



INSIGHTS

Is It Time to Upgrade Your Environmental Monitoring Program?

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Executive Summary

A pharmaceutical company's Environmental Monitoring (EM) Program is one of its most critical quality systems. In addition to the quality aspects of EM, advances in monitoring technology have made EM programs an area where companies can obtain tangible business benefits. Whether you have one sterile manufacturing facility or a host of sterile and non-sterile manufacturing facilities, the following four items highlight the potential benefits that a pharmaceutical company can experience from upgrading their EM program.

Simplify Operations with Common Processes Between Sites. Life sciences companies can benefit from upgrading their EM programs by instituting common processes between sites. Companies spend millions of dollars a year on their EM programs; whether this spending is related to facilities, equipment, procedures, or training, it is usually a material item in the budget. When a new facility is added, spending increases incrementally as well. Obviously, many aspects of an EM program have to be site and product specific. However, if you have not looked lately across your sites at sampling methods, incubation conditions, sampling frequencies, microbial identification procedures, trend analyses, and corrective actions, you may be missing an opportunity

to simplify operations, improve efficiencies, and reduce costs. Consider taking best practices from different locations and applying them where possible organization-wide. This will help you achieve a quality program that is both defensible and cost effective.

Improve the Effectiveness of Trending and Analyses while Reducing Costs. It is widely known in the industry that the ability to trend and analyze provides an advantage in identifying and eliminating potential problems. Until now, many companies have used spreadsheets or augmented their LIMS systems to meet EM data requirements. Because of the volume of EM data and the requirements of 21 CFR Part 11, these approaches are quickly becoming sub-optimal. With the creation of new computer applications designed specifically for environmental monitoring, trending and analysis of EM data can be simplified, centralized, and standardized. Much of the manual effort (and error) around alerts, actions, trend reports, and data analysis can be reduced or eliminated all together, translating into direct bottom-line savings—especially if multiple locations are utilizing the same functions.

Achieve 21 CFR Part 11 Compliance. Much has been said and written about Part 11 and how pharmaceutical companies are adopting and implementing its standards.

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Obviously, EM systems must meet these standards. The use of spreadsheets or other non-validated systems to record, track, and trend EM data is no longer a viable long-term solution. With new technologies, automated systems that manage EM data are simple and can be validated and implemented quickly and usually at a fraction of a company's overall Part 11 compliance budget. With advances in the area of EM software applications, there is no reason not to address EM as a quick and cost-effective Part 11 win.

Avoiding Error and Cost with Automated Particle Monitoring. A potential area of great savings from an upgraded EM program comes from automating the collection and recording of particle data. A continuous particle monitoring system has many benefits, including reducing line intrusions and data entry errors, increasing the consistency and accuracy of non-viable data collected in rooms, and reducing personnel costs by eliminating manual processes. For companies adding new facilities or with a good EM program, the addition of automated monitoring capabilities is a next logical step that can improve product quality and reduce costs.

Conclusion

These four benefits demonstrate that a world-class EM program cannot only help ensure the highest quality products available, but it can also avoid unnecessary costs and achieve tangible benefits. Is it time to upgrade your environmental monitoring program?

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