Qualifying Visual Inspectors - The benchmarking process

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Topics

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

**Preparation**: To ensure the best result, prepare a solution in a manner that suits your specific needs. Ensure that the vial container is clean and free from contamination.

**Preliminary Check**: Examine the vial container for any external defects. If necessary, use a damp cloth to wipe down the container.

1. **Inspect cup defects before placing clip:** Look for any cup defects before placing the clip.
2. **Insert cup with clip and slide to the light:** Place the clip into the vial container and slide it towards the light source.
3. **Inspect cup defects in the neck:** Carefully inspect the neck of the vial for any defects.
4. **Remove vial in upright position:** Ensure the vial is in an upright position while inspecting for cup defects.
5. **Repeat step 3, inspecting the other side of vial:** Inspect the other side of the vial for any defects.
6. **Inspect cup with both hands:** Inspect the cup with both hands to ensure no defects are missed.
7. **Brake vial down against the white background:** Place the vial against a white background to inspect for any defects.
8. **Continue with step 3:** Continue with the inspection process as described above.
9. **Close clip and turn to the other side:** After completing the initial inspection, close the clip and turn the vial to the other side for inspection.
10. **Repeat step 1, inspecting other side of vial:** Repeat the inspection process on the other side of the vial.
11. **Close clip:** Close the clip and proceed as per the inspection results.
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
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

<table>
<thead>
<tr>
<th>Description</th>
<th>Classification</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Underfill/Overfill</td>
<td>MA</td>
<td>4</td>
</tr>
<tr>
<td>2 Metall particle</td>
<td>MA</td>
<td>2</td>
</tr>
<tr>
<td>3 Glass particle</td>
<td>C</td>
<td>2</td>
</tr>
<tr>
<td>4 Fiber</td>
<td>MA</td>
<td>5</td>
</tr>
<tr>
<td>5 Scratches outside</td>
<td>m</td>
<td>3</td>
</tr>
<tr>
<td>6 Crack</td>
<td>C</td>
<td>4</td>
</tr>
<tr>
<td>7 Missing flip off cap</td>
<td>MA</td>
<td>2</td>
</tr>
<tr>
<td>8 Spots on rubber</td>
<td>m</td>
<td>2</td>
</tr>
<tr>
<td>9 Damaged closure component</td>
<td>C</td>
<td>4</td>
</tr>
<tr>
<td>10 Precipitation</td>
<td>C</td>
<td>3</td>
</tr>
<tr>
<td>11 Dirty container</td>
<td>n</td>
<td>2</td>
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</table>
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
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

### Procedure Audit

<table>
<thead>
<tr>
<th>Percentage</th>
<th>98 – 100%</th>
<th>90 – 97%</th>
<th>80 – 89%</th>
<th>70 – 79%</th>
<th>&lt;70%</th>
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<tr>
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<td>21</td>
<td>22</td>
<td>23</td>
<td>24</td>
<td>25</td>
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<tr>
<td>Below Expectations</td>
<td>13</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>20</td>
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<tr>
<td>At Expectations</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>Exceeds Expectations</td>
<td>3</td>
<td>4</td>
<td>6</td>
<td>11</td>
<td>18</td>
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<tr>
<td>Exceptional</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>10</td>
<td>17</td>
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</table>

### Tray Audit

<table>
<thead>
<tr>
<th>&lt;70%</th>
<th>70 – 79%</th>
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</thead>
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<tr>
<td>Unacceptable</td>
<td>20</td>
<td>Unacceptable</td>
<td>19 Unacceptable</td>
<td>18 Unacceptable</td>
</tr>
</tbody>
</table>
Breaks

- Breaks help to keep inspector focues
- 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

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Never</td>
<td>5%</td>
<td>21%</td>
<td>8%</td>
<td>35%</td>
</tr>
<tr>
<td>Monthly</td>
<td>1%</td>
<td>5%</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>Quarterly</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>Semi-Annually</td>
<td>11%</td>
<td>11%</td>
<td>»%</td>
<td>16%</td>
</tr>
<tr>
<td>Annually</td>
<td>79%</td>
<td>63%</td>
<td>75%</td>
<td>69%</td>
</tr>
</tbody>
</table>
The composition of test kits used to qualify inspectors.

**Total Units in Test Kit**
- 100-300: 52%
- 301-500: 17%
- 501-750: 4%
- 751-1,000: 8%
- >1,000: 7%
- <100: 12%

**Defect Rate in Test Kit**
- 5-10%: 34%
- 11-15%: 17%
- 16-20%: 21%
- >20%: 18%
- <5%: 10%
How frequently do inspectors take a break or rotate to a non-inspection task?

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<tbody>
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<td>2%</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>&lt;30 min</td>
<td>5%</td>
<td>16%</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td>30 min</td>
<td>27%</td>
<td>32%</td>
<td>15%</td>
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<tr>
<td>45 min</td>
<td>3%</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
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<tr>
<td>60 min</td>
<td>49%</td>
<td>32%</td>
<td>62%</td>
<td>32%</td>
</tr>
<tr>
<td>2 hours</td>
<td>10%</td>
<td>11%</td>
<td>12%</td>
<td>37%</td>
</tr>
<tr>
<td>4 hours</td>
<td>4%</td>
<td>0%</td>
<td>0%</td>
<td>5%</td>
</tr>
</tbody>
</table>

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
• Roy Cherris
• John Shabushnig