

Training Course Agenda

PDA EU00134 Mastering Automated Visual Inspection

Day 1, 25 May 2023		
9:00	Welcome and Introduction of Trainers and Participants	
9:30	Module 1: Introduction to Regulatory Requirements of Visual Inspection <ul style="list-style-type: none"> 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, <i>GSK/Pharma Solution</i>
10:45	<i>Coffee Break</i>	
11:15	Module 2: Introduction to Technical Principles of Automated Inspection Machines <ul style="list-style-type: none"> 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 	Aurélien Genet, <i>GSK Vaccine</i>
12:15	<i>Lunch Break</i>	
13:15	Module 2: Introduction to Technical Principles of Automated Inspection Machines (cont.)	Aurélien Genet, <i>GSK Vaccine</i>
14:15	Module 3: Considerations on Primary Containers and Product Properties <ul style="list-style-type: none"> Vials, Ampoules, Syringes, Blow – Fill - Seal, Viscous liquids, Air bubbles/scratches, Refrigerated product containers Product impact study 	Fernand Koert, <i>GSK/Pharma Solution</i>
14:45	Exercise 1: Developing Risk Assessment based on URS	Fernand Koert, <i>GSK/Pharma Solution</i>

15:45	<i>Coffee Break</i>	
16:15	Module 4: Selection and Purchasing of an Automated Inspection System <ul style="list-style-type: none"> • 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	<i>End of Training Course Day 1</i>	
Day 2, 26 May 2023		
9:00	Recap of Day 1	
09:15	Module 5: Transition from Manual Inspection to Automated Inspection <ul style="list-style-type: none"> • 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 	Aurélien Genet, GSK Vaccine
10:15	Exercise 2: Principle Basic Image Processing Using an Open Source and Commercial Library	Fernand Koert, GSK/Pharma Solution
11:00	<i>Coffee Break</i>	
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 <ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> Quality requirements 	
13:00	Lunch Break	
14:00	Module 7: Visual Inspection Lifecycle and Control Strategy <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Moving toward deep learning 	Fernand Koert, GSK/Pharma Solution
16:30	End of Training Course	