



Training Course Agenda

Fundamentals of Visual Inspection Training Course (PDA 417)

-DAY 1

8:30 Welcome and Introductions

Why We Inspect

9:00

- 1) Regulatory Requirements
- 2) Compendial Requirements
- 3) Other Standards

10:00 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 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 Break

10:00 Acceptance Sampling
1) Sampling Plan Variables
2) ANSI Z1.4
3) Single and Double Sampling Plans

11:00 Inspector Selection and Qualification
1) Vision Screening
2) Initial Training and Qualification
3) Periodic Requalification

11:30 Lunch

12:30 Inspection Strategies
1) Reinspection
2) 2-Stage Inspection
3) Focused Inspection
4) Empty Vial Inspection

13:00 Inspection Validation Methods
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