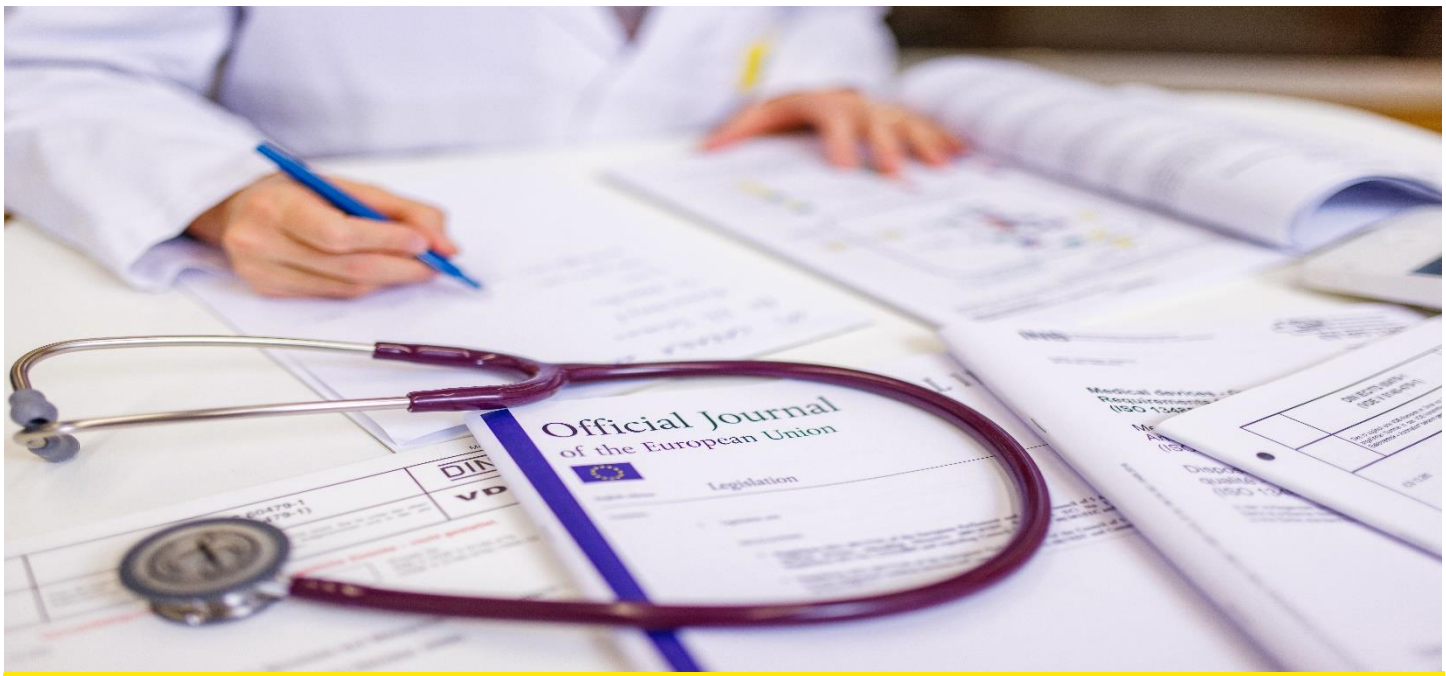

CAS CARAQA
Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics

The European market for medical devices and in-vitro diagnostics, the second largest such market in the world, is undergoing a significant evolution with the implementation of the new Medical Device Regulation (EU 2017/745) and In-Vitro Diagnostics Regulation (EU 2017/746).

Compared to the EU Directives, the Regulations have expanded the requirements for achieving a high level of medical device safety and performance in Europe.

To satisfy these requirements, the demand for regulatory, quality and clinical affairs professionals throughout Europe has increased significantly. The CAS CARAQA programme offered by FHNW and Veranex, is designed to equip participants with these essential skills required by the medical device and in vitro diagnostic industries.

Contents

Our education programme provides participants with advanced knowledge, hands-on experience and first-hand skills from industry experts.

The structure of the programme enables participants to assume responsibility within their organisation for regulatory compliance (PRRC) in accordance with Art. 15 MDR and IVDR. This will enable professionals to make key organisational decisions and play a vital role in maintaining the competitiveness and longevity of the business.

The programme provides an in-depth insight into regulatory, clinical and quality management issues and emphasises the application of this knowledge in a practical professional context.

Target Group

The programme is aimed at people in medical device and in-vitro medical device companies and suppliers who are directly or indirectly facing challenges in a CA/RA/QA environment. Individuals wishing to develop their skills in this direction are also very welcome.

- 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
- Employees involved in clinical studies or quality/regulatory processes in healthcare organisations

The admission criteria are set out in the programme description on our website.

Degree / ECTS
Certificate of Advanced Studies FHNW Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics / 13 ECTS

Location
FHNW Campus Muttenz, Switzerland

Programme Managers
Prof. Dr. David Hradetzky
T +41 61 228 54 58 (direct)
david.hradetzky@fhnw.ch

Dr. Elena Lucano
T +41 76 270 37 51
elena.lucano@veranex.com

Programme Administration
Veranex
Zuzana Tumova
T +41 21 311 20 59
admin@caraqa.com

FHNW School of Life Sciences
Elzbieta Lehmann
T +41 61 228 55 40
weiterbildung.lifesciences@fhnw.ch

Further Information and Registration
www.fhnw.ch/caraqa

About the programme partner
Veranex is the only comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. They offer expert guidance from concept through to commercialization, including product design and engineering, preclinical and clinical development, data management, market access, regulatory affairs and quality assurance. Veranex enables accelerated speed to market, controlled development costs, development risk mitigation and rapid market viability assessment. Veranex partners the world's most influential life science and medical device companies to research, design, develop and commercialize new healthcare technologies and treatments in order to advance patient care.