



Training Course Agenda

PDA #

417

Title: An Introduction to Visual Inspection

DAY 1

8:30 Welcome and Introductions

Why We Inspect

- 9:00
 - 1) Regulatory Requirements
 - 2) Compendial Requirements
 - 3) Other Standards

10:00 Coffee/Tea Break

Inspection Methods and Technologies

- 10:30
 - 1) Manual Inspection
 - 2) Critical Parameters
 - 3) Semi-Automated Inspection
 - 4) Automated Inspection

12:00 Lunch

Manual Inspection Exercise (Lab)

- 13:00
 - 1) Basic Inspection Method Instruction
 - 2) Light Measurement
 - 3) Effect of Critical Inspection Parameters on Particulate Inspection

15:00 Coffee/Tea Break

15:30 Manual Inspection Exercise (Lab) – cont.

16:30 Wrap-Up Discussion / Q&A

17:00 End of Day 1



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DAY 2

8:00 Inspection Data Review (from previous day's lab)

9:00 Defect Classification Strategies

9:30 Coffee/Tea Break

Acceptance Sampling

10:00 1) Sampling Plan Variables

2) ANSI Z1.4

3) Single and Double Sampling Plans

Inspector Selection and Qualification

11:00 1) Vision Screening

2) Initial Training and Qualification

3) Periodic Requalification

11:30 Lunch

Inspection Strategies

1) Reinspection

2) 2-Stage Inspection

3) Focused Inspection

4) Empty Vial Inspection

Inspection Validation Methods

13:00 1) Comparing Inspection Methods

2) Acceptance Criteria

13:30 Mythbusting

14:00 Wrap-Up Discussion / Q&A

14:30 Alternative Inspection Methods and Inspection Challenges (Lab)

16:00 End of Training Course