Deviation Report

Record ID: DEV_20250808_035305 **Generated:** August 08, 2025 03:54 AM

Report Information

Title:	Lasair particle monitoring equipment stopped recording results after first sample	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Equipment
Date of Occurrence:	March 21, 2025	**Department(s):**	QA
Batch/Lot Number:	10000056	**Quantity Impacted:**	full batch
Planned Deviation:	No	**Initiator:**	Clara-Lea

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 in the QA department stopped recording results after the first 400L sample was taken for Batch/Lot 10000056. The printout indicated "invalid" without any alerts or alarms, affecting the entire batch. The equipment sampled continuously from 0838 to 1631 on the same day, but no particle quantification was recorded. The current status requires investigation to determine the root cause.

Event Timeline

- March 21, 2025, 0838: Lasair particle monitoring equipment began sampling.
- March 21, 2025, after first 400L sample: Equipment stopped recording results, printout showed "invalid."
- March 21, 2025, 1631: Equipment continued sampling until this time without recording particle quantification.

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 functionality and printout validation processes.
- Process: Sampling process needs evaluation of data integrity and equipment calibration parameters.
- Personnel: Review operator actions for compliance with equipment operation SOPs, particularly regarding monitoring and response to equipment status.

Investigation will use Fishbone diagram to identify the root cause.

⚠ Impact Assessment

- Product Quality: Lack of particle quantification may compromise product sterility assurance.
- Batch Disposition: The batch requires additional testing for particle contamination to ensure compliance with quality standards.
- Risk Level: Classified as Major due to potential impact on product sterility and compliance with regulatory requirements.
- Other Batches: No immediate risk identified for other batches, as the issue is isolated to the specific equipment and batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine Batch/Lot 10000056 pending further investigation and testing.
- Stop the use of Lasair particle monitoring equipment until functionality is verified.
- Initiate sampling for particle testing on affected batch to assess quality impact.

Corrective Actions:

- Recalibrate Lasair equipment and verify data recording functionality.
- Conduct a thorough review and retraining of operators on equipment operation SOPs.
- Implement a comprehensive review of the sampling process to ensure data integrity.

Preventive Actions:

- Add automated alarm for data recording anomalies in Lasair equipment.
- Revise SOP to include mandatory verification of equipment status and printout validation before and after sampling.
- Implement additional in-process control checks to detect equipment malfunctions early.