Preparing and qualifying the visual inspection defect kits

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Defect Kits

- Type of defect kits

- Challenges in preparing Defect kits

- Batch size of Defect kits

- What defects should be included?

- Qualification of defect kits

- Defect kit maintenance and expiry

Type of Defect kits (Based on preparing kits)

- **Naturally occurring defects**
  Taken from the actual defects observed in production
  - Represent the actual product and defects
  - Expiry is short
  - Need frequent inspection to verify its state of qualification
  - Types of defects knowledge is based on the defect knowledge of the site
  - Batch to batch variation

- **Intentionally created defects.**
  Created defects by an external laboratory or in-house laboratory
  - Not a true representation of actual rejects. Comparability studies needs to be performed.
  - Creating defects ensures all defect types can be obtained at any point in time
  - Longer Expiry
  - Inspection frequency can be relaxed.
  - Types of defects knowledge is based on the overall defects in industry across sites
 - UV marking for easy identification of defects from inspected units

Type of Defect kits (Based on use)

Manual / Semi automated

- Visual Inspector's training

- Visual Inspector qualification

Automated inspection

- automated inspection development

- automated inspection setup

- automated inspection qualification

Set up

Qualification

Development / Training

Defect Kit
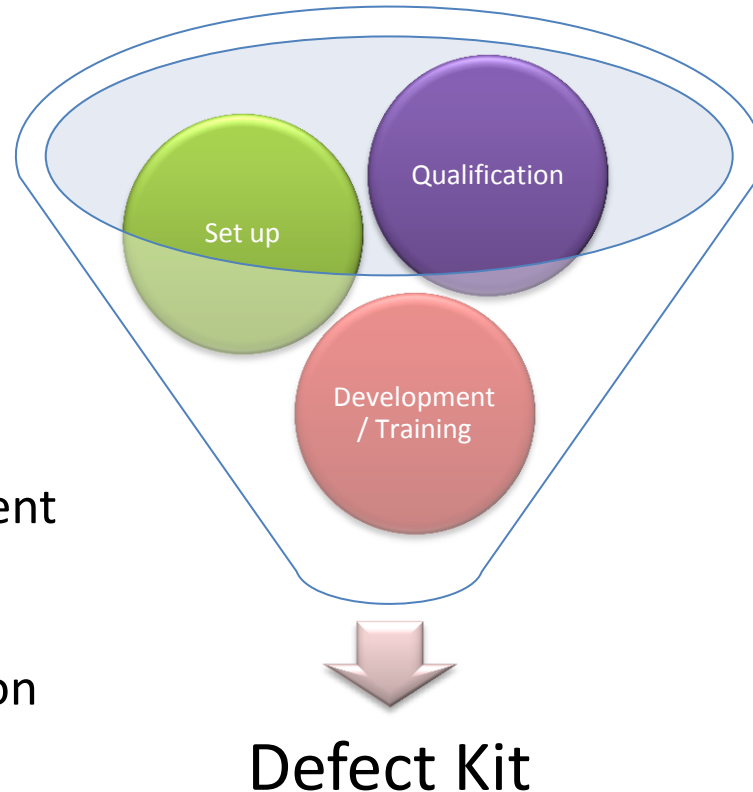
Selection of defect

Defect selection

Data analysis on deviations, complaints, production rejection trend to select the defects to be included in the defect library

Defect Test for each Unique Configuration?

Scientific Justification & Rationale Required

Factors for Bracketing
- Type of Container
- Size
- Fill Volume
- Typical Defect Type/Size
- Unique Product Characteristics-Emulsion/Suspension/Lyo
- Manufacturing Conditions-Equipment Setup, Filling Line Speed..etc.
- Inspection parameters-Equipment Setup/Solution Scan Time

Generally followed industry practice

Defect selection

Data analysis on deviations, complaints, production rejection trend to select the defects to be included in the defect library

Qualification Kit

- Batch size to complete full inspection between two eye rest

- Having 5-20% defect containers mixed with acceptable containers

- Defect distribution

    - Critical   : 5-7%

    - Major   : 3-7%

    - Minor   : 2-6%

Total 10% rejects

Set-up kit

- Having 80% defect containers mixed with acceptable containers

Defect Kit : Particles size

- Lowest particle which can be seen by a unaided eye
  - The lowest detectable size for 20/20 human vision under controlled inspection conditions is generally accepted to be 50 μm.

- Should particle size be ~50μ?
  - The probability of detection for a single 50 μm particle is ~10%.

- This probability of detection increases to approximately:
  - 40% for a 100 μm particle
  - 70% for a 150 um particle
  - >80-90% for particles 200 μm and larger

- Particle size has to be of a size providing >70% detection probability

Defect Kit : Particles size
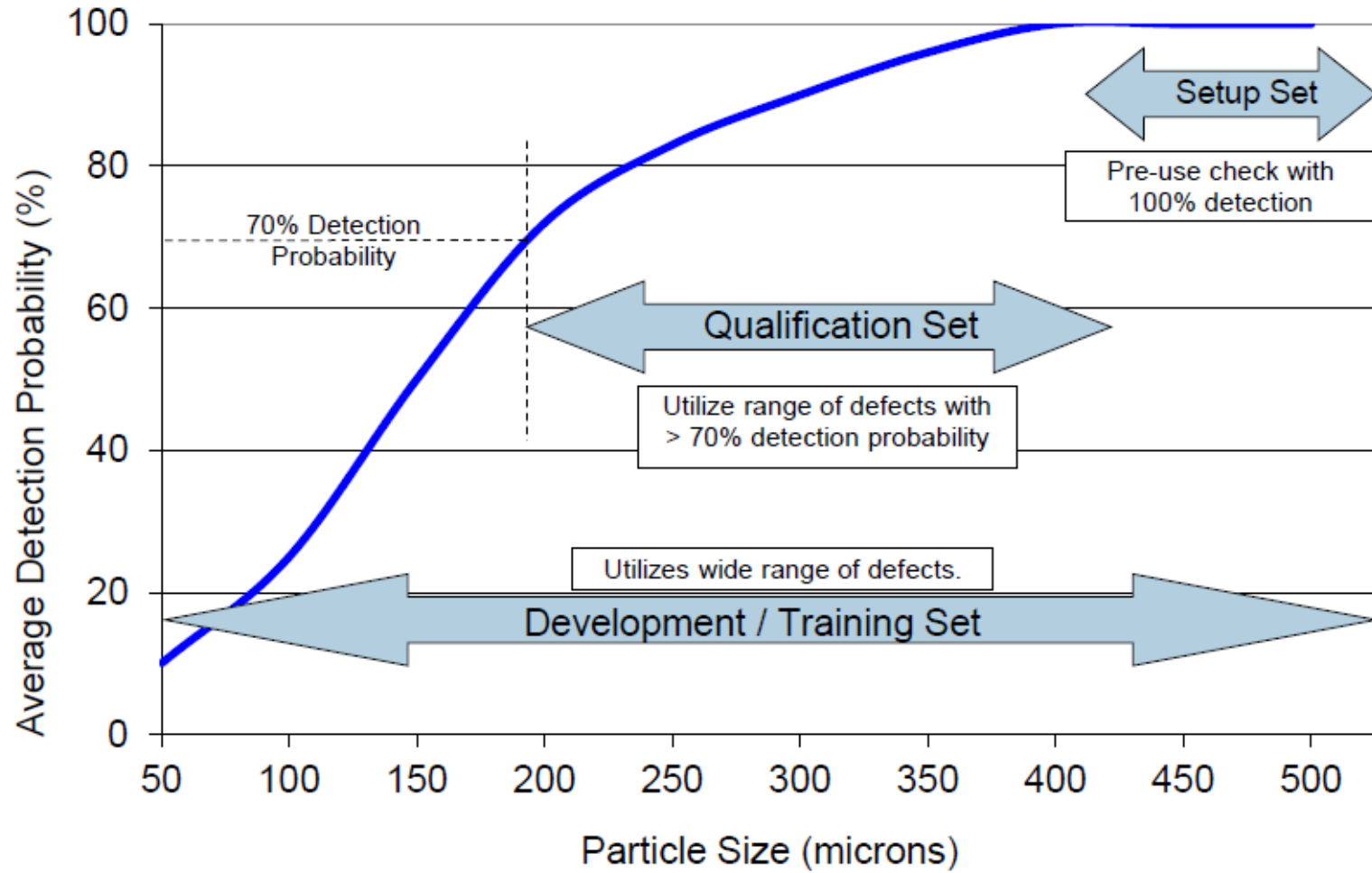
Qualification of defect kits

- Multiple inspections with a detection probability of >70%

- Qualified inspectors to be used for detection

- No. of inspectors should be more to remove operator to operator variability

- No. of inspections depend upon detection probability

    - Higher detection probability, lower multiple inspection

    - Lower detection probability, higher multiple inspection

    - Generally varies between 10-30 inspection

- Defect categorization should be uniform

- Sufficient inspector pool (person to person variability)

- Acceptable units should not be rejected or should have a probability of detection less than 30%

Defect kit maintenance

Defect sets are standards by which process is measured, they require careful maintenance!

- Should be ideally stored in the respective storage conditions for Naturally occurring defects

- Requalification is required frequently to ensure maintenance of detection probability

- Expiry to be defined

- Inspections prior to use to ensure the set is in good condition at all times

- Replacement and tracking of defects becomes damaged

Acceptance Criteria

100% defect identification by operator during qualification!! (Too stringent acceptance criteria)

- Guidance acceptance criteria
    - Detection of 100% of critical defects
    - Detection of ≥ 90% of major defects (For particulates)
    - Detection of ≥ 80% of minor defects

    - Also False Reject acceptance criteria is must. General acceptable value is LT 5%.
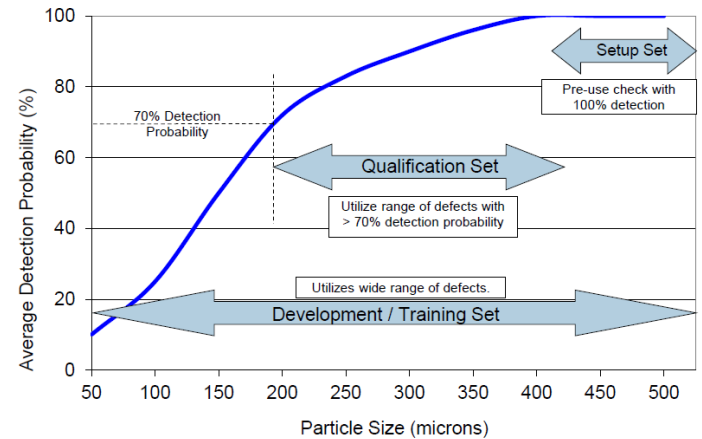
Key point

Defect kits

- Should be developed for each product/container family unless justified

- Units should not have extraneous markings (UV preferred) or defects present that may result in false rejection or rejection for something other than the target defect.

- Need to have clear procedures with detailed descriptions of containers utilized in defect sets

- Clear benefits in having specialized group or specially trained individuals make sets

- Well designed and maintained defect sets are required to have successful manual and automated inspection operations

- Created defected should be evaluated as it provides lot of advantages

Thanks