



Qualifying Visual Inspectors - The benchmarking process



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Topics

- Selection criteria
- Trainings process
- Test Kits
- Performance Monitoring of
Inspectors

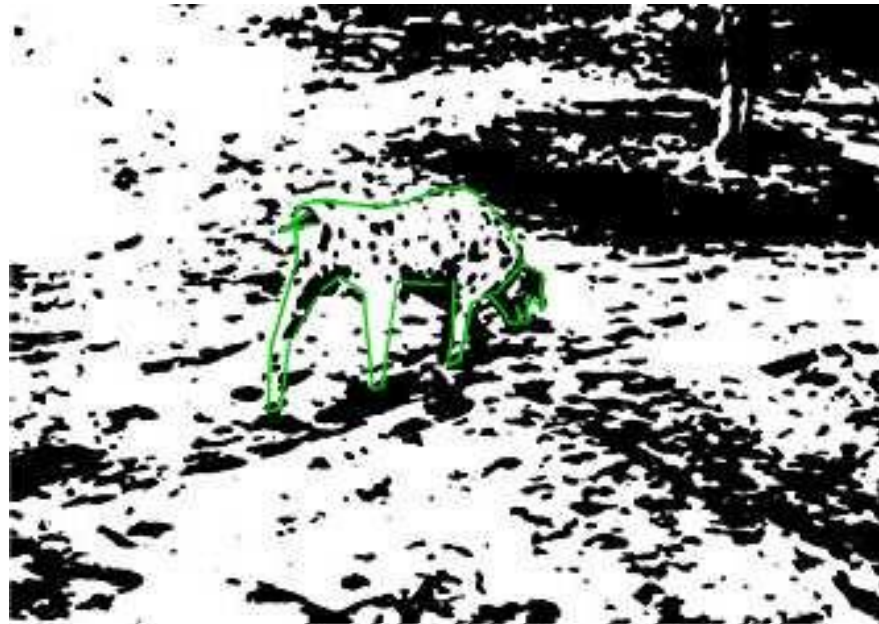


Manual Inspection

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 > 90 % corrected

All operators should have a near vision visual acuity / color blindness test prior to inspector training
The achievement of 14/14 acuity is required



J. G. ROSENBAUM POCKET VISION SCREENER

95

distance
equivalent

874

Point
Jaeger

$\frac{20}{400}$

2843

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 O W E X X O

5 2 $\frac{20}{30}$

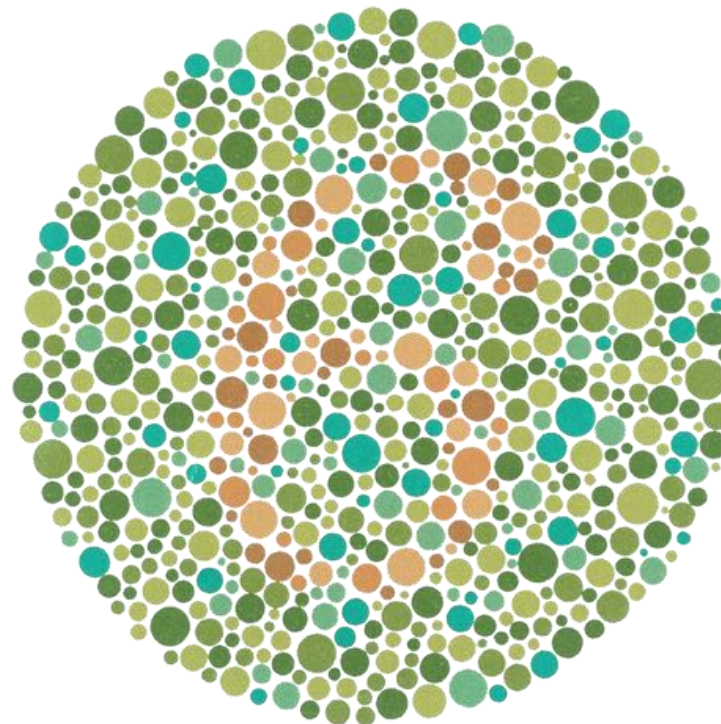
6 X 1 X 1 K U L L X O O

4 1 $\frac{20}{25}$

4 J 4 2 1 1 K U L L 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.





Selection Criteria

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



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 - Overview

- Eye inspections are performed prior to employment and at least once annually
- Training of relevant SOPs and Work-Instructions
- Introduction to defects using training kits
- Learning individual defects using training kits and defect libraries
- Basic qualification:
- Additional qualification in small teams more complicated products
- Requalification once a year



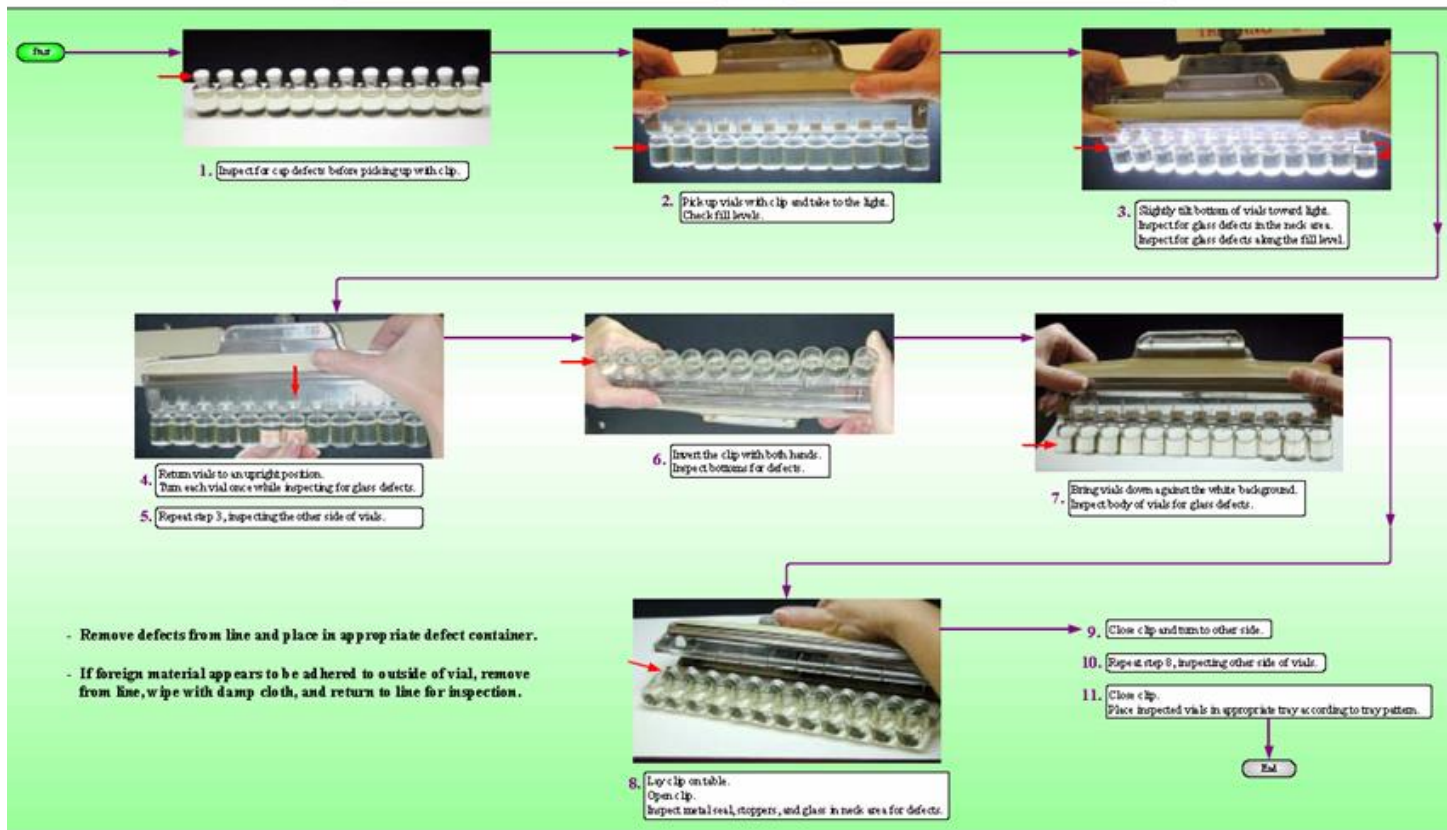
Training of Visual Inspectors Phase 1

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

MANUAL INSPECTION - SOLUTION VIAL CONTAINER

PURPOSE: To supplement the batch record by providing a trained team member with the necessary information to manually inspect a vial container, prior to or after its production on the machine.

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





Training of Visual Inspectors

Phase 2

- Seeded containers diluted with blanks-familiarization.
- Distinguish particle types.
- Distinguish bubble forming Drug Products.
- Timing.
- Use of tools (e.g. clip)



Training of Visual Inspectors Phase 3

- Best inspectors offer 'tricks', methods, advice
- Visual inspection under supervision and 100 % re-inspection (T-o-J)
- Further introduction to defects using test kits
- Qualification using test kits
- Requalification once a year



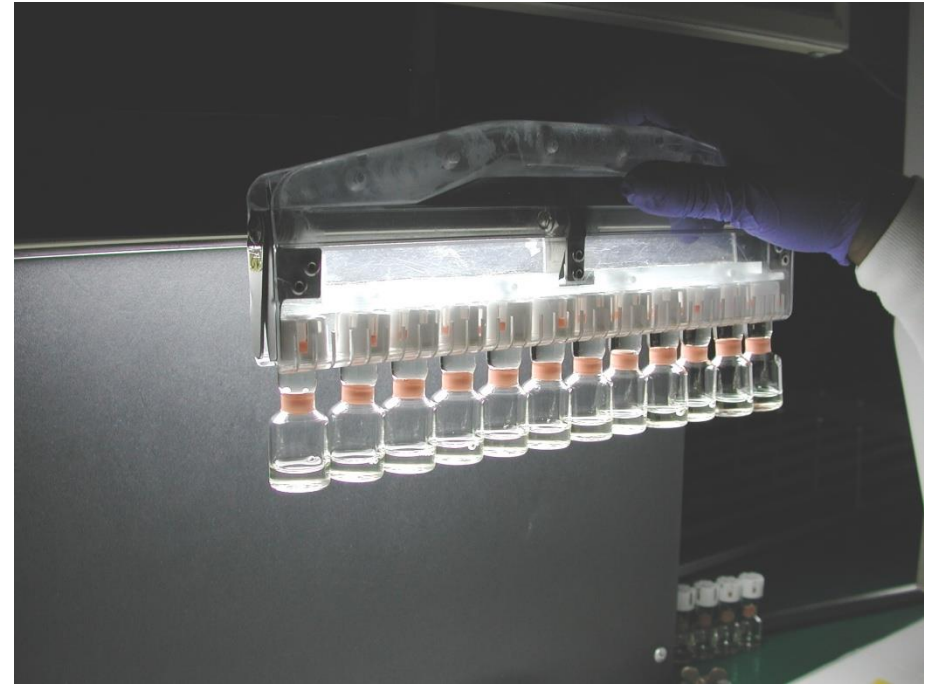
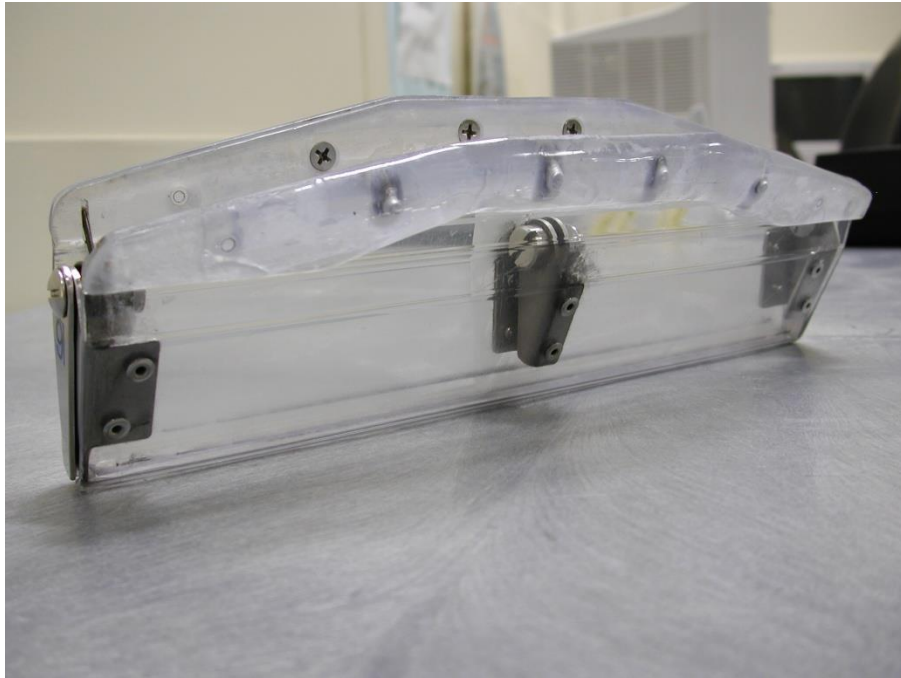
Training



Manual Inspection Line (10 stations)



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 / Training Kits:** - Contain all possible defects for one product / Constant growing library
Test Kits: - Special defects are selected
- Build test kits from defect library. They should cover most 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 and 85-90 defects



Building Test Kits: Points to consider

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



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

Test Kit (Example):

600 vials with 65 rejects

Acceptance criteria:

0 non detected criticals

1 non detected major

5 non detected minors

< 35 rejected good pieces



Test Kits

Time limits

Max. 120 minutes for initial qualification

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

Results are given instantly using UV light

An better alternative is the use of QR barcode



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 Metall 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			n	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 and 3 part trays each month making sure that each product is audited annually



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



Performance Maintenance & Monitoring

- A tool designed to provide management and the inspector instant inspection performance feedback through audits, working towards the goal of zero defects
- Integral component of the colleagues' Annual Performance Review
- A means to measure and document real-time human performance



Performance Matrix

INSPECTION OPERATOR PERFORMANCE MATRIX						
PROCEDURE AUDIT	98 – 100%	21 Unacceptable	13 Below Expectations	7 At Expectations	3 Exceeds Expectations	1 Exceptional
	90 – 97%	22 Unacceptable	14 Below Expectations	8 At Expectations	4 Exceeds Expectations	2 Exceeds Expectations
	80 – 89%	23 Unacceptable	15 Below Expectations	9 At Expectations	6 At Expectations	5 At Expectations
	70 – 79%	24 Unacceptable	16 Below Expectations	12 Below Expectations	11 Below Expectations	10 Below Expectations
	<70%	25 Unacceptable	20 Unacceptable	19 Unacceptable	18 Unacceptable	17 Unacceptable
		<70%	70 – 79%	80 – 89%	90 – 97%	98 – 100%
TRAY AUDIT						



Breaks

- Breaks help to keep inspector focuses
- Minimum of 8 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



Survey 2014 Results: Selection criteria Inspector

- Visual Acuity..... 92%
- Color Vision 76%
- Education..... 42%
- Training..... 94%
- Test of Inspection Ability..... 90%
- Experience..... 32%
- 22% have different selection and training
Production and QA inspectors?



Survey 2014 Results

- 98% describe defects and inspection conditions in a written procedure.

Qualification conditions

- - Simulated: 64%
- - Actual Manufacturing: 36%

Standards

- - Production Defects: 92%
- - Non-Spherical Standards: 35%
- - Spherical Standards: 33%



Survey 2014 Results

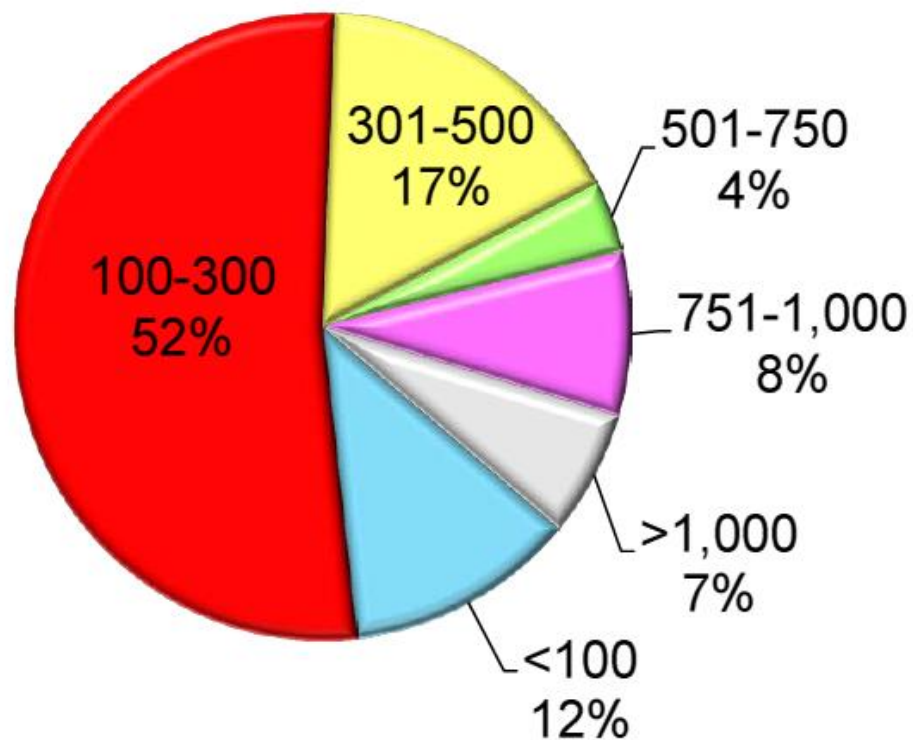
Requalification intervals

	2014	2008	2003	1996
• Never.....	5%	21%	8%	35%
• Monthly.....	1%	5%	0%	8%
• Quarterly.....	4%	0%	0%	8%
• Semi-Annually.....	11%	11%	»%	16%
• Annually.....	79%	63%	75%	69%

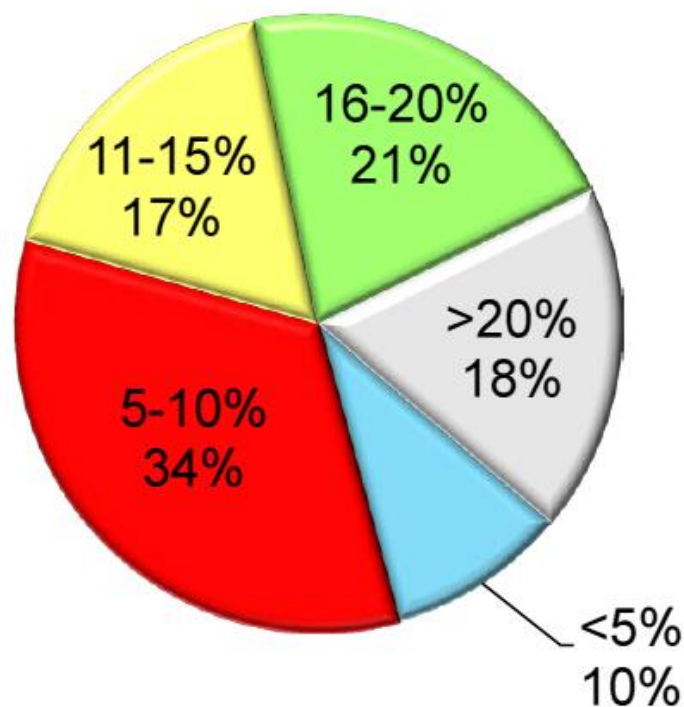


The composition of test kits used to qualify inspectors.

Total Units in Test Kit



Defect Rate in Test Kit





How frequently do inspectors take a break or rotate to a non-inspection task?

	<u>2014</u>	<u>2008</u>	<u>2003</u>	<u>1996</u>
• Never	2%	NA	NA	NA
• <30 min	5%	16%	12%	5%
• 30 min	27%	32%	15%	21%
• 45 min.....	3%	ND	ND	ND
• 60 min	49%	32%	62%	32%
• 2 hours	10%	11%	12%	37%
• 4 hours	4%	0%	0%	5%

ND = No Data, question not asked in survey from this year



Survey 2014 results

- In 2014 glass particles are classified as:

- **- Critical: 60%**

- - Major: 30%

- - Minor: 1%

- - Other: 9% (size dependent)

In 2008:

- - 45% of firms classified particles as Critical and 45% as Major.

- - 63% of firms use the same AQL for all particles (including glass).



Acknowledgments

- Georg Roessling
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