

Training Course Agenda

PDA EU00009 An Introduction to Visual Inspection: A hands-on course

Day 1, 15 November 2023		
9:00	Welcome and Introduction of Trainers and Participants	
9:05	Introduction <ul style="list-style-type: none"> • Why do We Inspect • Patient Safety • Regulatory Requirements • Compendial Requirements 	John G. Shabushnig, <i>Insight Pharma Consulting, LLC</i>
10:30	<i>Coffee Break</i>	
11:00	Inspection Methods and Technologies <ul style="list-style-type: none"> • Critical Parameters (lighting, time, contrast, and motion) • Manual Visual Inspection (MVI) • Semi-Automated Visual Inspection (SAVI) • Automated Visual Inspection (AVI) 	John G. Shabushnig, <i>Insight Pharma Consulting, LLC</i>
12:30	<i>Lunch Break</i>	
13:30	Particle Identification	Markus Lankers, <i>MIBIC</i>
14:30	Laboratory Exercise: Manual Visual Inspection <ul style="list-style-type: none"> • Light Measurement • Assessment of the effect of changing critical Variables <ul style="list-style-type: none"> ○ Time (10-sec vs. 20 sec) ○ Lighting (2,500 lux vs. 1,250 lux) ○ Motion/Agitation (with vs. without) 	Markus Lankers, <i>MIBIC</i>
15:30	<i>Coffee Break</i>	
16:00	Continue Laboratory	John G. Shabushnig, <i>Insight Pharma Consulting, LLC</i> Markus Lankers, <i>MIBIC</i>
17:30	Wrap-up Discussion / Q&A	
18:00	<i>End of Day 1 & Networking Reception</i>	
Day 2, 16 November 2023		
9:00	Inspection Data Review <ul style="list-style-type: none"> • From the previous day's laboratory exercise 	John G. Shabushnig, <i>Insight Pharma Consulting, LLC</i>
10:00	Defect Classification Strategies <ul style="list-style-type: none"> • Risk classification definitions • Critical, Major, and Minor defects 	Markus Lankers, <i>MIBIC</i>
10:30	<i>Coffee Break</i>	
11:00	Acceptance Sampling <ul style="list-style-type: none"> • Sampling Plan Variables <ul style="list-style-type: none"> ○ Sample SizeTime ○ AQL and UQL • Common Standards <ul style="list-style-type: none"> ○ ANSI/ASQ Z1.4 ○ ISO 2859 	John G. Shabushnig, <i>Insight Pharma Consulting, LLC</i>
12:00	Inspector Selection and Qualification <ul style="list-style-type: none"> • Vision Screening • Initial Training • Initial Qualification • Requalification 	Markus Lankers, <i>MIBIC</i>
12:30	<i>Lunch Break</i>	

13:30	Inspection Strategies <ul style="list-style-type: none"> • Reinspection • 2-Stage Inspection • Focused inspection • Empty Vial Inspection 	Markus Lankers, MIBIC
14:00	Inspection Validation <ul style="list-style-type: none"> • Inspection performance Assessment <ul style="list-style-type: none"> ○ Knapp Method • Acceptance Criteria 	John G. Shabushnig, Insight Pharma Consulting, LLC
14:30	<i>Coffee Break</i>	
15:00	Mythbusting <ul style="list-style-type: none"> • Common misperceptions in visual inspection 	John G. Shabushnig, Insight Pharma Consulting, LLC
15:30	Wrap-up Discussion / Q&A	
16:30	<i>End of Training Course</i>	