Risks – Requirements – Regulatory Management

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Training pharmaceutical regulations applicable to IT (Ref VAL103)

Regulatory requirements come from different sources and are not always fully understood. The purpose of this training is to shed light on the different roles of the supervisory bodies, to draw a parallel between them, and other organizations at the origin of guides or methods:

- Understand the origins of what
- Better texts master

Duration:

1 day

Concerned public :

- IT Validation Manager
- Computer scientists
- QA of IT services
- Sophisticated users

Content:

- The FDA (Food and Drug Administration)
  - Schematic representations
  - How is the FDA organized?
  - Who drafts and manages the regulatory texts?

- Requirements in a context cGMP
  - 21 CFR Part 210
  - 21 CFR Part 211
  - 21 CFR Part 820

- Requirements in a GLP and GCP context
  - OECD Texts
  - 21 CFR Part 58

- Requirements in a GxP context
  - OECD texts
  - 21CRRPart58
  - 21 CFR Part 820

- European BPD and French BPF
    - Presentation
    - Who drafts and manages the regulatory texts?
    - What is the difference with GxP?

- The ICH (and VICH)
    - Presentation
    - Security
    - Quality
    - Effectiveness
    - Multidisciplinary activities

- ISO standards: what interest?
    - ISO17799
    - ISO13485
    - ISO / TR 10450, ISO 3511, ISO 10303

- Roles of some organizations
    - ISPE
    - IEPA
    - IEEE, IEC, ISA

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.