Training Course Agenda

PDA EU00134 Mastering Automated Visual Inspection

Day 1, 15 November 2023		
9:00	**Welcome and Introduction of Trainers and Participants**	
9:30	**Module 1: Introduction to Regulatory Requirements of Visual Inspection** • USP 1, USP 788 and 1788, USP 790 and 1790 • PhEur e.g. 2.9.20 • JP e.g. 6.06 • Annex 1 • Similarities and differences in compendial methods • 100% inspection and AQL testing • Definitions and practical examples of inherent, intrinsic, and extrinsic particles • Findings from audits	**Fernand Koert,** *GSK/Pharma Solution*
10:45	*Coffee Break*	
11:15	**Module 2: Introduction to Technical Principles of Automated Inspection Machines** • The functionality of automated inspection machines • Camera systems / light / motion • Image processing and database system • Interlinkage of parameters: Speed, Rotation speed, Inspection parameters, Detection probability, False reject rate • Properties, capabilities, and limitations of automated inspection systems • Scope of Automated Visual Inspection • Leak testing principle	**Romain Veillon,** *GSK*
12:15	*Lunch Break*	
13:15	**Module 2: Introduction to Technical Principles of Automated Inspection Machines (cont.)**	**Romain Veillon,** *GSK*
14:15	**Module 3: Considerations on Primary Containers and Product Properties** • Vials, Ampoules, Syringes, Blow – Fill - Seal, Viscous liquids, Air bubbles/scratches, Refrigerated product containers • Product impact study	**Fernand Koert,** *GSK/Pharma Solution*
14:45	**Exercise 1: Developing Risk Assessment based on URS**	**Fernand Koert,** *GSK/Pharma Solution*

15:45	*Coffee Break*	
16:15	**Module 4: Selection and Purchasing of an Automated Inspection System** • Technical requirements • Integration into existing processes, lines/ machines, and systems • Cost and effort considerations • Risk Assessment	**Fernand Koert,** *GSK/Pharma Solution*
17:15	**Exercise 1 (cont.): Presentation of the Results of the Sub-Groups and Discussion of the Results** **Q&A from Day 1**	
17:30	*End of Training Course Day 1*	

Day 2, 16 November 2023

9:00	**Recap of Day 1**	
09:15	**Module 5: Transition from Manual Inspection to Automated Inspection** • Manual inspection as a prerequisite for transition to automated inspection • Interpretation of inspection results and validation data • Considerations on validation program for automated inspection • Performance measurement • Maintaining the manual inspection • Knapp Principle/Fixed criteria	**Romain Veillon,** *GSK*
10:15	**Exercise 2: Principle Basic Image Processing Using an Open Source and Commercial Library**	**Fernand Koert,** *GSK/Pharma Solution*
11:00	*Coffee Break*	
11:15	**Exercise 2 (cont.): Q & A on Image Processing**	**Fernand Koert,** *GSK/Pharma Solution*
12:00	**Module 6: Qualification Test Set and Routine Test Set** • Statistical considerations on the number of objects containing defects • Particle selection, particle size, and size uniformity • Labeling of test set objects • Supply/purchase of test sets • Maintaining and lifecycle of test sets • Sampling from rejects • Defect master library • Types of defects	**Fernand Koert,** *GSK/Pharma Solution*

	• Quality requirements	
13:00	*Lunch Break*	
14:00	**Module 7: Visual Inspection Lifecycle and Control Strategy** • Integration of visual inspection into the overall manufacturing process • Elements of lifecycle • Particle identification/characterization • Defect libraries as dynamic database • AQL sampling principle • Control Charting	**Fernand Koert,** *GSK/Pharma Solution*
15:00	**Module 8: Operation and Maintenance of Automated Inspection Systems** • Spare part list • Predictive maintenance • First-line maintenance • Calibration	**Fernand Koert,** *GSK/Pharma Solution*
15:30	*Coffee Break*	
16:00	**Module 9: Future Trend of Automated Visual Inspection** • Moving toward deep learning	**Fernand Koert,** *GSK/Pharma Solution*
16:30	*End of Training Course*	