



Inspection Strategies

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Inspection Strategies

Agenda

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



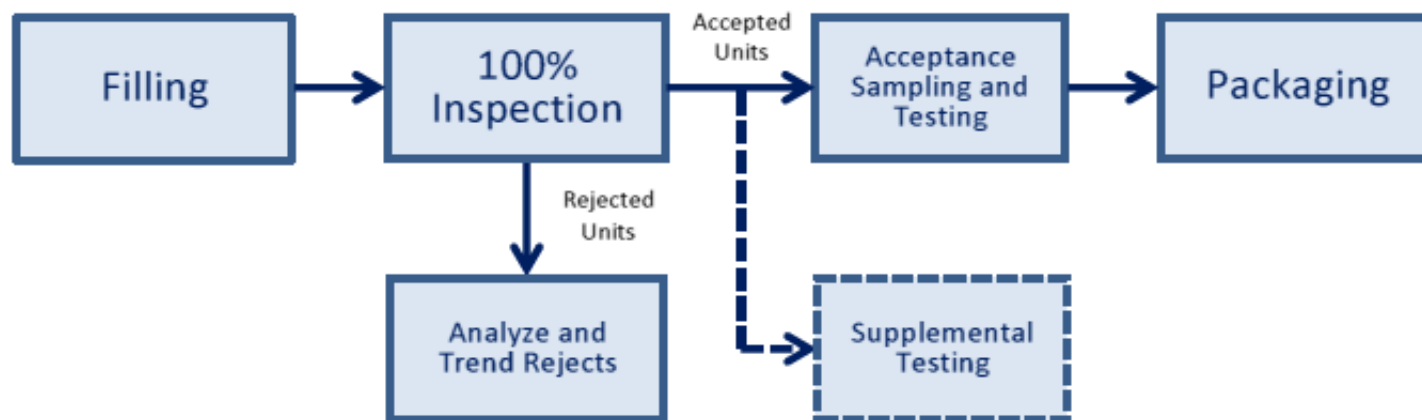
Normal Inspection

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



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
- If Limits are exceeded initiate investigation





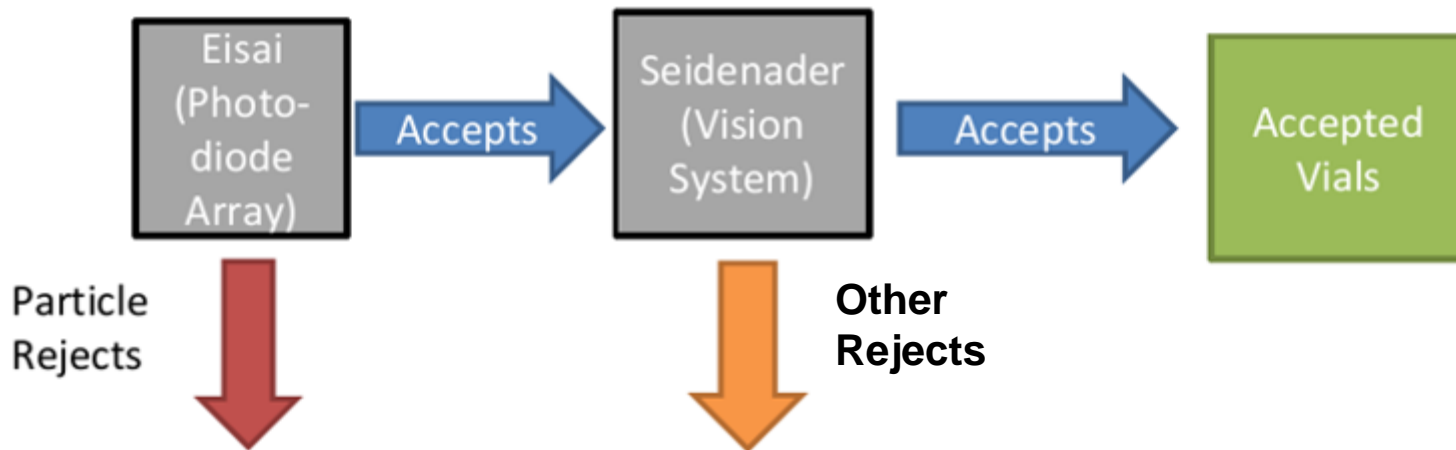
Sequential Inspection Process

- 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

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





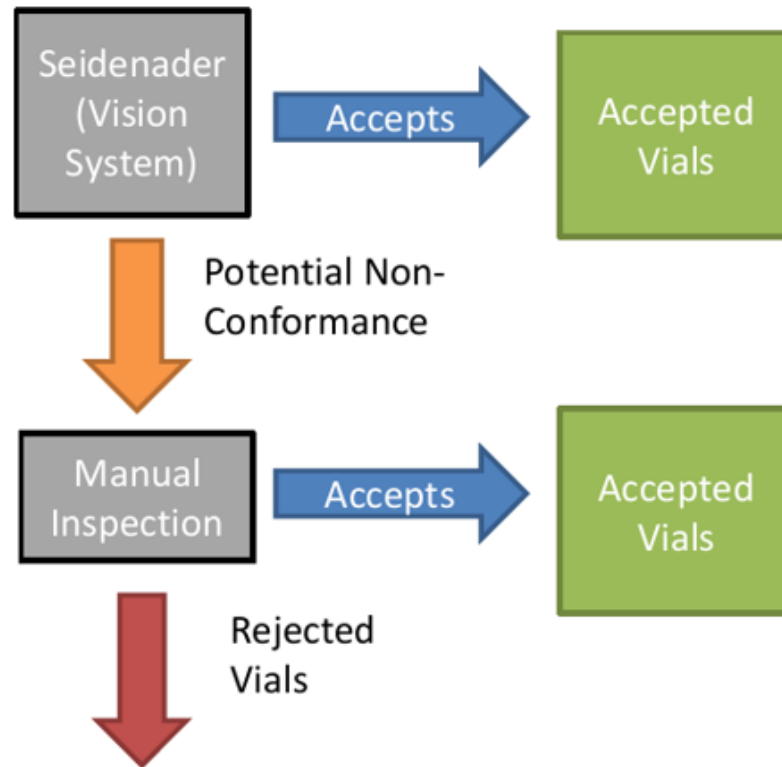
2-Stage Inspection Process

- 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 (i.e. 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
 - Some automated vision systems allow the ‘offending’ camera to be turned off inspecting all other attributes are then inspected leaving the focus attribute for manual
- 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

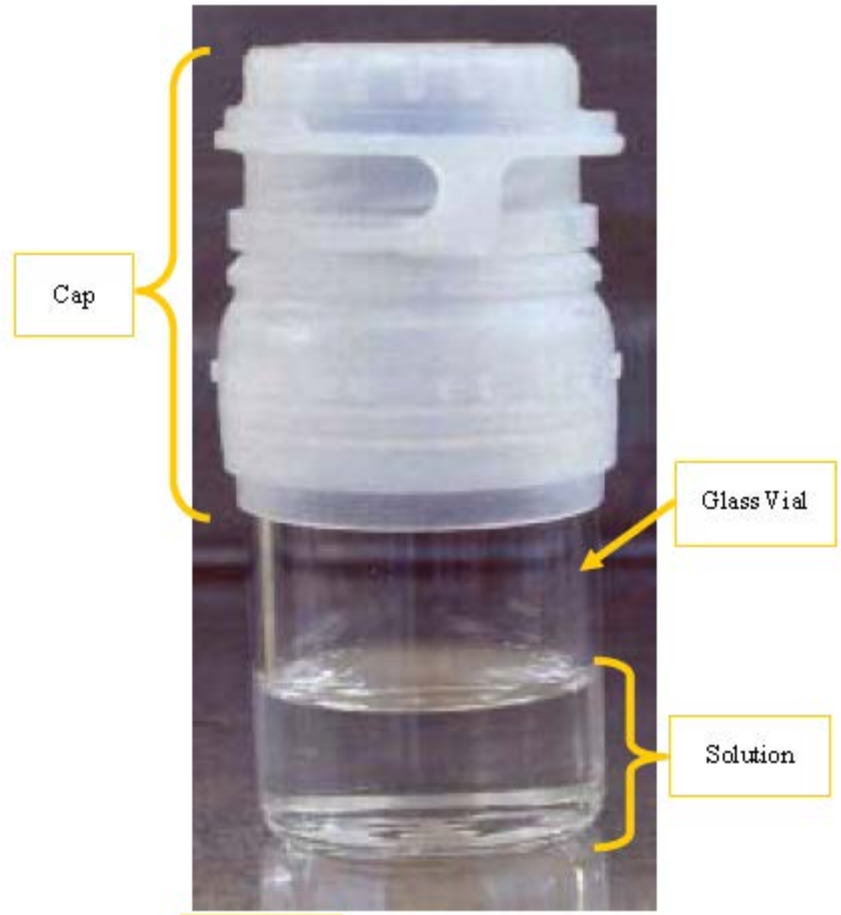
- Inspection process of product container (vial) before filling
 - Used when API is extremely expensive
 - Customer requested
 - Can be used in conjunction with Incoming Quality process to verify glass quality levels
 - Used when the capping process would inhibit the visual inspection process
 - ADD-Vantage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



Empty Container Inspection



Empty ADD-Vantage Vial



Filled Vial with cap



Questions?