Inspector Selection and Qualification

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November 2025
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PDA
Parenteral Drug Association

CONNECTING PEOPLE SCIENCE AND REGULATION®

Topics

- Selection criteria
- Trainings process
- Test Kits
- Performance Monitoring
- Breaks

Manual Inspection

Objective of the Manual Inspection Process:

Detect and remove units of drug product with predefined defects in a reproducible manner in a controlled process

You have to know what your are looking for: Training is essential

Selection Criteria

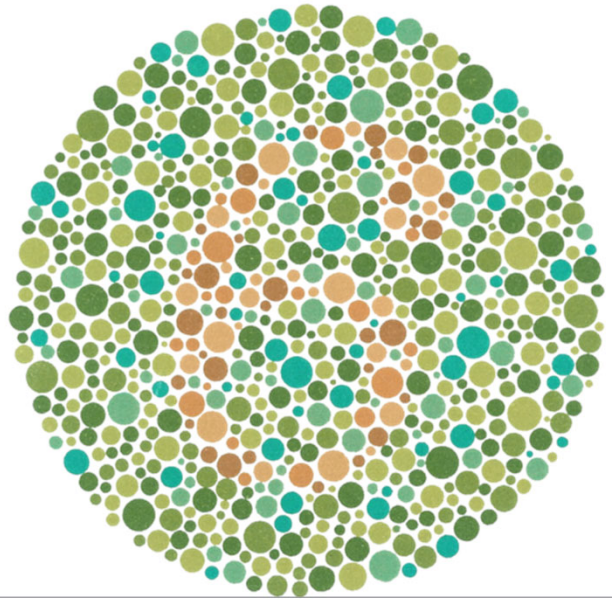
Prerequisites

- Pre-employment Health check
- Pre-employment eye test – requirement > 100 % corrected

All operators should have a near vision visual acuity / color blindness test prior to inspector training
For near vision. 14/14 (the ability to read what the average person can read at a distance at 14 in.)

Eye Test


J. G. ROSENBAUM POCKET VISION SCREENER
95
distance equivalent
874
2843
Point
Jaeger
26 16
638
14 10
8745
10 7
63925
8 5
6 3
5 2
4 1
3 1+
Card is held in good light 14 inches from eye. Record vision for each eye separately with and without glasses. Presbyopic patients should read thru bifocal segment. Check myopes with glasses only.



Selection Criteria

Character

The inspector should realize the importance of his task

The inspector should be able to perform repetive work

Ability to learn and adapt new ideas

The inspector should have good observation skills and should also be patient

483 Observations

Training

The training of personnel to perform the 100% visual inspection does not include:

b. Verification of operators abilities to detect defects at speeds used in production for the ….. sorting machines.
c. A provision for recertification.

a. Inspectors for final finished product vials are not provided the training to assure adequate abilities to detect particulates smaller than one millimeter.

Training of Visual Inspectors

ML2

1. Eye inspections are performed prior to employment and at least once annually
2. Training of relevant SOPs and Work-Instructions
3. Introduction to defects using training kits
4. Learning individual defects using training kits and defect libraries
5. **Qualification** as an inspector
6. **Requalification** once a year

ML2 dies ist eine Zusammenfassung

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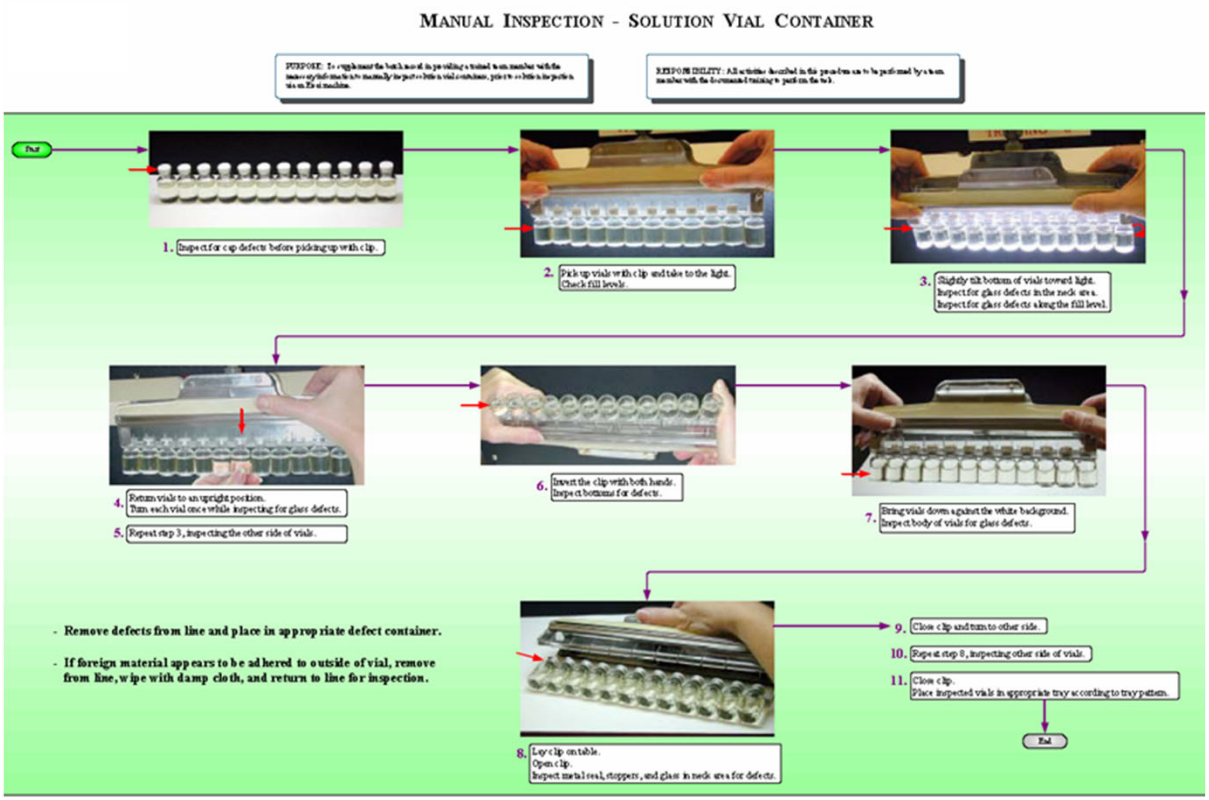
Inspection SOP

ML4



ML4 eigens Beispile

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Training of Visual Inspectors

ML3

Example Introduction

- All training is defined in a SOP
- Classroom instruction
- Product specific physical characteristics
- Small number of defect vials with large particles
- Introduce manipulation methods
- Move to real inspection station
- Practice manipulation, timing & detection
- Seeded containers no blanks – familiarization.

ML3 dies ist eine Zusammenfassung

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Training of Visual Inspectors

ML5

- Seeded containers diluted with blanks- familiarization.
- Distinguish particle types
- Distinguish bubble forming Drug Products.
- Use of tools (e.g. clip) Best inspectors offer 'tricks', methods, advice
- Visual inspection under supervision and 100 % re-inspection (T-o-J)
- Qualification using test kits
- Requalification once a year

ML5 dies ist eine Zusammenfassung

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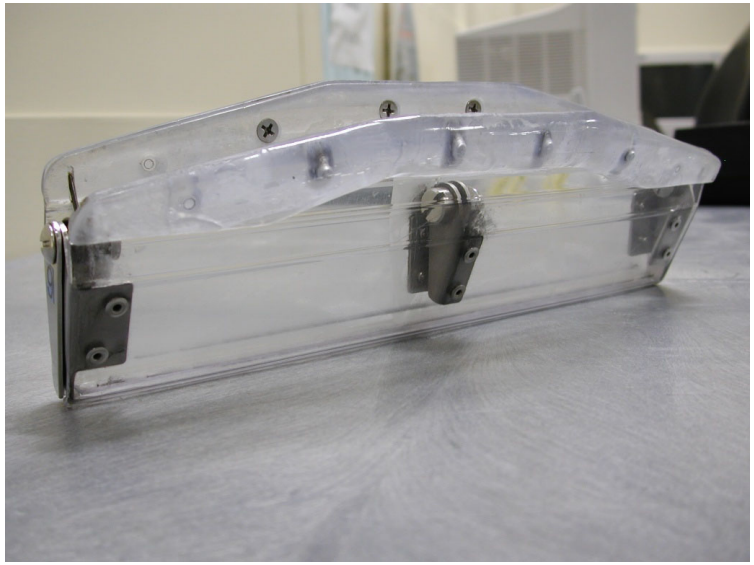
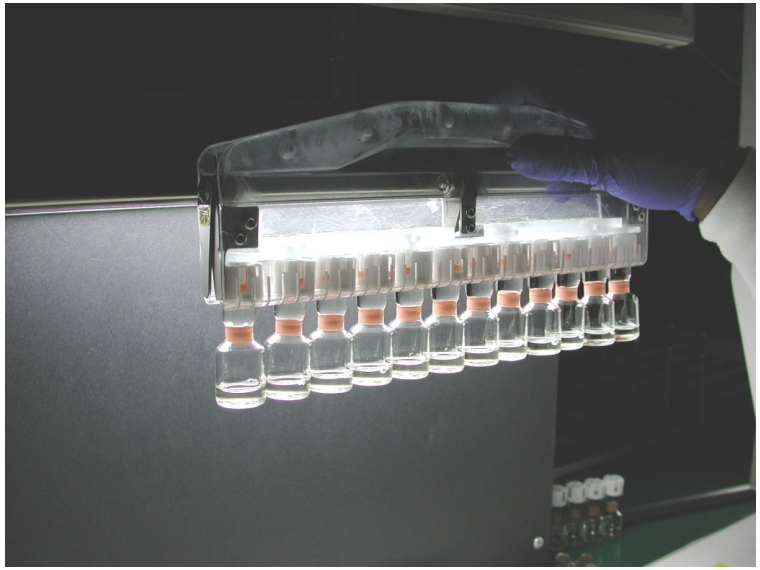
Training – Special Tools





Inspection
Clip

483 Observations

Defect set

a. *The type of particles/defects are not always representative of the current manufacturing process or reflective of complaints received which may be generated from the equipment, components and materials used in the manufacturing process.*

b. *Examples of particles in suspensions. The set of vials used in training includes only vials of clear solutions with particles.*

Test Kits

- Inspectors must demonstrate proficiency of removing defects from a seeded population of typical "in-house“ defects.
- Definition: **Defect library** : - “Bible” of observed defects for one product / Constant growing library
- **Test Kits**: - defects are selected from Defect Library. Multiple examples of known defects. Consider criticality
- Requirement for adding new defect types to the library refreshing the defect library/test kits and annual assessment.
- Test kit should contain 5-15 % rejects

ML7

ML7

defect kits für ein produkt

wieviel test kits

Größe

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Building Test Kits:

Points to consider

- Particle types, sizes and properties – Characterize the particles in your process
- Defect Library characterizations (knowledge)
- Define effect class: Critical, Major, Minor and particle types
- Take rejects from process (best source but not always available)
- For artificial defects consider:
  - Container properties: type, size, surfaces, etc.
  - Packaging components.
  - Liquid (physical) properties Inspection methods/techniques.

Survey 2023 Results

99% describe defects and inspection conditions in a written procedure.

The qualification conditions are:

- Simulated/Offline: 84%
- Actual Manufacturing: 33%
- Worst-case fatigue: 63%

89% use test kits to qualify inspectors.

These test kits are composed of:

- Production Defects: 76%
- Nonspherical Standards: 40%
- Spherical Standards: 30%

Test Kit: Example

Several test kits (3-10)

Representative defined defects from routine production and specifically prepared units

Kit is routinely checked after each test and annually

Qualification within manufacturing conditions

- Consider fatigue conditions
- Typically 3 qualification runs

Test Kit (Example):

400 vials with 40 rejects adjusted to RZE e.g. 90 %

acceptance criteria:

1 non detected critical

2 non detected major

4 non detected minors

< 20 rejected good pieces

Test Kits

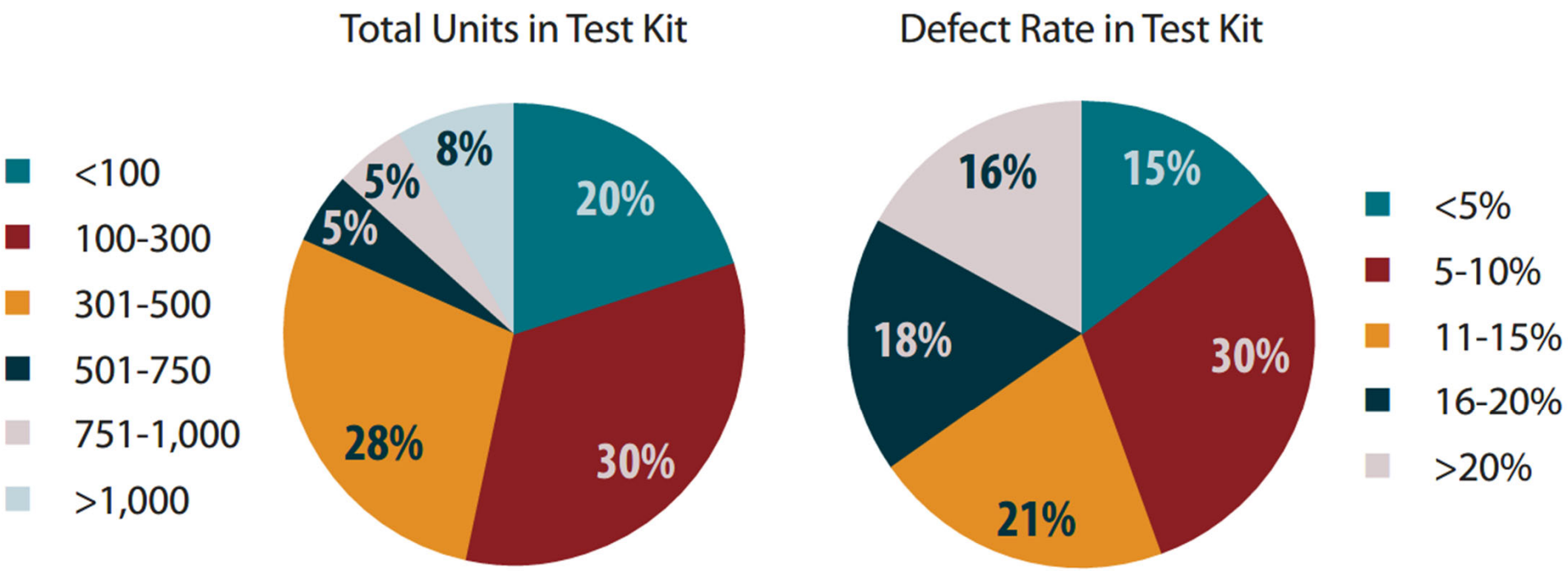
Time limits

Standard inspection period (~ 60 minutes for qualification run)

Test sets can be UV marked. However, some lighting conditions can lead to visibilty of UV marks. UV marks can be lost

An better alternative is the use of QR barcode

Composition of test kits to qualify inspectors



Test Kits

Training and Test-Kits are routinely cleaned after usage cleaned and inspected for defects at least every 6 months

	Description	Classification	Amount
Vial			
1	Underfill/Overfill	MA	4
2	Black particle	MA	2
3	Glass particle	C	2
4	Fiber	MA	5
5	Scratches outisde	m	3
6	Crack	C	4
7	Missing flip off cap	MA	2
8	Spots on rubber	m	2
9	Damaged closure component	C	4
10	Precipitation	C	3
11	Dirty container	m	2

Performance Maintenance & Monitoring

Tray Audit

- Evaluation for missed defects in inspected tray
- On-line immediate feedback after inspection
- A customized database is maintained
- Profile individuals, shift, or unit results
- The inspectors product trays are audited at a rate of 1 full each month making sure that each product is audited annually

ML8 jeder Punkt muss diskutiert werden

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Performance Maintenance & Monitoring

Procedure Audit

- Each inspector's inspection procedure is blindly audited to be sure that they are performing the correct inspection steps
- Confirm compliance to SOP
- Immediate feedback to inspector
- Each inspector is audited at a rate of 2 audits/week making sure that each product type is audited annually

Breaks

- Breaks help to keep inspector focuses
- Minimum of 5 minutes per hour eye break
- Eye break is defined as “time away from the lamp” and may include:
  - Break (i.e. lunch, …)
  - Change-over of batch/order
  - Discussions, trainings, etc.
  - Rotation to different products

Frequence of breaks

	2023	2014
Never	4%	2%
<30 min	4%	2%
30 min	26%	33%
45 min	6%	3%
60 min	46%	47%
2 hrs	12%	9%
4 hrs	2%	4%

66 % of the breaks are between 1-10 minutes