

Deviation Report

Record ID: DEV_20250808_191221 Generated: August 08, 2025 07:14 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:	1000076	QUANTITY IMPACTED:	400L
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 ceased recording results after the first 400L sample was taken, as indicated by the data printout. The instrument sampled continuously from 08:38 to 16:31 on the same day, but the printout displayed "invalid" with no alerts or alarms and lacked particle quantification. This deviation impacted Batch/Lot 1000076, affecting 400L of product. The issue was identified by the Quality Assurance (QA) department.

Event Timeline

- March 21, 2025, 08:38: Lasair particle monitoring equipment began sampling.
- March 21, 2025, after first 400L sample: Equipment stopped recording results on the printout.
- March 21, 2025, 16:31: Sampling concluded, but printout showed "invalid" with 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 system functionality.
- Process: Sampling process needs evaluation of data integrity and validation procedures.
- Personnel: Review operator's compliance with equipment operation SOPs for potential procedural lapses.

⚠ Impact Assessment

- Product Quality: Lack of particle quantification raises concerns about potential contamination levels in the 400L sample.
- Batch Disposition: The batch requires additional testing to verify particle levels and ensure compliance with quality standards.
- Risk Level: Classified as Major due to potential impact on product quality and lack of data integrity.
- Other Batches: No immediate risk to other batches identified, as the issue appears isolated to the specific equipment and batch.

CAPA Plan

Immediate Actions (24-48 hours):

- Quarantine Batch/Lot 1000076 pending further investigation.
- Halt use of the Lasair particle monitoring equipment until functionality is verified.
- Initiate additional particle testing on the affected 400L sample.

Corrective Actions:

- Recalibrate the Lasair particle monitoring equipment to ensure accurate data recording.
- Conduct a thorough review and update of the equipment's data logging and alert systems.
- Retrain operators on the correct procedures for equipment operation and data verification.

Preventive Actions:

- Implement an automated alarm system for data recording failures in the Lasair equipment.
- Revise SOPs to include mandatory double verification of data integrity during sampling.
- Schedule regular maintenance and validation checks for all particle monitoring equipment to prevent recurrence.