

**CAS CARAQA
Clinical, Regulatory and Quality Affairs
for Medical Devices
and In-Vitro Diagnostics**



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Context

The medical device industry is an important contributor to the economy in Switzerland and Southern Germany. This industry is currently undergoing major changes due to developments in the European regulatory landscape.

The transition from European Directives on medical devices, active implantable medical devices and in-vitro medical devices, to the European Regulations on medical devices and in-vitro diagnostic medical devices will have a serious impact on companies in the sector. Employees in this field have to deal with the challenge of staying up-to-date in the face of changing requirements in clinical affairs (CA), regulatory affairs (RA) and quality assurance (QA).

For areas outside Europe the requirements are of a similar or even greater complexity, requiring appropriate preparation when entering those markets.

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Training objectives

Participants in the CAS CARAQA will gain deep insight and hands-on experience in clinical affairs, the regulatory environment and quality assurance within this evolving sector. They will develop a broad range of technical and human skills to advance their careers and help them move into decision-making positions in the organization. They will play a key role in boosting a firm's competitiveness and sustainability in the context of rapidly changing CA/RA/QA functions.

Lecturers from a range of organizations in the medical device and in-vitro medical device sector, as well as from academia, will share their extensive experience and understanding of current and emerging topics within the CA/RA/QA environment.

The CAS for Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics (CAS CARAQA) develops knowledge and practical experience for the following competences according to **article 15 of MDR/ IVDR**:

- Optimal preparation for MDR 2017/745 and IVDR 2017/746 regulatory changes
- Strategic planning and management of clinical evaluations, ISO 14155 investigations and IVD performance studies
- Strategic and tactical communication for interaction with Notified Bodies and National Competent Authorities and for dealing with crisis situations
- Management and engineering support during new product development projects
- Leadership in the deployment and maintenance of Quality Management Systems according to ISO 13485 and US QSR
- Structuring of supply chain, production and marketing
- Technical expertise in key subjects such as risk management, biocompatibility, usability and software validation, according to current standards

Target participants

The CAS CARAQA is aimed at people in medical device and in-vitro medical device companies, as well as subcontractors, who are facing direct or indirect challenges in a CA/RA/QA environment.

In particular, the program addresses

- Employees in the regulatory, clinical and/or quality assurance department
- Engineers from electronics, mechanical or software disciplines, in charge of medical device or in-vitro medical device projects
- Experts in manufacturing and production
- Physicians, scientists or inventors of medical products
- Laboratory assistants involved in the development of new analytical methods or process automation
- Employees involved in clinical studies or quality/regulatory processes within a healthcare organization

Advantages

- On-the-job training
- **Fulfills the requirements of article 15 of MDR/IVDR**
- Excellent job opportunities
- Duration: 26 days over 6 months, maximum one day per week
- Three courses and a personal project

After training, CA/RA/QA specialists may be responsible for or involved in different stages of the medical product life cycle, covering development up to market conformity, production and post market activities.

Admission criteria

Formal entry qualifications:

Tertiary Educational Qualification (BSc or MSc level) combined with relevant work experience within the medical device sector
or

Diploma HF (from a Swiss «Höhere Fachschule») and relevant work experience.



Portfolio Admissions:

At least 3 years' work experience corresponding to or related to the relevant Continuing Education Program.

As the instruction and educational materials are in English, proficiency in English is a prerequisite.

Online-platform

During the program all participants will have access to relevant information, publications and support material via an online platform. Besides information storage, this platform enables wider dialogue between participants and lecturers, to provide additional background to the program topics as well as to answer open questions.

Training concept

The CAS-Program is run alongside participants' daily work. It will take place one day per week and covers three sequential courses on regulatory, clinical affairs and quality assurance. All three courses are an integral part of the program and none may be taken separately. Additionally each participant will run an individual project, supervised by an experienced lecturer.

All courses consist of talks introducing the topic. Lectures may be accompanied by exercises or hands-on workshops, individually or in small groups, supported by experienced staff.

The program will be completed by passing a final exam and by providing a written report and performing a final presentation of the individual project.

Lecturers

Lectures, workshops and supervision during the program will be provided by industrial partners within the medical device and in-vitro medical device sector, experienced consultants as well as academics.



BEAT RATE 96 bpm

Course descriptions

The CAS-Program covers the main requirements emerging from the European Regulation landscape (MDR and IVDR) and is divided into three major courses focusing on regulatory affairs, design and submission (course 1), quality management (course 2) and clinical affairs (course 3) for medical devices and in-vitro diagnostic medical devices.

Introduction to the world of medical devices and in-vitro diagnostic medical devices

- Understanding the environment for medical devices and in-vitro medical devices
- The medical device market and medical product lifecycle
- Interacting with the organisations involved

Course 1: Regulatory affairs, design and submissions

- Defining medical device product development in accordance with ISO 13485
- Structuring and implementing risk management (ISO 14971)
- Integrating regulatory requirements during design
- Managing the implementation of directives, standards (e.g. ISO 10993, EN 60601, EN 62366) and corresponding recommendations or guidance documents
- Managing software compliance (EN 62304)
- Accompanying product design and industrialization
- Structuring regulatory submissions documentation
- Managing market events: incidents, reporting, recalls
- Maintaining regulatory conformity during product lifecycle
- Preparing the company for audits
- Insight and comparison to the US (FDA) and other non-European registration procedures

Course 2: Quality Management

- Structuring the deployment of the Quality Management System (ISO 13485)
- Organizing the documentation and its evolution
- Definition, duties and responsibilities of various subsystems within the quality management system
- Supervising process controls
- Managing critical quality processes such as audit, improvement, changes
- Implementing change management

Course 3: Clinical Affairs

- Regulatory requirements for clinical evaluation
- Structuring, organizing and documentation of clinical and performance evaluations (EN 14155)
- Setting up a clinical evaluation report (CER)
- Organizing a clinical investigation
- Performing a literature review
- Managing post-marketing studies (PMS)
- Updating clinical evaluation reports

Examination

All 3 courses will be subjected to a final written exam.

CAS thesis

The completion of the program will be accompanied by the writing and presentation of an extensive individual thesis. The subject of the thesis is a complete CA/RA/QA study of a medical device or in-vitro diagnostic medical device as per the 3 courses of the program. The device can be chosen by each participant, possibly linked to his/her professional activity.

A personal coach will be assigned to each participant with the responsibility to support and supervise the CAS thesis.

The thesis is written in English (workload approximately 50–60 hours).

Qualification

CAS (Certificate of Advanced Studies) FHNW in Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics.

Duration

Start of the program in January each year; 26 days over 6 months, one day per week. 13 ECTS.

Registration

Registrations are to be sent with the necessary documents by calendar week 44 to:

Medidee Services SA
Chemin de Rovéréaz 5, 1012 Lausanne
T +41 (0) 21 311 2059
training@medidee.com

Program fee

CHF 8'800 (including examination fee). Members of the FHNW Alumni organization receive a 5% reduction.

Location(s)

The program will take place at the School of Life Sciences FHNW (Campus Muttens). Visits to manufacturers may be organized during the program. This training is offered in partnership with Medidee Services SA, an international partner involved in clinical, regulatory and quality affairs for medical devices and in-vitro diagnostics.

FHNW University of Applied Sciences and Arts Northwestern Switzerland General information

The University of Applied Sciences and Arts Northwestern Switzerland (FHNW) is a leading education and research institution that enjoys strong regional ties. It has established itself as one of Switzerland's most innovative Universities of Applied Sciences. The FHNW consists of nine Schools: Applied Psychology, Architecture, Civil Engineering and Geomatics, Art and Design, Life Sciences, Music, Teacher Training, Social Work, Engineering and Business. It occupies a number of sites in its four sponsor Cantons: Aargau, Basel-Landschaft, Basel-Stadt and Solothurn and has more than 11,000 students. Its market-focused practical education and training is provided by 800 lecturers in 29 bachelor's and 18 master's degree programs, as well as numerous continuing education courses; FHNW graduates are in great demand as professionals. As well as education and training, applied research and development is a high priority. The FHNW participates in research projects with national and international partners from industry, business, culture and the public sector and is involved in many European research programs. The University promotes the transfer of knowledge and technology to industry and institutions and in 2016 its R&D activities included 1067 research projects and 314 service provision projects.

Medidee Services SA General information

Medidee is a consulting firm specialised in Regulatory, Clinical affairs and Quality for medical devices and IVD.

Medidee supports manufacturers, public organisations and health professionals facing the complex topics of compliance with legal requirements associated with the development, manufacture, validation and commercialisation of a wide range of technologies in the MedTech and BioTech fields.

The products may include medical devices, active implants, IVD, stand-alone & embedded software or standardised transplants.

Support often starts as early as the ideation and innovation phase. For this reason, the company keeps in close contact with academic and startup ecosystems. Interaction with suppliers during the industrialisation phase is often key.

At later stages, Medidee acts as CRO to strategise, design and obtain the approval of clinical investigations and to support the execution.

Another important area of activity is the development and ISO 13485 certification / 21 CFR 820 compliance of quality management systems to make sure that the product is developed and manufactured correctly. Medidee has offices in Switzerland, Germany, Belgium, Denmark and the USA.

Contact

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June 2019
Print run: 500
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School of Life Sciences
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The FHNW incorporates nine faculties:

- FHNW School of Applied Psychology
- FHNW School of Architecture, Civil Engineering and Geomatics
- FHNW Academy of Art and Design
- FHNW School of Business
- FHNW School of Engineering
- **FHNW School of Life Sciences**
- FHNW Academy of Music
- FHNW School of Social Work
- FHNW School of Education

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