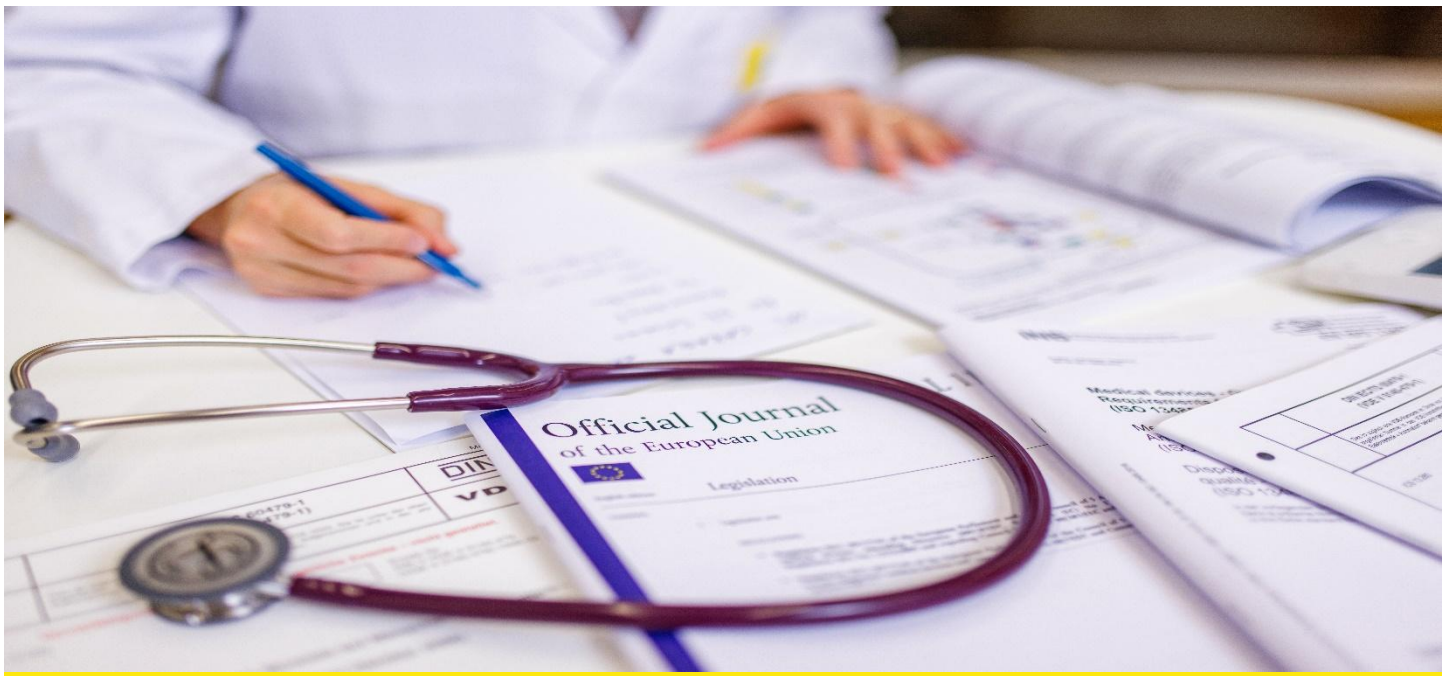

CAS CARAQA
Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics

The complexity of tasks in regulatory, quality and clinical affairs poses major challenges for the industry, affecting each of those disciplines individually as well as the links between them. Companies that recognise and anticipate these challenges can overcome regulatory hurdles efficiently and ensure the long-term conformity of their products.

The CAS CARAQA enables staff to acquire expertise in these issues and develop their understanding of what links the three disciplines. Participants are trained to ensure appropriate communication and cooperation, both within their organization and with third parties. The knowledge and skills gained on the course are crucial for regulatory compliance and product quality, and thus for the tasks of a Person Responsible for Regulatory Compliance according to Art. 15 of the regulations.

The CAS CARAQA in Muttenz is offered by the FHNW School of Life Sciences in cooperation with Veranex. The programme is part of the European CARAQA network.

Contents
The programme is divided into the three specialist disciplines of Regulatory, Quality Assurance and Clinical Affairs. All three are highly dynamic, particularly in Europe, and the programme's content is constantly updated to reflect current developments. This is ensured by the involvement of proven experts in the field, whose experience is incorporated into the training in addition to the practical elements. On-site events give participants the opportunity to make valuable contacts and network with industry colleagues.

At the beginning of the programme, participants receive an introduction to MedTech products and their market, a comprehensive overview of European regulations, and a detailed look at the players involved such as notified bodies and competent authorities.

The area of regulatory affairs includes in-depth insights into the European Medical Device Regulation (EU 2017/745) and In-vitro Diagnostic Medical Device Regulation (EU 2017/746), supplemented by corresponding

publications of the Medical Device Coordination Group (MDCG guidance). It also examines the approval process for the US market (FDA) and procedures in other global markets such as China, Australia, Canada, the UK and the Association of Southeast Asian Nations (ASEAN). Special features of the Swiss market are also covered.

Content such as MDR and IVDR classification, risk management (ISO 14971), electrical safety and electromagnetic compatibility (IEC 60601), biocompatibility (ISO 10993-1) and usability (ISO 62366) requirements are examined in detail. Obligations resulting from increasing digitalization, such as the Cyber-security Act, the European Artificial Intelligence Act or the General Data Protection Regulation, are also taken into account. These are accompanied by input on the creation and organisation of technical documentation required for European and international markets.

Putting regulatory requirements into practice needs an efficient, compliant quality management system. The programme introduces suitable structures and system organisation, goes into detail on ISO 13485 and discusses implementation options. In addition to European requirements, those for the global market (US 21 CFR part 820, MDSAP) are also addressed.

Another key part of the programme is training in clinical evaluation, medical device testing and in-vitro diagnostics. Participants learn the latest strategies and organizational techniques for clinical trials, and gain insights into Post-Market Clinical Follow-up (PMCF) and Post-Market Performance Follow-up (PMPF). Also highlighted are implementation of these downstream quality management activities, manufacturers' reporting obligations and the integration of new findings into risk management.

The course ends with an examination, and the completion and defence of a small final project.

Target Group
The CAS CARAQA is a comprehensive continuing education programme, specifically tailored to the needs of medical technology and in-vitro diagnostics professionals. It is aimed at anyone involved in the life cycle of a medical device, from supplier to manufacturer to distributor:

- Employees at manufacturers and suppliers of in-vitro diagnostics and medical devices who work in regulatory affairs, quality management or clinical affairs
- Staff who support in-vitro diagnostics or medical devices during market approval.
- Employees in medical device or in-vitro diagnostics development
- Manufacturing and production staff
- Doctors, scientists or inventors of medical devices
- Staff involved in clinical studies or quality/regulatory processes in healthcare facilities

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

Location
FHNW Campus Muttenz, Switzerland

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.

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