



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

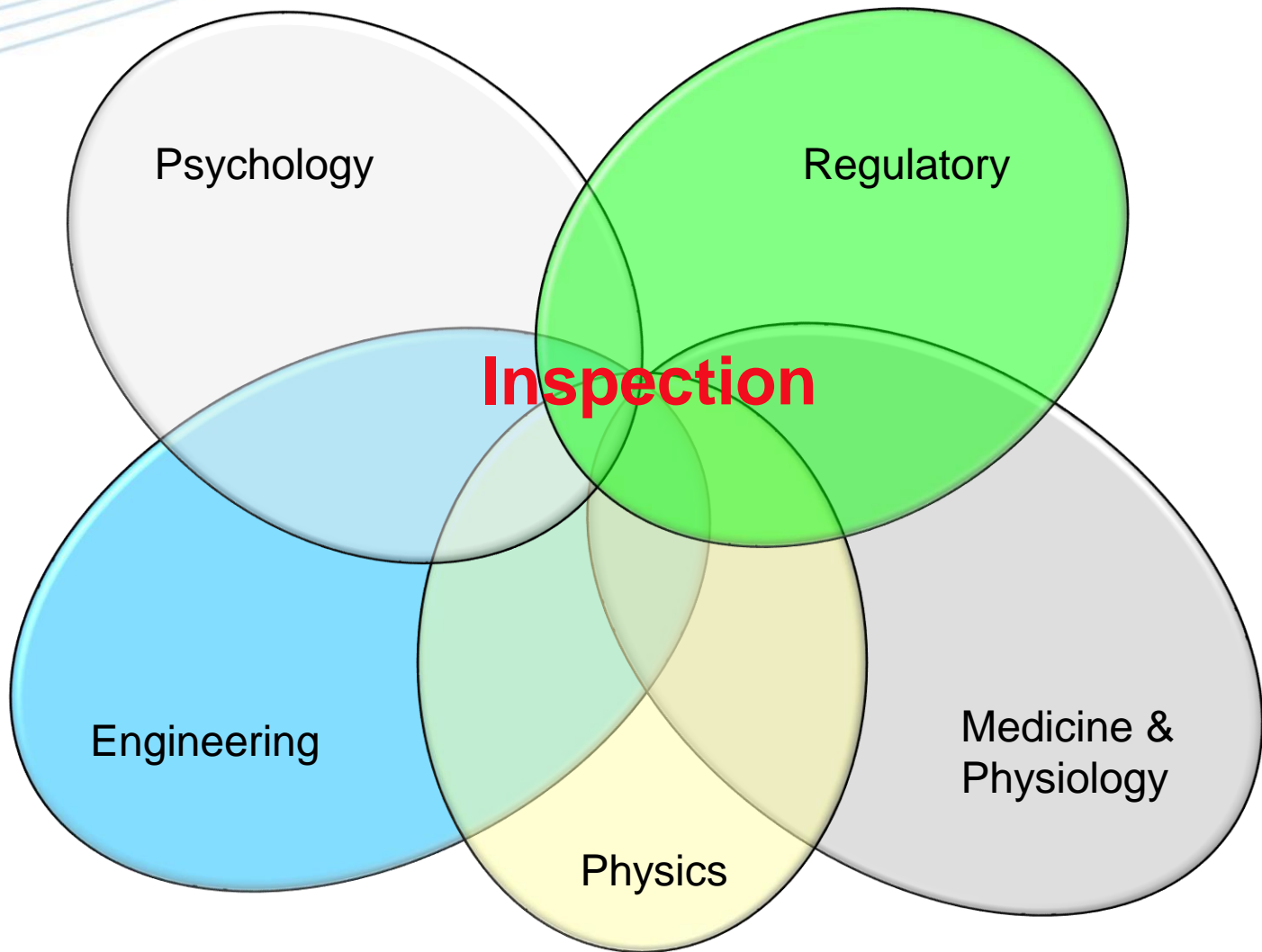
- Manual Inspection
- Semi-Automated Inspection
- Automated Inspection



Manual Inspection

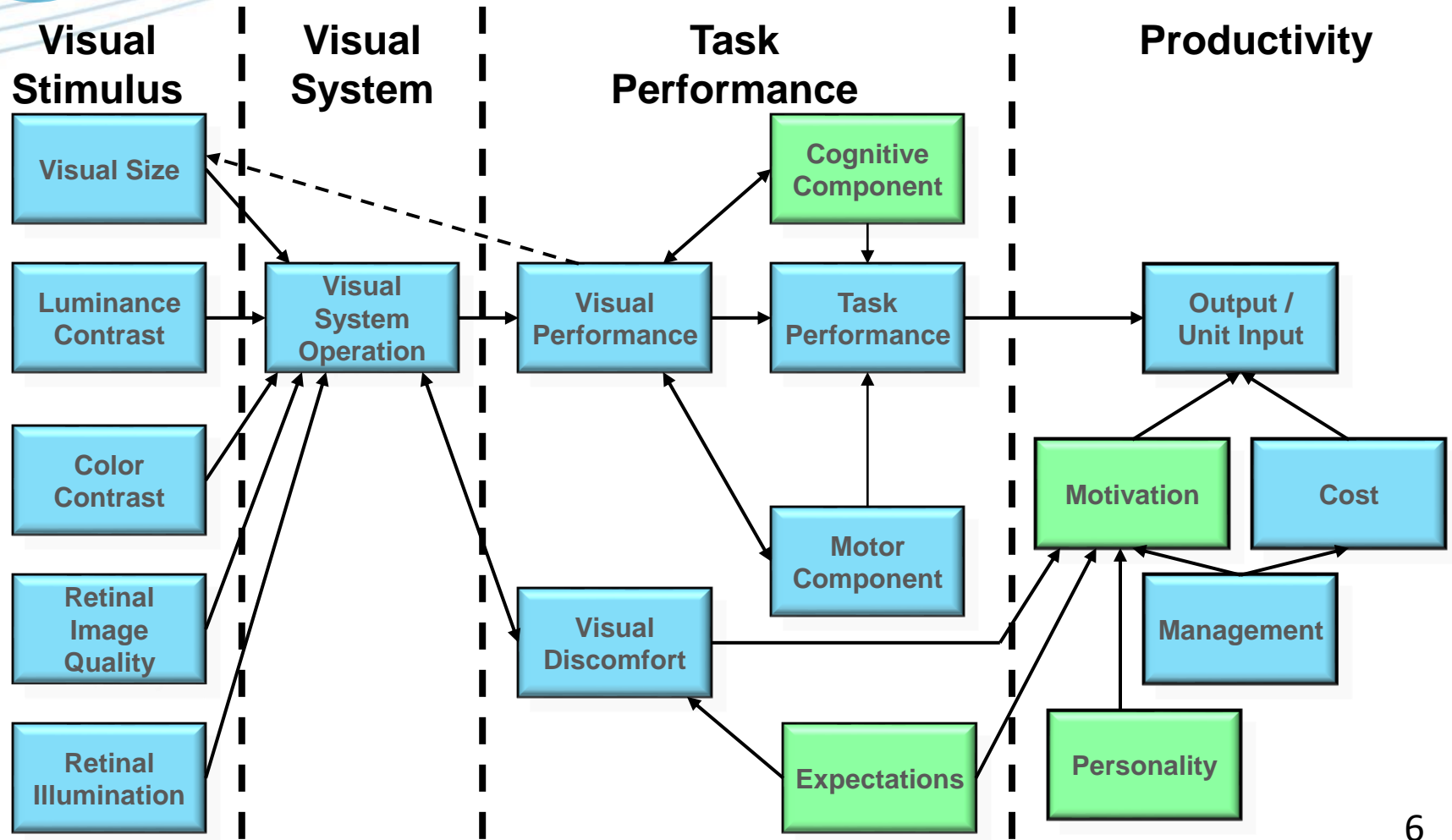


Inspection Influences





Inspection

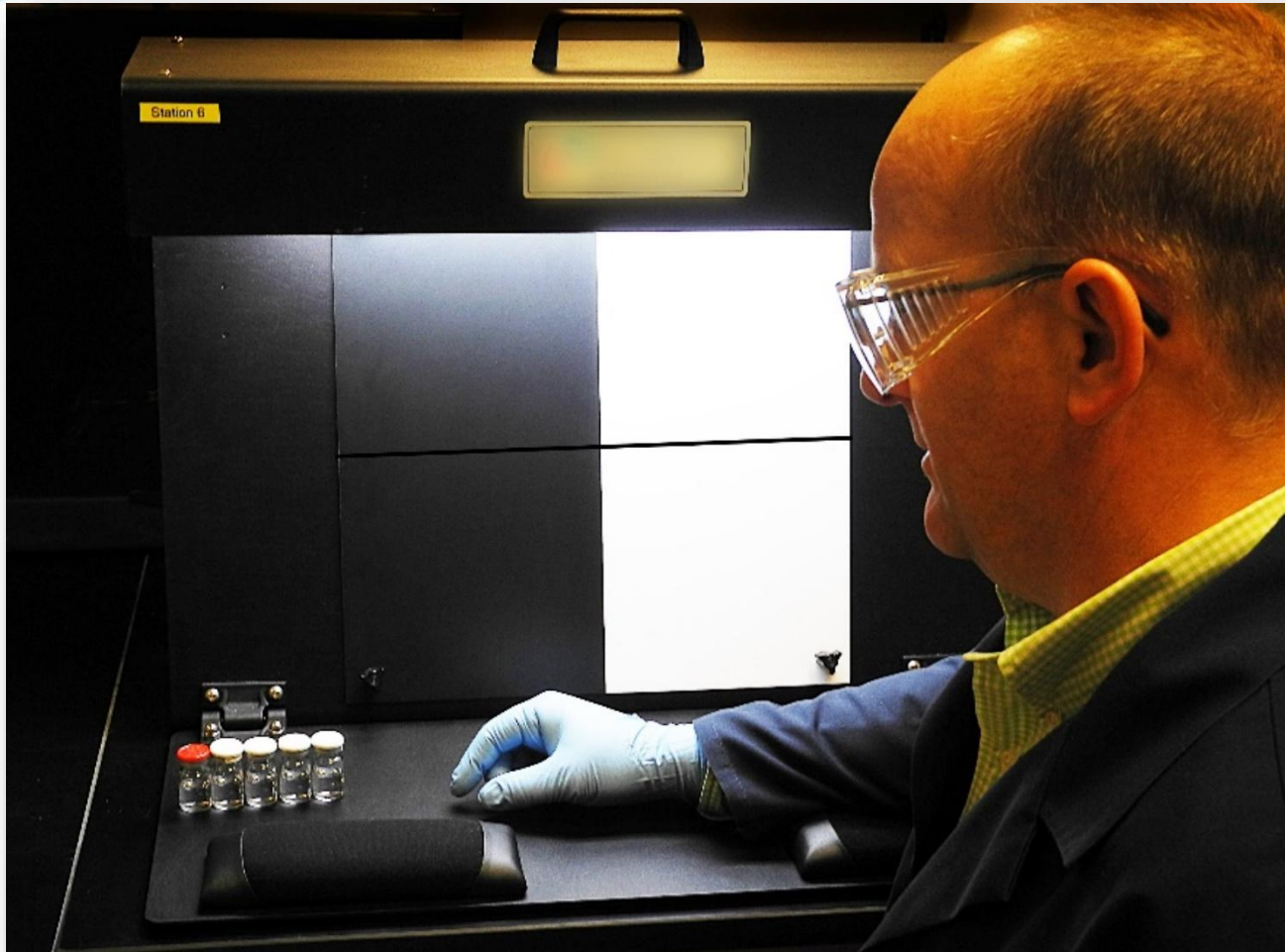


From G. Salvendy, Handbook of Human Factors and Ergonomics, 2nd Edition

Fundamentals of Visual Inspection



Manual Inspection





Manual Inspection



Phoenix Imaging MIB-100



Manual Inspection





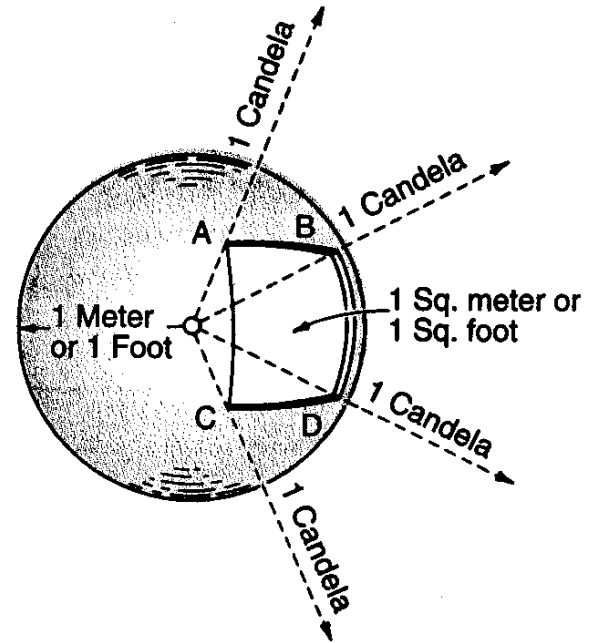
Critical Inspection Parameters

- Lighting
 - Illumination Intensity (2,000-3,750 lux)
 - Uniform, Flicker-free
 - LED, Fluorescent, Incandescent
 - Tyndall (dark-field)
- Background
 - Black / White
- Presentation and Manipulation
 - Swirl and/or invert
- Pace
 - 10 sec / container (per pharmacopeias)



Illuminance

- Luminous Intensity (output)
 - 1 candela = 1/638 W/sr
 - 1 lumen = 1 candela in all directions
 - 1 candela formerly 1 candlepower
- Illuminance
 - 1 lux = 1 lumen/m²
 - 1 foot-candle = 1 lumen/ft²
 - 1 fc = 10.75 lux
- Inverse Square Law
 - illumination = luminous intensity/d²





Common Light Levels

- Bright sunny day: 100,000 lux
- Full daylight: 10,000 lux
- **Visual Inspection: 1,000-10,000 lux**
- Typical office lighting: 300-500 lux
- Typical stairway: 50-100 lux
- Twilight: 10 lux
- Full moon: <1 lux

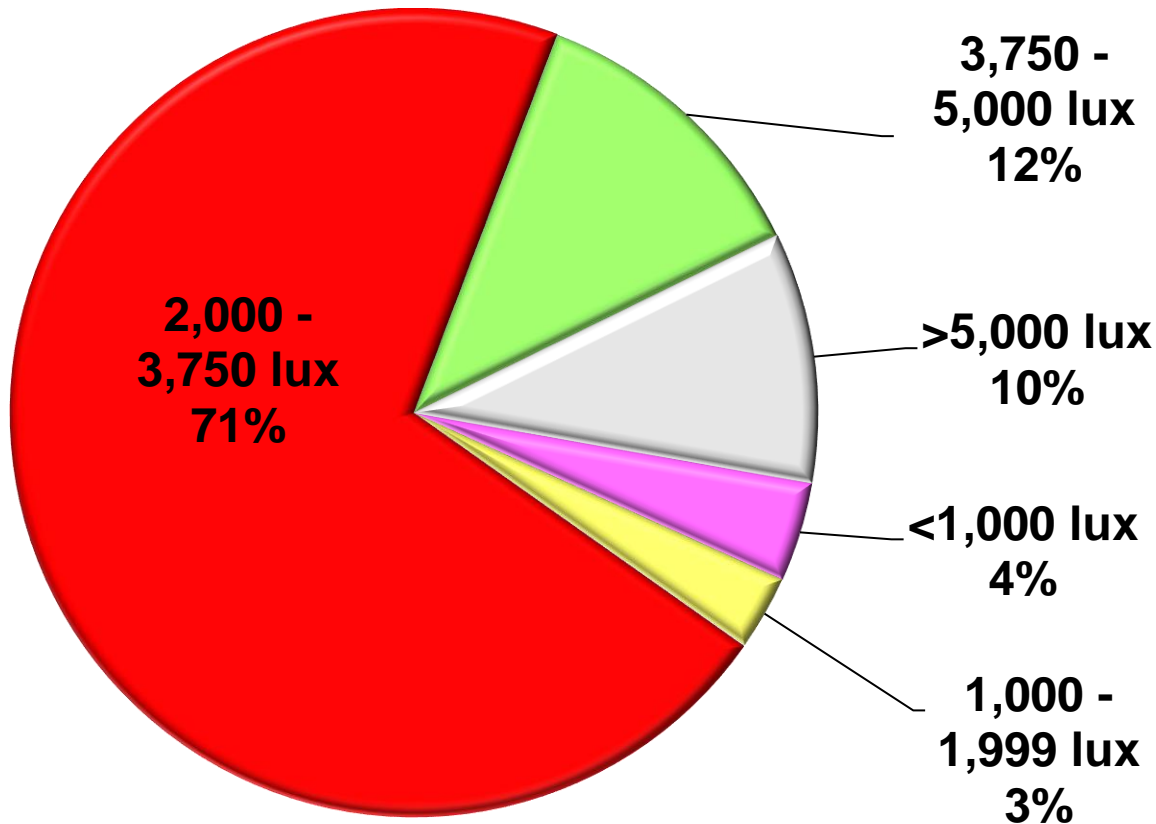


Illumination Intensity

- 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



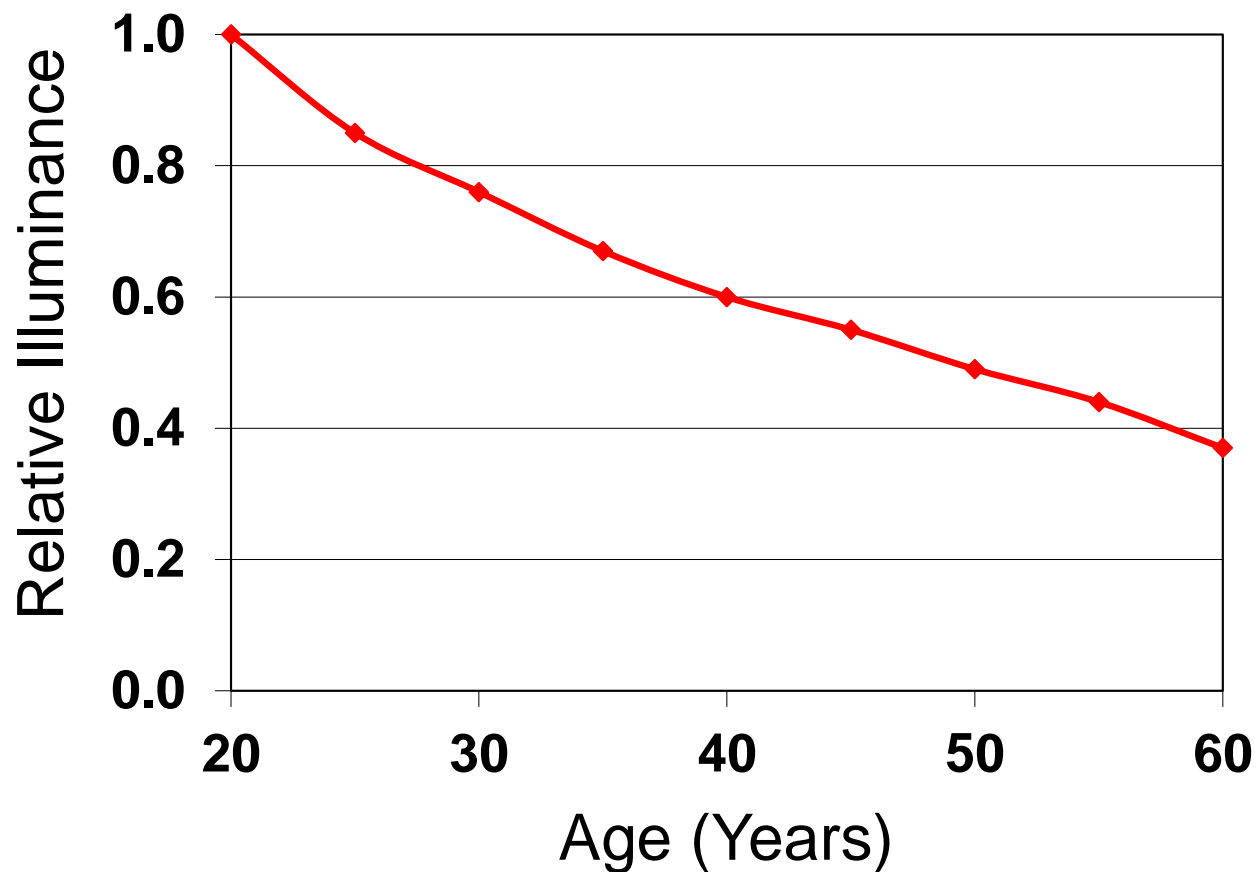
What is the average illumination intensity at the container during manual inspection?



From 2023 PDA Visual Inspection Survey



Aging and Relative Illuminance



From IESNA Lighting Handbook, 9th Edition



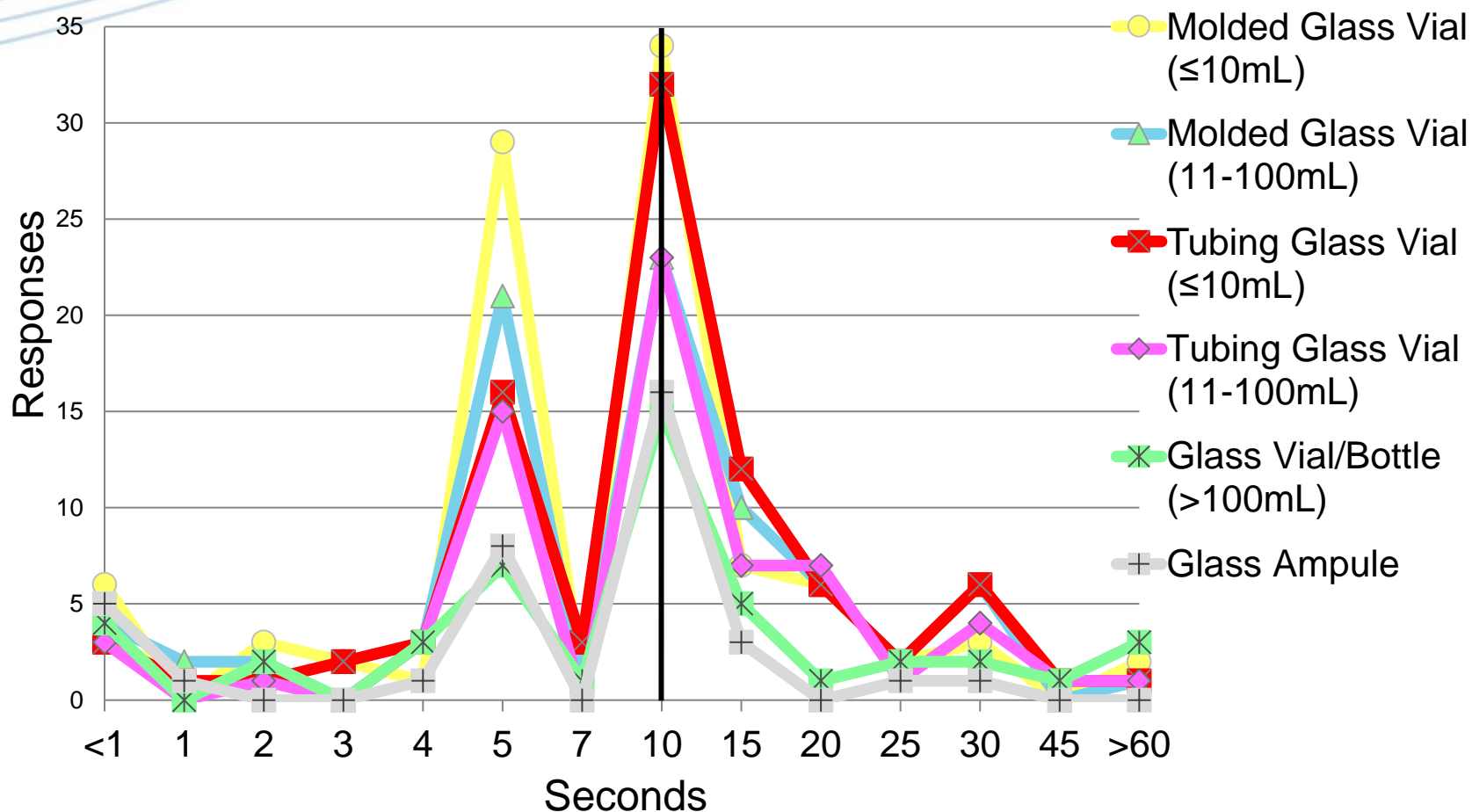
Manual Inspection Conditions

- 73% control inspection time or the pace of inspection.
 - 80% by SOP
 - 33% with Timer
 - 19% with Conveyor
- 15% use a magnifier.
 - 29% 2X, 24% 3X, 10% 4X, 24% 5X, 14% >5X
- Light Source used:
 - 62% LED, 44% Fluorescent, 12% Incandescent,

From 2023 PDA Visual Inspection Survey



What is the average inspection time for this container type?

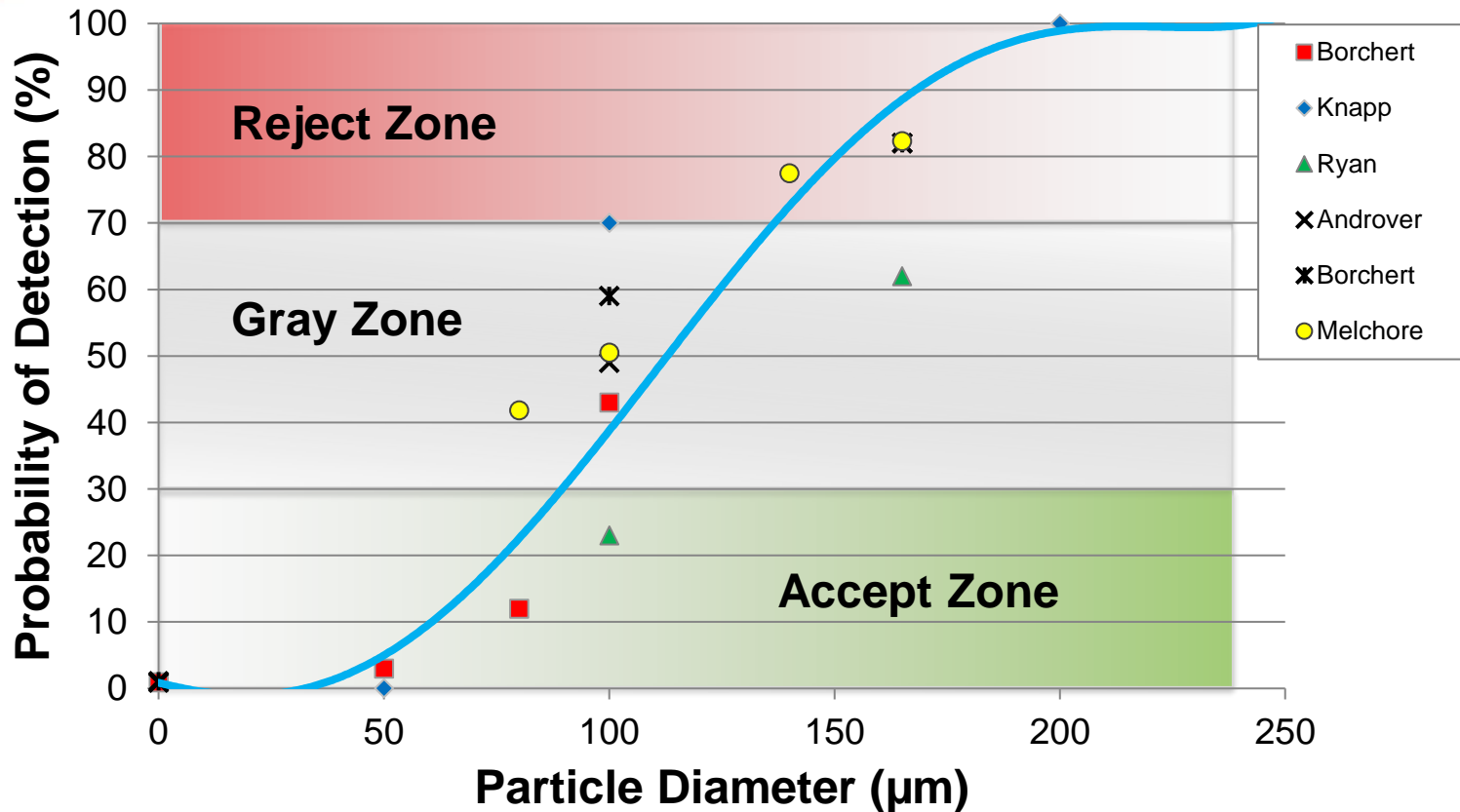


From 2023 PDA Visual Inspection Survey

Fundamentals of Visual Inspection



Human Inspection Performance



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

Fundamentals of Visual Inspection

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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



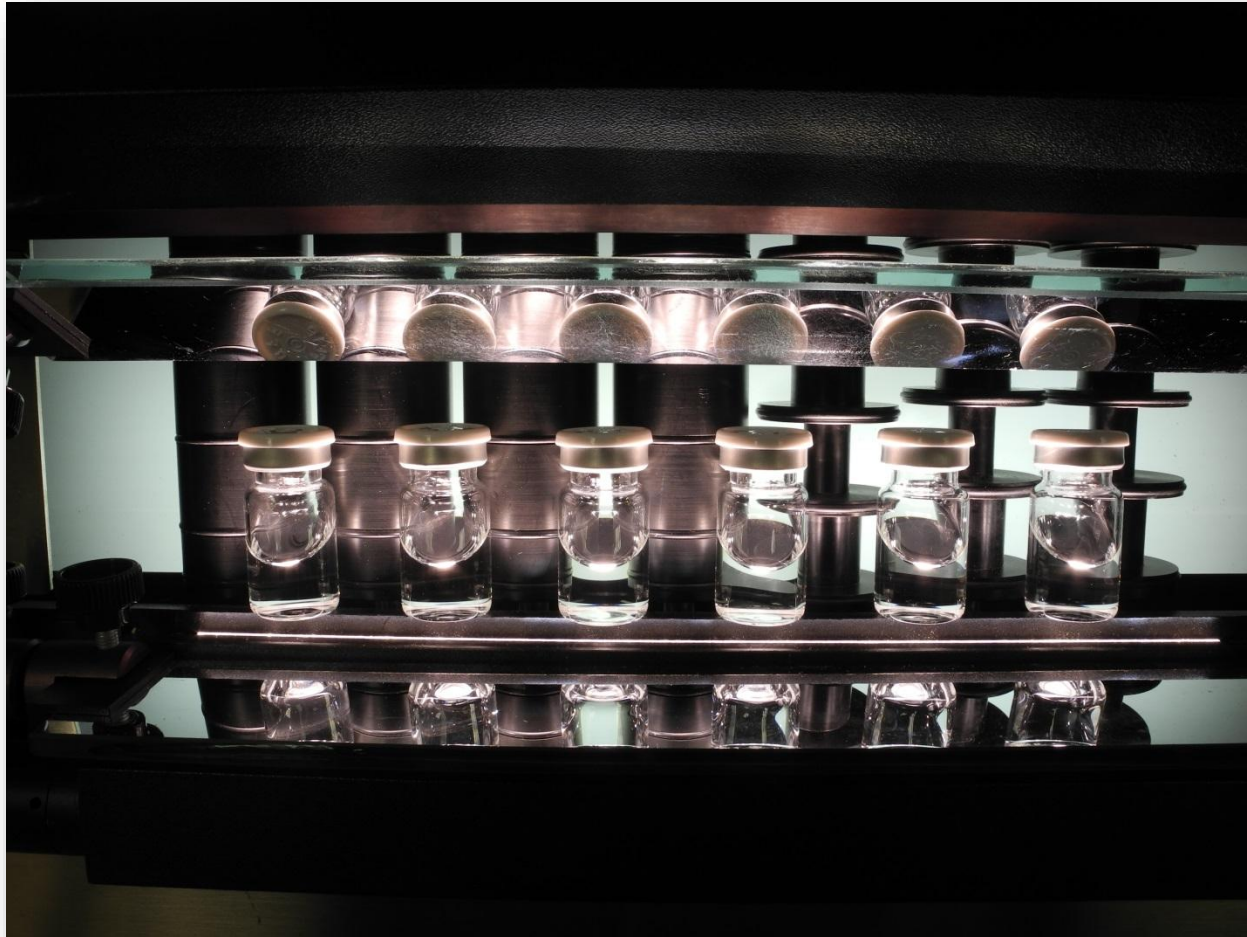
Semi-Automated Inspection



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

Fundamentals of Visual Inspection

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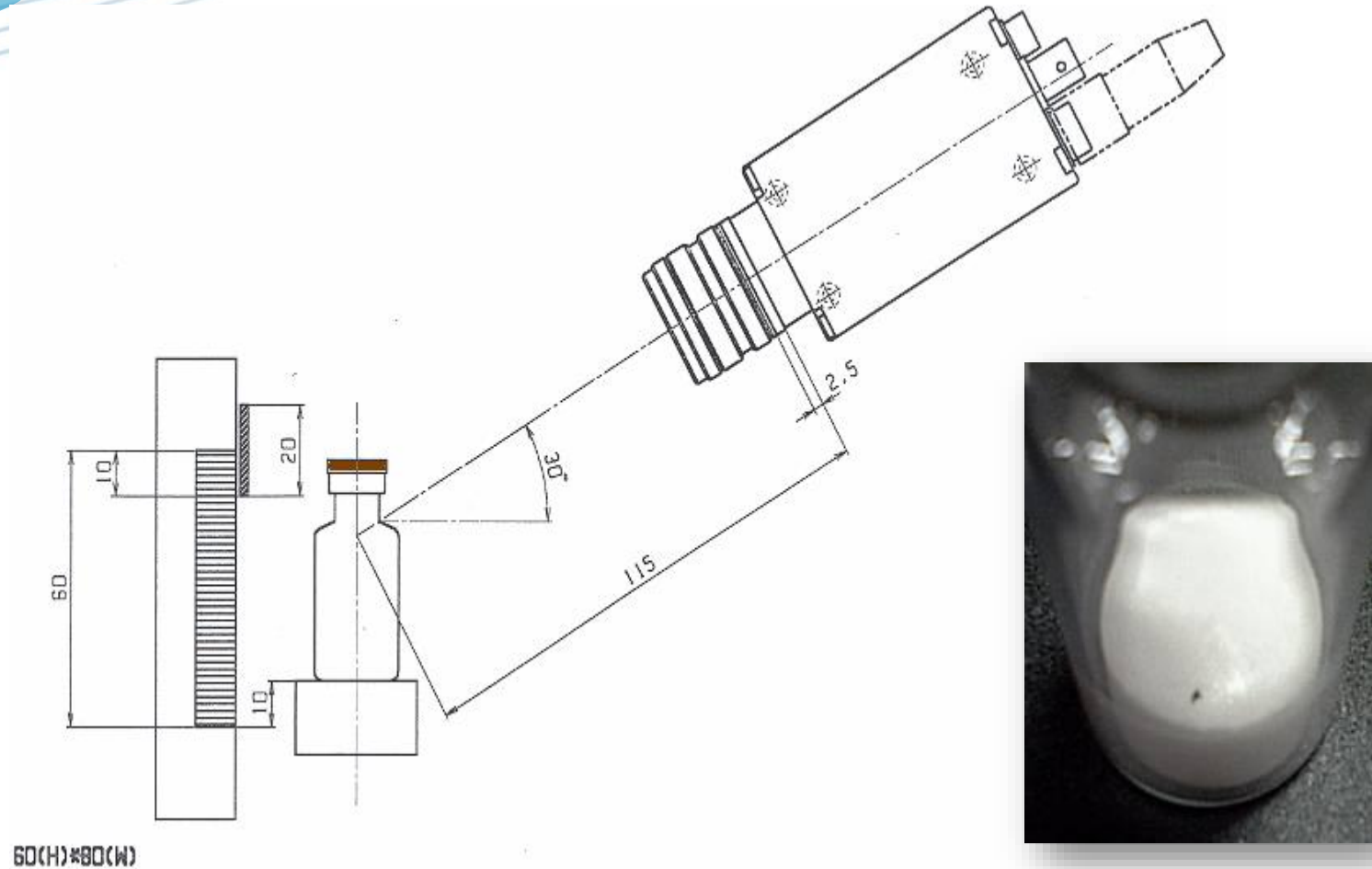
Automated Inspection



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



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

	2023	2014	2008	2003	1996
Particles:					
Manual	50%	49%	33%	46%	33%
Semi-Automated	21%	17%	24%	19%	20%
Automated	30%	33%	43%	35%	42%
Container/Closure:					
Manual	48%	54%	36%	63%	48%
Semi-Automated	20%	18%	26%	15%	42%
Automated	29%	28%	39%	20%	5%



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

	2023	2014	2008	2003	1996
Shift to Automated Inspection	57%	50%	67%	50%	68%
	Justification:				
Quality	66%	85%	75%	92%	92%
Productivity	ND	87%	92%	92%	100%
Increased Capacity	69%	ND	ND	ND	ND
Cost Savings	54%	ND	ND	ND	ND
Ergonomics	2%	ND	ND	ND	ND

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

Fundamentals of Visual Inspection



How frequently do you challenge or retest automated inspection equipment?

	2023	2014	2008	2003	1996
Never	4%	1%	0%	0%	15%
Each Shift	7%	1%	8%	13%	8%
Start of Lot	50%	46%	42%	75%	38%
End of Lot	3%	ND	ND	ND	ND
Start and End of Lot	1%	8%	ND	ND	ND
Daily	15%	15%	25%	19%	23%
Weekly	2%	2%	0%	0%	8%
Monthly	0%	2%	ND	ND	ND
Quarterly	4%	1%	ND	ND	ND
Annually	25%	19%	ND	ND	ND
Other	3%	ND	ND	ND	ND

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

Fundamentals of Visual Inspection



Questions?

**BEAUTIFUL,
BUT OBSOLETE.**

