Inspection Strategies

Markus Lankers, PhD
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markus.lankers@mibi-c.com

Inspection Strategies

Agenda

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

ML9

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%

ML9 stimmen die AQL werte s survey

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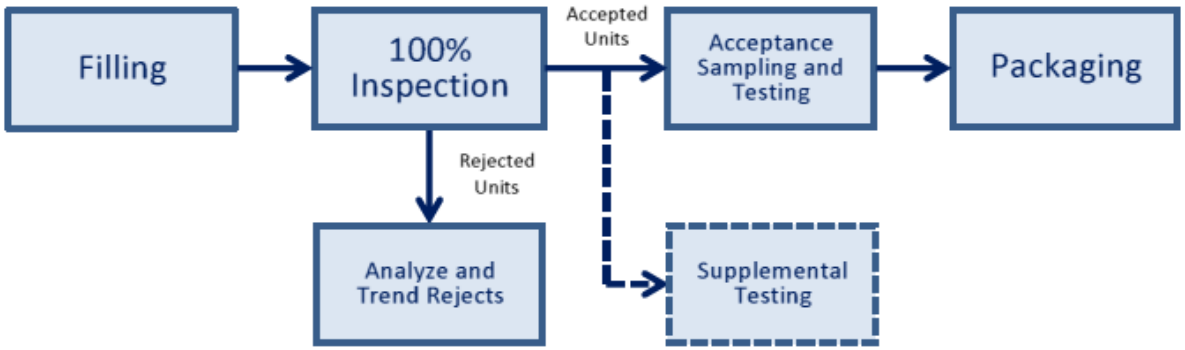
Normal Inspection

- 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



ML10 quellen 1790

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ML11

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 two steps

ML11 eigene worte bzw kürzer

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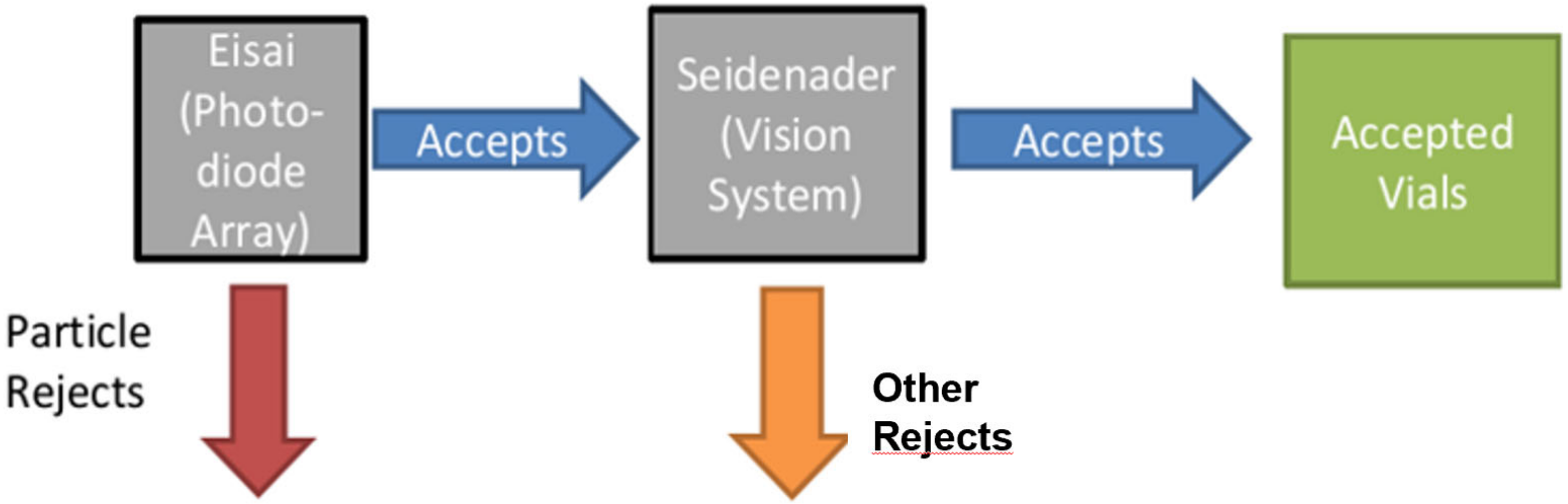
ML12

Sequential Inspection Process



ML12 quelle

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ML13

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 (tighter) limits
- Predefined/Approved as inspection process

ML14

ML13 explizit unterschied zwischen sequential and 2 stage formulieren
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ML14 GRafik vorziehen
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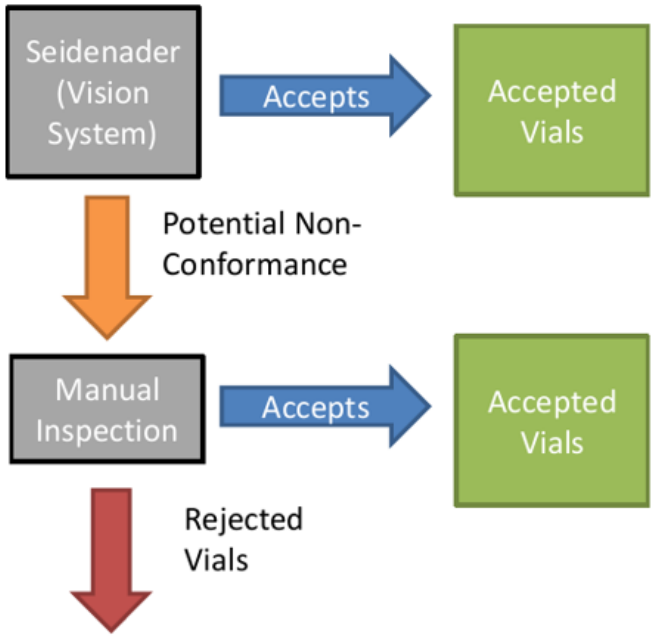
ML16

2-Stage Inspection Process

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

ML15
ML17



Folie 8

ML15 wording anpassen
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ML16 Markus Lankers; 04.04.2017

ML17 standard 2 stage formulieren
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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

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

ML18

ML18 besser formulieren

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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

- 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
  - Will use specified inspection steps from overall inspection procedure
  - Limits/actions would be pre-approved by QO and Operations management for each incident

ML19

Folie 13

ML19 aufeigene formulierung anpassen

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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

ML20 ev allgemeineres Beispiel

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Questions?