

## **Event Agenda**

## Fundamentals of Automated Visual Inspection (PDA 593)

DAY 1	
8:30	Welcome and Introductions
9:00	<ul> <li>Theory 1: Introduction to Visual Inspection and Regulatory Requirements</li> <li>Purpose of visual inspection</li> <li>Regulations review: United States, Europe, Japan, China</li> <li>Similarities and differences in compendial methods</li> <li>100% inspection and acceptance testing (AQL) incl. DIP</li> <li>Definitions and practical examples of inherent, intrinsic, and extrinsic particles</li> </ul>
10:00	<ul> <li>Theory 2: Life Cycle Approach and Risk Evaluation Part I</li> <li>Contamination control strategy</li> <li>Holistic particle life cycle management</li> </ul>
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	<ul> <li>Theory 3: Technical Principles of Automated Inspection Machines Part II</li> <li>Properties, capabilities, and limitations of automated inspection systems</li> <li>Scope of Automated Visual Inspection</li> <li>Considerations on Primary Containers and Product Properties</li> </ul>
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	<ul> <li>Theory 4: Transition from Manual to Automated Inspection</li> <li>Manual inspection as a prerequisite for transition to automated inspection</li> <li>Manual inspection baseline assessment</li> <li>Interpretation of inspection results and validation of data</li> <li>Threshold studies and usage of Quality Factors</li> <li>AVI implementation journey - overview</li> <li>Types and functions of the different test sets</li> </ul>
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