Training Course Agenda

PDA EU00134 Mastering Automated Visual Inspection

Day 1, 28 April 2022		
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	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
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*** **Fernand Koert, *GSK***
12:15	***Lunch Break***	
13:15	**Module 2: Introduction To Technical Principles of Automated Inspection Machines (cont.)**	**Romain Veillon, *GSK*** **Fernand Koert, *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	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
14:45	**Exercise 1: Developing Risk Assessment based on URS**	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***

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	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
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 Day 1 & Networking Reception***	
Day 2, 29 April 2022		
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*** **Fernand Koert, *GSK***
10:15	**Exercise 2: Principle Basic Image Processing Using an Open Source and Commercial Library**	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
11:00	***Coffee Break***	
11:15	**Exercise 2 (cont.): Q & A on Image Processing**	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
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	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***

	• 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	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
15:00	**Module 8: Operation and Maintenance of Automated Inspection Systems** • Spare part list • Predictive maintenance • First-line maintenance • Calibration	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
15:30	***Coffee Break***	
16:00	**Future Trend of Automated Visual Inspection** • Moving toward deep learning	**Romain Veillon, *GSK*** **Fernand Koert, *GSK***
16:30	***End of Training Course***	