# CAS Pharmaceutical Project Management

## Advanced training in pharmaceutical project management – designed for professionals in regulatory, quality assurance, drug development and compliance

The programme blends project management skills with scientific expertise, empowering professionals to lead complex projects in the pharmaceutical sector.

**Contents**

The first module provides a comprehensive overview of the pharmaceutical industry, focusing on regulatory frameworks and Good Manufacturing Practice (GMP). It covers the key phases of drug development, from discovery to post-market stages, while exploring different project types and the ISO 21502 standard. Participants learn about agile, waterfall and hybrid project management approaches, as well as the roles and responsibilities of project teammembers and stakeholders, with a focus on the RACI model.

In the second module, participants explore the roles of regulatory bodies such as the FDA and EMA and the importance of quality management systems. It also covers essential agreements, including quality assurance, master service and shipment agreements, along with developing user requirement specifications and statements of work.

The next module covers project initiation basics, including R&D, manufacturing and maintenance. It focuses on structuring projects with checklists, SOPs, work packages, milestones, and establishing budgets and schedules. Participants also learn about supply chain management, resource planning and introducing new equipment, including IQ/OQ/PQ processes and validation.

The fourth module teaches critical project monitoring and controlling skills, including risk management, reporting and cost control. It emphasizes managing changes and deviations to keep projects on track. The module also covers stakeholder management and organizing team meetings for ongoing communication and progress tracking.

The fifth module explores strategies for building effective teams across departments, with a focus on conflict management and fostering collaboration. Participants learn about the importance of effective communication within

project teams to avoid common pitfalls and ensure project success. Finally, the module covers methods for optimizing project workflows, improving efficiency, and achieving the best possible project delivery outcomes.

**Target Group**
This part-time course is suitable for current project managers in pharmaceutical companies, professionals aspiring to enter project management within the pharmaceutical industry, research and development professionals, regulatory affairs specialists and quality assurance managers.

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

**Format**
The modules are taught on Thursdays and Fridays. About half the lessons take place online, while the other half are held in person at the FHNW campus in Muttenz.
The programme concludes with an individual written thesis, followed by a presentation and defence.

**Degree / ECTS**
Certificate of Advanced Studies FHNW Pharmaceutical Project Management, 10 ECTS

**Location**
Online and FHNW Campus Muttenz

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**Further Information and Registration**
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