



**PDA An Introduction to Visual Inspection: A Hands-on Course**  
**Training Course**  
**12-13 November 2025**  
**Berlin, Germany**

**Day 1: Wednesday, 12 November 2025**

9:00	Welcome and Introduction	
9:05	Introduction Why do We Inspect Patient Safety Regulatory Requirements Compendial Requirements	John G. Shabushnig, Insight Pharma Consulting, LLC
10:30	Coffee Break	
11:00	Inspection Methods and Technologies Critical Parameters (lighting, time, contrast, and motion) Manual Visual Inspection (MVI) Semi-Automated Visual Inspection (SAVI) Automated Visual Inspection (AVI)	John G. Shabushnig, Insight Pharma Consulting, LLC
12:30	Lunch Break	
13:30	Particle Identification	Markus Lankers, MIBIC
14:30	Laboratory Exercise: Manual Visual Inspection Light Measurement Assessment of the effect of changing critical Variables Time (10 sec vs. 20 sec) Lighting (2,500 lux vs. 1,250 lux) Motion/Agitation (with vs. without)	Markus Lankers, MIBIC
15:30	Coffee Break	
16:00	Continue Laboratory	John G. Shabushnig, Insight Pharma Consulting, LLC Markus Lankers, MIBIC
17:30	Wrap-up Discussion / Q&A	
18:00	End of Day 1	



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**Day 2: Thursday, 13 November 2025**

9:00	Inspection Data Review from the previous day's laboratory exercise	John G. Shabushnig, Insight Pharma Consulting, LLC
10:00	Defect Classification Strategies Risk classification definitions Critical, Major, and Minor defects	Markus Lankers, MIBIC
10:30	<b>Coffee Break</b>	
11:00	Acceptance Sampling Sampling Plan Variables Sample Size AQL and UQL Common Standards ANSI/ASQ Z1.4 ISO 2859	John G. Shabushnig, Insight Pharma Consulting, LLC
12:00	Inspector Selection and Qualification Vision Screening Initial Training Initial Qualification Requalification	Markus Lankers, MIBIC
12:30	<b>Lunch Break</b>	
13:30	Inspection Strategies Reinspection 2-Stage Inspection Focused inspection Empty Vial Inspection	Markus Lankers, MIBIC
14:00	Inspection Validation Inspection Performance Assessment Knapp Method Acceptance Criteria	John G. Shabushnig, Insight Pharma Consulting, LLC
14:30	<b>Coffee Break</b>	
15:00	Mythbusting Common misperceptions in visual inspection	John G. Shabushnig, Insight Pharma Consulting, LLC
15:30	Wrap-up Discussion / Q&A Evaluation of the training course	
16:30	<b>End of Training Course</b>	