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Environmental Monitoring and Control in the Pharmacy

Q&A

with **Fran McAteer**, MBA
vice president at Microbiology
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Pharmacy Purchasing & Products: What are the challenges to conducting in-house environmental monitoring in the pharmacy?

Fran McAteer: In the hospital pharmacy setting, challenges to successful in-house environmental monitoring programs tend to correlate with deficiencies in USP <797> expertise and compliance. It is not uncommon for pharmacists to believe they have the capacity and knowledge to conduct effective environmental monitoring in-house, but oftentimes, such programs vary widely in testing methodology (if formalized at all), microbiology expertise, and cleanroom operations and maintenance.

To address expertise issues, some hospital pharmacies co-opt the facility's clinical microbiology lab to operate an environmental monitoring program. No doubt clinical microbiologists have the acumen to understand the concepts that drive environmental monitoring, but hospital laboratories have their own direc-

tives and processes, and their application of expertise in enabling proper patient care differs from that of a pharmacy environmental monitoring program. Given their workload, the microbiology lab may be disinclined to learn and adopt the methods and application of science related to sample collection, incubation temperatures and durations, growth promotion, low-level contamination detection, cleanroom remediation, and other concepts specific to the pharmacy setting. In addition, hospital microbiology labs typically are not USP <797> compliant, as this is not an appropriate standard for their normal operating environment.

Another challenge to effective in-house environmental monitoring is developing and implementing policies and procedures (P&Ps) that cover multiple sample sites, enable the collection of relevant data, ensure appropriate action levels, and incorporate corrective and preventive action (CAPA) plans. This last element requires performing root cause analyses and applying established corrective action and remediation plans. For example, if microbial action levels are exceeded, the sampling site environment must be cleaned, disinfected, and retested to show evidence of microbial elimination or reduction to safe levels. If action levels are exceeded in sample sites over an extended period of time, this is an indication of more systemic causes, requiring an investigation of the cleanroom's integrity, engineering controls and design, HEPA filtration performance, and personnel training and proficiency. Many pharmacies are unable to perform these actions to an exacting standard.

PP&P: In your experience, why do organizations make the decision to outsource environmental monitoring?

McAteer: The vast majority of the pharmacists we work with, especially at the director level, understand that their training and background do not necessarily coincide with the rigors of modern microbial detection, prevention, containment, and elimination. They also realize that outside consultants and contracted service providers that specialize in environmental monitoring may be better qualified to perform this task.

Establishing what amounts to a pharmacy-specific microbiology laboratory, within the pharmacy, can be quite formidable in terms of the requisite equipment, skill sets, and physical space. Given that the quality of the environment in which pharmaceuticals are manipulated directly impacts patient safety—both in ensuring the efficacy of medications and preventing the introduction or spread of pernicious microbial agents—self-operating a microbial monitoring program may open the pharmacy up to questions of liability in terms of testing expertise. Doing so also may lead to FDA and state board of pharmacy inspections for integrity and comprehensiveness. Collectively, these are some of the reasons facilities seek outside providers, with extensive and established USP <797> expertise, as well as FDA registration (including establishment inspection reports), which are a matter of public record.

SIDEBAR

Managing Primary Engineering Controls

PP&P: What are some trends to look for when monitoring primary engineering controls, such as LAFWs and BSCs?

McAteer: The most important trends to look for when testing PECs include:

- ▶ Cleaning and disinfection performance indicators
- ▶ New employee proficiency as it relates to established quality parameters
- ▶ New construction impact from facility build out projects

PP&P: What issues in the cleanroom tend to prompt contamination of PECs?

McAteer: Contamination of PECs tends to stem from one of the following catalysts:

- ▶ Mechanical failure (eg, HEPA integrity failure)
- ▶ Personnel issues (eg, improper gowning and gloving; new or inexperienced employees)
- ▶ Cleaning and disinfection issues (eg, insufficient or improper cleaning and disinfection of materials that then enter the PEC)
- ▶ Facility updates (eg, new construction and/or equipment)

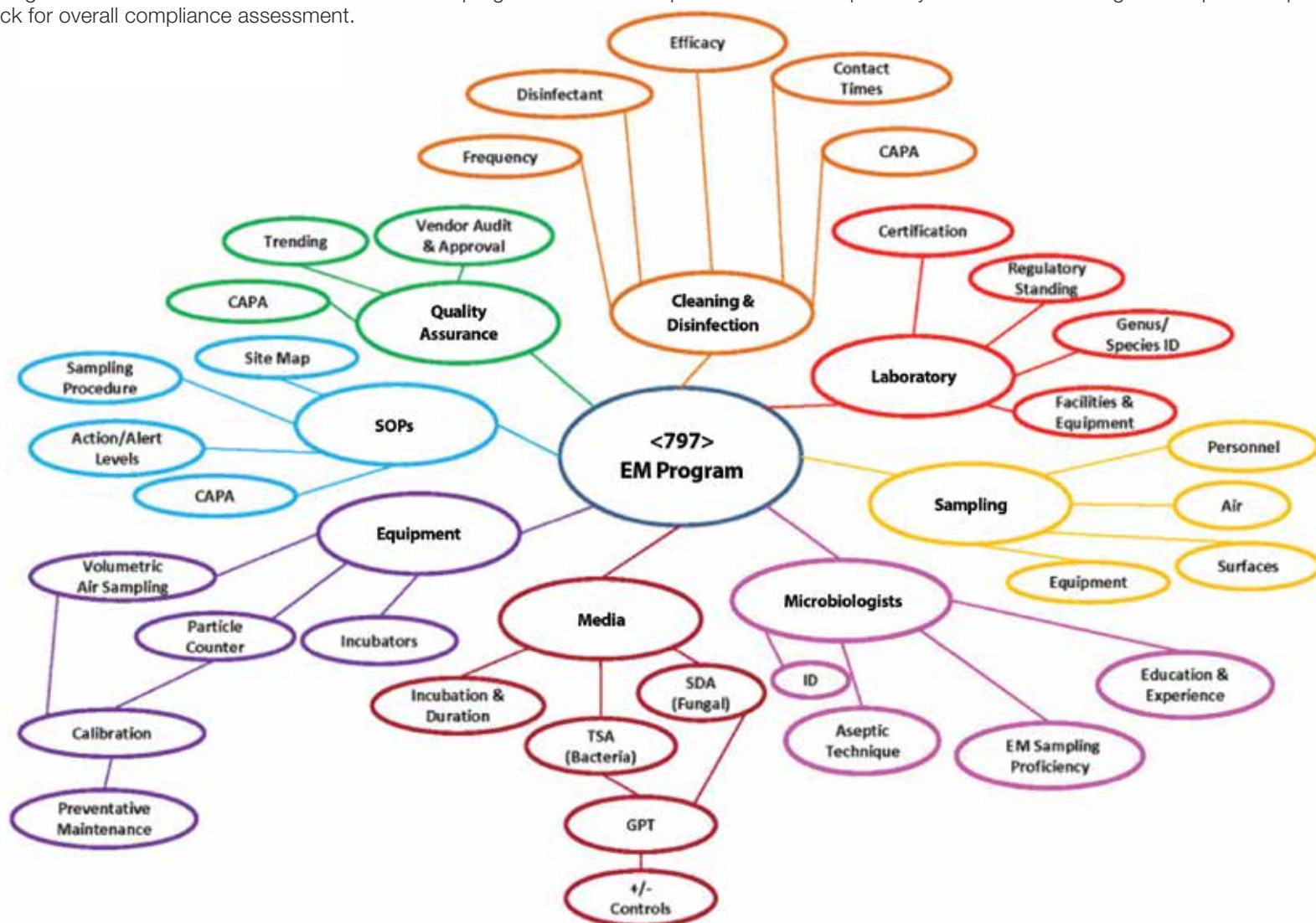


Environmental Monitoring & Engineering Controls

FIGURE 1

Elements of a USP <797>-Compliant Environmental Monitoring (EM) Program

The primary function of EM is to demonstrate the nature and level of environmental control in the pharmacy. The chart below shows the various disciplines comprising the foundation of a robust and successful EM program. The colors represent the various pathways that should be integrated to provide optimal feedback for overall compliance assessment.



CAPA=corrective and preventive action; GPT=growth promotion test; SDA=Sabouraud dextrose agar; TSA=trypticase soy agar
Image courtesy of Microbiology Research Associates, Inc

This brings forth perhaps the most important aspect of contracting with an outside entity for environmental monitoring: the individuals or companies under consideration should have a credible public record indicating they have been inspected by state and federal entities, have established International Organization for Standardization (ISO) certification, and have a history of quality compliance. Such an assessment should be standard for any pharmacy considering contracted services.

PP&P: What expertise is required for effective environmental monitoring?

McAteer: First, pharmaceutical microbiology expertise is required, which is distinct from clinical microbiology or similar disciplines. This means practitioners must have experience with advanced pharmacy cleanroom design and engineering principles, as well as proper cleaning and disinfection principles; there must be working knowledge of the types of organisms that tend to develop in the pharmacy setting and what agents can be used to kill them and prevent their return. Furthermore, to preclude the development of resistance, cleaning and disinfecting

agents must be used with discretion while maintaining efficacy.

This scientific expertise should then be applied using a formalized quality manual comprising standard and custom P&Ps, as well as documentation of regulatory compliance and inspection history. The manual also may include biographies of key staff to indicate that the organization employs individuals with the proper background. As environmental monitoring is governed by certain standard operating procedures (SOPs) put forth by organizations such as the ISO and the FDA, quality manuals often include SOPs. For example, Microbiology Research Associates (MRA) has more than 150 SOPs listed in an index, which describe how we perform sampling, conduct testing, and determine speciation; the index also defines our quality controls in terms of data analysis and reporting, and outlines microbiologist proficiency training.

Ultimately, service providers should present themselves as capable of comprehensive environmental monitoring management (see **FIGURE 1**). The work must withstand both internal and external scrutiny, so SOPs must be vetted, maintained, strictly controlled, and transparent, which enhances program traceability and accountability.



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PP&P: What types of reporting should the pharmacy expect from an outsourced provider?

McAteer: The environmental monitoring outsourcer should provide the following:

- **Environmental Monitoring Report.** This should include the test date and location address, a list of sample sites that were tested, what media was utilized in the testing, the incubation parameters, and the type of testing that was performed (ie, air or surfaces). The report should list any colony counts and whether they are above appropriate action levels.
- **Objectionable Organisms Report.** If testing indicates exceeded action levels, speciation ID and genus ID are important. There are specific organisms that are particularly objectionable, such as mold or any *Staphylococcus* genera, which should be closely identified. In the case of a *Staph* genus, *Staph aureus* should be quickly identified and indicated, given its pathogenicity.

When reports are received in the pharmacy, review them immediately. Any evidence of excessive action levels should be quickly communicated to all relevant staff in a formal notification, and the contaminated area must be cleaned, sanitized, and retested promptly.

PP&P: What can pharmacy do to educate and protect itself?

McAteer: Review USP <1116>—Microbiological Evaluation of Clean Rooms and Other Controlled Environments, a guidance chapter (also referenced by Chapter <797>) that provides an overview of environmental monitoring for aseptic processes. USP <1116> offers more detail than <797> regarding proper procedure, methodology, materials and equipment, and techniques for environmental monitoring and maintenance.

In the event of an above-action-levels report, most quality outsourcer laboratories will conduct a review of their sampling and testing processes to make sure no internal mistakes contributed to the result. The quality manual checklist will be reviewed to ensure that all SOPs were followed, all equipment was calibrated and validated before sampling and testing, and that all involved staff members were appropriately trained. This type of report (often referred to as an out-of-specification report) can provide clarity to the pharmacy director as to whether the result is correct or if the laboratory made an error. As with all medical disciplines, an outsourcer laboratory may introduce sample contamination via methodology, equipment, or personnel error. Accordingly, the best service providers will make a concerted effort to validate any findings.

The goal of any health care provider should be to seek total compliance with microbial management concepts; environmental monitoring in the pharmacy is just one aspect of this. As hospitals become more aware of practical and financial penalties related to nosocomial events and seek to eliminate their catalysts, additional outsourcer interactions may include any combination of the following:

- Instruction for pharmacists and technicians on proper garbing and hand washing, as well as cleanroom cleaning and disinfection
- Educational seminars on the relationship between sterile compounding and microbiology, including the principles of cleaning and disinfection
- Guidance for, and compounding validation of, TPN pumps to identify worst-case scenarios
- Direction on the proper extension of environmental monitoring and infection prevention strategies into pharmacy robotics

These are just a few examples of the possible expansion of microbiological services in hospital pharmacy operations.

PP&P: Can you provide some tips for gaining administrative budget approval for outsourcing environmental monitoring?

McAteer: The outsourced compounding scandal of 2012 significantly affected hospital administrations' perspectives on the value—both financially and in human lives—of preventing microbial contamination. Now, most hospital administrators

consider such measures an operational necessity and actively investigate how to expand microbial management throughout their facilities. Thus, the facility can gain feedback on the efficacy of all cleaning and disinfection programs throughout the hospital. Instead of simply running a sampling scenario and identifying a contamination, larger programs can shed light on the overall organizational state of control, not just from a microbiological standpoint, but also from a training, staffing, and patient safety perspective.

PP&P: What information should be included in contracts for environmental monitoring services?

McAteer: Contracting for environmental monitoring services varies widely based on the scale, scope, and duration of services. The exact role of the outsourcer, in terms of what services and information will be provided to the pharmacy and hospital administration, should be included in the contract. These services also must be backed up by the outsourcer's own documentation and self-analysis.

The services provided by an outsourced laboratory vendor are only as good as the tools and conditions with which the company operates. The pharmacy director, or whoever is involved in contract negotiations with the outsourcer, should be provided with open access to the vendor's regulatory history up to the present. Maintaining a working relationship with a specific outsourcer can be advantageous, as they are able to aggregate and trend data over time, allowing for more efficient response to microbial excursions. Regardless, the contract should include a detailed listing of the exact services to be provided, how the billing and payment structure will function, what information and reports will be provided, as well as assurances of regulatory compliance. The contract also may stipulate pricing breakdowns based on the contract term: the longer the contract, the better the price. This may not always be the case, but such concepts should be addressed in the formal business contract.

PP&P: Do you have any parting words for pharmacy directors considering outsourcing environmental monitoring?

McAteer: Keep in mind that even though environmental monitoring is a required performance indicator, it is vital that the information garnered through monitoring not only indicates contamination control, but also facilitates education and remediation actions. If a monitoring event indicates an area of the compounding cleanroom is out of specification, not only should that situation be remedied, but measures should be taken to determine the cause. For example, fingertip contamination is a common culprit; the data may show that over a period of time, a specific technician was having trouble with aseptic technique. Trended out, this data can provide valuable information about which staff members are best suited for sterile compounding.

Another situation, which generally applies to bigger hospitals, is the presence of students and contract employees in the pharmacy. Using monitoring data to evaluate their skills also can lead to valuable hiring or termination information.

Last of all, given the introduction of the Drug Quality and Security Act, and all of the attendant classifications, such as 503A and 503B, both hospital pharmacies and contracted service providers must adhere to strict requirements. In addition to educating yourself about these concepts, it is wise to partner with an environmental monitoring company that offers expertise and experience to ensure future compliance activities are consistent. Some companies include environmental monitoring as a side or add-on service, and this should raise red flags. Partner with a vendor that specializes in environmental monitoring in the pharmacy. The pharmacy director's license is on the line, so he or she should be comfortable that the service will cover them in the event of regulatory scrutiny. ■

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