In collaboration with Medidee, 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