Validation of computerized systems : From basics to optimization

Duration: 7 hours

Training: in-house

Target group: Quality assurance and IT, quality control and pharmaceutical production

Prerequisites: no prerequisites

Pedagogical objectives

- Master the key stages in the validation of computerized systems.
- Increase productivity in this area.

Training content

- Validation of computerized systems is based on widely-accepted guidelines and standards; however, if taken literally, these standards can generate a significant workload and questionable efficiency.
    - How do you practically approach a computerized system validation?
    - What critical points need to be mastered?
    - What tools and key documents can be used?
- Using a practical example from start to finish, the course will cover the key points for mastering computerized systems:
    - Criticality analysis,
    - Specifications: Specifications (URS)...
    - Risk analysis,
    - Strategy, testing methods and documentation,
    - Change management,
    - Periodicals...

Training organization

Speaker(s): Jean-Louis JOUVE or Christophe Fagard

Teaching and technical resources

- Pre-training positioning questionnaire
- Training and regulatory documents.
- Theoretical input, case studies
- Participatory teaching
- Question-and-answer sessions

System for monitoring and evaluating training results

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