Programme
Barrier technologies in sterile pharmaceutical production environments

Duration: 2 days - (14 hours)

Training: in-house

Public : Production, Maintenance, Qualification / Validation, Sterility Assurance, Operational Quality Assurance

Pre - Requirements: no pre - requirements

Training accessible to people with disabilities

Pedagogical objectives

- Identify and know the regulatory requirements
- Mastering aseptic practices and identifying associated risks
- Know the technical fundamentals and constraints Annex 1
- Identify areas of concern
- To be able to put into practice the notions acquired on the site

Content of the training

- Reminder of regulatory requirements:
    - Eudralex - volume 4 Good Manufacturing Practice (GMP) guideline
    - Annex 1 GMP
- Definition, technologies, aseptic practices and associated risks:
    - Definition and differences between RABS vs Isolator
    - Aseptic practices
    - Decontamination update
- Technical fundamentals - User expectations and constraints
    - Isolator project, the importance of understanding customer processes
    - Classification and management of air in the isolator / in the ZAC
    - Glove management
    - EMS
    - Management of external connections and inputs/outputs
    - Mock up / FAT / SAT
- Point of vigilance:
    - Validation process of disinfection cycle in the isolator
    - Manufacturing process / specific handling
    - Management of moving parts
    - Management of environmental variables
- To be able to put into practice the notions acquired on the site

Organisation of the training

Speaker :
Patrick COPPENS

Pedagogical and technical means

- Training materials and regulatory documents.
- Theoretical input, concrete case examples
- Participatory pedagogy
- Question and answer sessions
- Self-assessment using a grid

Monitoring and evaluation of training results

- Attendance sheets.
- Test of knowledge acquisition
- Training certificate.