IMPACT OF TRAINING ON VISUAL INSPECTION PROCESS CAPABILITY

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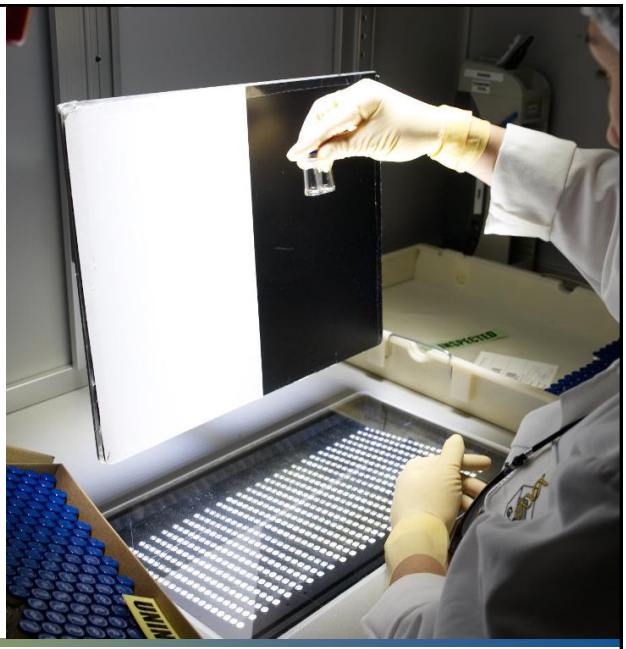

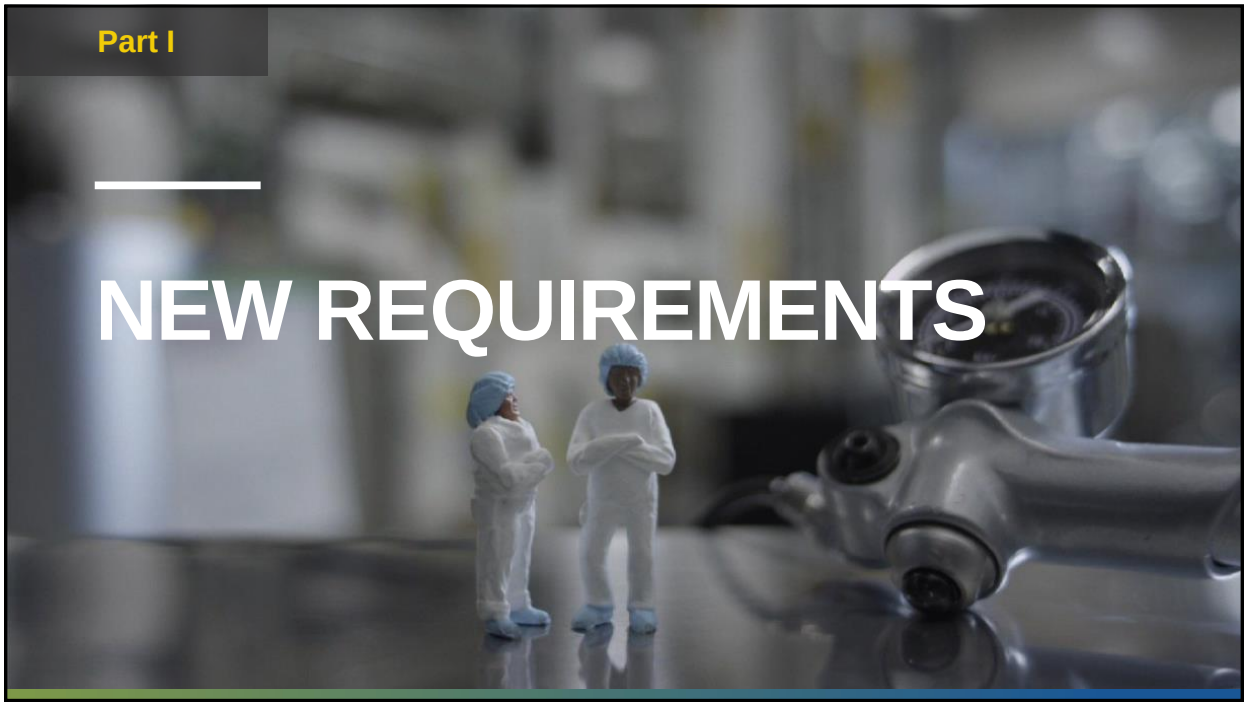

Roche Global Visual Inspection (VI) Standard

Objective:

Develop global standard requirements document for Visual Inspection

Scope:

- Visual Inspection of Parenteral Drug Products (e.g., liquid vial, lyophilized vial, PFS, ampoule, diluent)
- Automated, Semi-Automated, Manual Inspection
- Global Roche Pharmaceutical Operations

Timeline:

2010 Start Document Development

Q1 2012 Document Approval

Q3 2012 Local Plant Implementation

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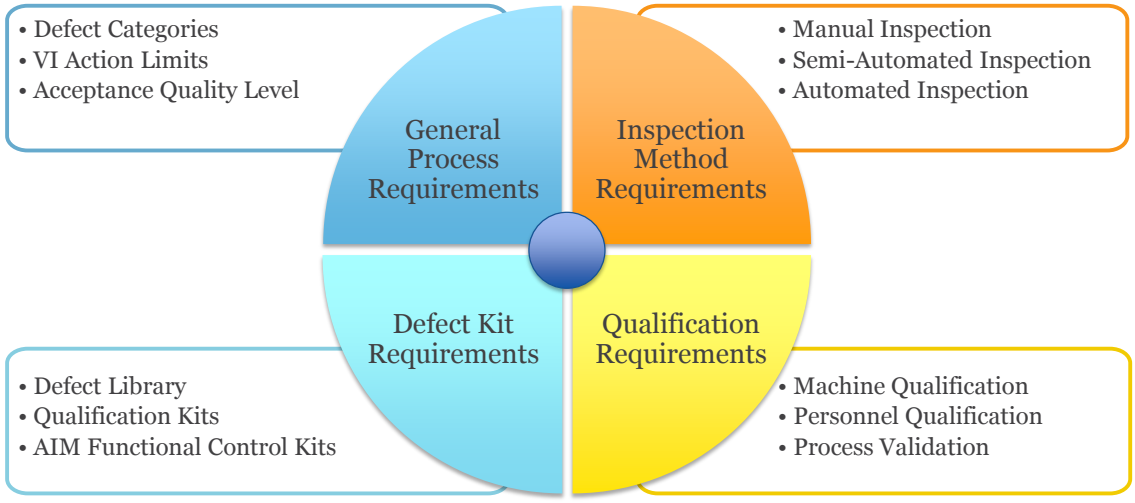
Visual Inspection Standard



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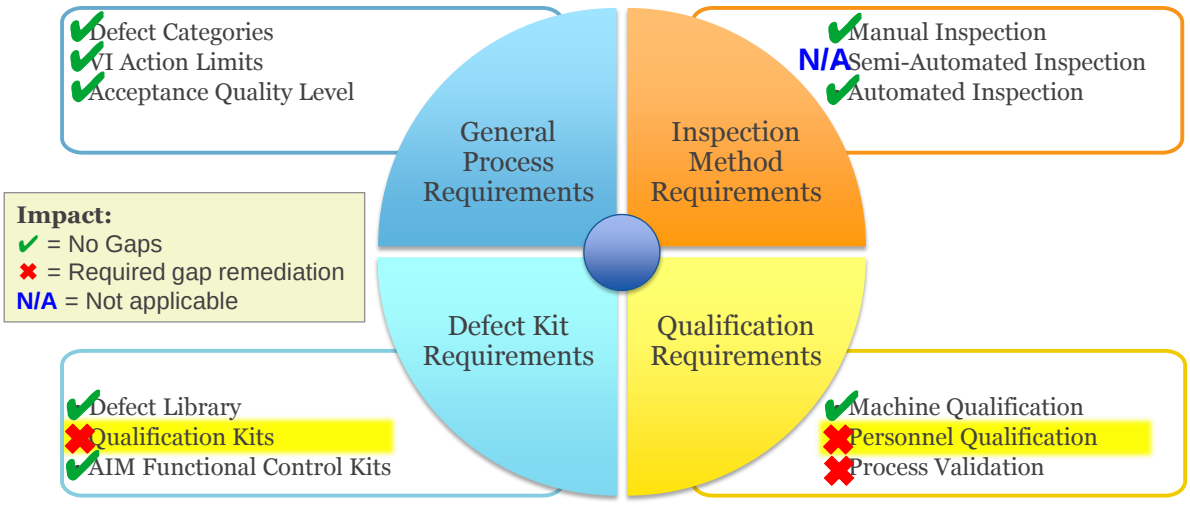
Local Impact – Hillsboro, OR



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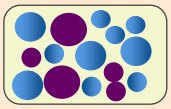
Manual Inspection Qualification

Elements of Legacy Model:

Mixed
Vials: 2-50cc
Fill: 5-20mL

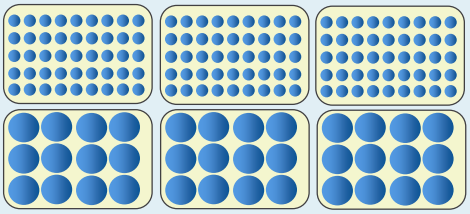


General Particulate Requirements

Elements of New Model:

2cc
0.3mL

50cc
20mL

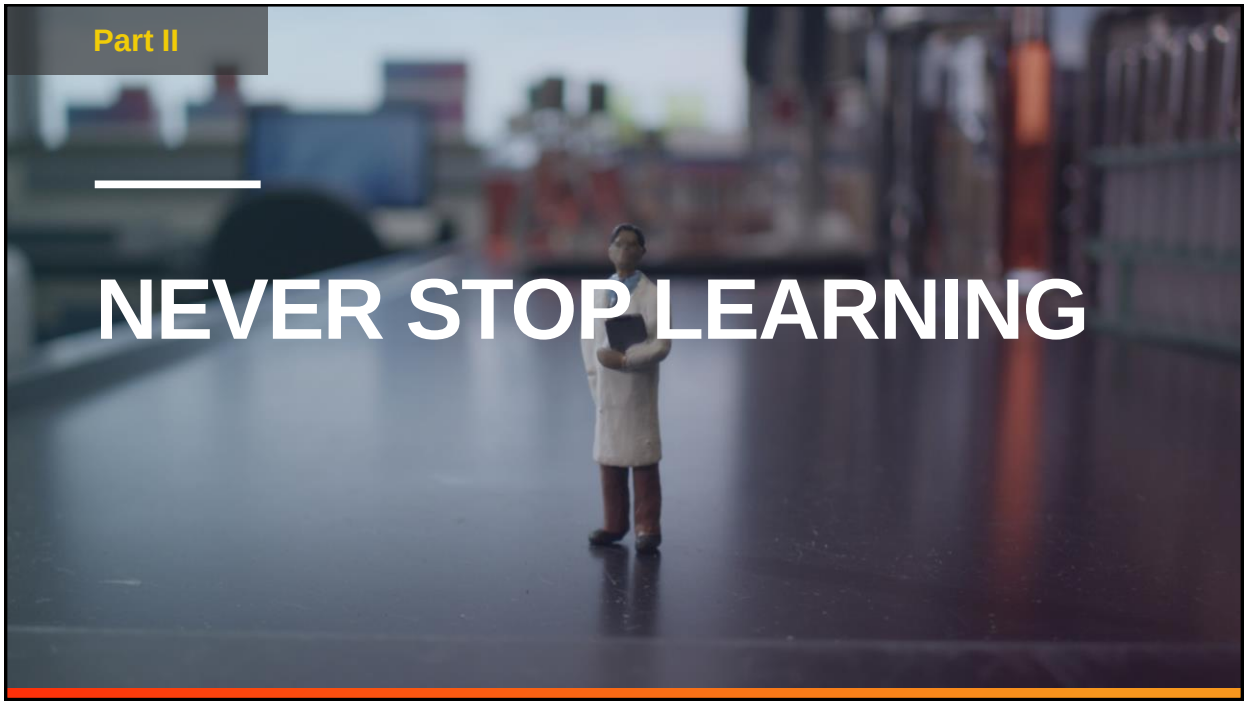


Specific Particulate Requirements

Raising the Bar

"Good news! Our inspector qualification is much more robust."

"Now, no one can pass it."



Inspector Qualification Improvement

Define
- Inspectors cannot reliably pass the new qualification test
- Improve process to provide qualified inspection staff

Measure
- Collect detection data from qualification tests
- Identify problem areas to determine root cause

Analyze

Improve

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Inspector Qualification Improvement: Measure

What
1% pass rate; 99% failure rate
Inspectors get 3 tries to pass – many failed 3x

Who
99% is practically all inspectors
New & Experienced: No correlation with experience level

How
Failure to detect fibers @ 100% (200µm-1000µm)
No correlation to specific qualification kits

Inspector Qualification Improvement

Define
- Inspectors cannot reliably pass the new qualification test
- Improve process to provide qualified inspection staff

Measure
- Failures due primarily to fiber particulate inspection
- Broad-based issue – all inspectors

Analyze
- What are root causes for qualification test failures?

Improve

Inspector Qualification Improvement: Analyze

What is working:
- Inspectors understand basic technique – lift, swirl, etc.
- Good performance on container, closure, solution defects
- Speed of inspection, lighting, equipment aligned with EP/USP standards

Opportunities:
- Specifics vary– no aligned best practice for finding particles
- Insufficient practice prior to testing - Training kits not representative of qualification kits
- Insufficient technique for 2cc vial, 0.3mL format

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Improving Inspector Capabilities

Define	• Inspectors cannot reliably pass the new qualification test • Improve process to provide qualified inspection staff
Measure	• Collect detection data from qualification tests • Identify problem areas to determine root cause
Analyze	• What are root causes for qualification test failures?
Improve	• Improve particulate detection training • Inspector practice prior to qualification • 2cc inspection technique

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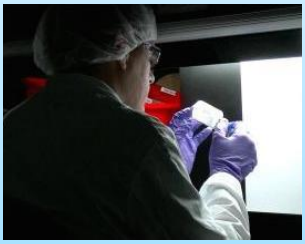
Inspector Qualification Improvement: Improve

Particulate Training

- Updated inspector training videos
- 1:1 particle hunter training

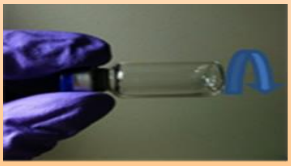


Inspector Practice

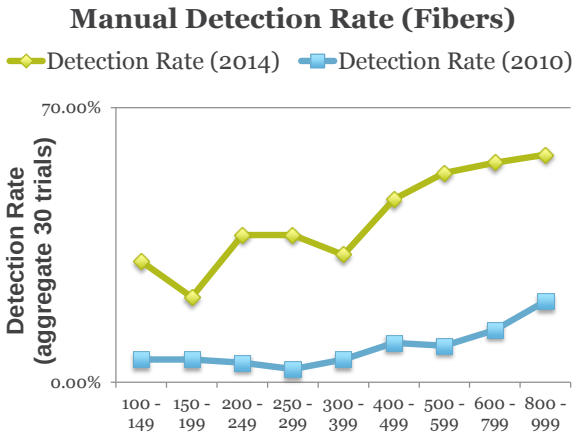
- Aligned training kit contents
- Build confidence - extensive practice prior to qualification

2cc technique

- Insufficient volume for standard swirl technique
- Developed "roll" technique



Impact



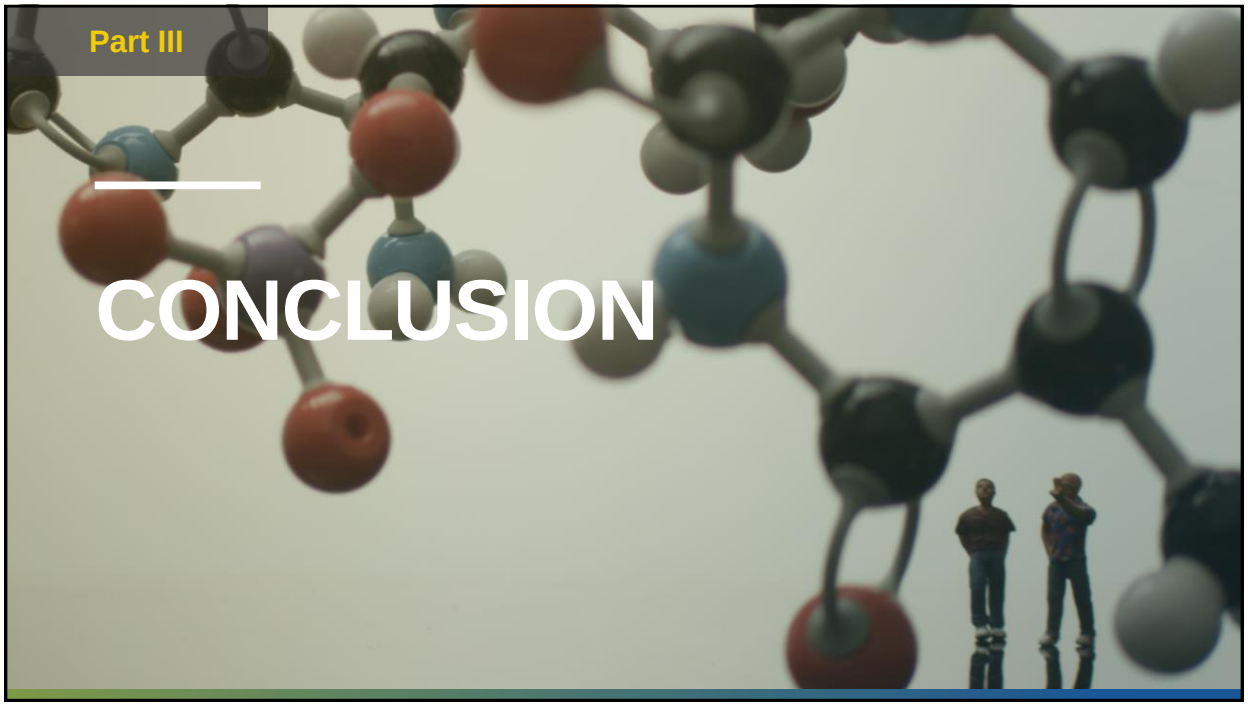
Results:

- Significant increase in fiber detection
- 99% qualification test pass rate
- Culture of continuous improvement and best practice sharing

Note:

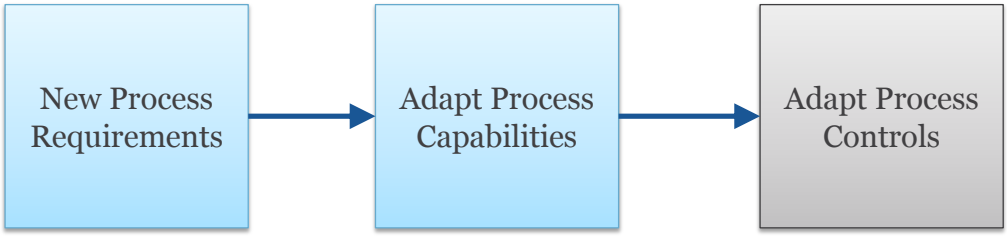
Increases in visual inspection capability required adjustments in action limits and process controls

Source: Genentech AIM manual inspection characterization, 50cc liquid inspection



Conclusion

- Manual Visual Inspection is a complex process
- In all processes there are opportunities to optimize
- Particulate detection requires skills development beyond basic technique



Questions?

Doing now what patients need next

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THANK YOU

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