Deviation Report

Record ID: DEV_20250812_211637 **Generated:** August 12, 2025 09:17 PM

Report Information

TITLE:	Lasair particle monitoring equipment stopped recording results after first 400L sample	**PRIORITY:**	MAJOR
STATUS:	In Progress	**DEVIATION TYPE:**	Equipment
DATE OF OCCURRENCE:	March 21, 2025	**DEPARTMENT(S):**	QA
BATCH/LOT NUMBER:	1000023	**QUANTITY IMPACTED:**	400L
PLANNED DEVIATION:	No	**INITIATOR:**	Cl

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 March 21, 2025, the Lasair particle monitoring equipment failed to record results after the first 400L sample for Batch/Lot 1000023. The printout displayed "invalid" without any alerts or alarms, impacting a total of 400L. The issue was identified by the Quality Assurance (QA) department. The equipment sampled continuously from 0838 to 1631, but no particle quantification was recorded.

Event Timeline

- March 21, 2025, 0838: Lasair particle monitoring equipment began sampling.
- March 21, 2025, First 400L sample: Equipment recorded results.
- March 21, 2025, Post first 400L sample: Equipment printout displayed "invalid" with no particle quantification.
- March 21, 2025, 1631: Sampling concluded.

Root Cause Analysis

Root cause investigation focuses on the following areas based on the deviation details:

- Equipment: Lasair particle monitoring equipment requires review of data recording and alert system functionality.
- Process: Sampling process needs evaluation of data validation and recording protocols.
- Personnel: Review operator's adherence to equipment monitoring SOPs for compliance.

⚠ Impact Assessment

- Product Quality: Lack of particle quantification raises concerns about potential contamination.
- Batch Disposition: The batch requires additional testing for particle count to ensure compliance with quality standards.
- Risk Level: Classified as Major due to potential impact on product quality and compliance with regulatory standards.
- Other Batches: No immediate risk identified for other batches as the issue appears isolated to this specific sampling event.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine Batch 1000023 pending further investigation and testing.
- Halt use of Lasair particle monitoring equipment until functionality is verified.
- Initiate immediate sampling for particle count testing on the affected batch.

Corrective Actions:

- Recalibrate Lasair particle monitoring equipment to ensure accurate data recording.
- Conduct a thorough review and update of the sampling process to include data validation checks.
- Retrain operators on equipment monitoring and SOP compliance to prevent recurrence.

Preventive Actions:

- Implement automated alerts for data recording anomalies in the Lasair system.
- Revise SOPs to include mandatory double verification of equipment functionality before sampling.
- Establish additional in-process controls for continuous monitoring of particle count data integrity.