

## Training Course Agenda

# PDA EU00176 An Introduction to Manual Visual Inspection

W. Europe Summer Time (UTC +1)

Tuesday, 16 November 2021	
1:30 PM	Welcome and Introduction of Trainers and Participants
1:45 PM	<b>Why We Inspect</b> <ul style="list-style-type: none"> <li>• Why We Inspect</li> <li>• Regulatory Requirements               <ul style="list-style-type: none"> <li>○ FDA                   <ul style="list-style-type: none"> <li>• Recalls / 483's</li> <li>• FD&amp;C Act</li> </ul> </li> <li>○ EMA                   <ul style="list-style-type: none"> <li>• Annex 1</li> </ul> </li> </ul> </li> <li>• Compendial Requirements               <ul style="list-style-type: none"> <li>○ USP / EP / JP</li> </ul> </li> <li>• Other Standards</li> </ul>
2:30 PM	Recreational Break
2:40 PM	<b>Inspection Methods and Technologies</b> <ul style="list-style-type: none"> <li>• Manual Inspection</li> <li>• Critical parameters               <ul style="list-style-type: none"> <li>○ Lighting</li> <li>○ Duration / Speed</li> <li>○ Contrast</li> <li>○ Agitation</li> </ul> </li> <li>▪ Semi-automated Inspection</li> <li>▪ Automated Inspection</li> </ul>
3:00 PM	Recreational Break
3:10 PM	<b>Laboratory: Manual Inspection Exercise</b> <ul style="list-style-type: none"> <li>• Basic Inspection Method Instruction</li> <li>• Light Measurement</li> <li>• Effect of critical inspection parameters on particulate inspection               <ul style="list-style-type: none"> <li>○ Time (5 sec/background, 10 sec/background)</li> <li>○ Lighting (2500 lux, 1250 lux)</li> <li>○ Agitation (with and without)</li> </ul> </li> <li>• Inspection Process Data Review               <ul style="list-style-type: none"> <li>○ Typical class inspection data analysis</li> </ul> </li> </ul>
4:00 PM	Particle Identification and Investigation
4:30 PM	Wrap-up Discussion / Q&A
5:00 PM	<i>End of Day 1</i>

**Wednesday, 17 November 2021**

<p><b>1:30 PM</b></p>	<p><b>Defect Classification Strategies</b></p> <ul style="list-style-type: none"> <li>• Defect Definitions             <ul style="list-style-type: none"> <li>○ Critical / Major / Minor</li> </ul> </li> </ul>
<p><b>2:00 PM</b></p>	<p><b>Inspector Selection and Qualification</b></p> <ul style="list-style-type: none"> <li>• Vision Screening             <ul style="list-style-type: none"> <li>○ Acuity</li> <li>○ Correction</li> <li>○ Color Blindness</li> </ul> </li> <li>• Initial Training</li> <li>• Initial Qualification</li> <li>• Periodic Requalification</li> </ul>
<p><b>2:30 PM</b></p>	<p><b>Recreational Break</b></p>
<p><b>2:40 PM</b></p>	<p><b>Acceptance Sampling</b></p> <ul style="list-style-type: none"> <li>• Sampling Plan Variables             <ul style="list-style-type: none"> <li>○ Operational Characteristic Curves</li> <li>○ AQL's and UQL's</li> <li>○ Sample size</li> </ul> </li> <li>• ANSI Z1.4</li> <li>• Single and Double Sampling Plans</li> </ul>
<p><b>3:30 PM</b></p>	<p><b>Inspection Strategies</b></p> <ul style="list-style-type: none"> <li>• Reinspection</li> <li>• 2-Stage Inspection</li> <li>• Focused Inspection</li> <li>• Empty Vial Inspection</li> </ul>
<p><b>4:00 PM</b></p>	<p><b>Mythbusting</b> <b>Wrap-up Discussion / Q&amp;A</b></p>
<p><b>4:30 PM</b></p>	<p><i>End of Course</i></p>