Bern University
of Applied Sciences

Certificate of Advanced Studies CAS

Regulatory Affairs Pharma

In this CAS you will achieve the key skills to work in this highly regulated environment and learn how to act as a liaison person between companies and regulatory authorities. This continuing education programme teaches the general framework: structure and function of EU bodies, marketing authorization procedures and legal framework, labelling, GXP, 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 develop the scientific technical dossier to accompany a marketing authorisation application.
- You learn how post-approval changes are regulated and how pharmacovigilance is performed.
- You learn about product classes that are subject to special regulation.

Target audience

- You are planning to work in the field of regulatory affairs in the pharmaceutical industry.
- You are working in the development, manufacturing, quality management or in the field of regulatory affairs and want to improve your knowledge in regulatory affairs for medicinal products for human use.

Further information

bfh.ch/en/cas-rapharma

Factsheet

Degree/Certificate
Certificate of Advanced Studies Regulatory Affairs Pharma

ECTS-Credits
12 ECTS-Credits

Costs
CHF 7500

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

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