

## Training Course Agenda

## PDA 593 Fundamentals of Automated Visual Inspection

| DAY 1 |   |
|-------|---|
| 8:30  | Welcome and Introductions   |
| 9:00  | Theory 1: Introduction into 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        |
| 10:30 | Break   |
| 10:45 | Theory 2: Life Cycle Approach and Risk Evaluation  Contamination control strategy Holistic particle life cycle management Particle investigations Risk evaluation of particulate matter Monitoring and trending   |
| 12:00 | Lunch   |
| 13:00 | 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   |
| 13:45 | Break   |
| 14:00 | <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> <li>Artificial Intelligence – how and when to apply it in AVI</li> </ul> |
| 15:30 | Exercise 1: Principle Basic Image Acquisition and Processing, Test Samples Parametrization  |
| 16:30 | 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>URS &amp; feasibility studies</li> </ul> |
| 10:30 | Break   |
| 10:45 | <ul> <li>Theory 5: Qualification Test Set and Routine Test Set</li> <li>What to include in test sets for qualification</li> <li>How to ensure the test set is representative and challenging</li> <li>Routine defects vs. artificial defects</li> </ul>   |
| 12:00 | Lunch   |
| 13:00 | Theory 6: Validation of AVI processes  Considerations on validation strategy for automated inspection  2-stage inspection process with MVI/SAVI  Performance measurement – comparing apples to apples  Maintaining the manual inspection  |
| 14:15 | Break   |
| 14:30 | Theory 7: Validation Maintenance  Risk management  Routine functional tests  Monitoring of performance  Change control  Re-validation   |
| 15:00 | Exercise 2: Quality Factors and Knapp Simulation  |
| 16:00 | End of Training Course  |