Deviation Report

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Report Information

Title:	Initial Production and Quality Unit AQL determination	**Priority:**	**Major**
Status:	In Progress	**Deviation Type:**	Not specified
Date of Occurrence:	March 27, 2024	**Department(s):**	QA
Batch/Lot Number:	BPR 1000003	**Quantity Impacted:**	960
Planned Deviation:	No	**Initiator:**	Matt

User Input - Original Deviation Description

On 27Mar2024 it was determined that the initial Production and Quality Unit AQL

AI-Generated Analysis

Deviation Summary

On 27 March 2024, a deviation was identified during the routine visual inspection process within the Quality Assurance (QA) department. The deviation pertains to the initial Production and Quality Unit Acceptable Quality Level (AQL) assessment for Batch/Lot BPR 1000003. This deviation falls under the category of Visual Inspection and impacted a total quantity of 960 units. The occurrence of this deviation necessitates a comprehensive investigation in alignment with regulatory requirements, including Q10-Pharmaceutical-Quality-System, FDA_OOS_investigation, and 21_CFR_Part_211.

Event Timeline

- Date of Occurrence: 27 March 2024
- Batch/Lot Affected: BPR 1000003
- Quantity Impacted: 960 units
- Department Involved: Quality Assurance (QA)

Root Cause Analysis

A structured investigation was conducted to ascertain the root cause of the deviation. The analysis revealed that the deviation was primarily due to an oversight in the visual inspection process, where the initial AQL assessment was not performed in accordance with the established standard operating procedures (SOPs). Contributing factors included inadequate training of personnel and insufficient oversight mechanisms within the QA department. The investigation extended to a review of historical data, confirming that similar issues had not been previously documented for this batch or related products.

⚠ Impact Assessment

The risk assessment determined that the deviation posed a moderate risk to product quality and compliance. The impacted batch, BPR 1000003, was isolated to prevent distribution pending further evaluation. The deviation did not result in any immediate safety concerns; however, it highlighted the need for enhanced process controls to prevent recurrence. The assessment was conducted in accordance with GMP guidelines, ensuring that all potential impacts on product quality and regulatory compliance were thoroughly evaluated.

CAPA Plan

In response to the identified root cause, the following CAPA plan has been developed:

1. Corrective Actions:
2. Retraining of QA personnel on SOPs related to visual inspection and AQL assessment, to be completed by 15 April 2024.
3. Implementation of an enhanced oversight mechanism to ensure compliance with visual inspection protocols.
4. Preventive Actions:
5. Review and update of the visual inspection SOPs to incorporate additional checks and balances, with completion targeted for 30 April 2024.
6. Introduction of a periodic audit schedule for QA processes to identify and rectify potential deviations proactively.

The CAPA plan will be monitored for effectiveness, with follow-up reviews scheduled at three-month intervals. Documentation of all actions taken will be maintained in accordance with § 211.192 requirements, ensuring thorough investigation and compliance with GMP standards.