



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

Day 1: Wednesday, 12 November 2025

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| 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

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| 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 | Coffee Break | |
| 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 | Lunch Break | |
| 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 | Coffee Break | |
| 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 | End of Training Course | |