Excursion Investigations in Sterile Compounding

How Lab Results can Prompt and Support Inquiries

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Background

Recurrent excursions in microbial growth within sterile compounding environments present a persistent challenge to ensuring patient safety in home infusion practice. Historical evaluations of environmental monitoring data across sterile compounding facilities demonstrate that contamination events are frequently linked to inconsistent environmental controls, insufficient airflow integrity, and workflow-related vulnerabilities. Prior research highlights the importance of robust environmental monitoring programs; however, gaps remain in understanding how facility-specific variables—such as HVAC performance, pressure differentials, and aseptic practices—interact to contribute to excursions.

These gaps underscore the need for a systematic investigation that correlates environmental data with certification findings and operational practices. The purpose of this project is directly aligned with addressing these gaps by conducting a structured evaluation of contamination sources, risk levels within controlled spaces, and environmental control performance. This background provides the necessary context for understanding the objective of the study and the relevance of the findings.

Outline

- Sampling Map Review
- Certification Data Review
- Bioburden Over Time
- Root Cause Investigation
- Summary of Findings

Purpose

The purpose of this project is to determine the underlying contributors to recurrent microbial growth excursions in a sterile compounding environment and to evaluate whether targeted environmental and procedural interventions can reduce contamination frequency. The central question guiding the study is: *What environmental, procedural, or system-level factors contribute most significantly to microbial excursions, and can targeted CAPA (Corrective and Preventive Action) measures mitigate these events?*

Based on available literature and prior experience with environmental monitoring and sterile compounding assessments, the hypothesis is that contamination excursions are primarily driven by deficiencies in airflow integrity, inconsistent environmental control parameters, and gaps in operational workflow. It is expected that a comprehensive analysis integrating environmental monitoring data, certification reports, and risk mapping will identify specific high-risk areas and support targeted corrective actions.

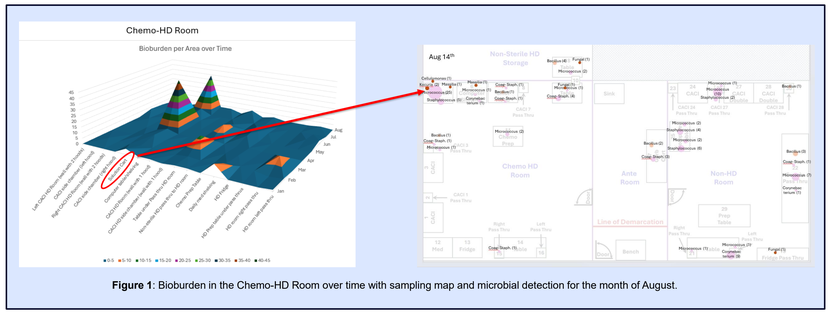

Figure 1: Bioburden in the Chemo-HD Room over time with sampling map and microbial detection for the month of August.

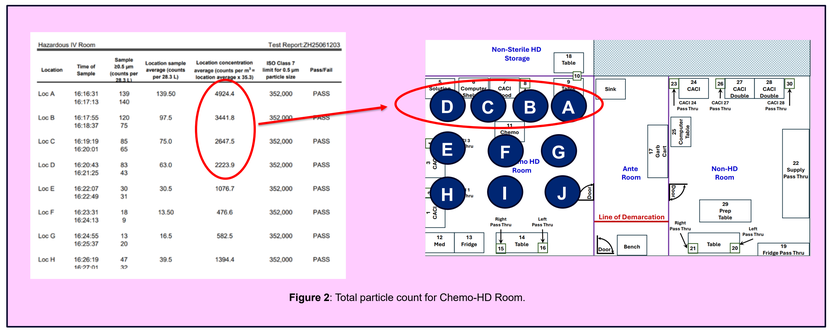

Figure 2: Total particle count for Chemo-HD Room.

Methods

This project employed a structured observational and retrospective analysis design. Data sources included environmental monitoring (EM) results, certification documents, facility-supplied photographs, and mapped trends of bioburden levels over a six-month period. The investigation followed a predefined procedure for data collection and documentation aligned with a standard assessment framework.

The study examined environmental control parameters, airflow performance, pressure differentials, and EM results to identify patterns and areas of concern. A visual floorplan was developed to map sampling grid points, overlaid with a risk-scoring system ranging from 1 (minimal risk) to 5 (critical risk). The population consisted of environmental sampling sites within ISO-classified spaces, including the anteroom, non-HD room, and HD room. Inclusion criteria required all sites with consistent sampling data over the six-month timeframe.

Data were reviewed for consistency with certification findings, and statistical comparisons were made using descriptive trending analysis to evaluate changes over time. No human subjects were involved in this study; therefore, IRB approval was not required. The project was conducted from April through August of the evaluation year.

Results

Quantitative review identified elevated bioburden events at multiple timepoints across the six-month period, with notable clustering in zones classified as high or critical risk during risk score assessment. Certification review showed discrepancies between documented airflow performance and on-site environmental behavior, indicating misalignment in reported versus actual conditions. Descriptive statistical trending established a clear correlation between environmental control instability and excursion frequency.

A review of the sampling sites in relation to microbial growth indicated that the highest risk in the Chemo-HD Room was at and in the vicinity of the “solution cart” (Fig.1) . A review of the certification data revealed that that highest particle counts were found in the same area (Fig. 2). The Air Changes per Hour (ACPH) for the room were just above minimum criteria for ISO 7 space. In addition, temperature and humidity data was missing from the certification reports. During the root cause investigation, the head pharmacists noted that the temperature of the room is consistently above target.

The study findings supported the initial hypothesis. Analysis demonstrated that microbial excursions were associated with inconsistent airflow integrity, insufficient or unverified HEPA filtration performance, and elevated differential pressures in select controlled spaces. EM mapping highlighted repeated contamination in specific high-risk zones, particularly within the HD room where airflow and environmental control anomalies were most pronounced.

Discussion

The analysis demonstrated that the hypothesis was supported: environmental and system-level factors significantly contributed to recurrent microbial growth excursions. The findings suggest that strengthening environmental controls, improving certification alignment, and enhancing risk-based monitoring practices can reduce contamination events.

This project contributes meaningfully to home infusion practice by providing evidence that environmental monitoring should be paired with dynamic risk mapping and verification of certification data to ensure reliability. The results highlight the need for consistent HVAC evaluation, validated HEPA integrity testing, and ongoing process assessments.

This study was performed for a single site. Limitations include that the results cannot be transferred to other locations. While the outcome is unique to the study site, the approach to this investigation may prompt discussions and development of meaningful tools and methods for Environmental Monitoring Risk Assessments (EMRA).

EMRA[1] Consideration

- Review bioburden and total particle counts
  - a) Certifier data
  - b) Monthly surface testing
- Identify areas of concern
- Contributing factors
  - a) Airflow
  - b) Personnel and product movement
  - c) Temperature and humidity
  - d) Other factors
- Determine root cause for excursion
- Develop corrective action plan
- Verify and validate

[1]EMRA: Environmental Monitoring Risk Assessment

Conclusion

This investigation identified critical environmental and workflow factors contributing to microbial excursions in a sterile compounding environment. The findings support the need for targeted environmental control improvements and implementation of a structured risk-mapping approach. The development of additional tools and feedback incorporating laboratory data from monthly surface and bi-annual surface and air testing are instrumental in this approach and will strengthen practices that enhance sterile compounding safety to reduce contamination risk.

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