

Program

Control of Particulate and Microbial Contamination in Manufacturing of Sterile and Non-Sterile Drugs

Length :14 hours (2 days)

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

Target audience : Management and support service staff (production methods, qualification/validation, maintenance, microbiology laboratory, etc.),

Pre-requisites : no pre-requisite

Training accessible to people with disabilities

Teaching goals

- Identify applicable international standards
- Identify particulate and microbial contaminants causing deviations on site
- Identify all the elements of its ZAC (HVAC, personal flow, material flow, layout of zones,...)
- Know the terms of Qualification / Classification and especially Monitoring allowing to participate in field investigations in the case of proven contamination
- Integrate the behavioral requirements (hygiene, gowning and activity in ZAC) to be put into practice on a daily basis and in correlation with their function (practices described and adapted according to the group present)
- Integrate the particularities of the different configurations used for aseptic distribution processes and alternative processes
- Identify the operations of Cleaning and Disinfection of the premises

Training content

- Identify the international texts available for the control of particulate and microbial contaminants,
- Define, characterize and classify the different types of contaminants,
- Describe the different elements constituting a cleanroom to be able to identify in situ the risks of contamination in your cleanrooms,
- Retain the key points of the Qualification, Classification and Monitoring strategies to lead an investigation and interpret the associated results,
- Discuss general hygiene measures and dressing practices to implement in your activities to control entries to ZAC,
- Adopt good behavioral practices in correlation with your activities,
- Distinguish the different configurations that can be used to manufacture sterile drugs,
- Describe the good aseptic practices for Class A and discern the expectations of the aseptic simulation process,
- Cite the main steps of a non-critical surface decontamination process in premises and understand the associated issues related to environmental monitoring

How the course is organised

Speakers:

Elodie PASTRE or Clémence PRETTE

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 assessments

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