

Program

Management of Barrier Technologies (RABS and Isolator)

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

Organisation of the training

Speaker :

Patrick COPPENS or Jules BOULICOT

Pedagogical and technical means

- Training materials and regulatory documents.
- Theoretical input, concrete case examples
- Participatory pedagogy
- Question and answer sessions

Monitoring and evaluation of training results

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