



Diploma of Advanced Studies DAS

Regulatory Affairs

This programme prepares regulatory affairs professionals to work in the ever-changing regulatory environment of the medical device, pharmaceutical, and biotechnology industries. It covers CH and EU regulations, global regulatory strategies, and quality management at every stage of the healthcare product lifecycle.

Objectives

- You learn about CH, EU, and global regulatory strategies.
- You know the different regulatory pathways for obtaining marketing authorization.
- You learn how to interact with regulators, e.g., how meetings between the applicant and the regulator take place and how audits are carried out.
- You become familiar with GxP.
- You learn how to report serious incidents and take corrective action.

Target audience

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

Further Information

bfh.ch/das-ra

Factsheet

Degree/Certificate

Diploma of Advanced Studies in Regulatory Affairs

ECTS credits

36 ECTS-Credits

Duration

3 semesters (3 CAS)

Costs

from CHF 22 500

Location

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

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