

PDA How to Handle Test Sets in Visual Inspection Training Course

Agenda

Thursday, 21 May

BST Daylight Time (UTC +1:00)

09:00 – 09:15 **Welcome, Introduction, and Collecting Participants' Expectations**

1.1 Introduction to Test Sets for Visual Inspection (MVI, SAVI, and AVI) – Current Regulatory Requirements and Best Practices

- Overview of the agenda and goals of the training course
- VI Test sets – purpose, usage, and requirements
 - Current regulatory requirements to VI & VI test sets
 - Regional differences, terminology, and defect classification
 - Examples from recent FDA 483s and Warning Letters
- MVI operator training and qualification, AVI qualification/ validation, transition from MVI to SAVI/ AVI, daily functional checks

09:15 – 10:15

Probabilistic nature of visual inspection - statistical methodology, Knapp approach, Probabilities of detection (PoD), false rejects

- The VI qualification journey (MVI/ SAVI/ AVI) - Test set design, manufacturing, creation, qualification, and usage (a process flowchart)

10:15 – 10:45 **Coffee Break**

1.2 Fundamentals of Test Set Design

- Risk assessment – why is it needed and how to carry it out?
- Defect libraries
- Considerations for test set design
 - Primary packaging
 - Product attributes
 - Types and sizes of defects
 - Additional considerations
 - Test set size; defect-containing and defect-free units
- Types of defects
- Defect Categories
 - Major
 - Minor
 - Critical

10:45 – 11:30

1.3 Practical Considerations for Use and Creation of VI Test Sets Defects

- Particles
 - Spherical particles
 - Irregular particles
 - Particle behavior (e.g., adhering vs. floating particles)
- Other defects
 - Container defects
 - Glass (Cracks, Scratches, Leaking)
 - Stopper defects
 - Cap defects or crimping defects
 - Contaminations (inside-outside)
 - Product defects - discoloration, turbidity, fill defects, etc.
- Distinction of test sets required for visual inspection from test sets required for CCI testing

11:30 – 12:15

12:15 – 13:15 **Lunch Break**

13:15 – 13:45	<p>1.4 Introduction to Test Sets for Automated Visual Inspection</p> <ul style="list-style-type: none"> • How to handle test sets during a project? • Test set for validation of automated visual inspection machine, including AVI development test set • Test set for daily performance check of automated visual inspection machine • Knapp test set
13:45 – 14:15	<p>1.5 Requirements Related to Automated Visual Inspection</p> <ul style="list-style-type: none"> • Transformation of the main principles from manual visual inspection to automated visual inspection • Challenges in the manual inspection • Transition to the automation • Advantages of the automated inspection
14:15 – 15:00	1.6 Practical Exercise – Test set design
15:00 – 15:30	Coffee Break
15:30 – 16:00	<p>1.7 Vision Evaluation Done Right: Test Sets, Steps, Results</p> <ul style="list-style-type: none"> • How to handle the test set in a vision evaluation • Step-by-step explanation of the evaluation process and what's important • Evaluation Result and how to proceed with the results in the further process
16:00 – 16:45	<p>Wrap-up Training Course Day 1</p> <ul style="list-style-type: none"> • Questionnaire • Q&A for all questions on training course day 1 (if not yet answered) • Feedback session
16:45 – 16:45	End of Training Day 1

Friday, 22 May

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09:00 – 09:15	What Are Your Practical Challenges with Test Sets?
09:15 – 09:30	<p>1.8 Test Sets for Difficult to Inspect Products (DIPs)</p> <ul style="list-style-type: none"> • General considerations for defect detectability and additional regulatory requirements • Types of DIP <ul style="list-style-type: none"> ◦ Lyophilized products ◦ ATMPs ◦ Colored glass containers ◦ Emulsions ◦ Suspensions ◦ Turbid liquids ◦ Surrogate solutions versus product
09:30 – 10:30	<p>1.9 Discussion on Technical Challenges with Difficult-to-Inspect Products – Test Set Manufacturing, MVI, and AVI-Specific Challenges</p> <ul style="list-style-type: none"> • Small-volume and large-volume containers • Lyophilized products Infusion bags • BFS containers • Highly turbid products • Colored solutions and containers • Highly viscous products
10:30 – 11:00	Coffee Break
	2.0 Test Set Challenges = (Pharma Perspective, Test Set Manufacturer's Perspective, AVI System Supplier's Perspective)

11:00 – 12:00	<ul style="list-style-type: none"> • Product-specific vs bracketing approaches • Special containers • MVI vs AVI • False Reject Rates • Challenging defects • Air bubbles
12:00 – 13:00	Lunch Break
2.1 Virtual Facility Tour at Körber Pharma Inspection Site	
13:00 – 14:10	<ul style="list-style-type: none"> • Operational Walkthrough • Close-Up Views • Automatic sample sorting
2.2 Lifecycle Management of Test Sets	
14:10 – 15:00	<ul style="list-style-type: none"> • Required data and documentation: <ul style="list-style-type: none"> ◦ Certificate of manufacturing (expected characterization data) ◦ Qualification report ◦ Training certificates ◦ Inspector re-qualification (different approaches) • Lifecycle management: <ul style="list-style-type: none"> ◦ Storage and shelf-life, provisional shelf-life setting ◦ "Disappearing" defects ◦ Replacement of units ◦ Re-qualification of test sets • Multi-site setup (same product, different facilities) - harmonization of practices, benchmarking • Phase-appropriate approaches: <ul style="list-style-type: none"> ◦ Early phase vs. BLA and commercial • Product-specific vs. bracketing approaches
15:00 – 15:15	Coffee Break
Wrap-up Training Course Day 2	
15:15 – 16:15	<ul style="list-style-type: none"> • Knowledge check - multiple choice test • Q&A training course day 2 • Review results from practical exercise Day 1 – additional considerations/ modifications
16:15 – 16:15	End of Training Course

PDA An Introduction to Visual Inspection: A Hands-On Training Course Spring Edition 2026

21 May - 22 May

PDA Mastering Automated Visual Inspection Training Course Spring Edition 2026

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