Medical Device Software – Application of MDR requirements

This new one day training "Medical Device Software" will give you an overview of the applicable regulation and standards for Medical Device Software and will provide you with practical knowledge on how to apply the requirements of the MDR (Medical Devices Regulation) and the applicable standards in your software development process.

Over the last years, medical devices increasingly contain software. Also more and more stand-alone software for medical applications, like apps and decision support software, is launched in the market. In most cases, such software needs to comply to the requirements of the EU Medical Devices Regulation (MDR) when it will be marketed within Europe.

A practical guide on the application of MDR requirements for Medical Device Software!

Register: www.holland-innovative.nl

Compliance of your medical device software to EU regulations 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 amongst others to classify your software, determine the applicable requirements and standards, plan your software development, perform risk assessments, test your software, perform usability tests and provide documented evidence.
Most of these requirements need to be planned early-on during the development and maintenance of your medical device software to ensure safety and performance of the software and to achieve and maintain CE certification.

This one day training can be attended on top of the training "CE Certification of your Medical Device" as it will provide deeper knowledge on the application of requirements for Medical Device Software, but it can also be attended without this foreknowledge.

During the course, theory will be alternated with practical exercises, so you will actually learn how to apply the requirements in your process and documentation.

Course duration and number of participants One day training from 09.00 to 16.00. Maximum group size: 10 participants.

Location and costs The costs are € 795,- (excl. VAT) per participant. Included is one interactive training day and paper course material, which will be sent to you in advance.

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

Contact HI Team Academy, tel. +31 40 85 14 611, academy@holland-innovative.nl

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A selection of subjects that will be addressed

- When does software need to comply to the MDR?
- Classification of Medical Device Software
- Summary on CE certification and when do you need a Notified Body?
- Determine applicable Safety and Performance Requirements and Standards
- Quality Management System based on ISO 13485 for a software company
- Software life cycle processes according to IEC 62304
- Safety Risk Management according to ISO 14971
- Usability Engineering according to IEC 62366-1
- Agile practices

Target group for this course

- The course "Medical Device Software – Application of MDR requirements" is suited for:
  - Medical Device software engineers, project managers, product managers, testers, quality and regulatory engineers
  - Management of medical device software manufacturers and suppliers.
- The course is suited for professionals with a master or bachelor level, or equivalent knowledge gained through experience.
- Knowledge of Software development, CE certification, MDR or standards is not required.

Trainer

Jolande Koobs - Sr. Project Manager Medical Devices

After the training, Holland Innovative optionally offers on-the-job coaching to support you in CE certification of your medical device software or to further improve and implement the software development process, documentation 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 your medical device
- Project Management

June 2020

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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