



USP Enverify™ Leveraging surface sampling performance data to strengthen environmental monitoring

Application Note

1. Background: Role of surface sampling in modern manufacturing

Viable surface sampling provides meaningful information that supports the understanding of how effective contamination control strategies are in pharmaceutical manufacturing operations. As an indirect control mechanism, surface sampling functions as a retrospective insight into the environmental conditions during a defined period of operation. It serves as a key tool when verifying the effectiveness of cleaning, disinfection, and environmental controls of a facility.

Across pharmaceutical manufacturing environments, classified cleanroom and controlled areas are designed to support products and processes with varying levels of microbial risk. Maintaining these conditions throughout routine operations relies on integrated facility design, engineering controls, procedural controls, and personnel practices. Environmental monitoring (EM), including surface sampling, is the mechanism by which performance of these systems is assessed over a duration of time.

True value in surface sampling comes from the ability to evaluate data collectively over time and in consideration with other observed environmental factors. When reviewed as part of a broader dataset, surface sampling results contribute to an understanding of environmental performance and support confidence that specific contamination controls functioned as intended during manufacturing activities.

As pharmaceutical manufacturing technologies continue to advance through automation, closed processing, and enhanced barrier systems, expectations for sustained environmental control have increased accordingly. Regulatory

guidance increasingly emphasizes consistent sampling during routine operations, elevating the importance of EM data that can be meaningfully interpreted and used to inform actions and improvements, rather than simply collected.

With this perspective, it becomes important to consider not only where surface sampling fits within EM programs, but how the data generated are interpreted and used in practice. Reliable interpretation of EM data requires confidence in both the monitoring program and the surface sampling performance that underpins it.

2. Discussion: EM as a measurement system and the importance of data quality

EM provides insight into environmental conditions during manufacturing and processing activities by capturing information from defined operational windows, such as routine production runs, aseptic interventions, equipment setup and breakdown, or extended processing campaigns. When used appropriately, these data support assessment of how effectively environmental controls are performing throughout routine operations.

Interpretive in nature, EM results are most appropriately evaluated in context and over time rather than as isolated values. While individual results can be significant, particularly in highly controlled manufacturing environments, the primary strength of viable EM, and surface sampling in particular, lies in the ability to trend data and identify meaningful patterns or shifts in environmental performance.

These principles are reflected in U.S. FDA guidance, which states that “environmental monitoring data will provide information on the quality of the manufacturing environment,”

BIO.117.A

and that “each individual sample result should be evaluated for its significance” (FDA Guidance for Industry: *Sterile Drug Products Produced by Aseptic Processing*, 2004). The guidance further notes that quality support should include “routine oversight of near-term (e.g., daily, weekly, monthly, quarterly) and long-term trends in environmental and personnel monitoring data.”

The reliability of EM trends depends on the quality and consistency of the data generated. For surface sampling, this requires that results accurately reflect potential environmental bioburden on controlled surfaces during critical aspects of routine operations. Consistent execution using defined techniques and conditions improves interpretability and supports confidence in long-term EM trends.

Surface sampling performance is a critical contributor to data interpretability. As a manual microbiological method, surface sampling can introduce inherent variability related to technique, pressure, contact time, and surface interaction. In highly controlled environments where contamination events are infrequent by design, this variability can complicate interpretation and make it more difficult to distinguish the real effect of microbial-control efforts from sampling-related influences.

These considerations are also reflected in USP guidance. [USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments](#) (2012) notes that “microbiological sampling has the potential to contribute to microbial contamination caused by inappropriate sampling techniques or by placing personnel in or near the critical zone,” and emphasizes that “a formal training program is required to minimize this risk.” The chapter further states that interventions, including those required for monitoring activities, should be minimized and, when unavoidable, “conducted with aseptic technique that approaches perfection as closely as possible.”

Historically, surface sampling performance has often been evaluated through observational or demonstration-based approaches. While these methods support procedural understanding, they provide limited objective information about recovery, consistency, or aseptic handling under conditions representative of actual sampling use. In practice, objective training and assessment are further complicated by the fact that designated training surfaces in controlled environments are typically low-bioburden or intentionally negative, limiting the ability to directly evaluate recovery efficiency during routine training. As expectations for data quality, data integrity, and contamination control oversight continue to increase, there is a growing need for objective,



quantitative approaches that strengthen confidence in surface sampling data and the quality decisions informed by those data over the lifecycle of a manufacturing batch.

These considerations are further reinforced by EU GMP Annex 1, which states that “sampling methods and equipment used should be fully understood and procedures should be in place for the correct operation and interpretation of results obtained,” and that “supporting data for the recovery efficiency of the sampling methods chosen should be available” (EU Annex 1, Section 9.29, 2022).

Taken together, these considerations highlight the importance of understanding where and how surface sampling performance is assessed within the larger EM program lifecycle in order to support meaningful data interpretation and ultimately, product quality.

3. Integration: Placement of Enverify™ within GMP EM systems

EM programs are designed to generate data that provide assurance of environmental control throughout pharmaceutical manufacturing operations. For surface sampling in particular, the interpretability of that data depends not only on monitoring frequency and consistency, but also on how the sampling method is implemented and how personnel execute that method in practice.

Tools used to generate objective information about surface sampling performance must therefore be positioned thoughtfully within the EM program lifecycle. Their value is greatest when applied at defined qualification and reassessment points, where they can support confidence in method performance and personnel technique without altering routine monitoring execution.

Within this framework, Enverify™ supports qualification of surface sampling methods and assessment of personnel performance while remaining distinct from day-to-day EM activities. Understanding where Enverify™ is applied, and how the resulting data are used, provides important context for interpreting its role within a GMP EM program and the broader contamination control strategy, as illustrated in **Figure 1**.

4. Trending: Generation, use, and trending of surface sampling performance data

Surface sampling performance assessments using Enverify™ are conducted using the same sampling devices, techniques, approved procedures, and laboratory practices applied during routine EM. This approach ensures that the data generated are representative of how surface sampling methods are implemented in practice. Enverify™ test surfaces and controls are incorporated to help enable objective evaluation of sampling performance without altering standard workflows. Assessments are typically planned as part of program qualification, personnel qualification, or defined reassessment activities rather than routine monitoring execution.

Following sampling, test units are handled, incubated, and evaluated using established microbiology laboratory practices. Enumeration results generate quantitative performance data, which may include recovery outcomes, consistency across repeated assessments, and results from blinded control samples. These data provide objective insight into both method performance and personnel technique under routine conditions.

Surface sampling performance data are reviewed alongside routine EM results during data review and trending activities. When evaluated over time, performance data provide supplementary context for interpreting EM trends, particularly in environments where contamination events are infrequent by design.

Trending of performance data may be conducted across personnel, shifts, rooms, or operational periods depending on program objectives and risk considerations. Repeated assessments support evaluation of training effectiveness, personnel consistency, and overall program maturity, contributing to confidence in the EM program.



EM Program Design & Performance Qualification

- ▶ Assess surface sampling recovery at representative locations during EMPQ.
- ▶ Compare recovery performance across surface sampling media or suppliers.
- ▶ Use qualification data to inform acceptance criteria and reassessment triggers.



Personnel Surface Sampling Method Qualification

- ▶ Support initial qualification of personnel performing surface sampling.
- ▶ Establish baseline operator variability across shifts, rooms, or teams
- ▶ Document competency to support contamination control expectations.



Environmental Monitoring Data Review & Trending

- ▶ Review recovery trends to identify potential performance drift over time.
- ▶ Use stable recovery data to support interpretation of EM excursions and adverse trends in classified areas.



Contamination Control Strategy Oversight

- ▶ Incorporate performance metrics into CCS review and oversight activities.
- ▶ Use data to support investigations, CAPA and training effectiveness.

Figure 1. Enverify™ Within the Environmental Monitoring Program Lifecycle.

5. Use of surface sampling performance data to support contamination control

Surface sampling performance data support contamination control strategies by reinforcing confidence in how EM methods are implemented and sustained over time. When generated using objective, repeatable approaches and reviewed in context, these data help demonstrate that surface sampling methods and personnel techniques remain suitable for their intended use within GMP EM programs.

Performance data can also support personnel qualification programs, evaluation of training effectiveness, and ongoing EM program oversight. When EM trends or investigations raise questions related to sampling execution or technique, performance data provide additional context to help distinguish method-related factors from true environmental conditions.

Well-documented surface sampling performance records also support audit and inspection readiness by demonstrating that sampling methods are understood, qualified, and periodically reassessed in alignment with regulatory expectations. Over time, consistent evaluation and use of surface sampling performance data contribute to cumulative assurance by strengthening confidence in EM outcomes and reinforcing a robust, risk-based contamination control strategy.

Sustained confidence in environmental monitoring requires more than routine sampling; it requires demonstrable assurance that surface sampling methods and techniques perform as intended over time.



Product details

- ▶ **Cat #** [1800494](#)
- ▶ **Product:** Enverify™ Viable Surface Sampling Self-Evaluation Kit
- ▶ **Description:** Includes three (3) microbial-coated test surfaces and two (2) sterile blinded blank test surfaces.



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