



Program

Aseptic Process Simulation (APS), from strategy to results

Duration : 14 hours (2 days)

Training: In-house or inter-site / Face-to-face or remotely

Target audience: Quality Assurance, Sterility Assurance, Production, Process Validation, Maintenance teams

Prerequisites: no pre-requisite

Training is accessible to people with disabilities

Learning objectives

- Identify what is an aseptic process?
- Understand the regulations applicable to Aseptic Process Simulation (EU and US)
- Be familiar with the changes brought by the update of Annex 1 of the European GMP
- Understand the different stages involved in establishing and implementing an APS strategy on a sterile site
- Know how to draw up the documentation required to produce an APS in compliance with the regulations
- Understand the roles and responsibilities of the various stakeholders involved

Training content

- How to define an aseptic process:
 - What are the key steps in an aseptic process?
 - What are the critical stages ?
 - Why APS and not MFT (Media Fill Test)
- Generality with APS:
 - Definition, objectives, conditions, means of implementation, frequency of realization, batch size, etc.
- Regulations applicable in Europe:
 - Detailed explanation of the latest European GMP Annex 1
- Differences and particularities with other applicable texts:
 - FDA Guidance aseptic 2004 pages 20 to 27
 - USFDA Questions and Answers on Current Good Manufacturing Practices-Production and Process Controls - Questions on Media Fill Test
 - PDA TR22 & TR28 - TR36 - PDA aseptic point to consider part 2
 - USP 797
 - PIC/S Recommendation on the Validation of Aseptic Processes

- Japan Guideline on Manufacture of Sterile Medicinal Products by Aseptic Processing 2011 - part related to aseptic simulation: section 20
 - WHO good manufacturing practices for sterile pharmaceutical products
 - PDA Points to consider 2023
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- How to design the APS Plan?
 - The key documents associated with an APS: from the drafting of a Strategy including risk analyses to the approval of the Report
 - The various actions to be simulated and validated
 - Validation in campaign mode using RABS and isolator
 - Personnel qualification and concept of interventions
 - Supervision of APS's
 - Incubation times, reading and interpreting results

How the course is organized

Speakers: Laurent Merli or Pierre Devaux

Teaching and technical tools

- Training materials
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Questions / answers sessions

Tool for monitoring the implementation of the training results assessment

- Attendance sheets
- Assessment tests of the acquisition of knowledge
- Training certificate