



# 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

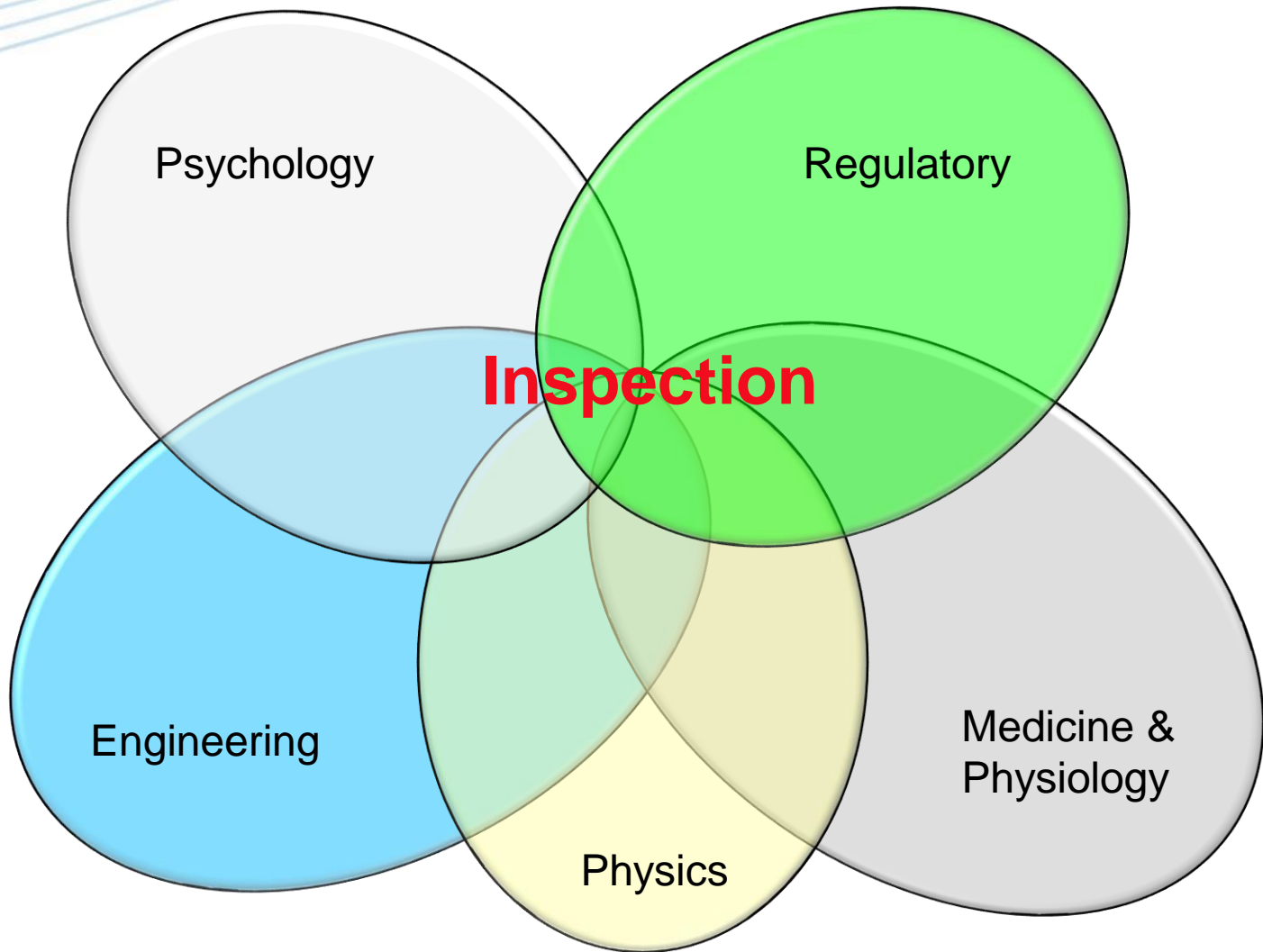
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



# Manual Inspection

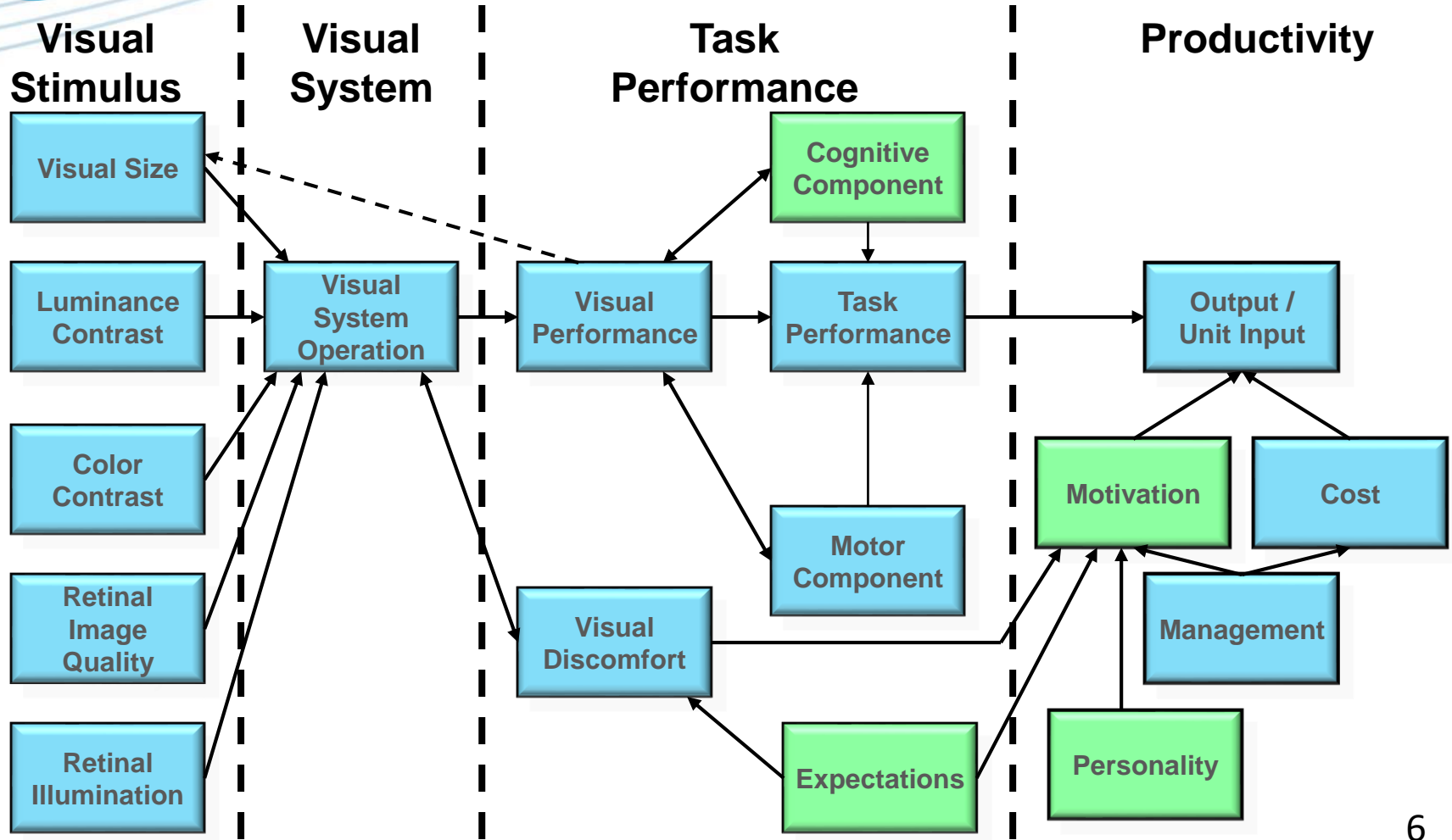


# Inspection Influences





# Inspection



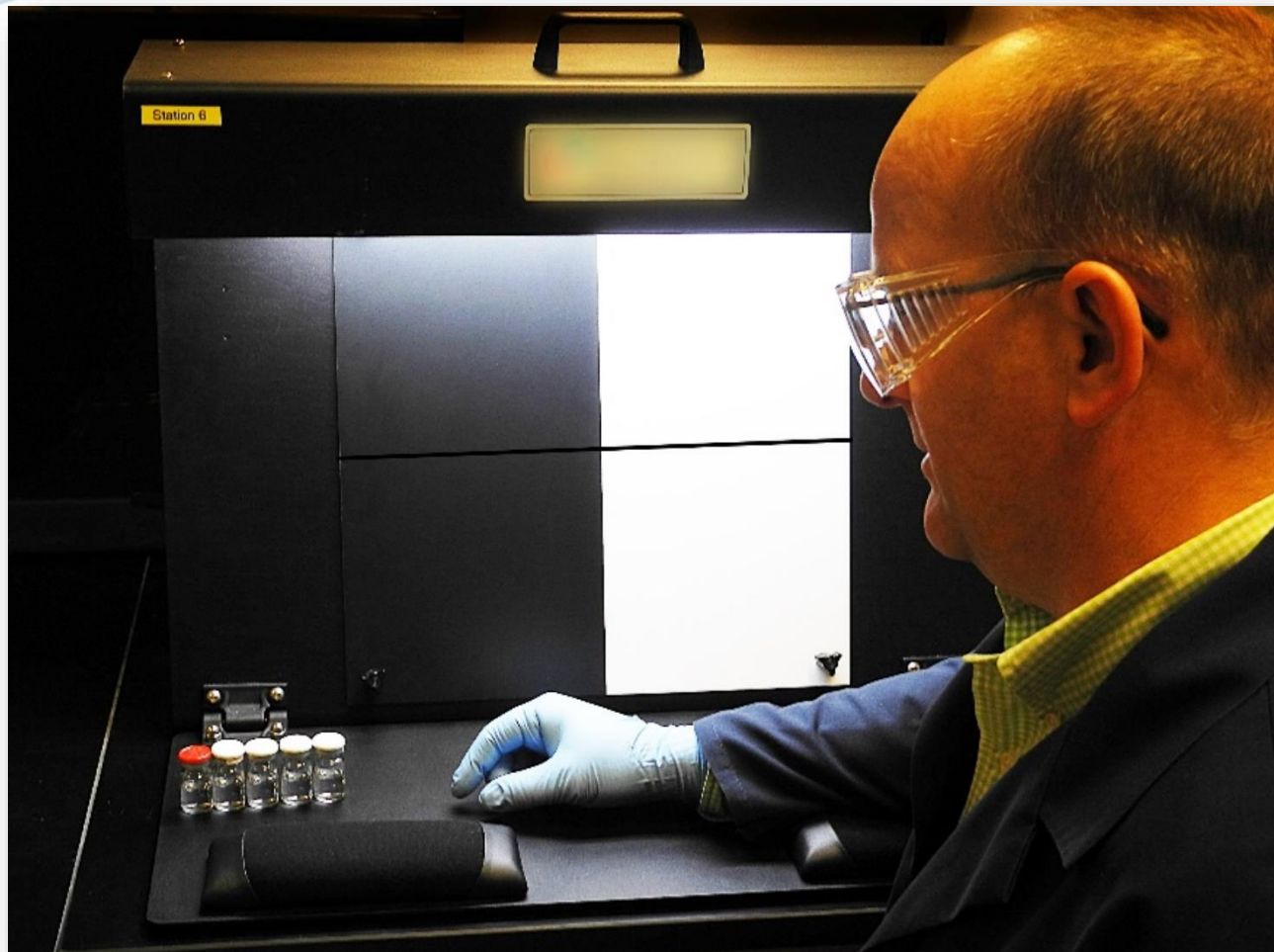
From G. Salvendy, Handbook of Human Factors and Ergonomics, 2<sup>nd</sup> Edition

## An Introduction to Visual Inspection

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# Manual Inspection



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# Manual Inspection



Phoenix Imaging MIB-100





# Manual Inspection





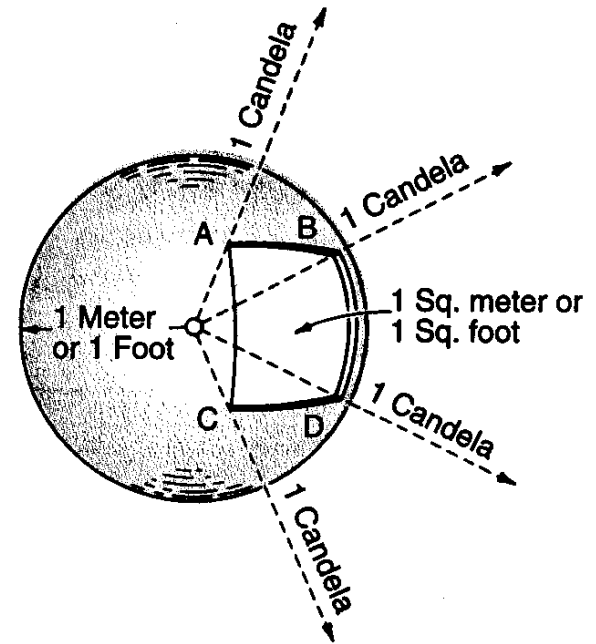
# Critical Inspection Parameters

- 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



# Illuminance

- Luminous Intensity
  - 1 candela = 1/638 W/sr
    - formerly candlepower
- Illuminance
  - 1 lux = 1 lumen/m<sup>2</sup>
  - 1 foot-candle = 1 lumen/ft<sup>2</sup>
  - 1 fc = 10.75 lux
- Inverse Square Law
  - illumination = luminous intensity/d<sup>2</sup>



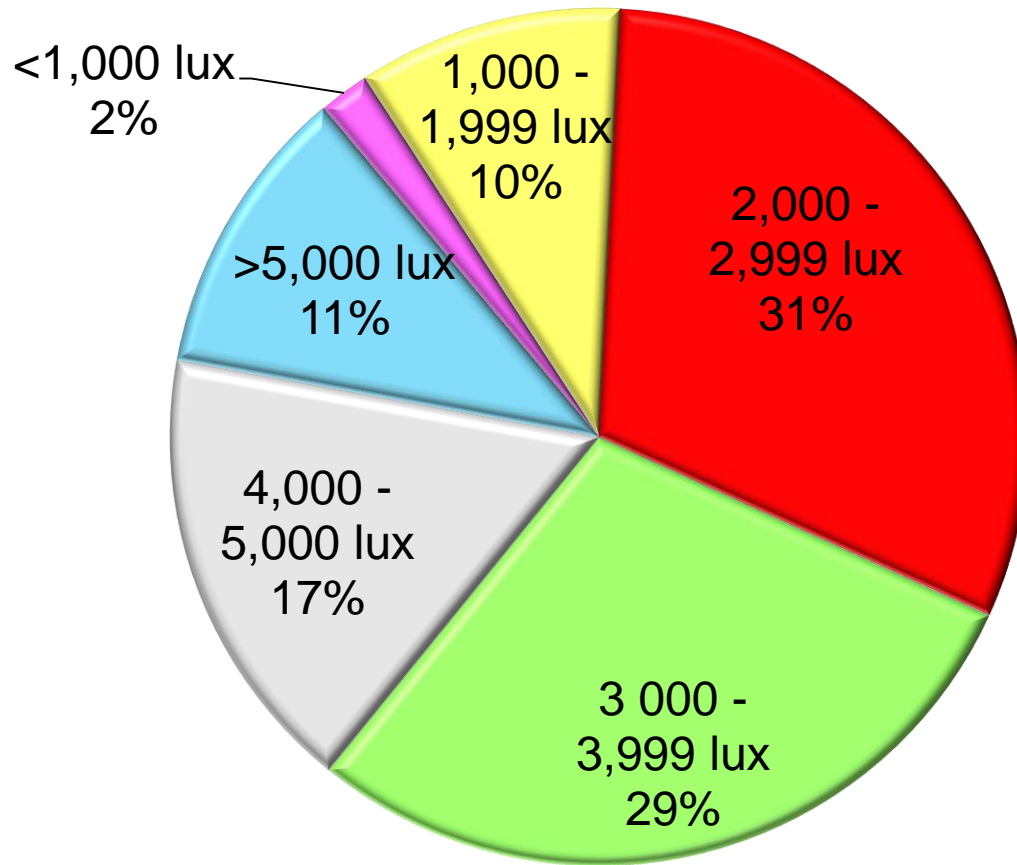


# Illumination Intensity

- USP, EP, JP and WHO
  - 2,000-3,750 lux, Higher (e.g., 8,000-10,000 lux for difficult to inspect containers and products)
- ChP
  - 1,000-1,500 lux (clear solutions), 2,000-3,000 lux (colored solutions and glass, plastic containers)
  - 4,000 lux (suspensions, emulsions)
- IESNA
  - “Difficult Inspection”, visual tasks of low contrast and small size. 1,000 lux
  - “Exacting Inspection”, visual tasks near threshold. 3,000-10,000 lux

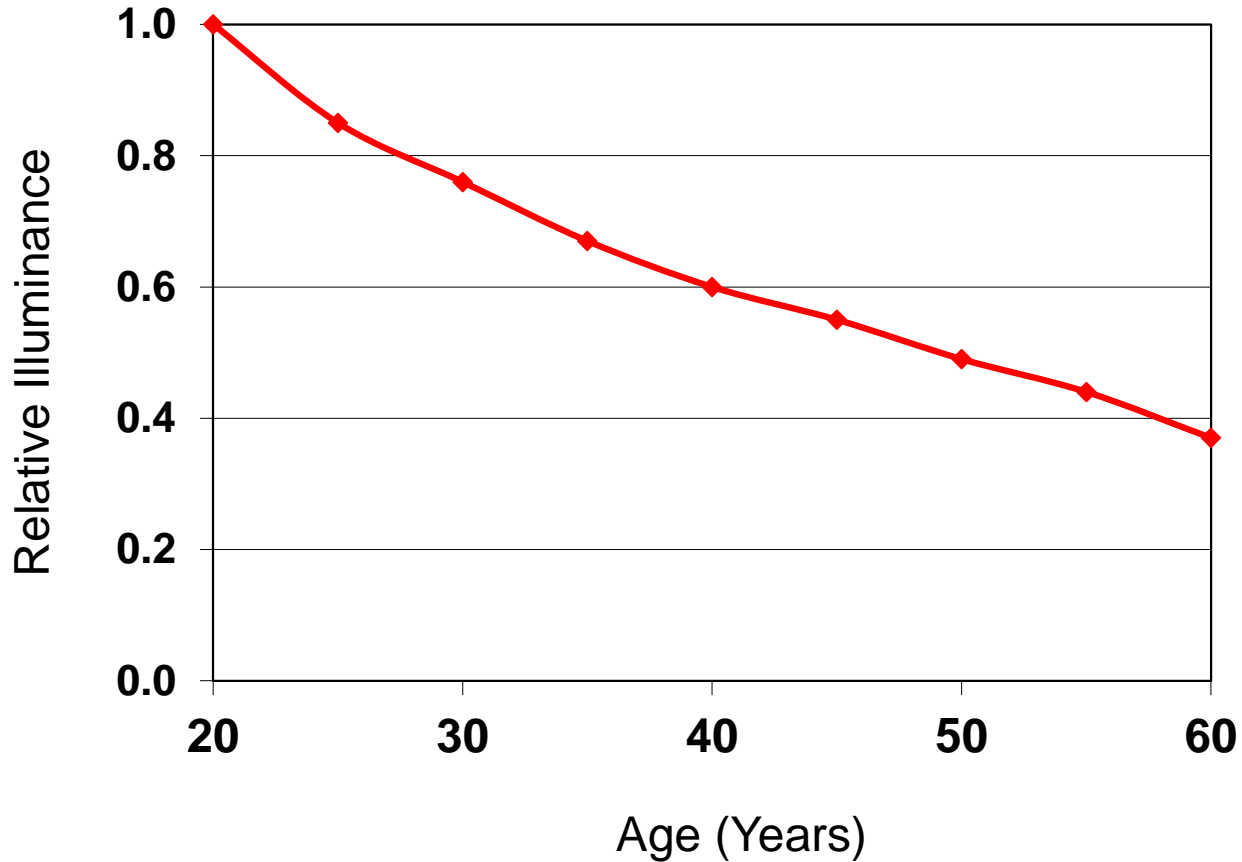


# What is the average illumination intensity at the container during manual inspection?





# Aging and Relative Illuminance



From IESNA Lighting Handbook, 9<sup>th</sup> Edition

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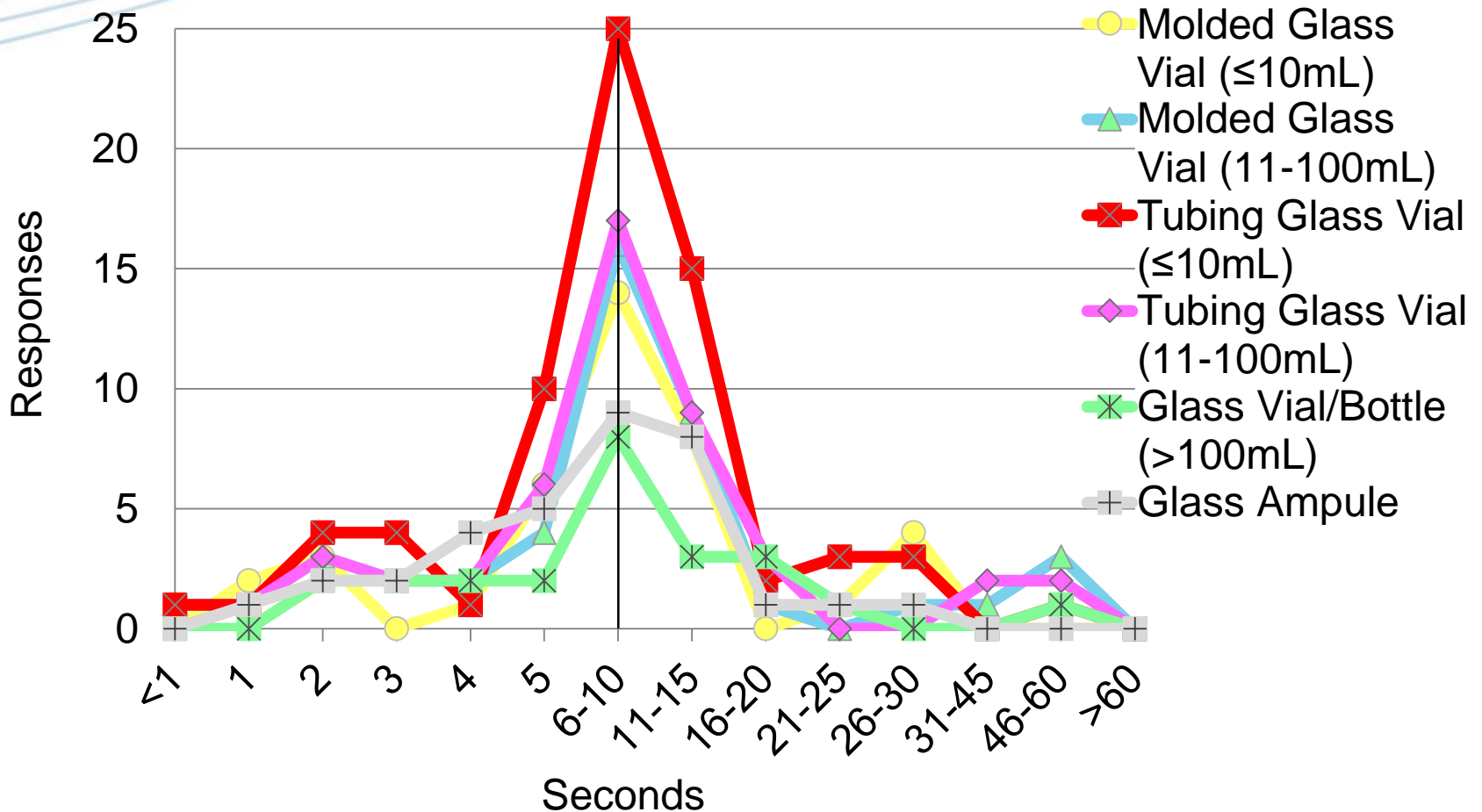


# Manual Inspection Conditions

- 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,



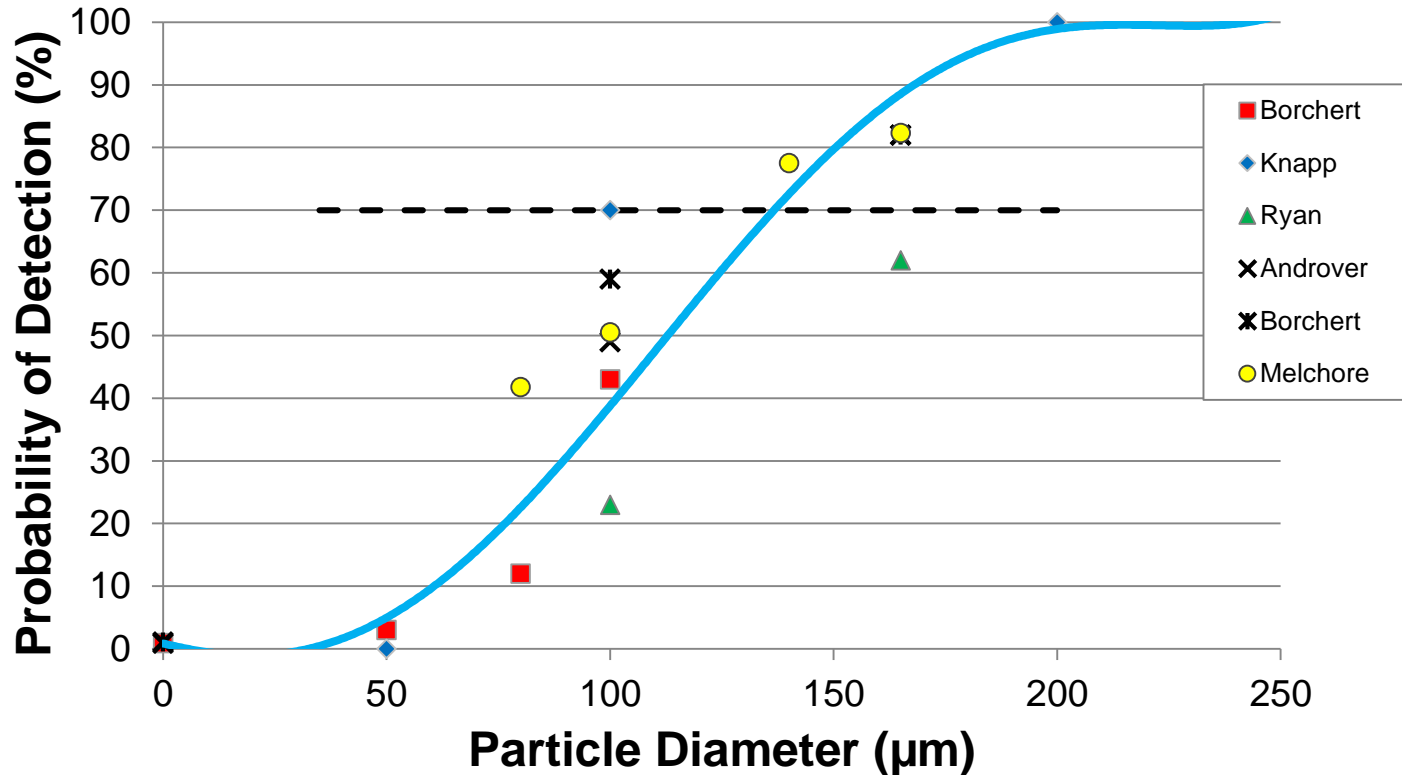
# What is the average inspection time for this container type?







# 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



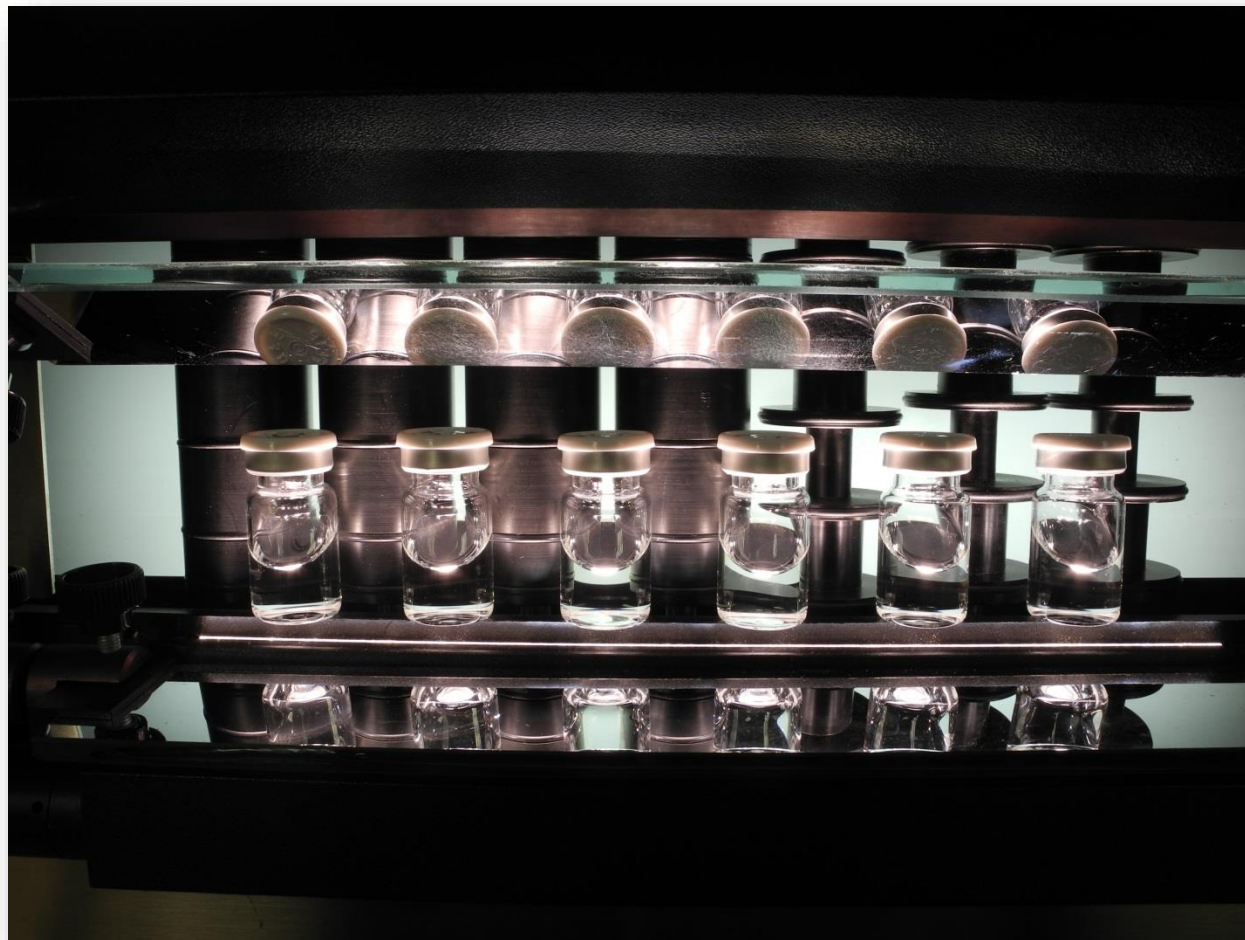
# Semi-Automated Inspection



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 Particle Inspection

Light Source

Product

Linear Detector



Bosch Static Detection (SD)



# Automated Particle Inspection



Eisai AIM-288

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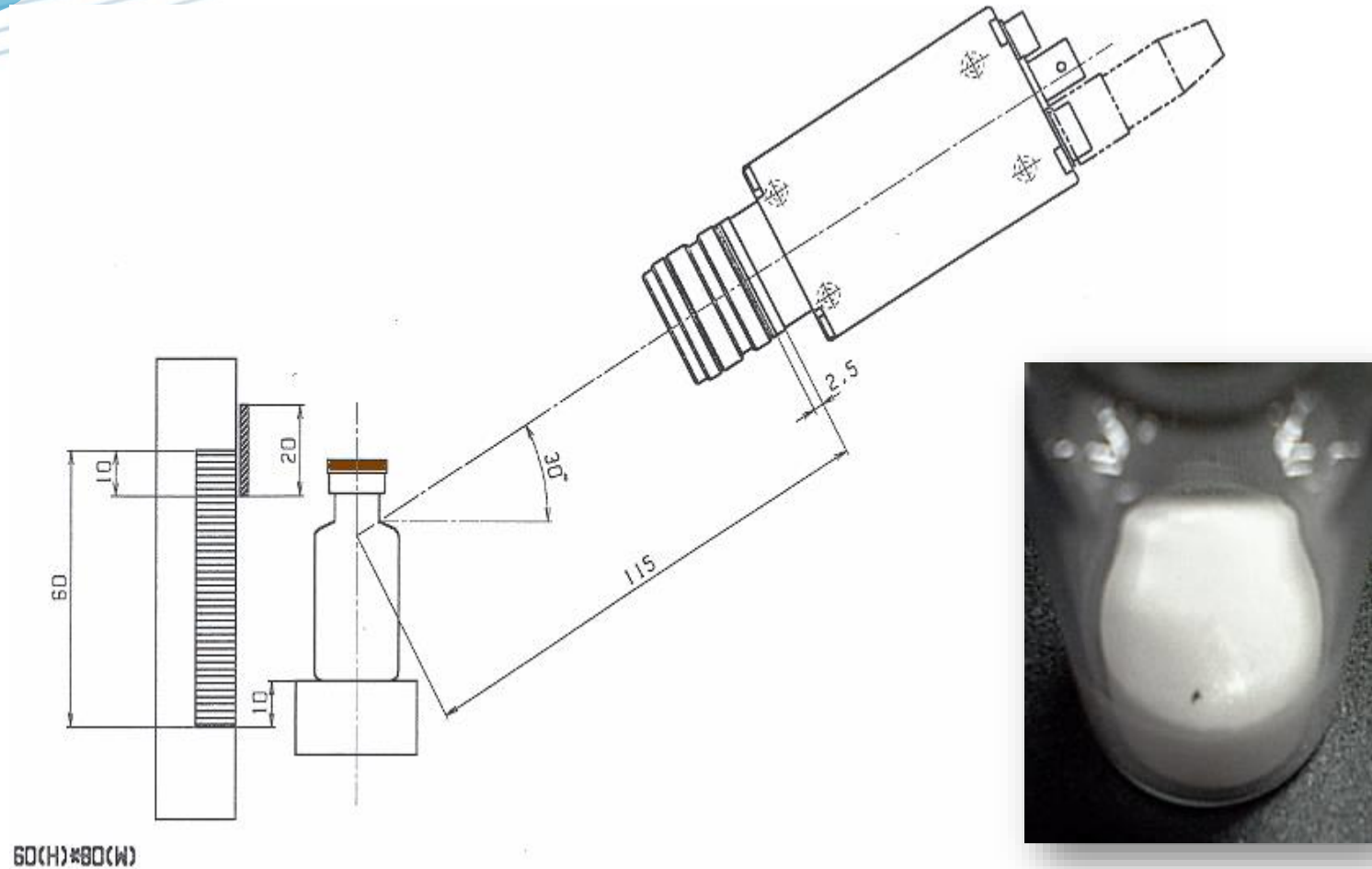
# Automated Inspection



Eisai EIS-596



# Automated Inspection





# Inspection Performance

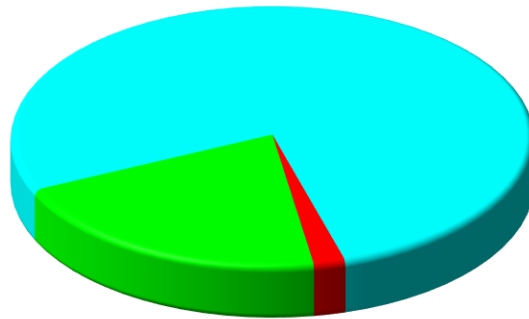
- Machine Inspection
  - Adjustable Sensitivity
    - Increased sensitivity must be balanced with increased false rejection rates.
    - Often product dependent
      - viscosity, surface tension, container design and variability
- Improved Reproducibility
- Improved Throughput
- High Initial Investment



# Machine Inspection Performance

## Human

Inconclusive

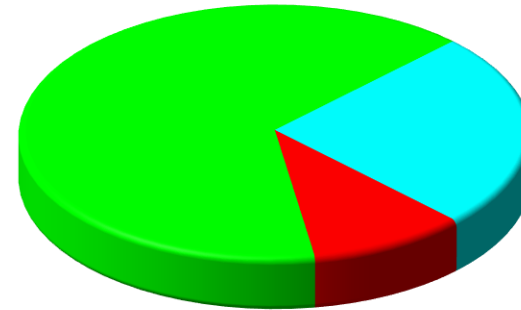


Good

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



# Does your firm have plans to replace manual inspection with automated inspection?

	2014	2008	2003	1996
<b>Shift to Automated Inspection</b>	<b>50%</b>	<b>67%</b>	<b>50%</b>	<b>68%</b>
<b>Justification</b>				
<b>Quality</b>	<b>85%</b>	<b>75%</b>	<b>92%</b>	<b>92%</b>
<b>Productivity</b>	<b>87%</b>	<b>92%</b>	<b>92%</b>	<b>100%</b>
<b>Other</b>	<b>5%</b>	<b>0%</b>	<b>8%</b>	<b>17%</b>





# Inspection Standards





## How frequently do you challenge or retest automated inspection equipment?

	2014	2008	2003	1996
<b>Never</b>	<b>1%</b>	<b>0%</b>	<b>0%</b>	<b>15%</b>
<b>Each Shift</b>	<b>1%</b>	<b>8%</b>	<b>13%</b>	<b>8%</b>
<b>Start of Lot</b>	<b>46%</b>	<b>42%</b>	<b>75%</b>	<b>38%</b>
<b>Start and End of Lot</b>	<b>8%</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>
<b>Daily</b>	<b>15%</b>	<b>25%</b>	<b>19%</b>	<b>23%</b>
<b>Weekly</b>	<b>2%</b>	<b>0%</b>	<b>0%</b>	<b>8%</b>
<b>Monthly</b>	<b>2%</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>
<b>Quarterly</b>	<b>1%</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>
<b>Annually</b>	<b>19%</b>	<b>ND</b>	<b>ND</b>	<b>ND</b>

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

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# Questions?

**BEAUTIFUL,  
BUT OBSOLETE.**

