Software Validation

Code: VAS
Type: Workshop
Time: 16 Hours

Objective:

- By attending this course, participants will be able to apply the general concepts of computerized system validation in regulated contexts like medical devices and pharmaceutical industries.

Audience:

- Engineers and technicians that shall plan, execute or lead software validations as part of their responsibilities
- Professionals that shall review and approve software validation documents
- Professionals of other disciplines, faculty staff and students who need to have this knowledge

Contents:

- Applicable regulations and standards
- Definitions and key terms
- Validation planning and risk assessment
- Specification development phase
- Software validation process
- Protocols and reports
- Change control and revalidation

Mode:

- Face-to-face or virtual

Methodology:

- The course is a combination of keynote presentations, individual and group exercises and application examples

Equipment and materials

- Computer with MS Office, MS Teams and Internet for virtual mode

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