Certificate of Advanced Studies HES-SO (CAS)

CLINICAL AFFAIRS, REGULATORY, AND QUALITY FOR MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC

CONTACT

This training is offered in partnership with Medidee Services SA, an international partner involved in clinical, regulatory and quality affairs for Medical Devices and IVD.

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Medidee Services SA

Details and registration:
www.cas-caraqa.ch

Reviewed in 2017 by the Medical Device Committee of the RAPS Switzerland Chapter

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HAUTE ÉCOLE

formation continue

heig-vd

Hes·so
Haute Ecole Spécialisée de Suisse occidentale
Fachhochschule Westschweiz
University of Applied Sciences and Arts Western Switzerland

Reviewed by RAPS Switzerland Chapter

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CONTEXT

The adoption of the new European regulation on medical devices and in vitro diagnostic requires serious adaptations in the Medtech sector, and most notably the involvement of a "Qualified Person" within the company itself.

These changes result in major pressure on the employees in charge of activities including Clinical Affairs, Regulatory Affairs and Quality Assurance – CA / RA / QA.

Countries of the Gulf, Asia and South America now also have requirements that are as complex as in Europe or the USA. Exporting to these countries is therefore a challenge for Swiss companies.

TRAINING OBJECTIVES

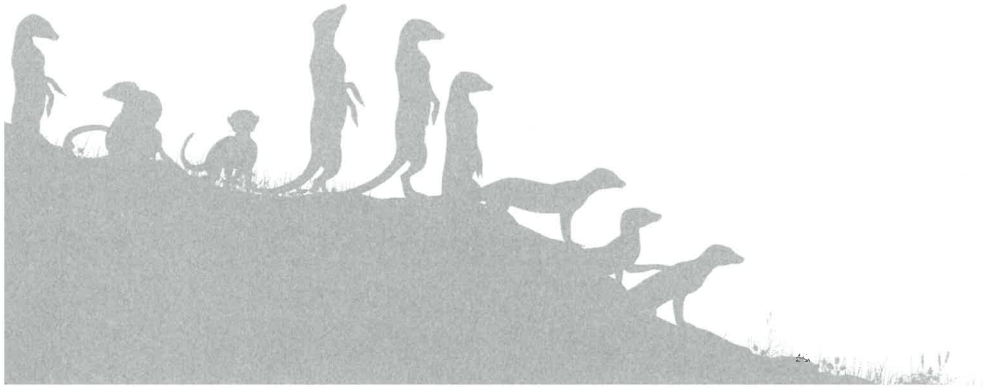
Develop a broad range of technical and human skills in order to evolve towards the company's decision-making centres and to play a key role in maintaining the company's competitiveness and sustainability, faced with the evolution of the CA / RA / QA functions.

The Certificate of Advanced Studies (CAS) HES-SO contributes to the development of skills including:

- Optimal preparation in view of the regulatory changes with the MDR 2017 / 745 and the IVDR 2017 / 746
- Ability to strategically plan and manage clinical evaluations, investigation and performance studies (IVD)
- Strategic, tactical and communications aptitude faced with crisis situations and interaction difficulties with Notified Bodies and the Authorities,
- Managerial competence to lead the deployment and maintenance of a QMS
- Managerial capabilities surrounding production and marketing processes for new medical products,
- Technical expertise in key subjects such as biocompatibility, usability, clinical investigation and evaluation, software validation,
- Management support during the development projects for new products.

TARGET AUDIENCE

- Employee within the regulatory, clinical and / or quality department of a manufacturing or subcontracting company,
- Specialist involved in the manufacturing of sensitive medical products,
- Laboratory assistant involved in the development of new analytical methods or process automation,
- Mechanical, electronic or software engineer in charge of medical devices or IVD development projects,
- Physician, scientist or inventor of medical products,
- Employee involved in clinical studies or quality / regulatory processes within a healthcare organization.



TRAINING

- On-the-job training type
- Duration: 28 days of course over 7 months (including final exam)
  Class every Friday
  2 months personal work with coaching on CAS Thesis
- Start of the program: each year
- Location: HEIG-VD, Centre St-Roch, Yverdon-les-Bains
- Three modules and a personal project:

Introduction to the world of devices

Understanding the MedTech environment

Grasping the product's lifecycle

Positioning and interacting with involved entities

Module 1: Regulatory affairs, design and submissions

Structuring and implementing risk management

Integrating regulatory requirements during design

Managing the implementation of directives, standards and recommendations

Managing software compliance

Accompanying a product design and industrialization effort

Structuring the documentation of regulatory submissions

Managing market events: incidents, reporting, recalls

Maintaining regulatory conformity during product lifecycle

Preparing the company for audits

Module 2: Quality Management

Structuring the deployment of the Quality Management System

Organising the documentation and its evolution

Supervising the control of processes

Managing critical quality processes such audit, improvement, changes

Module 3: Clinical

Structuring and organising clinical / performance evaluations

Organising a clinical investigation

Performing a literature review

Managing post-marketing studies

PRICE

CHF 7000.– (including examination taxes)

ADMISSION CONDITIONS

High education degree such as a Bachelor or Master's degree, of the type HES or EPF / UNI or equivalent, in the following fields:

- Engineering, chemistry, biology or life science
- Graduate in management or corporate economics
- High education in nursing, radiology or physiotherapy

Admission by application possible for holders of ET or CFC level education in a suitable educational domain (physical or chemical laboratory assistant) with extensive professional experience.

As the instruction and educational materials are provided in English, proficiency in English (reading and writing) is a prerequisite.