

Inspection Strategies

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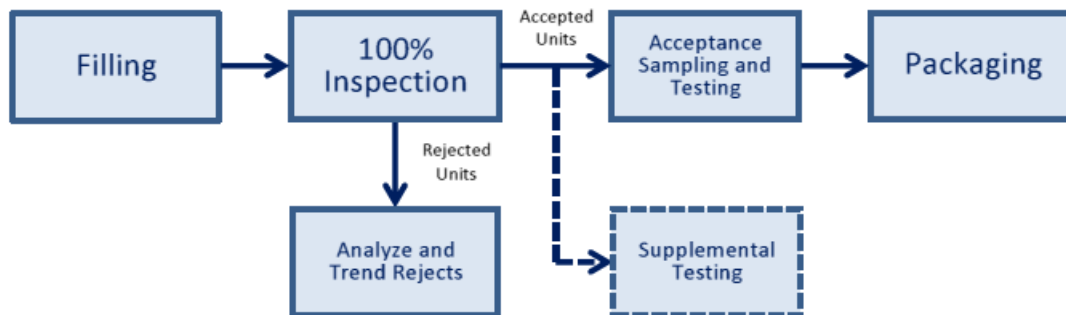


Agenda

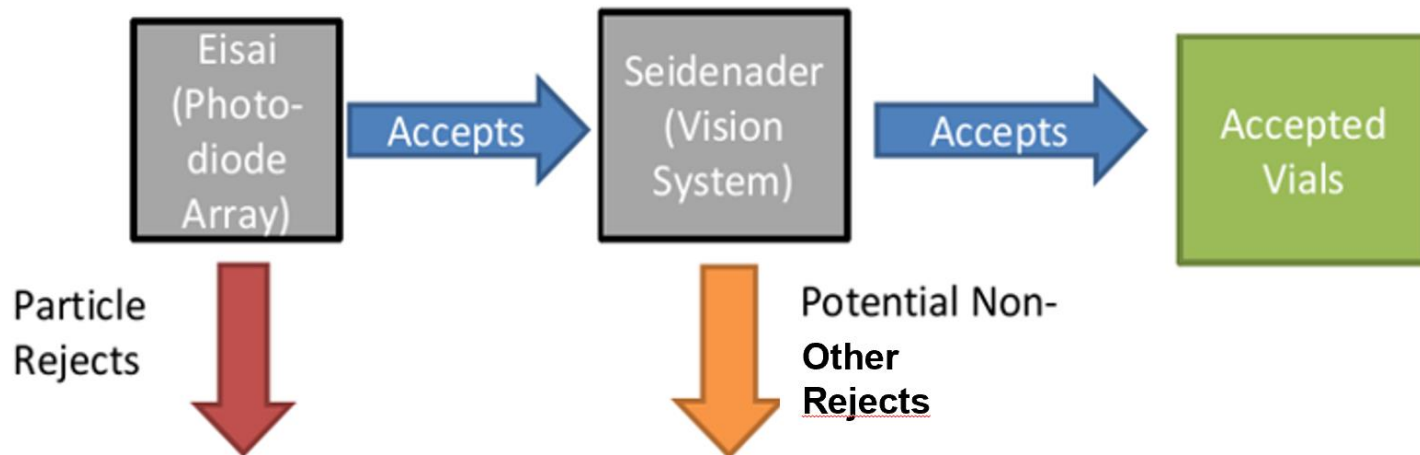
- Normal Inspection
- Sequential Inspection
- 2-Stage Process
- Re-Inspection Process
- Focused Inspection Process
- Empty Container Inspection

- 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%

- 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

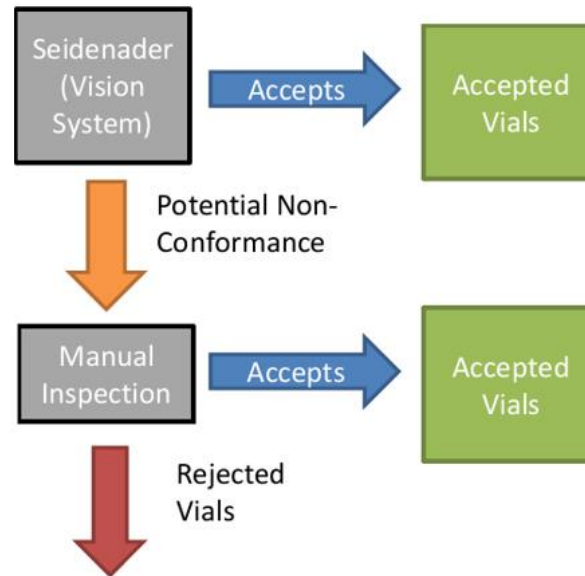


- A two-step process often a hybrid of an automated inspection (for some specific attributes, i.e. particulate) and a Manual Inspection for the remaining attributes of the product (container, product, closure, etc.)
- Also used in conjunction with Vial Integrity systems with manual inspection
- Using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



- 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

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



- 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 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

- 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



- 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

- 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

- 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 ADD-Vantage Vial



Filled Vial with cap

Questions?