

Program Description CAS CARAQA

1. Overview

Proposed Program title	Certificate of Advanced Studies FHNW in clinical affairs, regulatory and quality for medical devices and in-vitro diagnostics (CAS CARAQA)
Type of Program	Part-Time
Language of instruction	English
Program scale	13 ECTS-Credits
Maximum duration	6 months of lectures (Tuesdays) plus additional thesis preparation time
Learning outcomes and competences to be attained	<ul style="list-style-type: none"> ▪ Optimal preparation in view of the regulatory changes with the MDR 2017/745 and the IVDR 2017/746 ▪ Ability to strategically plan and manage clinical evaluations, investigation and performance studies (IVD) ▪ Strategic, tactical and communications aptitude faced with crisis situations and interaction difficulties with Notified Bodies and the Authorities, ▪ Managerial competence to lead the deployment and maintenance of a QMS ▪ Managerial capabilities surrounding production and marketing processes for new medical products, ▪ Technical expertise in key subjects such as biocompatibility, usability, clinical investigation and evaluation, software validation, ▪ Management support during the development projects for new products.
Program begins on	Calendar week 2
Application deadline	9 weeks before start
Admission criteria	<p>Formal entry qualifications:</p> <p>Tertiary Educational Qualification (at least Bachelor level) and relevant work experience</p> <p>or</p>

	<p>Diplom HF (from a Swiss "Höhere Fachschule") and relevant work experience</p> <p>Portfolio Admissions:</p> <p>At least 3 years work experience corresponding to or related to the relevant Continuing Education Program.</p> <p>As the instruction and educational materials are provided in English, proficiency in English (reading and writing) is a prerequisite</p>
Prerequisites for beginning the final thesis	Supervisors agreement
Graduation requirements	<p>Final exam: satisfactory mark</p> <p>and</p> <p>Final thesis: satisfactory mark</p>
Scale ECTS of final thesis	2 ECTS
Program fee	As mentioned in the actual brochure
Terms of payment	As per invoice or Conditions of Admission
Heads of Program	<p>Prof. Dr. David Hradetzky, Tel. 061 228 54 58</p> <p>david.hradetzky@fhnw.ch</p> <p>Philippe Etter, Tel. 079 202 09 29</p> <p>philippe.etter@medidee.com</p>
Program administration	<p>Training manager, T +41 (0)21 311 20 59</p> <p>training@medidee.com</p> <p>Nicole-Astha Horlacher, Tel. 061 228 55 40</p>

	weiterbildung.lifesciences@fhnw.ch
Further information	www.fhnw.ch/caraqa

2. Module Plan

No.	Module description and content (key words)	Testing method ¹ for each module	Assessment ²	ECTS (per module*)	Work volume/ Study hours (including preparatory and follow-up work)	Proximate or distance learning
1	Regulatory affairs, design and submissions	Written examination	Scale of 2	5	125-150 h	proximate
2	Quality Management	Written examination	Scale of 2	4	100-120 h	proximate
3	Clinical Affairs	Written examination	Scale of 2	2	50-60 h	proximate
4	Thesis	Final thesis and presentation	Scale of 2	2	50-60 h	proximate
			TOTAL	13	325-390 hours	

¹ e.g. written examination, presentation, case analysis, reflection report, e-exam, final thesis

² 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