Event Agenda

Fundamentals of Automated Visual Inspection (PDA 593.2)

DAY 1	
8:30	**Welcome and Introductions**
9:00	Theory 1: Introduction to Visual Inspection and Regulatory Requirements ● Purpose of visual inspection ● Regulations review: United States, Europe, Japan, China ● Similarities and differences in compendial methods ● 100% inspection and acceptance testing (AQL) incl. DIP ● Definitions and practical examples of inherent, intrinsic, and extrinsic particles
10:00	Theory 2: Life Cycle Approach and Risk Evaluation Part I ● Contamination control strategy ● Holistic particle life cycle management
10:30	**Break**
10:45	Theory 2: Life Cycle Approach and Risk Evaluation Part II ● Particle investigations ● Risk evaluation of particulate matter ● Monitoring and trending
11:15	Theory 3: Technical Principles of Automated Inspection Machines Part I ● 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
12:00	**Lunch**
13:00	Theory 3: Technical Principles of Automated Inspection Machines Part II ● Properties, capabilities, and limitations of automated inspection systems ● Scope of Automated Visual Inspection ● Considerations on Primary Containers and Product Properties
13:45	**Break**
14:00	Exercise 1: Principle Basic Image Acquisition and Processing, Test Samples Parametrization
14:45	Theory 3: Technical Principles of Automated Inspection Machines Part III ● Artificial Intelligence – how and when to apply it in AVI
15:45	**Break**
16:00	Exercise 2: Principle of AI Image Processing, Advantages for Detection and Utility for False Reject Rate Minimization
17:00	**End of Day 1**

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DAY 2	
8:30	Theory 4: Transition from Manual to Automated Inspection ● Manual inspection as a prerequisite for transition to automated inspection ● Manual inspection baseline assessment ● Interpretation of inspection results and validation of data ● Threshold studies and usage of Quality Factors ● AVI implementation journey - overview ● Types and functions of the different test sets
10:30	**Break**
10:45	Theory 5: VI Test Sets ● What to include in test sets for qualification ● Defect types and categorization, different product configurations (e.g. liquid and lyo products) ● How to ensure the test set is representative and challenging ● Defect ingress risk assessments and test set design ● Test set qualification and certificates ● Test set lifecycle management
12:00	**Lunch**
13:00	Theory 6: Validation of AVI processes ● Considerations on validation strategy for automated inspection ● AVI implementation journey in detail - from URS to qualification ● Performance measurement – comparing apples to apples ● 2-stage inspection process with MVI/SAVI ● AQL inspection ● Maintaining the inspection process - MVI and AVI
14:15	**Break**
14:30	Theory 7: Validation Maintenance ● Risk management ● Routine functional tests ● Monitoring of performance ● Change control ● Re-validation
15:30	**End of Event**