PRACTICAL INFORMATION

LOCATION AND SCHEDULE

The course is organized from September 2020 to February 2021. Lectures are held in Louvain-la-Neuve. A detailed schedule is available on the training programme website.

CONDITIONS FOR ADMISSION

Candidates must have a Master's degree, from a university or equivalent, in:

- Engineering: Biomedical, Mechanical, Electronic, Software, or Materials Science
- Bioengineering, Medicine, or Life Sciences
- Management or Business Economics

Good fluency in English is a prerequisite for registration.

If these requirements are not met, admission via accreditation of prior learning and work is possible.

REGISTRATION FEES

Registration costs are 4,800 euros.

These fees include tuition, course materials, practical exercises, student card, catering, and access to the site and facilities.

REGISTRATION

Applicants must fill in the online registration form, which can be found on the website of the certificate. They are requested to describe their:

- educational background
- experience
- motivations for taking the certificate

Applications will be reviewed by the programme jury in their order of submission.

THE UNIVERSITY CERTIFICATE

Participants attending the programme and passing the evaluation will be awarded a "University Certificate in Clinical, regulatory and quality affairs for medical devices and in-vitro diagnosis" and 17 ECTS credits. On top of the personal development value of the certificate for the attendees' training plan, these credits can be used to pursue other academic programmes in Europe, pending the approval by the committee in charge of the programmes for which the participant wishes to apply at a later date.

FIND OUT MORE

www.caraqa.be
+32 (0)10 47 80 73
caraqa@uclouvain.be

In collaboration with: medídee®

THINK UCLOUVAIN FOR YOUR CONTINUOUS TRAINING NEEDS!

More than 200 time-shifted or adapted courses focussing on your career progression and professional development...

FOLLOW US AND FIND OUT MORE ABOUT OUR COURSES AT :

www.facebook.com/FormationContinueUCL

www.linkedin.com/showcase/formation-continue-ucl

www.uclouvain.be/formation-continue

LEARN MORE ABOUT OUR PRIVACY AND COOKIE POLICY BY CLICKING ON THE FOLLOWING LINK :

https://uclouvain.be/en/study/iufc/continuing-education-privacy.html

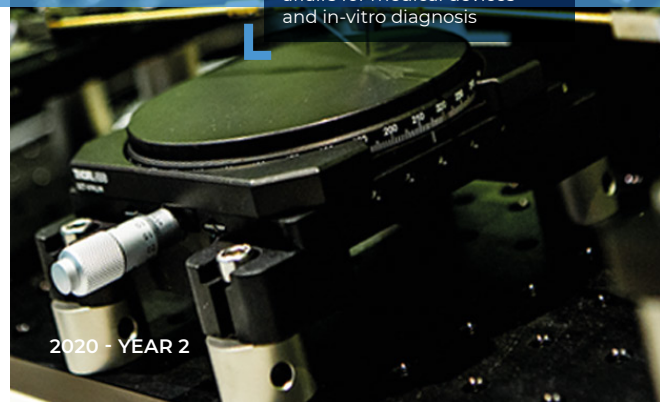
UCLouvain
Louvain School of Engineering

FORMATION CONTINUE

CARAQA.BE

UNIVERSITY CERTIFICATE

Clinical, regulatory and quality affairs for medical devices and in-vitro diagnosis



2020 - YEAR 2

UNIVERSITY CERTIFICATE (17 ECTS CREDITS)

CARAQA.be

University certificate in « Clinical, Regulatory and Quality Affairs for medical devices and in-vitro diagnosis »

TARGET AUDIENCE

Biomedical, mechanical, electronic, software or material science engineers, in charge of medical or IVD development projects

- Physicians, 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
- Specialists involved in the design of sensitive medical products

HIGHLIGHTS OF THE PROGRAMME

- New European regulation requiring experts in the field
- Critical know-how to boost innovation management in MedDev and IVD companies
- Crucial demand of start-ups, medium and large companies for this expertise
- Limited training offer in Benelux
- Covers the requirements of MDR / IVDR Article 15 " Person responsible for regulatory compliance

This programme has been designed in accordance with the "CARAQA" international training network, including Belgium, Switzerland, Germany and Denmark. For more information, go to: www.medidee.com/services/caraqa-training-network

OBJECTIVES

At the end of this certificate, students will be able to:

- Master the consequences of the regulatory changes due to the MDR 2017/745 and the IVDR 2017/746 directives, related to medical devices and in-vitro diagnosis
- Display strategic, tactical and communications skills when interacting with Notified Bodies and Authorities, in particular when facing crisis situations
- Display managerial capabilities surrounding production and marketing processes for new medical products
- Develop technical expertise in key topics such as risk management, biocompatibility, usability, clinical investigation and evaluation, and software validation
- Provide management and engineering support during the development projects for new biomedical products

www.caraqa.be

CURRICULUM

The curriculum is organized in four modules designed to cover in depth the different aspects of the training themes in a logical and progressive way. A personal report will have to be written by the participants, providing a personalized backbone through the entire training.

M1: Introduction to the world of devices

- Description of the Medtech ecosystem
- Description of the product life cycle
- Positioning and interaction of the stakeholders involved

M2: Regulatory Affairs, Design and Submission

- 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
- Structuring document ation 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

TEACHING APPROACH & ASSESSMENT

The learning curriculum includes:

- lectures
- demonstrations, practical exercises, and extramural visits

The final exam consists of a personal written report produced during the training modules, and developing the regulatory, clinical, and quality pathways of a selected technology. This report will further be presented to the certificate jury at the end of the training.

ORGANIZING STAFF

- **Renaud RONSSE**

Professor at UCLouvain and Academic Advisor

- **Sophie DEMOUSTIER**

Professor at UCLouvain and Academic Advisor

- **Pierre GEENS**

Senior consultant at Medidee

- **Philippe ETTER**

Senior partner at Medidee

> INNOVATION IN MEDICAL DEVICES AND IVD REQUIRES AN IN-DEPTH MASTERY OF THE CLINICAL, REGULATORY AND QUALITY AFFAIRS RELATED TO BIOMEDICAL TECHNOLOGIES. THIS CERTIFICATE BRINGS TOGETHER 25 INTERNATIONAL EXPERTS SHARING THEIR EXPERIENCE IN THESE EVER-EVOLVING FIELDS.