Bern University
of Applied Sciences

Certificate of Advanced Studies CAS

Regulatory Affairs Pharma

In this CAS, you will acquire the key competences for working in a regulated environment and learn how to act as a liaison between companies and regulatory authorities. The programme teaches the fundamentals of the function of EU bodies, authorisation procedures and legal frameworks, labelling, GXP and life cycle management.

Objectives

- You get insight into global regulatory strategies e.g. ICH (International Harmonization).
- You gain knowledge about the structure and function of relevant regulatory bodies.
- You learn the different regulatory pathways for the marketing authorisation.
- You know how to prepare the scientific and technical documentation for a marketing authorization application
- You learn how post-approval changes are regulated and how pharmacovigilance is performed.
- For your term paper (living case), you work on a real-life project to deepen the knowledge you have acquired.

Target audience

- You plan to work in the regulated environment of the healthcare industry or as a regulatory affairs professional in the pharmaceutical or biotechnology industry.
- You work in development, manufacturing, quality management or regulatory affairs in the healthcare industry and want to deepen your regulatory affairs knowledge.

Further information

bfh.ch/en/cas-rapharma

Factsheet

Degree/Certificate
Certificate of Advanced Studies in «Regulatory Affairs Pharma»

ECTS-Credits
12 ECTS-Credits

Costs
CHF 7 500

Location
Biel, Aarbergstrasse 46 (Switzerland Innovation Park Biel/Bienne)

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