

Increased Environmental Microbiology Surveillance of Compounding Operations by Expert System for Timely Contamination Prevention and Improved Resiliency



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Introduction

Some hospital pharmacies are increasing the frequency of environmental sampling for microbiological agents (bacteria and fungi) for improved resolution of quality assurance programs for product and patient safety. Until recently, many pharmacies only sampled for airborne and surface bacteria and fungi every six months in accord with current USP standards. Semi-annual testing is less likely to provide adequate resolution for determination of typical background levels or when levels of pathogens are approaching trigger points. Critical interpretation of data requires information on the activities at the time of sampling, an understanding of the limitations of methods used, and resources focused on microbial growth profiles. Increasing sampling frequency substantially improves the available information for decision-support with microbial contamination and drug quality. However, the volume of data for analysis and interpretation is daunting when moving from semi-annual to monthly testing as suggested by the revised USP 797, to even weekly testing performed at some hospitals. Furthermore, this analysis often falls to one staffer who shows an interest in microbiology.



Methods

To address analysis and interpretation of the new volume of data being collected and to enhance program continuity despite staff transitions, Brigham and Women's Hospital partnered with EH&E to develop an expert system to systematize, standardize and expedite the process. Previously, laboratory reports were compiled and reviewed in print. Now the expert system streams data direct from the laboratory into a web-based dashboard portal for automating species identification and quantification, trending, and risk analysis. Furthermore, email alerts are dispatched when pathogens are detected or levels exceed USP action limits.

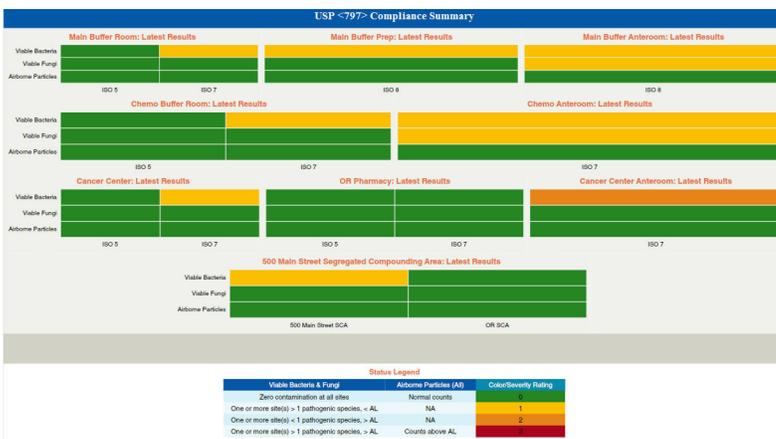


Figure 1: A web-based dashboard standardizes and expedites interpretation of environmental sampling data.

Results

The expert system improves environmental surveillance in managing pharmacy operations by:

1. Expediting the analysis of environmental sampling data by one-half times the typical turnaround time, enabling substantially earlier identification of environmental conditions of concern. Results are available within 7 days or less rather than the typical 12-14 days.
2. Interpreting data is automated on a 24/7 basis, without pharmacy staff involvement. Pharmacy leadership is notified via email alerts if there are suspect conditions of concern.
3. Managing documentation and recordkeeping for improved quality assurance, documentation management, and ease of data retrieval and reporting for internal audits or regulatory inquiries.

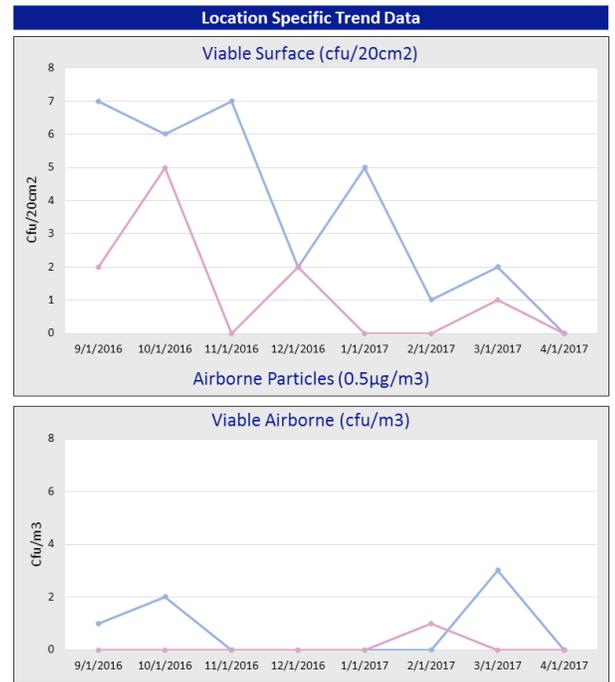


Figure 2: Trend data for specific locations is easily accessed using a web-based dashboard.

Conclusion

The web-accessible management dashboard rapidly and clearly displays the data needed to inform critical decisions regarding whether to implement interventions in the event of a potential contamination issue. This system enables the Pharmacy to improve surveillance into cleanroom operations, which can impact drug safety and patient protection and reduces liability risks for the hospital.

