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**

09:15 – 10:15	**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
	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**

10:45 – 11:30	**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

11:30 – 12:15	**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

12:15 – 13:15	**Lunch Break**

13:15 – 13:45	**1.4 Introduction to Test Sets for Automated Visual Inspection** • 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	**1.5 Requirements Related to Automated Visual Inspection** • 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	**1.7 Vision Evaluation Done Right: Test Sets, Steps, Results** • 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	**Wrap-up Training Course Day 1** • 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**
18:30 – 22:00	**Dinner**

Friday, 22 May

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09:00 – 09:15	**What Are Your Practical Challenges with Test Sets?**

09:15 – 09:30	**1.8 Test Sets for Difficult to Inspect Products (DIPs)**
	• General considerations for defect detectability and additional regulatory requirements
	• Types of DIP
	  ◦ Lyophilized products
	  ◦ ATMPs
	  ◦ Colored glass containers
	  ◦ Emulsions
	  ◦ Suspensions
	  ◦ Turbid liquids
	  ◦ Surrogate solutions versus product

09:30 – 10:30	**1.9 Discussion on Technical Challenges with Difficult-to-Inspect Products – Test Set Manufacturing, MVI, and AVI-Specific Challenges** • 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**

11:00 – 12:00	**2.0 Test Set Challenges = (Pharma Perspective, Test Set Manufacturer's Perspective, AVI System Supplier's Perspective)** • Product-specific vs bracketing approaches • Special containers • MVI vs AVI • False Reject Rates • Challenging defects • Air bubbles
12:00 – 13:00	**Lunch Break**
13:00 – 14:10	**2.1 Virtual Facility Tour at Körber Pharma Inspection Site** • Operational Walkthrough • Close-Up Views • Automatic sample sorting

14:10 – 15:00	**2.2 Lifecycle Management of Test Sets**
	• Required data and documentation:
	  ◦ Certificate of manufacturing (expected characterization data)
	  ◦ Qualification report
	  ◦ Training certificates
	  ◦ Inspector re-qualification (different approaches)
	• Lifecycle management:
	  ◦ 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:
	  ◦ Early phase vs. BLA and commercial
	• Product-specific vs. bracketing approaches

15:00 – 15:15	**Coffee Break**
15:15 – 16:15	**Wrap-up Training Course Day 2** • 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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