

Programme Description CAS Pharmaceutical Project Management

1. Overview

Degree to be acquired	Certificate of Advanced Studies FHNW Pharmaceutical Project Management
Type of Programme	Part-time
Language	English
ECTS-points	10
Duration	15 days
Learning Outcomes / Competences	<p>Upon completion of this programme, participants will be able to:</p> <ul style="list-style-type: none"> • Understand the pharmaceutical development lifecycle and its impact on project management. • Apply specialized project management methodologies and tools for pharmaceutical projects. • Navigate regulatory requirements and ensure compliance within project management frameworks. • Develop and implement effective risk management strategies tailored to the pharmaceutical industry. • Communicate seamlessly with cross-functional teams, including R&D, regulatory affairs, marketing, and manufacturing
Programme Start	As mentioned on the website
Application Deadline	As mentioned on the website

Admission Criteria	<p>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.</p> <p>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 successfully completed various continuing training courses (in-company or CAS/MAS/DAS) or discontinuation of tertiary education with advanced participation or partial achievement (> 50%)</p> <p>As the instruction and educational materials are in English, proficiency in English (minimum level C1) is a prerequisite.</p>
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	Dr. Christoph Heinzen; T +41 61 228 55 40, Email: christoph.heinzen@fhnw.ch
Programme Administration	Elzbieta Lehmann; T +41 61 228 55 40; weiterbildung.lifesciences@fhnw.ch
Further Information / Links	www.fhnw.ch/ppm

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	Introduction to Pharmaceutical Project Management <ul style="list-style-type: none"> • Overview of the pharmaceutical industry, Regulatory & GMP frame • Key phases of drug development: discovery, preclinical, clinical, regulatory, and post-market • Types of projects, ISO 21502 • Agile, waterfall, and hybrid approaches • Tools and software for project management • Roles and responsibilities of project team members (RACI) and other stakeholders 	See below	See below	1	25-30h	Presence and Online
2	Regulatory affairs, quality & legal compliance <ul style="list-style-type: none"> • FDA, EMA and other regulatory bodies • Quality management system and key quality processes • Quality assurance agreement 	See below	See below	1	25-30h	Presence and Online

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

	<ul style="list-style-type: none"> • Master service agreement / product agreement, shipment agreement • User requirement specification / statement of work 					
3	Project initiation <ul style="list-style-type: none"> • R&D, manufacturing, maintenance • Project structuring: checklists, SOPs, work packages, milestones • Establishing a quote, preparing a budget, time schedule • Supply chain: procurement, ordering equipment & material • Resource planning: materials, equipment and individuals • Introduction of new equipment, IQ/OQ/PQ, validation/verification, commissioning 	See below	See below	2	50-60h	Presence
4	Project monitoring & controlling <ul style="list-style-type: none"> • Kick-off • Riskmanagement • Monitoring & reporting • Stakeholdermanagement, project team meetings & steering committee meetings • Manage project changes/deviations • Cost control 	See below	See below	2	50-60h	Online
5	Team building & project optimization strategies <ul style="list-style-type: none"> • Building effective teams across departments • Conflict management 	See below	See below	2	50-60h	Presence and Online

	<ul style="list-style-type: none"> • Effective communication • Typical pit falls, optimization of projects 					
6	Final thesis	Thesis and presentation	Scale of 6	2	50-60h	Presence
			TOTAL	10	250-300h	

Created on 08th April 2025