# Program

# The Management of Particulate and Microbial Contaminants in the Production 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 discrepancies at their site
- Identify all the elements in the ZAC (HVAC, personal flow, material flow, layout of areas, ...
- To know the Qualification / Classification terms and especially Monitoring terms to ensure participation in field investigations in the case of proven contamination
- Integrate the behavioural requirements (hygiene, dressing and activity in ZACs) to be put into practice on a daily basis and in accordance with the role (practices described and adapted depending on the group)
- Integrate the specific features of the different set-ups used for aseptic filling and alternative processes
- Identify the cleaning and disinfection operations of the premises

## Training content

- Identify the international texts available for the management of particulate and microbial contaminants,
- Define, characterize and categorise the different types of contaminants,
- Describe the different elements which make up a ZAC to be able to identify the risks of contamination in your ZACs in situ,
- Remember the key points of Qualification, Classification and Monitoring strategies to arrange an investigation and interpret the associated results,
- Discuss the general hygiene measures and dressing practices to be implemented in your activities to manage ZAC entrances,
- Adopt good behavioural practices consistent with your activities,
- Distinguish between the different set-ups that can be used to manufacture sterile drugs,
- Describe proper aseptic practices for Class A and understand the expectations of the aseptic simulation process,
- List the main stages of a process for decontaminating the non-critical surface of the premises and understand the associated issues as regards environmental monitoring

## How the course is organised

**Speakers:**
Pierre DEVAUX, Elodie PASTRE

**Teaching and technical Tools**

- Training materials.
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Questions / answers sessions
- Self-assessment using a grid

**Tool for monitoring the implementation of the training results assessments**

- Attendance sheets.
- Knowledge acquisition assessment test
- Training certificate.