



## Risks – Requirements – Regulatory Management

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## Training – Electronic archiving (Ref IF102)

The purpose of this training is to sensitize members of a project integrating computer science, to the problem of archiving.

The main objective of this internship is to show that archiving must be managed before any project and not at the end of a software's life and therefore it is not a purely problematic computer.

### Duration:

2 days

### Goal :

- Define the notions of electronic archiving, storage and backup
- Present regulatory and normative requirements for archiving
- Present the benefits of electronic archiving
- Address archiving technical and material solutions (demonstration)

### Concerned public :

- Project managers
- Quality assurance staff
- Users
- Archivists

### Content:

#### First day

- Introduction
- FDA regulation (PART 11 & Guidelines)
- ISPE positions
- Issues of electronic archiving
- Data formats to archive

#### Second day

- Hardware and software archiving solutions
- Management of an electronic archiving project
- Practical work: demonstration of a software solution available on the market

- Conclusion, balance sheet

## Educational, technical and coaching resources implemented

Participatory pedagogy alternating the presentation of formal presentations illustrated with a documentary support with interactive exchanges and discussions around case studies and tutorials.