

## CAS CARAQA

### Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics



**In collaboration with Medídee, the School of Life Sciences FHNW offers a unique training opportunity for MedTech professionals facing the European regulation changes.**

#### Training objectives

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

#### Contents

The CAS CARAQA contributes to the development of skills including:

- Optimal preparation in view of the regulatory changes with MDR 2017/745 and IVDR 2017/746
- Strategic planning and management of clinical evaluations, investigations according to ISO 14155 and performance studies for IVD
- Strategy, tactics and communications to deal with crisis situations and interaction with Notified Bodies and National Competent Authorities
- 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 audience**

- Employees in the regulatory, clinical and/or quality department of a manufacturing or subcontracting company
- Specialists involved in the manufacturing of sensitive medical products
- Laboratory assistants involved in the development of new analytical methods or process automation
- Mechanical, electronic or software engineers in charge of medical devices or IVD development projects
- Physicians, scientists or inventors of medical products
- Employees involved in clinical studies or quality/regulatory processes within a healthcare organization

**Qualification**

CAS FHNW in Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics

**Duration**

26 days (Tuesdays) over 6 months

**Program fee**

CHF 8'800 (including examination fees)

Members of the FHNW Alumni organization receive a 5% discount.

**Contact and 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 20 59  
training@medidee.com

Further information: [www.fhnw.ch/caraqa](http://www.fhnw.ch/caraqa)

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