

Inspector Selection and Qualification

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



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



Prerequisites

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

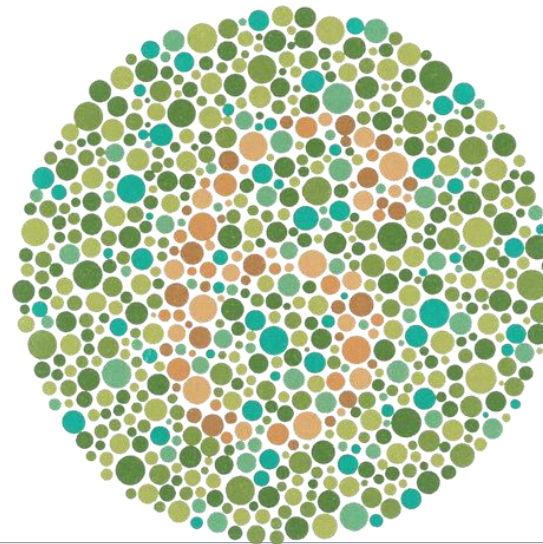
All operators should have a near vision visual acuity / color blindness test prior to inspector training
For near vision. 14/14 (the ability to read what the average person can read at a distance at 14 in.)



J. G. ROSENBAUM POCKET VISION SCREENER

95				distance equivalent
874				
2843	Point	Jaeger	$\frac{20}{400}$	
	26	16	$\frac{20}{200}$	
638 E W E X O O	14	10	$\frac{20}{100}$	
8 7 4 5 E M W O X O	10	7	$\frac{20}{70}$	
6 3 9 2 5 M E E X O X	8	5	$\frac{20}{50}$	
4 2 8 3 6 5 W E M O X O	6	3	$\frac{20}{40}$	
3 7 4 2 5 8 W W X X O O	5	2	$\frac{20}{30}$	
4 3 7 2 5 8 W W X X O O	4	1	$\frac{20}{25}$	
4 3 7 2 5 8 W W X X O O	3	1+	$\frac{20}{20}$	

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.





Character

The inspector should realize the importance of his task

The inspector should be able to perform repetitive work

Ability to learn and adapt new ideas

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



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.*

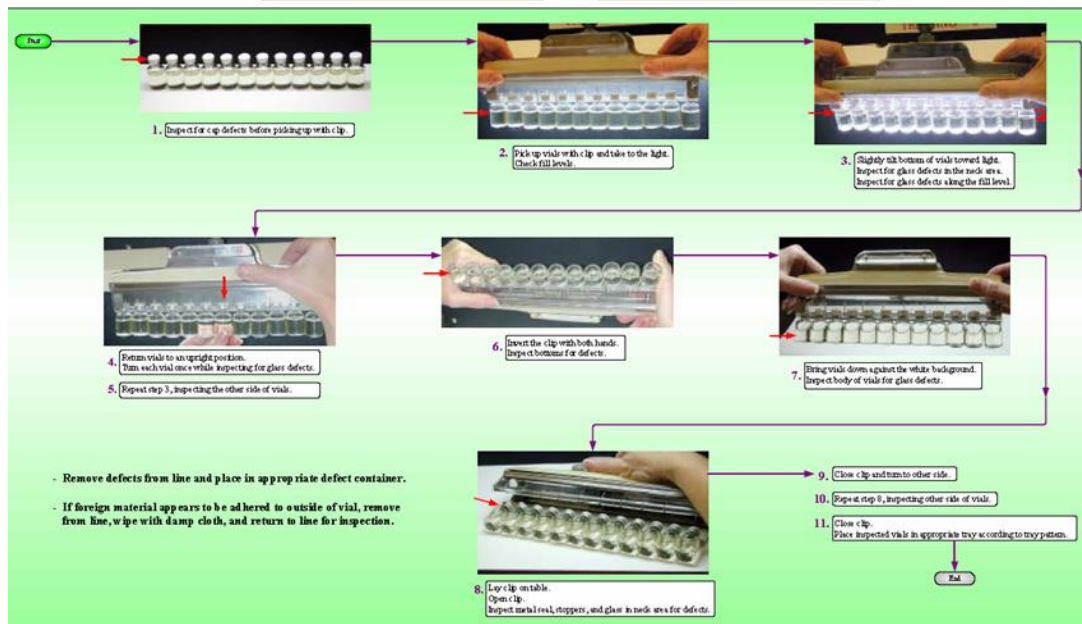
- a. Inspectors for final finished product vials are not provided **the training** to assure adequate abilities to detect particulates **smaller than one millimeter**.*

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

MANUAL INSPECTION - SOLUTION VIAL CONTAINER

PURPOSE: To recognize the look and feel of any vialing system to ensure vials are inspected manually by person or vial container, glass or plastic, as per the machine.

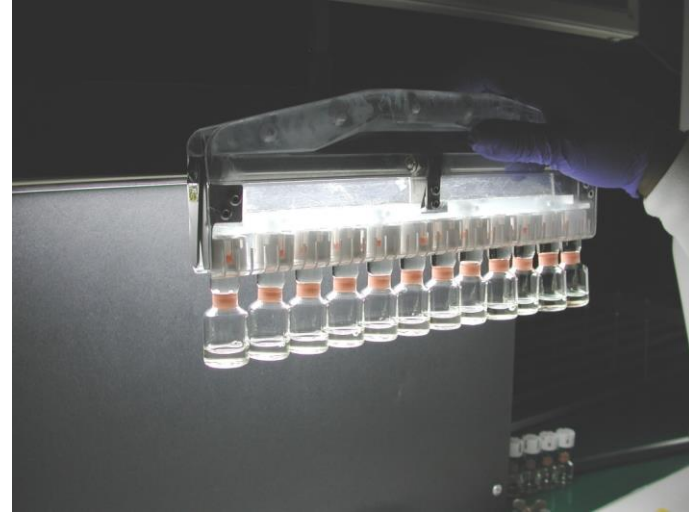
RESPONSIBILITY: All activities described in the procedure are to be performed by a person with the appropriate training to perform the job.



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.

- 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



Inspection
Clip



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.*

- 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

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.

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%

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



Time limits

Standard inspection period (~ 60 minutes for qualification run)

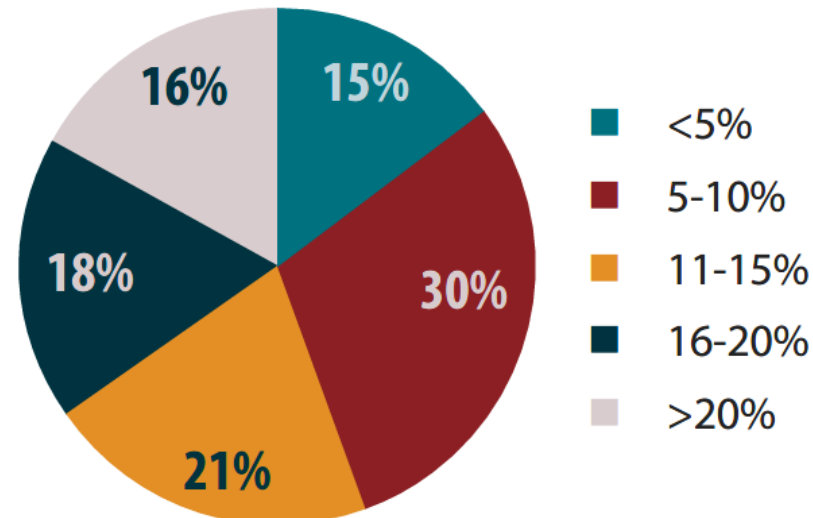
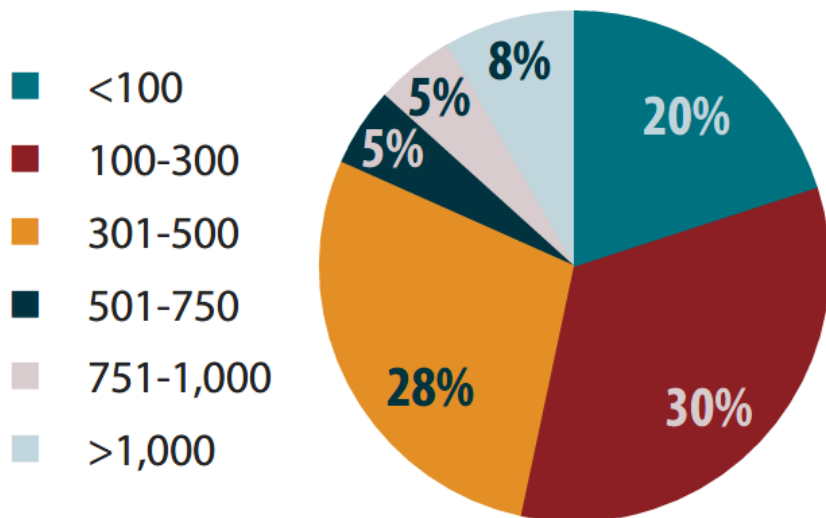
Test sets can be UV marked. However, some lighting conditions can lead to visibility of UV marks. UV marks can be lost

An better alternative is the use of QR barcode



Total Units in Test Kit

Defect Rate in Test Kit



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 outside			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



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

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 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

	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

- Georg Roessling
- Roy Cherris
- John Shabushnig