



Visual Inspection of Injectable Products: Inspection Technologies

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“I see no more than you,
but I have trained myself
to notice what I see.”

Sherlock Holmes
in *The Adventure of the Blanched Soldier*





Agenda

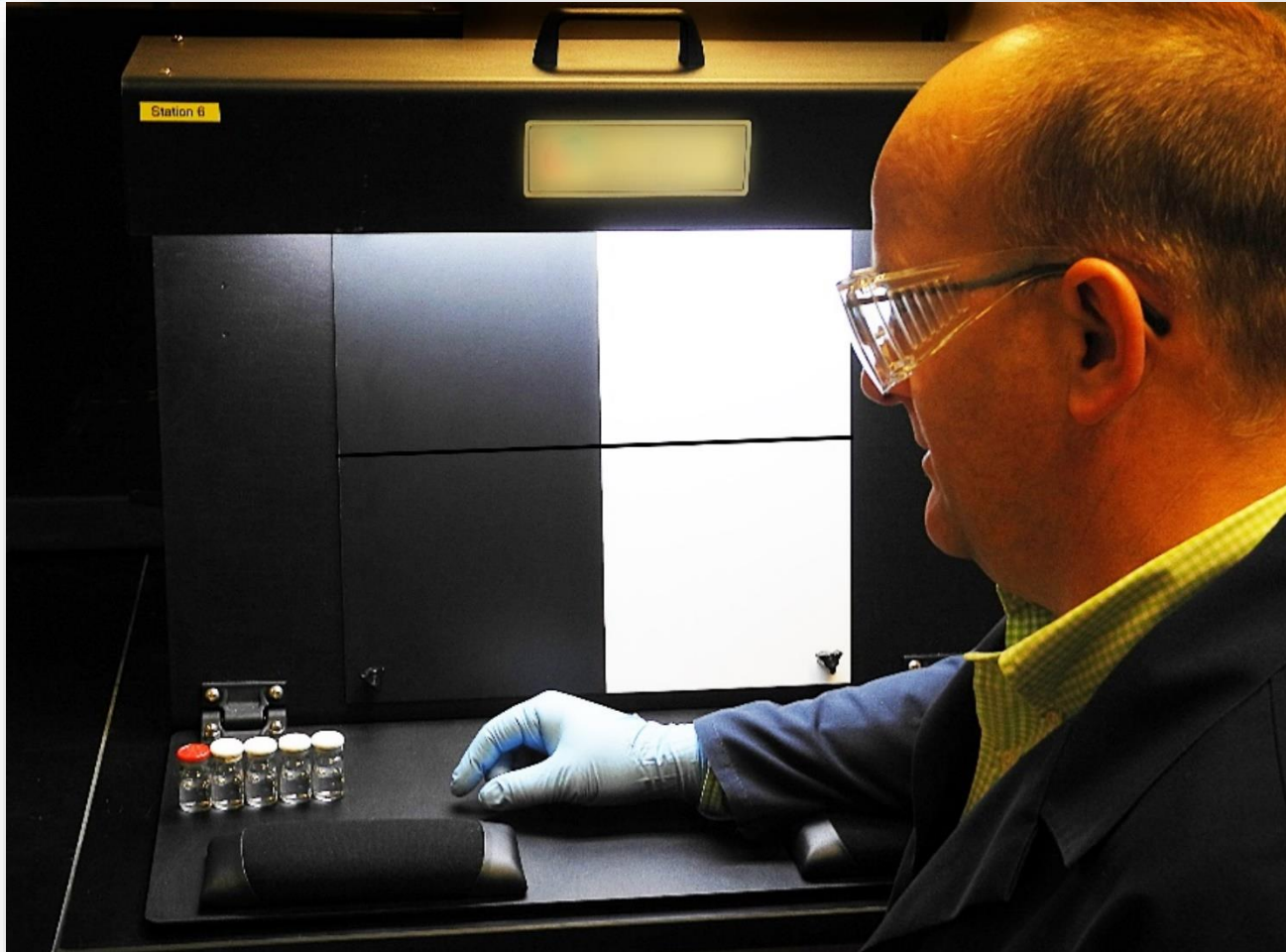
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



Manual Inspection



Manual Inspection



An Introduction to Visual Inspection

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Critical Inspection Parameters

- Lighting
 - Illumination Intensity
 - Uniform, Flicker-free
 - Fluorescent, Incandescent, LED
 - Tyndall (dark-field)
- Background
 - Black / White
- Presentation and Manipulation
 - Swirl and/or invert
- Pace
 - 10 sec / container reference

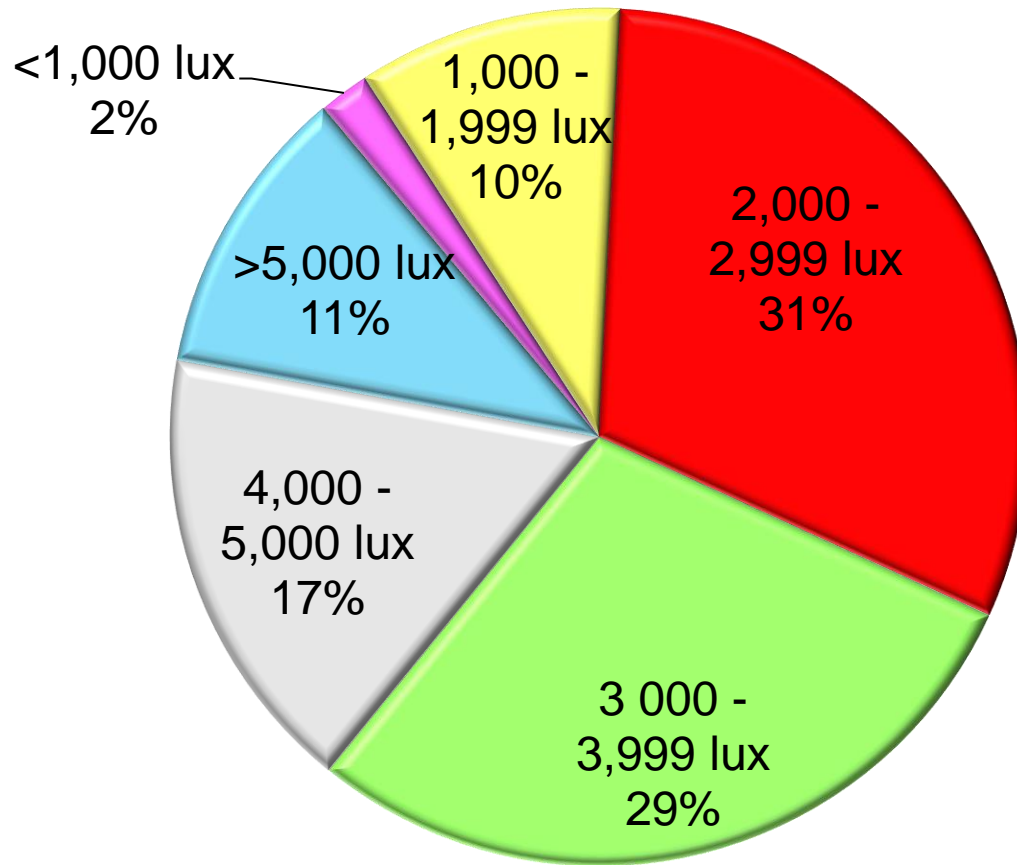


Manual Inspection Conditions

- 73% control inspection time or the pace of inspection.
 - 46% with Timer
 - 29% by SOP
 - 24% with Conveyor
- 26% use a magnifier.
 - 44% 2X, 25% 3X, 8% 4X, 8% 5X, 14% >5X
- 6% use a polarizer.
- Light Source used:
 - 73% Fluorescent, 19% LED, 18% Incandescent,

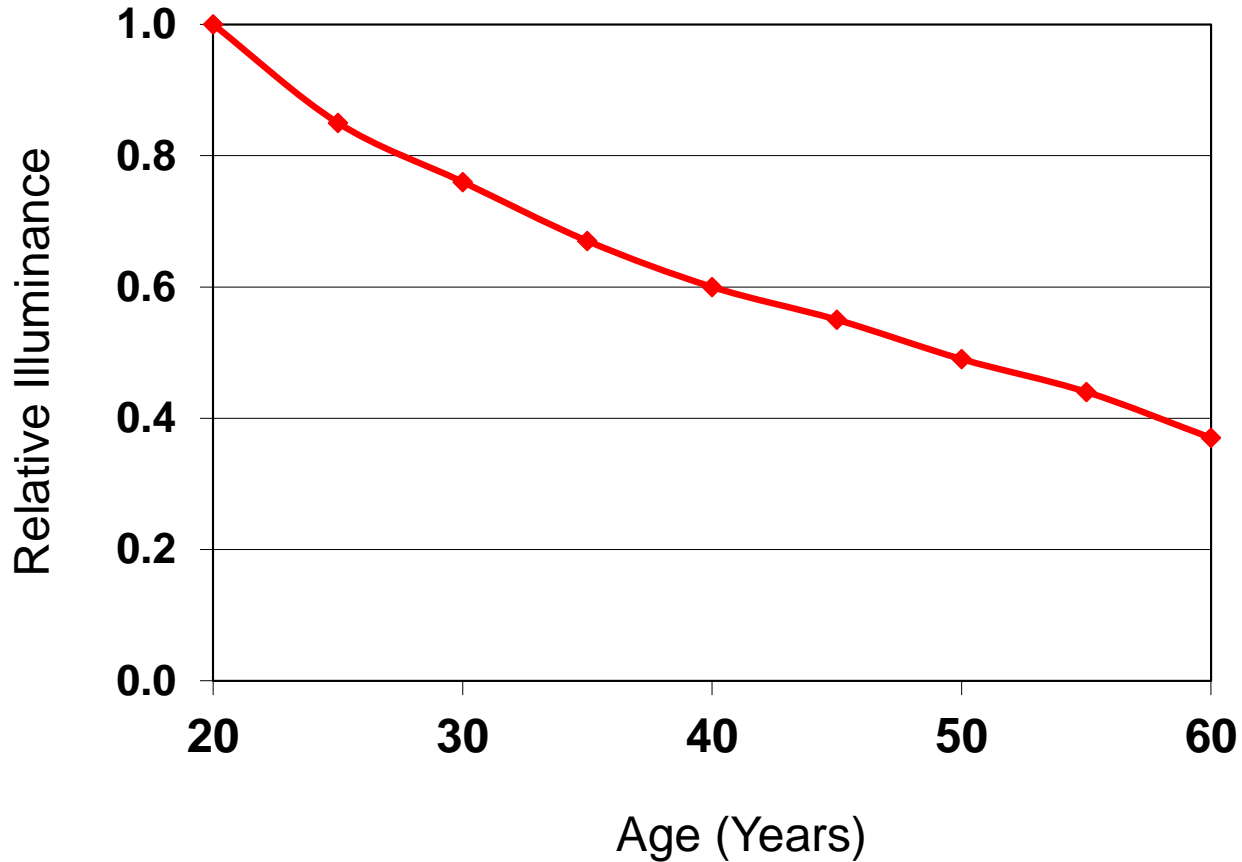


What is the average illumination intensity at the container during manual inspection?





Aging and Relative Illuminance

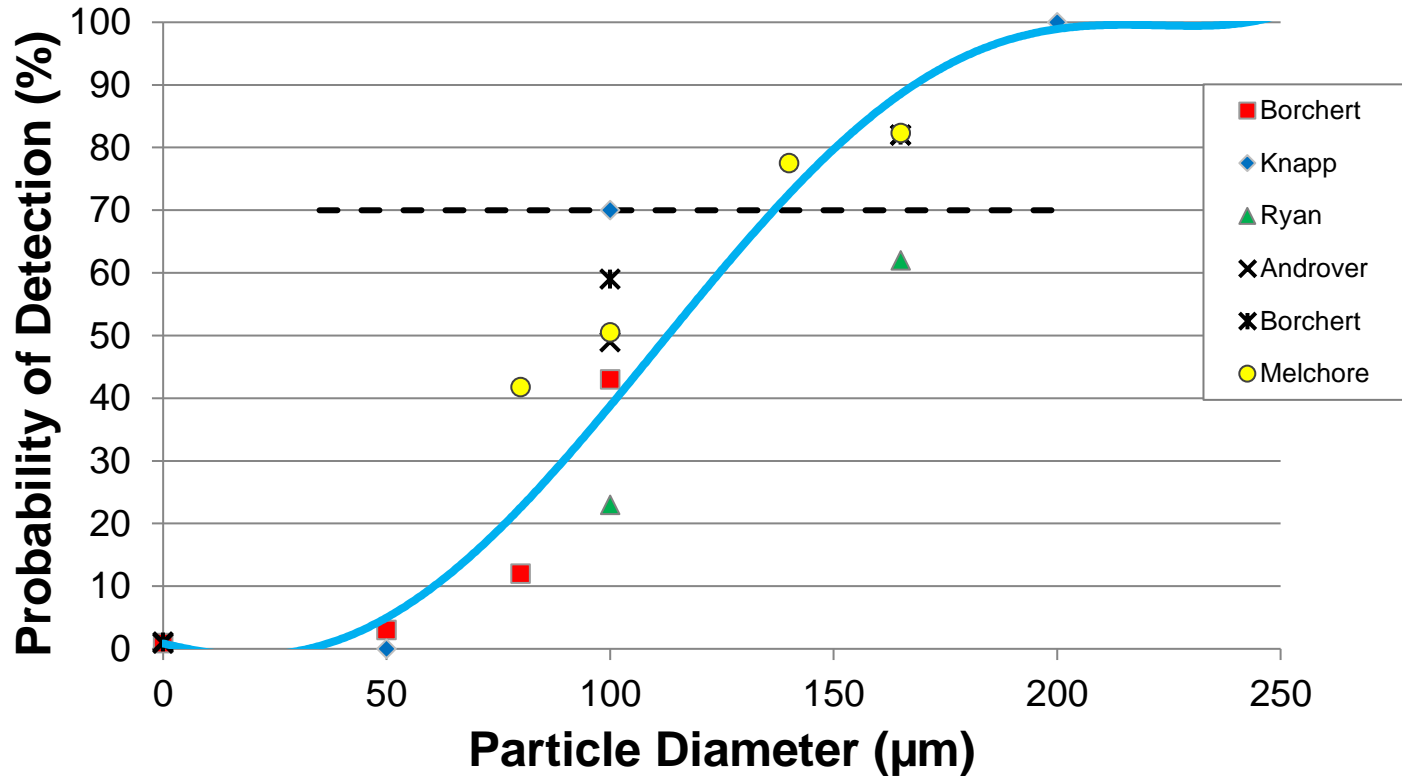


From IESNA Lighting Handbook, 9th Edition

An Introduction to Visual Inspection



Human Inspection Performance



From Shabushnig, Melchore, Geiger, Chrai and Gerger, PDA Annual Meeting 1995

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Inspection Performance

- Human Inspection
 - Visual acuity
 - Fatigue
 - Flexibility
- Probabilistic
 - Especially true for particulate matter due to continuously changing presentation.



Semi-Automated Inspection

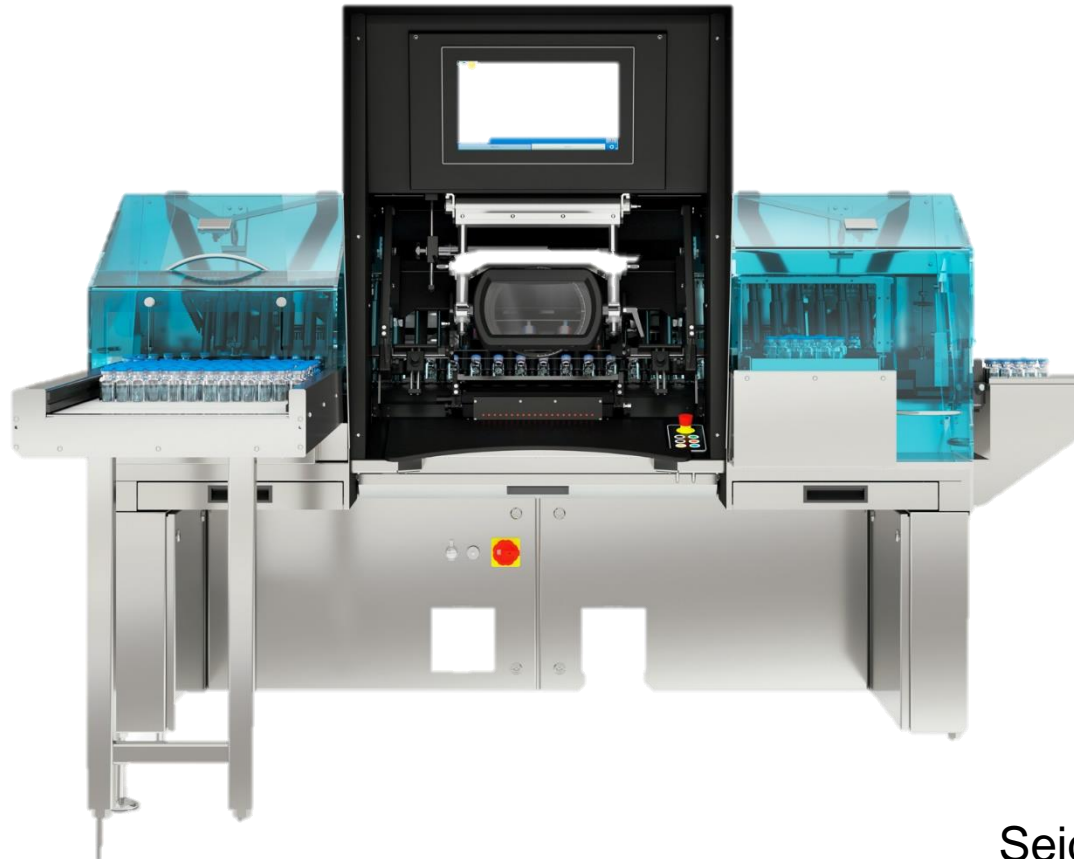


Semi-Automated Inspection

- Machine Material Handling
 - Transport, Spin/Rotation, Traying
 - Consistent lighting and presentation
 - Manual or Machine Rejection
- Human Inspection
 - Quality Decision



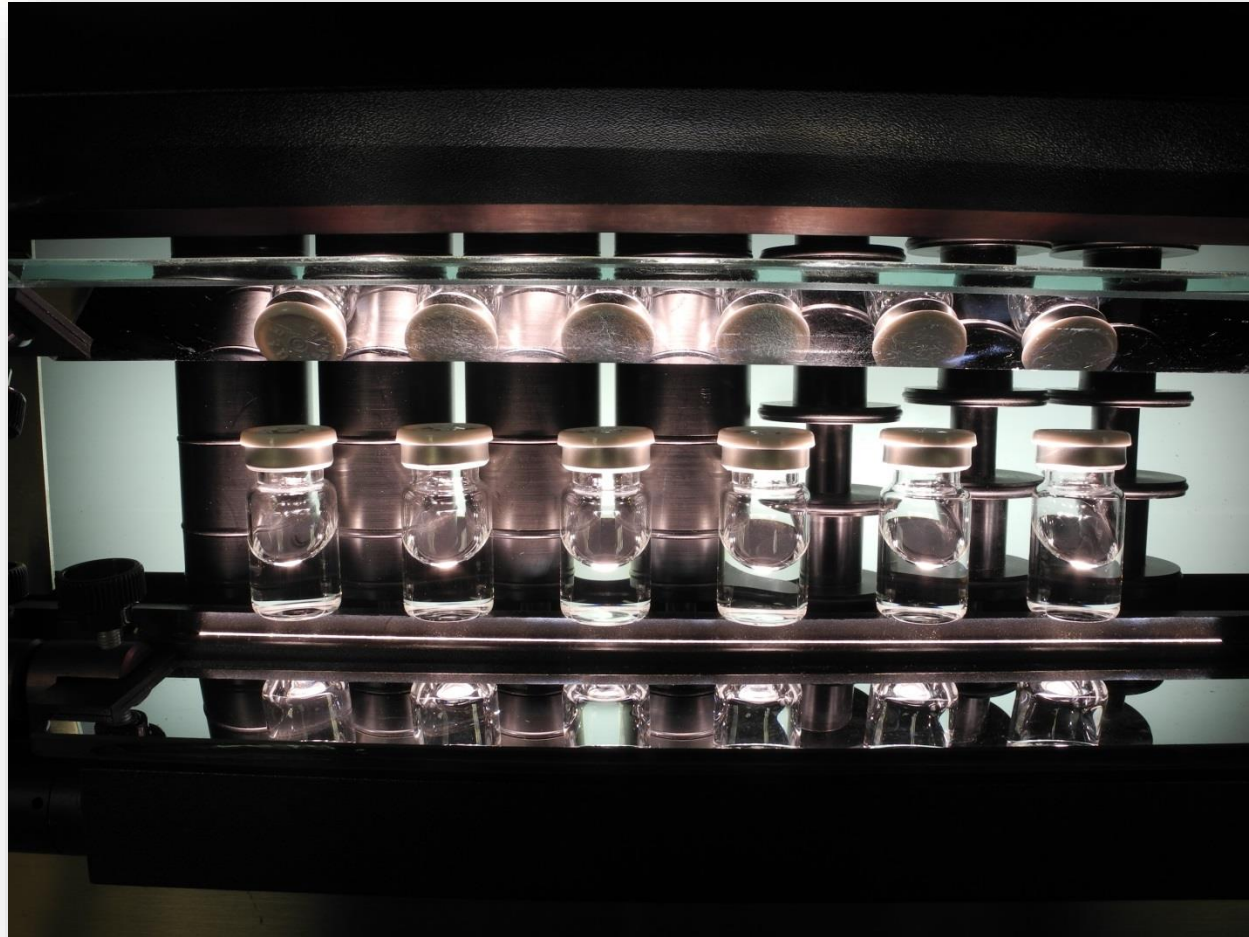
Semi-Automated Inspection



Seidenader



Semi-Automated Inspection



Seidenader



Inspection Performance

- Semi-Automated
 - Similar to manual
 - May have poor sensitivity for heavy particles
 - Particles stop moving before inspection
 - Improved ergonomics
 - Improved throughput



Automated Inspection



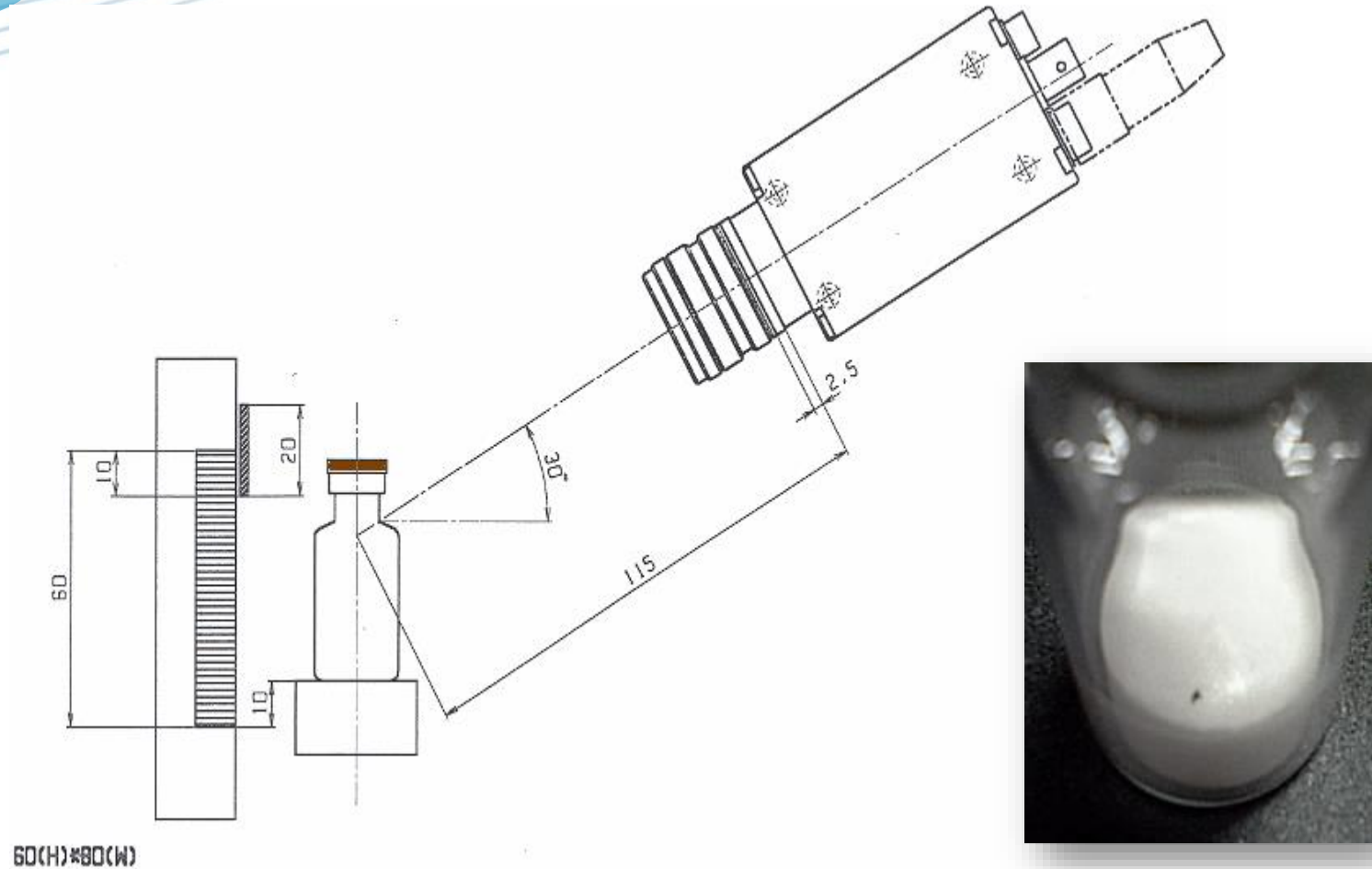
Automated Inspection



Eisai EIS-596



Automated Inspection





Inspection Performance

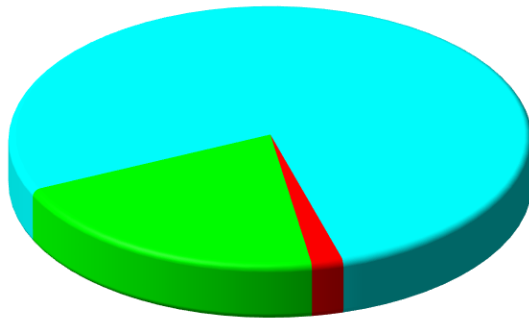
- Machine Inspection
 - Adjustable Sensitivity
 - Increased sensitivity must be balanced with increased false rejection rates.
 - Often product dependent
 - viscosity, surface tension, container design and variability
- Improved Reproducibility
- Improved Throughput
- High Initial Investment



Machine Inspection Performance

Human

Inconclusive

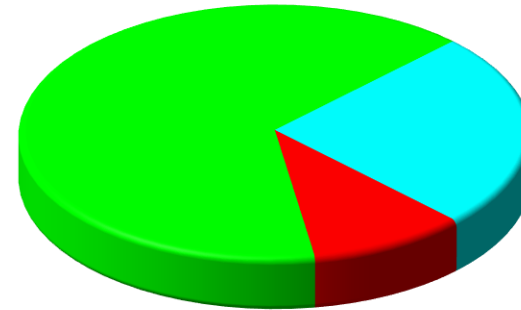


Good

Reject

Machine

Good



Inconclusive

Reject

A set of 250 vials was inspected 20 times by each method. Any vial not classified consistently 20 of 20 times was classified inconclusive.



What technique is used for inspection for / of ...

	2014	2008	2003	1996
Particles				
Manual	49%	33%	46%	33%
Semi-Automated	17%	24%	19%	20%
Automated	33%	43%	35%	42%
Container/Closure				
Manual	54%	36%	63%	48%
Semi-Automated	18%	26%	15%	42%
Automated	28%	39%	20%	5%



Questions?

**BEAUTIFUL,
BUT OBSOLETE.**

