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Getting started with CE certification of your medical device

In order to market a medical device within the European Economic Area (EEA), the device needs CE Certification.

This certification is a mandatory proof that:

- ***The medical device is safe and suitable for its intended purpose, according to the MDR and applicable standards.***
- ***The manufacturer is able to develop, produce and deliver safe products, according to the Quality Management standard for medical devices.***

This course "CE certification of your medical device" will give you an overview of the applicable regulation and standards and will provide you with practical knowledge on when and how to implement the regulatory requirements in your product development process and your organization.

Get an overview of the regulatory requirements and learn how to implement these in your development process!

Register: www.holland-innovative.nl

CE certification of a medical device is certainly not something you would do on a Friday afternoon but is often underestimated, especially now the regulations have been updated to the MDR. You need a.o. to plan your development, perform risk assessments, test your product and provide documented evidence. You have to set-up your technical documentation, have a quality management system in place with approved suppliers and have proven competent team members.

Most of these requirements need to be prepared early-on during the development of a medical device to create a safe, well performing and documented device and to efficiently support the compliance with CE regulations.

During the course, theory will be alternated with practical exercises, so you will actually learn how compliance is established.

A selection of subjects that will be addressed

- The product development process showing the correlation of regulatory requirements, project activities and deliverables
- Steps in CE certification according to the MDR, using applicable harmonized standards
- Quality Management System based on ISO 13485
- Safety Risk Management according to ISO 14971
- Verification and Validation
- Usability Engineering
- Clinical Evaluation

Course duration and number of participants One day workshop from 09.00 to 17.00. Maximum group size: 10 participants.

Instructors Sr. Project Manager Medical Devices Jolande Koobs and Lisette van Steinvoren.

Location and investment See website Holland Innovative for location of the next training. The investment is € 795,- (excl. VAT) per participant. Included is one training day, course material, lunch and refreshments.

Dates, registration and more info See www.holland-innovative.nl under Academy.

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Focus on complex business processes

Target group for this course

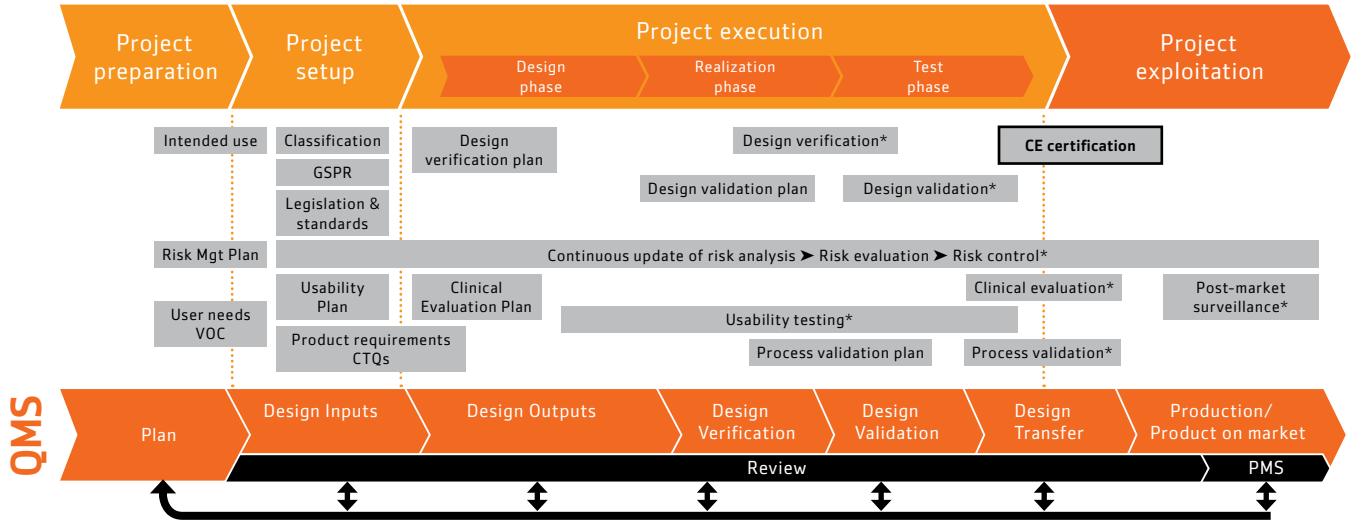
- The course "Getting started with CE certification of your medical device" is suited for:
  - members of a medical device development team, like project managers, development engineers, operational buyers, quality and regulatory engineers
  - management of medical device manufacturers and suppliers.
- The course is suited for professionals with a master or bachelor level, or equivalent knowledge gained through experience.
- Knowledge of the CE certification process, the MDR or the standards is not required.

Instructors

Sr. Project Manager Medical Devices Jolande Koobs and Lisette van Steinvoren

After the training, holland-innovative optionally offers on-the-job coaching to further improve and implement the medical device development process and practices in your company. This course can also be given within your company, tailored to your specific needs. The course can be extended with topics, like:

- CE certification of medical device software
- Project Management
- Design for Six Sigma



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The **Holland Innovative** House: *core* *results* *enablers*

Holland Innovative BV:

- For solutions in project management, product & process development and improvement, and reliability
- 40 professionals with an experience level of more than 20 years
- Market areas: HighTech, Automotive, Solar & Energy, MedTech, Agro & Food

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