Inspection Strategies

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PDA
Parenteral Drug Association

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Inspection Strategies

Agenda

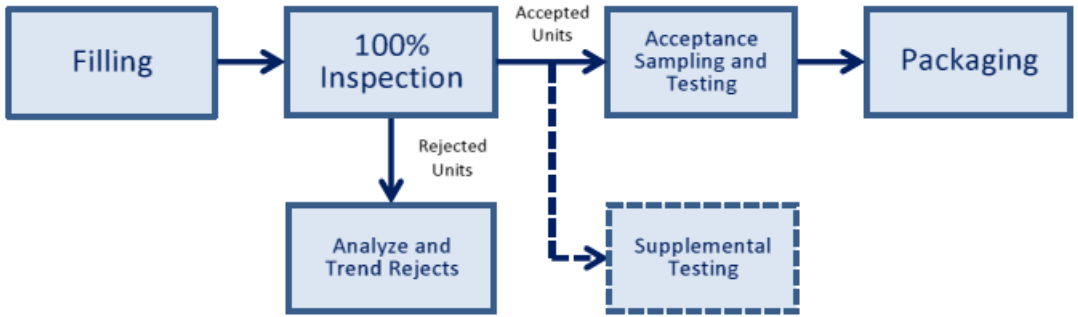
- Normal Inspection
- Sequential Inspection
- 2-Stage Process
- Re-Inspection Process
- Focused Inspection Process
- Empty Container Inspection

Normal Inspection

- Introduce product into inspection process
- Remove defects
- Classify defects
- Determine if batch is within the Maximum Allowable Defect Rate
  - e.g. Critical ~ 0.1%
  - Major ~ 3%
  - minor ~ 5%

Normal Inspection

- Perform AQL and check if limits are not exceeded
  - e.g. Critical ~ 0.1%
  - Major 0.65%
  - minor ~ 2-4%
- If no limits are exceeded the Inspection process is complete



Sequential Inspection Process

- A two-step process often a hybrid of an automated inspection (for some specific attributes, i.e. particulate) and a Manual Inspection for the remaining attributes of the product (container, product, closure, etc.)
- Also used in conjunction with Vial Integrity systems with manual inspection
- Using each method to their strengths
- Entire lot is inspected following the standard procedure which consist of at least to steps

Sequential Inspection Process

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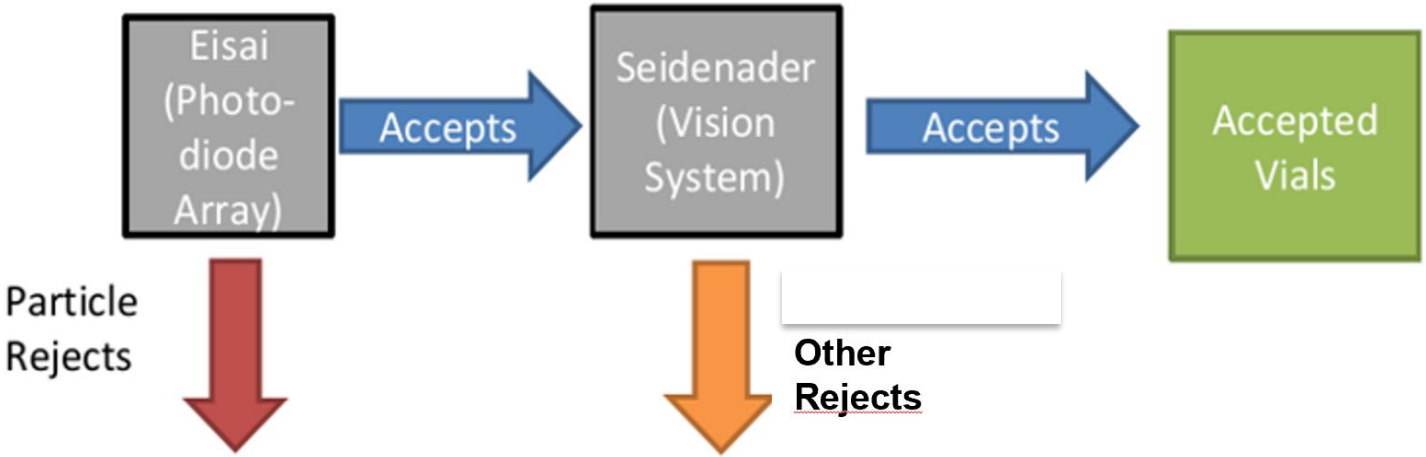
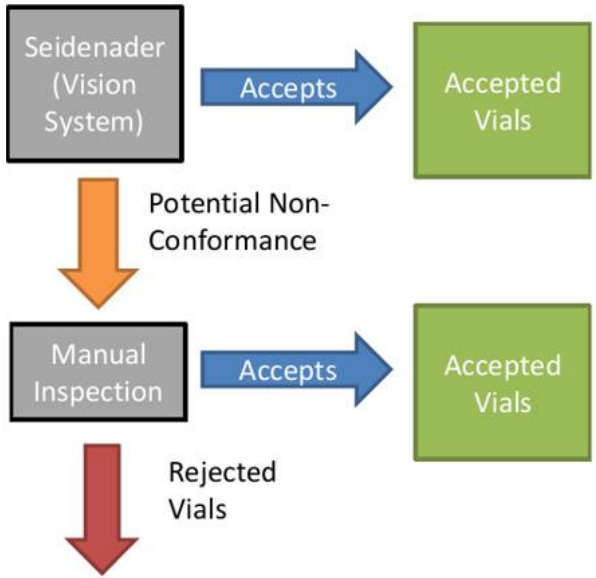


2-Stage Inspection Process

- A process to reduce mostly elevated false rejects from an automated inspection station
- Usually a two pass inspection system involves a second inspection of vials that were initially not accepted or uncertain
- First step machine inspection; Accepted units are sampled and assessed against AQL limits
- Second step with uncertain containers manual inspection. Accepted units are sampled and assessed against AQL limits
- Predefined/Approved as inspection process

2-Stage Inspection Process

- Adding in manual inspection to harvest vials falsely removed by the camera system.



2-Stage Inspection Process

- When is the inspection process complete?
  - Once all inspection steps are complete
  - All defects are identified, classified, and AQL is within acceptable limits

- Why is Re-evaluation performed
  - product cost
    - Some APIs are very expensive
    - More product available to the patient
  - over sensitive automated inspection process
    - Automated vision is conservative by design

Re-inspection Process

Re-inspection is a repeat of the normal inspection process when…

- AQL and/or Max Allowable Defect Limits are exceeded
  - Examples:
    - Critical ~ 0.1%
    - Major ~ 3%
    - Minor ~ 5%
- May be a response to an atypical finding impacting of Safety, Identity, Strength, Purity, Quality

Re-inspection Process

- Example:
  - Critical found post inspection (e.g. during packaging)
    - Deviation is written to investigate
    - Root cause/corrective action determined
    - Typically will not re-inspect if root cause is post inspection related
  - Tightened-AQL for this step might be appropriate

Focused Inspection Process

- Non-Routine process used to cull out an identified Critical or Major defect found during the normal inspection process (i.e. incomplete crimps, glass fragments, cracks) that exceeded either the AQL and/or the Maximum Allowable defect limit
- Used to 'focus' attention of the inspector on a specific attribute of the product/container
- Follow-up with additional AQL after inspection step

Focused Inspection Process

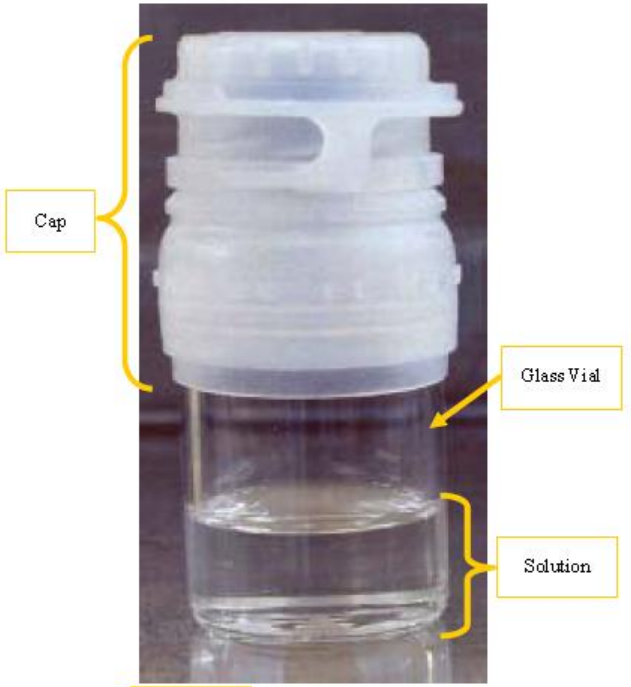
- Could be utilized with Automated and Manual or by Manual Inspection only
  - Focused on a specific portion of the container or product
- Pre-approved as a process variation through QO and Operations management
  - Will use specified inspection steps from overall inspection procedure
  - Limits/actions would be pre-approved by QO and Operations management for each incident

Empty Container Inspection

- Inspection process of product container (vial) before filling
  - Used when API is extremely expensive
  - Customer requested
  - Can be used in conjunction with Incoming Quality process to verify glass quality levels
  - Used when the capping process would inhibit the visual inspection process
    - ADD-Vantage vial presentations

Empty Container Inspection

Empty ADD-Vantage Vial



Filled Vial with cap

Questions?