

Deviation Report

Record ID: DEV_20250808_133557 **Generated:** August 08, 2025 01:36 PM

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):	Not specified
Batch/Lot Number:	1000062	Quantity Impacted:	whole 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 failed to record results after the first 400L sample during continuous sampling from 08:38 to 16:31. The printout displayed "invalid" without alerts or alarms, impacting the entire batch 1000062. The deviation was identified by the Quality department and currently affects the whole batch.

Event Timeline

- March 21, 2025, 08:38: Lasair particle monitoring equipment began sampling.
- March 21, 2025, after first 400L sample: Equipment stopped recording results.
- March 21, 2025, 16:31: Sampling concluded with "invalid" printout and no 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 and alert systems to identify any malfunctions or failures.
- Process: The sampling process needs evaluation of data integrity and validation procedures to ensure accurate recording and reporting.
- Personnel: Review the actions taken by operators during the sampling process for compliance with relevant SOPs, particularly regarding equipment monitoring and troubleshooting.

Impact Assessment

- **Product Quality:** The lack of particle quantification data raises concerns about potential contamination and product quality assurance.
- **Batch Disposition:** Batch 1000062 requires additional testing to verify particle levels and ensure compliance with quality standards.
- **Risk Level:** Classified as Major due to the potential impact on product quality and the need for additional testing.
- **Other Batches:** No immediate risk identified to other batches as this deviation is specific to the equipment and process used for batch 1000062.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine batch 1000062 pending further investigation and testing.
- Stop the use of the Lasair particle monitoring equipment until it is inspected and verified for proper function.
- Initiate sampling for additional testing to assess particle levels in batch 1000062.

Corrective Actions (address this event):

- Recalibrate and validate the Lasair particle monitoring equipment to ensure accurate data recording.
- Conduct a thorough review of the sampling process and retrain operators on equipment monitoring and troubleshooting procedures.

Preventive Actions (prevent recurrence):

- Implement an automated alarm system for the Lasair equipment to alert operators of data recording issues.
- Revise SOPs to include a double verification step for data integrity during the sampling process.
- Schedule regular maintenance and validation checks for the Lasair particle monitoring equipment to prevent future deviations.