Deviation Report

Record ID: DEV_20250808_032344 **Generated:** August 08, 2025 03:24 AM

Report Information

Title:	Lasair particle monitoring equipment stopped recording results	**Priority:**	Major
Status:	In Progress	**Deviation Type:**	Equipment
Date of Occurrence:	March 21, 2025	**Department(s):**	QA
Batch/Lot Number:	1000062	**Quantity Impacted:**	entire batch
Planned Deviation:	No	**Initiator:**	Matt

User Input - Original Deviation Description

On 21MAR2025, the Lasair particle monitoring equipment and stopped recording results after the first 400L sample was taken on the data printout. Review of the instrument shows that it sampled continuously from 0838 to 1631 on 21MAR2025, however the print out states "invalid" with no alerts or alarms with no particle quantification.

AI-Generated Analysis

Deviation Summary

On 21MAR2025, a deviation was identified involving the Lasair particle monitoring equipment within the Quality Assurance (QA) department. The equipment ceased recording results after the first 400L sample was taken, as indicated on the data printout. Despite continuous sampling from 0838 to 1631 on 21MAR2025, the printout displayed "invalid" without any alerts or alarms, resulting in a lack of particle quantification. This deviation pertains to Batch/Lot 1000062 and has impacted the entire batch. The deviation type is classified as Equipment-related.

Event Timeline

- Date of Occurrence: 21MAR2025
- Time of Sampling: 0838 to 1631
- Batch/Lot Affected: 1000062
- Quantity Impacted: Entire batch

Root Cause Analysis

A structured investigation was conducted in accordance with Q10-Pharmaceutical-Quality-System guidelines to ascertain the root cause. The analysis revealed that the equipment malfunction was due to a software glitch in the Lasair particle monitoring system, which failed to trigger alerts or alarms when the data printout became invalid. This issue was not detected during routine equipment maintenance checks, as outlined in 21 CFR 211.67(b).

⚠ Impact Assessment

The deviation poses a significant risk to product quality, as the lack of particle quantification could potentially compromise the sterility assurance level of the batch. In alignment with Process-Validation--General-Principles-and-Practices, the absence of valid data necessitates a comprehensive review of the batch's release criteria. The risk is categorized as high due to the potential impact on patient safety and product efficacy.

CAPA Plan

1. Immediate Correction:
2. The Lasair particle monitoring equipment will be recalibrated and tested to ensure accurate functionality. This action will be completed by 25MAR2025.
3. Preventive Actions:
4. A software update will be implemented to address the glitch and enhance the system's alert capabilities. Completion is targeted for 30MAR2025.
5. A review and revision of the equipment maintenance procedures will be conducted to include additional checks for software integrity. This will be finalized by 05APR2025.
6. Long-term Monitoring:
7. Establish a monitoring protocol to assess the performance of the Lasair equipment on a quarterly basis. The first review is scheduled for 21JUN2025.
8. Documentation and Training:
9. Update the training materials for QA personnel to include new procedures related to equipment monitoring and data validation. Training sessions will be conducted by 10APR2025.

All actions will be documented and reviewed for compliance with GMP standards, ensuring alignment with regulatory requirements and maintaining product quality integrity.