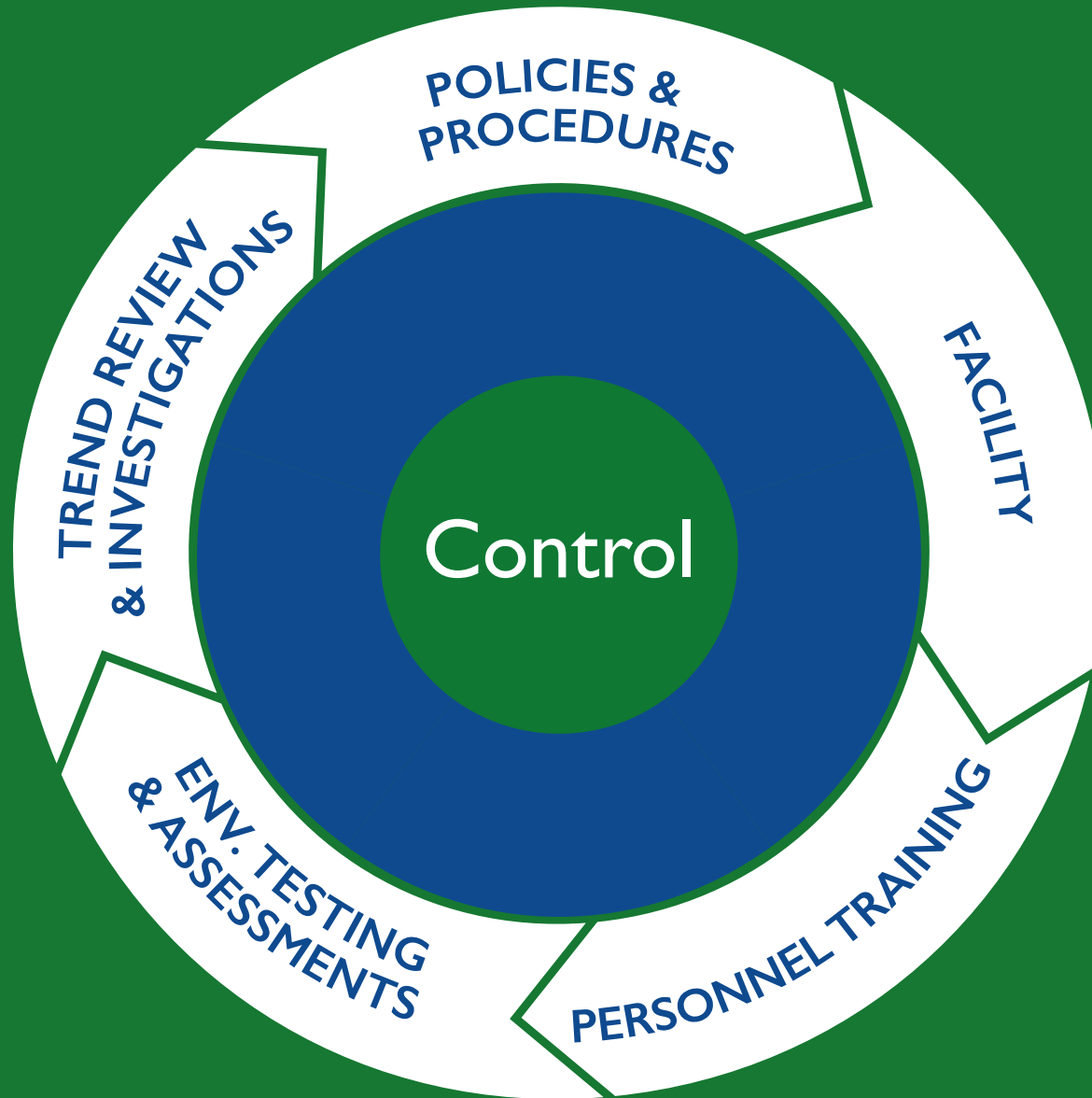
Flow of Materials and Personnel:

- Lines of demarcation
- Ineffective gowning
- Materials not wiped down

Incomplete training

Lack of on-going assessments

Quality Assurance Program



How QS Can Help



Certification & Environmental Testing



Environmental Monitoring (EM) Kits



Facility Design and Assessment



Personnel Training & Assessment Support



Quality System and Compliance Consulting

EM Kits



QS can provide Kits and Reports to self perform routine environmental sampling

QS can support your testing with incubation and enumeration of test samples

Ensuring a Return on the Cost of Quality

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