FDA Form 483: Inadequate Training of Visual Inspectors

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Auditee：Sterile and Non-Sterile Manufacturer

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OBSERVATION 3

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Your visual inspection process is inadequate. You depend on this inspection process to reject critical and major defects, including but not limited to units presenting with particles, seal integrity defects and xxx rejects, etc. Your visual inspection process is used to inspect finished products. Including xxx injection xxx mg/vial, xxx # xxx, approved xxx; and xxx injectable suspension xxx mg/vial, xxx # xxx.

Specifically,

A. Your visual inspection qualification kit lacked the defects for fibers, hair, and cosmetic vial defects such as air bubble, xxx defect, and chipped vial which are all included in the list of " Defects and the Rationale for the Kit Preparation", and required per the firm's Protocol, PB1/MI/0A055-07. titled "Preparation of Qualification Kits and Qualification of Visual Inspectors", dated 08 July 2023.

B. Your firm has established xxx visual inspection qualification kit which is used to qualify visual inspection operators during their initial visual inspection qualification and their xxx re-qualification. Using xxx kit repeatedly may allow operators to become familiar with the kit. Your firm reuses this xxx visual inspection defect kit xxx consecutive times, within a xxx period, on xxx.
   - Note: Kits expire and must be reprepared regularly. In general, it is necessary to periodically confirm the effectiveness of the defective kits. All representative defects from the production line should be included in these kits. If these defects need to be manufactured, they should be obtained from production (if available). These defects need to be classified
   - How long can I use the training kits?
   - The ECA's guidelines for visual inspection have the following answers：Training kits should contain all kind of defects and must be updated constantly with new evolving defects out of production. Expiry of specific defects depends on nature (a crack will not expire; small particles may clot together…). The set must be regularly released and reinspected by a supervisor.

C. You do not address inspection fatigue during the qualification and requalification of visual inspectors by testing under worst case conditions.

D. Discrepancies were observed in the qualification records for two visual inspectors. The end of test xxx overlapped with beginning of test xxx. For example:
   - Visual inspection initial qualification performed on 12 June 2023: The time for the xxx and the xxx test overlapped by xxx.

- Visual inspection initial qualification performed on 16 June 2023: The time for the xxx and the xxx test overlapped by xxx.
- The xxx visual inspectors performed visual inspection for the following two batches of xxx Injection, xxx mg/vial:
  - ☐ Batch# xxx, manufactured on 11 July 2023, and released to the U.S. Market on 25 Aug 2023.
  - ☐ Batch# xxx, manufactured on 20 July 2023, and released to the U.S. Market on 25 Aug 2023.
- Note: The overlapping time and whether the actual working hours meet the SOP, process specification or logic requirements are actually the so-called meta data audit trial in the audit trail.

E. Your process for the qualification of microbiologists for visual inspection of media fills is deficient, On 29 Apr 2023, microbiologists were qualified on xxx during xxx of xxx. Each microbiologist was qualified after identifying xxx defect vials in a total of xxx) medial fill vials. Per the firm's protocol PB1/M/OC 204-00, titled "Protocol for Qualification of Personnel for Visual Inspection of Media Fill Containers and Sterility Samples", effective date 22 Apr 2023. "Each microbiologist will be able to finish approximately xxx vials in xxx". The qualification of the xxx microbiologists would take at least xxx rather than xxx.

Source: FDA483: 異檢員培訓不足，包括(但不限於)缺陷套組不含毛髮缺陷品，初始缺陷套組一直長期使用，測試時間重疊等 (qq.com)