

Cloud computing and regulatory compliance

Duration: 7 hours

Training: in-house

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

Prerequisites: no prerequisites

Training is accessible to people with disabilities

Pedagogical objectives

- Understand the concept of "cloud computing" and its different characteristics.
- Understand pharmaceutical regulations (GxP) and their constraints on cloud computing systems.
- Evaluate the regulatory risks of different cloud proposals (IAAS, PAAS, SAAS) using examples.
- Derive the associated qualification/validation and risk control strategies.

Training content

Cloud computing is playing an increasingly important role in the healthcare IT landscape, through the outsourcing of IT resources and the "on-demand" use of regulated software. While it offers certain advantages (scalability, cost control, etc.), cloud computing also has its own constraints, linked to its use in a regulated context.

The aim of this training course is to use case studies based on industrial experience to take stock of the various cloud computing methods, identify their weaknesses in relation to applicable regulations, and draw up a suitable risk management plan

- Cloud computing: Definitions and technology, different offerings: IAAS, PAAS, SAAS, advantages and disadvantages
- Regulatory reminder of the main requirements applicable to cloud computing: electronic registration, open/closed systems, responsibilities, subcontracting, etc.)
- Case studies: IaaS outsourcing, SaaS SLAs.

Training organization

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

Teaching and technical resources

- Positioning questionnaire prior to training
- 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.