Programme Description CAS CARAQA

1. Overview

Degree to be acquired	Certificate of Advanced Studies FHNW Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics
Type of Programme	Part-time
Language	English
ECTS-points	13
Duration	26 days
Learning Outcomes / Competences	• Optimal preparation for regulation according to MDR 2017/745 and IVDR 2017/746 • Strategic planning and management of clinical evaluations, investigations in accordance with ISO 14155 and performance studies of IVDs • Strategic and tactical communications for interactions with Notified Bodies and National Competent Authorities, and crisis management • Management and technical support for new product development projects • Leadership in the implementation and maintenance of ISO 13485 and US QSR quality management systems • 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
Programme Start	As mentioned on the website
Application Deadline	As mentioned on the website

Admission Criteria	Tertiary educational qualification (at least Bachelor degree level) and relevant professional experience or Federal Diploma of Higher Education (from a Swiss “Höhere Fachschule” or “eidg. HFP” or “eidg. BP”), and at least 3 years of relevant professional experience in a subject relevant to or related to the continuing training programme. Interested persons without tertiary educational qualification can be admitted, if they have a minimum of 5 years professional experience in a subject relevant to or related to the continuing education programme and if they have successful completed various continuing training courses (in-company or CAS/MAS/DAS) or discontinuation of tertiary education with advanced participation or partial achievement (> 50%) As the instruction and educational materials are in English, proficiency in English (minimum level C1) is a prerequisite.
Prerequisites for beginning the Final Thesis	Proposal acknowledged by the programme committee
Graduation Requirements	Final exam: satisfactory mark and final thesis: satisfactory mark
Price (included services)	As mentioned on the website
Additional Fees	None
Terms of Payment	As per invoice or Conditions of Admission
Head of Programme	Prof. Dr. David Hradetzky; T +41 61 228 54 58, Email: david.hradetzky@fhnw.ch Dr. Elena Lucano, T +41 76 270 37 51, Email : elena.lucano@veranex.com
Programme Administration	Zuzana Tumova: T +41 21 311 20 59; admin@caraqa.com Elzbieta Lehmann: T +41 61 228 55 40; weiterbildung.lifesciences@fhnw.ch
Further Information / Links	https://www.fhnw.ch/caraqa

2. Module Plan

No.	Modules	Testing method for each module	Assessment[1]	ECTS (per module)	Work volume/ Study hours (including preparatory and follow-up work)	Mode (Presence, Online, Hybrid)
1	Regulatory Affairs	Written exam	Scale of 2	5	125-150h	Presence
2	Quality Management	Written exam	Scale of 2	4	100-120h	Presence
3	Clinical Affairs	Written exam	Scale of 2	2	50-60h	Presence
4	Final thesis	Thesis and presentation	Scale of 2	2	50-60h	Presence
			TOTAL	**13**	**325-390h**	

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[1] Scale of 2: satisfactory/unsatisfactory or scale of 6: 6=excellent, 5.5=very good, 5=good, 4.5=satisfactory, 4=sufficient, 3=inadequate, 2=poor, 1=very poor