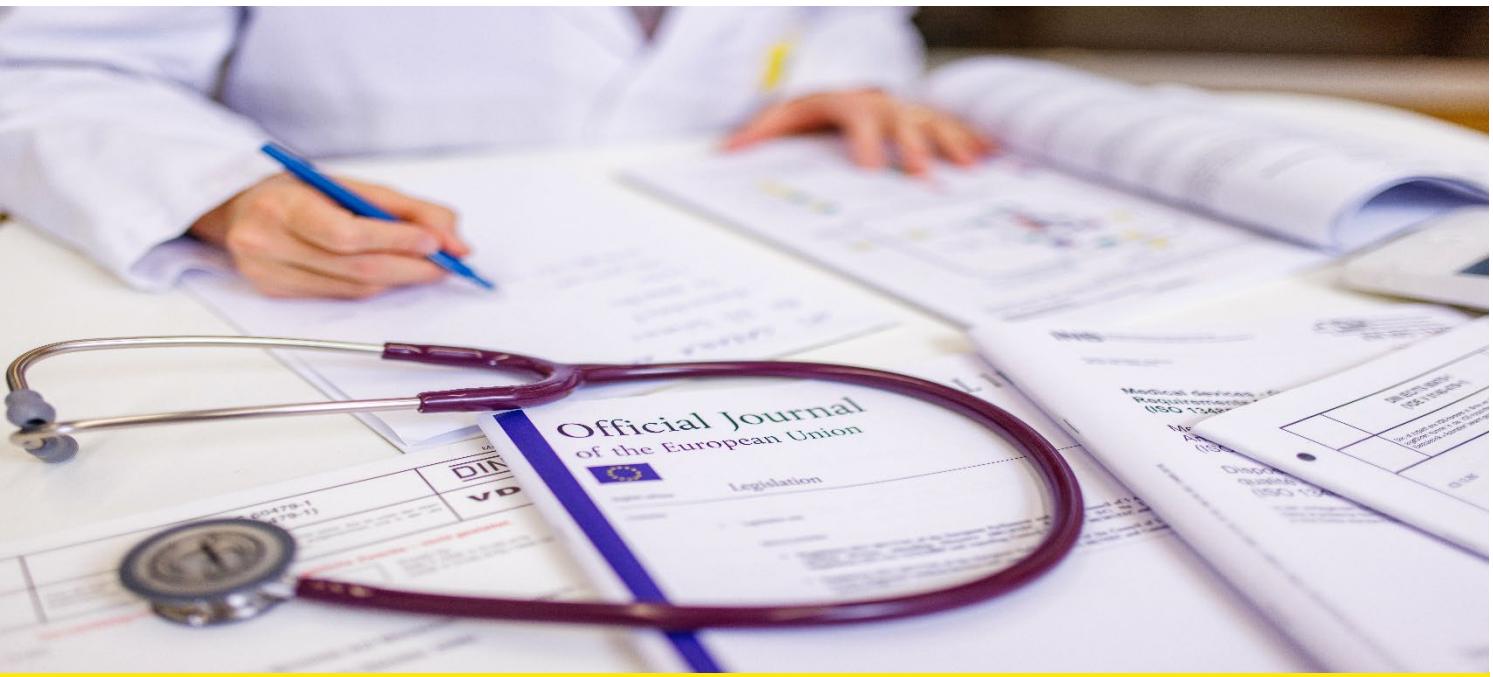

CAS CARAQA

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

To strengthen and maintain the economic power of the MedTech sector through development and empowerment of the MedTech professionals, Veranex and the FHNW School of Life Sciences offer a unique training program the Certificate of Advanced Studies in Clinical, Regulatory, and Quality affairs for Medical Devices and In-Vitro Diagnostics.

Programme Goals

CARAQA training is tailored to equip participants with the essential skills required by the MedTech industry. With the evolving dynamics of CA/RA/QA roles, our aim is to cultivate a diverse set of technical and interpersonal skills. This prepares participants to progress to decision-making positions within their organisations and play a pivotal role in maintaining the company's competitive edge and long-term viability. During the CARAQA training, participants will have the opportunity to fulfil professional development requirements that are compliant with both EU and US regulations.

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 Group
– 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

Duration
26 days (Tuesdays) over 6 months

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

Dates
see website

Location
FHNW Campus Muttenz, Switzerland

Costs
see website

Cooperation
This CAS is offered in cooperation with Veranex

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Further Information and Registration
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