CARAQA

Certified high level training in CLINICAL, REGULATORY, and QUALITY Affairs for medical devices and in-vitro diagnostic medical devices

ABOUT THE COURSE

In cooperation with Swiss MedTech company Medidee and Technische Hochschule Lübeck, oncampus offers a unique training for MedTech professionals facing the current major regulatory challenges.

Experts from the University sector and the MedTech company Medidee as well as regional and international industry representatives will share their insights and experience: They will train attendees how to demonstrate the requisite expertise in the field of medical devices and IVD medical devices in order to fulfill the tasks and responsibilities of a PRRC („person responsible for regulatory compliance“) according to Article 15, MDR/IVDR.

TRAINING CONTENT

The training consists of three main pillars: Clinical Affairs, Regulatory Affairs and Quality Assurance – CA/RA/QA.

Learners will be enabled to

- Identify, analyse and resolve the major challenges of the regulatory changes due to the MDR and IVDR
- Use strategic, tactical and communication skills when interacting with notified bodies and competent authorities
- Develop technical expertise in key topics of conformity assessment such as quality management, risk management, post-market surveillance, biocompatibility, usability, safety, clinical investigation and evaluation, and software validation
- Provide management and engineering support during the development and production of new biomedical products

CURRICULUM

The curriculum is organized in four modules designed to cover in depth the different aspects of the training topics in a logical and progressive way.

M1 : INTRODUCTION TO THE WORLD OF DEVICES

- Description of the Medtech stakeholder system
- New Approach/New Legislative framework
- Description of the product life cycle

M2 : REGULATORY AFFAIRS, DESIGN AND SUBMISSION

- Demarcation and classification of medical devices
- Structuring and managing risks
- Merging regulatory requirements with a design
- Managing the implementation of guidelines, standards and recommendations
- Managing software compliance
- Supporting product design and industrialization with special emphasis on aspects of electrical safety, biocompatibility, usability, sterilisation
- Structuring documentation of regulatory submissions
- Managing market events, incidents, announcements, reminders
- Maintaining regulatory compliance over time
- Preparing the company for audits

M3 : QUALITY MANAGEMENT

- Structuring the Quality Management System
- Organizing the documentation and its evolution
- Supervising process control
- Managing quality processes; audit, improvement, changes

M4 : CLINICAL AFFAIRS

- Structuring and organizing clinical / performance evaluation
- Organizing a clinical investigation
- Conducting a literature review
- Managing surveillance and post-marketing study

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TARGET AUDIENCE

- Biomedical, mechanical, electronic, software or material science engineers, in charge of medical or IVD development and production projects;
- Physicians, pharmacists, scientists or inventors of biomedical devices;
- Employees within the regulatory, clinical and/or quality department of a manufacturing or subcontracting company manufacturing medical devices or IVD, or in a healthcare organization

KEY DATA

- Course duration:
  Jan 21st- Jul 9th, 2022
- Registration deadline:
  Dec 1st, 2021
- Location:
  Campus of TH Lübeck and online training (50/50)
- Cost:
  5.000 € including VAT
- Language:
  English
- Workload:
  154 hours
- Certificate:
  University Certificate in Clinical, Regulatory and Quality Affairs for medical devices and in-vitro diagnostic medical devices

If you want to become an expert in the MedTech regulatory world, this is the course for you.

Prof. Dr. Folker Spitzenberger, M. D. R. A.
CARAQA lecturer

CONTACT AND REGISTRATION

Applicants must fill in the online registration here:
www.oncampus.de/caraqa

They are requested to describe their
- educational background
- experience
- motivations for taking the certificate course.

ANY QUESTIONS?

Sabrina will have the answers.

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