

Validation of Processes applied to Medical Devices and *In Vitro* Diagnostic Medical Devices

COURSE DESCRIPTION

Applicable regulations require control of the production of medical devices and *in vitro* diagnostic medical devices placed on the market to ensure their safety and performance.

The manufacturer must demonstrate that its processes are able to reproduce expected results. The validation phase is therefore crucial as it guarantees compliance with the requirements throughout the entire manufacturing cycle.

DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with applicable regulatory and normative requirements
- Learn the process validation methodology
- Establish the related documentation system
- Identify the actions required to maintain a "validated" status

TARGET TRAINEES

Manufacturers of *In Vitro* Diagnostic Medical Devices, and more particularly employees in the following departments:

- Methods/Industrialization/Validation
- Quality Assurance
- Production

PREREQUISITES

Familiarity with ISO 13485 and a production environment is recommended

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Experience sharing
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Normative and regulatory framework
2. Definitions
3. Process
 - a. Methodology
 - b. Scope of the qualification
 - c. Validation master plan
4. Process validation
 - a. QC/IQ/OQ/PQ
 - b. Documentation
 - c. Maintaining a "validated" status
5. Validation in an industrial context
 - a. Risk analysis
 - b. Process control
 - c. Transfer to production
 - d. Action plan
6. Summary/Q&A
7. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program (*success criteria* $\geq 75\%$).



Do you have a question? Contact us!

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