

## Training Course Agenda

# PDA EU00184 Understanding Sterilization

DAY 0 – Wednesday 31 May 2023	
Webinar	<b>Moist-heat sterilization principles</b> <ul style="list-style-type: none"> <li>• Sterility assurance concept (PNSU or SAL), D-values, z-values, F0</li> </ul>
DAY 1 – Tuesday 06 June 2023	
8:45	<b>Welcome and Introduction</b> Gathering expectations of participants
9:00	<b>Introduction to current sterilization methods</b> <ul style="list-style-type: none"> <li>• Distinguish disinfection, sterilization</li> <li>• E- Beam</li> <li>• <math>\gamma</math>-Irradiation</li> </ul>
10:00	<i>Coffee Break (30 min)</i>
10:30	<b>Introduction to current sterilization methods (EtO, <math>\gamma</math>-irradiation) continued</b> <ul style="list-style-type: none"> <li>• EtO</li> <li>• Nitrogen Dioxide</li> </ul>
11:30	<b>Introduction to current sterilization methods (EtO, <math>\gamma</math>-irradiation) continued</b> <ul style="list-style-type: none"> <li>• Hydrogen Peroxide: Principle and application in Pharma, Equipment</li> <li>• Regulations</li> </ul>
13:00	<i>Lunch Break (60 min)</i>
14:00	<b>Plant Tour</b>
15:00	<i>Coffee break (15 min)</i>
15:15	<b>Hydrogen Peroxide decontamination in practice</b> <ul style="list-style-type: none"> <li>• Group session with practical examples of correct / wrong cycles</li> <li>• Correct placement of probes and indicators for various load types</li> </ul>
17:15	<i>End of Training Course Day 1</i>
20:00	<b>Dinner</b>

DAY 2 – Wednesday 07 June 2023	
8:30	<b>Wrap-up of day 1 and questions</b>
9:00	<b>Moist-heat Sterilization, Load Types and Process/Autoclave Selection</b> <ul style="list-style-type: none"> <li>Counterpressure cycles</li> <li>Case studies</li> </ul>
10:30	<i>Coffee Break (30 min)</i>
11:00	<b>Moist-heat Sterilization, Load Types and Process/Autoclave Selection</b> <ul style="list-style-type: none"> <li>Steam sterilization: general concepts</li> <li>Case studies</li> </ul>
12:30	<i>Lunch Break (60 min)</i>
13:30	<b>Routinely and Operational tests: description</b> <ul style="list-style-type: none"> <li>Vacuum and pressure leak test</li> <li>Steam quality test</li> <li>Bowie &amp; Dick test</li> </ul>
14:30	<b>From Annex 1: Air Detector and Functioning</b> <ul style="list-style-type: none"> <li>Air removal failure – detection with Air detector System</li> </ul>
15:30	<i>Coffee Break (30 min)</i>
15:45	<b>From Annex 1: Air Detector and Functioning (cont.)</b> <ul style="list-style-type: none"> <li>Air removal failure – detection with Air detector System</li> </ul>
16:45	<b>Q&amp;A Session</b>
17:00	<i>End of Training Course Day 2</i>
DAY 3 – Thursday 08 June 2023	
8:30	<b>Wrap-up of day 2 and questions</b>
9:00	<b>Validation and equipment qualification concepts</b> <ul style="list-style-type: none"> <li>Temperature mapping and practical sessions common loads</li> <li>Equilibration time</li> </ul>
10:30	<i>Coffee Break (30 min)</i>
11:00	<b>Validation and equipment qualification concepts</b> <ul style="list-style-type: none"> <li>Biological Indicators and Validation</li> </ul>
12:30	<i>Lunch Break (60 min)</i>
13:30	<b>New Annex 1 revision – what changes for sterilization?</b>
14:30	<b>Parametric Release</b>

15:45	<i>Coffee Break (30 min)</i>
16:00	<b>How does Fedegari answer to Annex 1 Requirements</b>
17:00	<b>Q&amp;A Session</b>
17:30	<i>End of Training Course</i>