Training Course Agenda

PDA EU00186 How to Handle Test Sets in Visual Inspection

Day 1 – Tuesday, 13 February 2024		
9:00	**Welcome, Introduction, and Collecting Participants' Expectations**	***All trainers***

9:15	**1.1 Introduction to Test Sets for Manual Visual Inspection**
	• What is in principle a test set?
	• Why do we need test sets?
	• When should a test set be created?
	• Overview of agenda of the training course
	  ○ Naming the different types of test sets covered in the course
	  ○ Main purpose
	  ○ Timing when this type of test set will be covered during the course
	• Distinction of test sets required for visual inspection from test sets required for CCI testing
		Swen Maas & Matthias Eisele, ***Material Analytischer Service***

9:45	**1.2 Purposes of Test Sets and Background to the Test Set Qualification Process** • 100% VI and AQL • QC testing (e.g. stability) • Generation of supportive data for quality investigations/ Inspection support - justification of qualification process and control system	Atanas Koulov, ***Clear Solutions Laboratories***
10:15	**Coffee Break**	
10:45	**1.3 Design of Test Sets** • Introduction into a flowchart that has all the necessary steps to decide on the design of the test set (the flowchart should be one of the main course deliverables) • Why do I need a risk assessment? • How do I perform risk assessment? • What must the test set look like? • Which primary packaging do I have in the facility? • Which particle sources do I have in the facility? • Which product defects do I regularly see in the facility? • Which defects must be included in my test sets?	Atanas Koulov, ***Clear Solutions Laboratories***

11:45	**1.4 Particles and Defects**
	• Overview of types of particles
	  ○ Spherical particles (balls)
	  ○ Irregular glass fragments
	  ○ Adhering particles
	• Overview of other defects
	  ○ Container defects (Cracks, Scratches, Leaking)
	  ○ Stopper defects
		Swen Maas & Matthias Eisele, ***Material Analytischer Service***

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	○ Cap defects or crimping defects ○ Contaminations (inside-outside) ○ Solution defects • How many containers must be included in the test set? ○ "Defect-free" containers ○ "Defective" containers • What must my associated defect library look like? ○ Types of defects ○ Sizes of defects ○ Major defect ○ Minor defects ○ Critical defects • Which classes of defects must be included in the test set?	
12:15	**1.5 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	Severin Gumz, ***Körber Pharma***
12:30	**Lunch Break**	
13:30	**1.6 Tour to the Körber Vision Laboratory** Vision evaluation of a test set, step-by-step • Check the test set for completeness • Visibility of defects • Mechanical setup for test set evaluation • How do particles behave • Definition of camera stations and illumination for AVI • Creation of vision configuration for AVI, based on test set • Definition of detection rate & false eject rate of AVI	Marion Haberstetter, ***Körber Pharma***
15:00	**Coffee Break**	
15:30	**1.7 Special Test Sets - What Do They Need to Look Like?** • Lyophilized products • Difficult to inspect products ○ ATMPs ○ Colored glass containers ○ Emulsions ○ Suspensions ○ Turbid liquids	Atanas Koulov, ***Clear Solutions Laboratories***

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	• Substitute solutions versus real product	
16:00	**1.8 Technical Considerations on Test Sets for Difficult-to-Inspect Products** • Small-volume and large-volume containers • Lyo containers • Infusion bags • Solutions with turbidity • Colored solutions • Colored containers • Solutions with high viscosity	Swen Maas & Matthias Eisele, ***Material Analytischer Service***
16:30	**1.9 Challenges of Difficult to Inspect Products for Automated Visual Inspection** • Products prone to air bubbles • Foaming products • Highly viscous products • Toxic products • Lyophilized products • Emulsions / Suspensions / Turbid liquids	Christian Kolic, ***Körber Pharma***
17:00	**Wrap up training course day 1** • Q&A for all questions of training course day 1 (if not yet answered) • Multiple choice test 1	***All trainers***
17:45	**End of Training Day 1**	
18:30 – 22:00	**Dinner**	

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Day 2 – Wednesday, 14 February 2024		
9:00	**What Are Your Practical Challenges with Test Sets?**	***All trainers***
09:10	**2.1 Challenges from a Pharma Perspective** • Syringes/cartridges with sticky particles (due to siliconization) • Glass defects in tubular glass containers vs molded glass containers • Highly viscous products • Toxic products • Foaming products • Air bubbles in product	Atanas Koulov, ***Clear Solutions Laboratories***
09:20	**2.2 Challenges from a Laboratory Perspective** • Syringes/cartridges with sticky particles (due to siliconization) • Glass defects in tubular glass containers vs molded glass containers • High viscose products • Toxic products • Foaming products • Air bubbles in product	Swen Maas & Matthias Eisele, ***Material Analytischer Service***
09:40	**2.3 Challenges from the Machine Supplier's Perspective** • Sticking/floating particles • Glass defects in tubular glass containers vs molded glass containers • Large volume containers • Low-fill products • Unstable containers • Overlapping needle shield • Amber glass	Felix Riehn, ***Körber Pharma***
10:00	**Coffee Break**	

10:30	**2.4 Lifecycle Management of Test Sets**
	
	• Required data and documentation:
	  ○ Certificate of manufacturing (expected characterization data)
	  ○ Qualification report
	  ○ Training certificates
	• Lifecycle management:
	  ○ Storage and shelf-life
	  ○ „Disappearing" defects
	  ○ Replacement of units
	  ○ Re-qualification
	• Multi-site setup (same product different facilities) - harmonization of practices
	• Phase-appropriate approaches:
		Atanas Koulov, ***Clear Solutions Laboratories***
		
		&
		
		Swen Maas, ***Material Analytischer Service***

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	○ Early phase vs. BLA and commercial	
12:00	**Lunch Break**	
13:00	**2.5 Facility Tour at Körber Pharma Inspection Site** • Hands-on exercise 4 ○ Demonstration of a „simple“automated inspection machine • Hands-on exercise 5 • Demonstration of „sophisticated” automated inspection machine	***Körber Pharma***
14:30	**2.6 Requirements Related to Automated Visual Inspection** • Transformation of the main principles from manual visual inspection to automated visual inspection	Christian Kolic, ***Körber Pharma***
15:30	**Coffee Break**	
16:00	**Wrap-up training course day 2** • Q & A for all questions of training course day 2 (if not yet answered) • Multiple choice test 2	***All trainers***
16:30	**Final Wrap-up of training course**	***All trainers***
16:45	**End of Training Course**	