

Deviation Report

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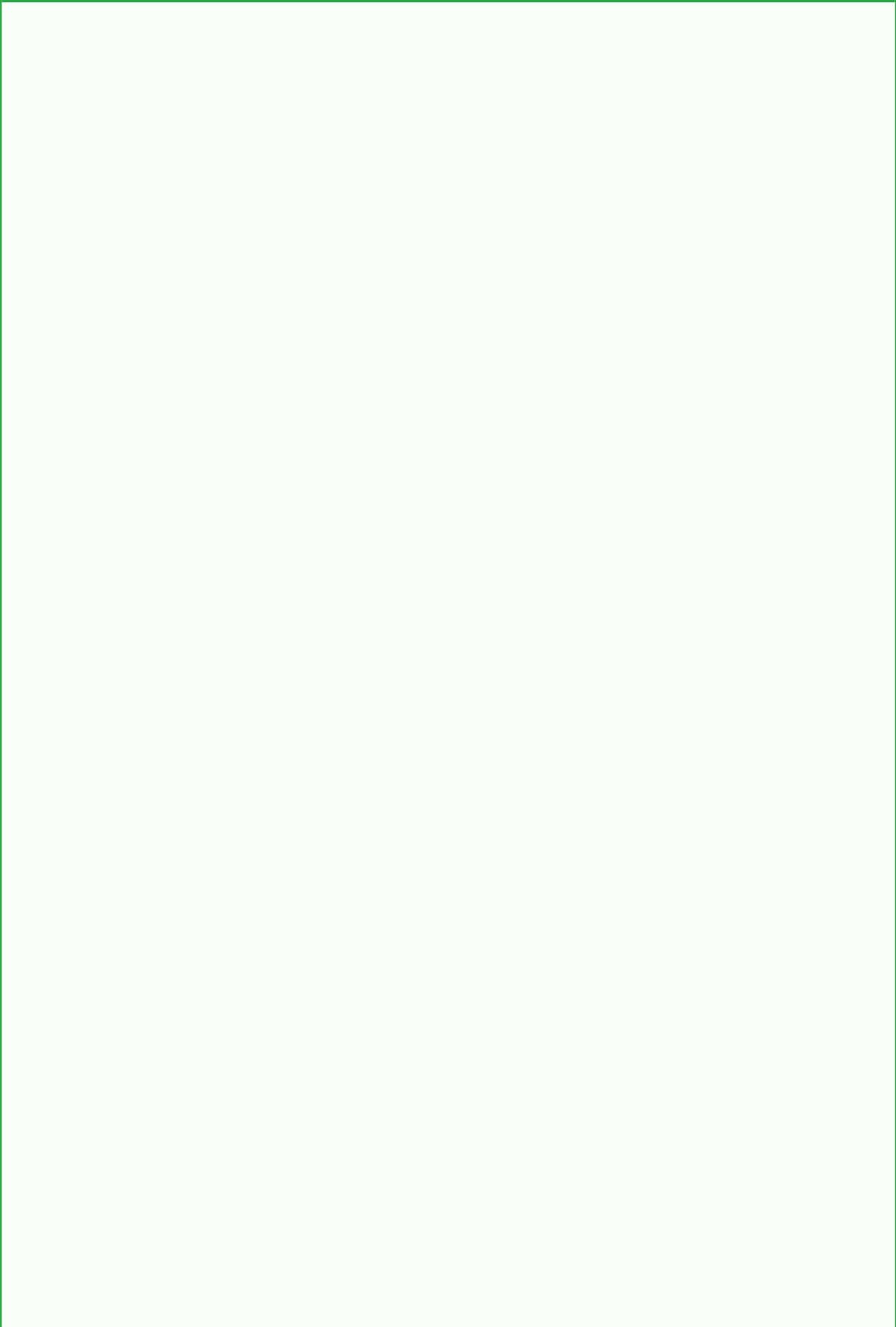
Deviation Information			
Title:	WFI Malfunction	Priority:	Minor
Status:	Open	Deviation Type:	Equipment
Date of Occurrence:	March 29, 2025	Department(s):	QA
Batch/Lot Number:	0	Quantity Impacted:	0
Planned Deviation:	No		

Deviation Description

Original Description:

On 29MAR2025, it was observed that the WFI skid pump was not operational on Additional details: established levels the WFI system cut off to reduce any possible damage.

AI-Enhanced Technical Analysis



Enhanced Analysis of Deviation: WFI Skid Pump Inoperability

#1. Technical Assessment with Regulatory Context

On March 29, 2025, the WFI (Water for Injection) skid pump was found to be non-operational. This incident is critical as WFI is essential for maintaining the sterility and quality of pharmaceutical products. According to 21 CFR Part 211, particularly §211.100, all components of the manufacturing process must be controlled to ensure that drug products meet their established specifications. The failure of the WFI system necessitates a thorough investigation to determine the root cause of the pump's inoperability and assess whether it has impacted the quality of any batches produced during the downtime. The investigation should also include a review of the system's maintenance logs and any previous deviations related to the WFI system.

#2. Potential Quality Impact

The inoperability of the WFI skid pump poses a significant risk to product quality. WFI is critical for the preparation of sterile products, and any interruption in its availability could lead to the use of non-sterile water, potentially compromising product sterility and safety. If the WFI system was down during the production of any batches, there is a risk of contamination, which could lead to product recalls or adverse events. A thorough assessment of the batches produced during this time is essential to evaluate the potential impact on product quality.

#3. Regulatory Compliance Implications

Failure to adequately investigate this deviation and implement corrective actions could result in non-compliance with FDA regulations, specifically 21 CFR Part 211. This could lead to regulatory actions, including warning letters, fines, or product recalls. Compliance with the regulations requires a documented investigation, including root cause analysis and corrective actions, to ensure that similar issues do not recur.

#4. Key Investigation Points

- **Root Cause Analysis:** Investigate why the WFI skid pump was non-operational. Review maintenance records, operational logs, and any alarms or alerts that may have been triggered.
- **Impact Assessment:** Determine if any batches were produced using WFI during the downtime. Assess the sterility and quality of these batches.

• **Historical Review:** Examine previous incidents involving the WFI system.

- **Corrective Actions:** Document and implement corrective actions to address the root cause and prevent recurrence. This may include equipment upgrades, enhanced maintenance protocols, or staff training.
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Immediate Actions

Original Response:

Monday, 31MAR2025. Review of system showed that a water valve was not fully

AI Assessment of Immediate Actions

- .. **Isolate the Equipment:** Immediately shut down the WFI skid pump and any associated systems to prevent further use and potential contamination. Clearly label the equipment as "Out of Service" to prevent accidental operation.
- .. **Notify Relevant Personnel:** Inform the Quality Assurance (QA) team, Maintenance, and Production Supervisors about the deviation. Ensure that all relevant stakeholders are aware of the situation to coordinate a response.
- .. **Conduct a Preliminary Investigation:** Assign a team to investigate the cause of the pump failure. Document the initial observations, including time of failure, operational parameters prior to the incident, and any maintenance history. Preserve any logs or records related to the pump's operation.
- .. **Perform a Risk Assessment:** Evaluate the potential impact of the pump failure on any ongoing processes or products. If any batches were affected, initiate a hold on those products and assess the quality implications.
- .. **Implement Temporary Workarounds:** If feasible, establish an alternative source

Risk Assessment Information

Initial Risk Assessment (User Input):

closed, which drained the holding tank. Once the tank water level was below

AI Risk Assessment

Risk Assessment for Pharmaceutical Deviation

Deviation: On 29MAR2025, it was observed that the WFI skid pump was not operational.

Type: Equipment

Quantity Impacted: 0

Product Quality Risk: Medium

Justification: While the pump was not operational, no product was impacted as indicated by the quantity impacted being zero. However, the potential for future product quality issues exists if the pump failure is not addressed, as WFI (Water for Injection) is critical for maintaining the quality of pharmaceutical products.

Patient Safety Risk: Low

Justification: Since no product was impacted and no batches were produced during the downtime, the immediate risk to patient safety is minimal. However, if the issue persists without resolution, it could lead to future risks.

Regulatory Risk: Medium

Justification: Regulatory bodies expect consistent operational performance of critical equipment like WFI systems. While there was no immediate impact on production or product quality, failure to address this deviation could lead to scrutiny during inspections or audits.

Overall Risk Level: Medium

Justification: The combination

Investigation Information

Investigation Assignee: Not assigned

Initiator: Clara

Investigation Results:

Investigation pending.

Final Conclusion:

Investigation in progress.