Certificate of Advanced Studies CAS

Regulatory Affairs in Life Sciences

This CAS provides you with the essential knowledge to work in the regulated medical device and life sciences industries. It covers regulations throughout the product life-cycle and focuses on areas such as development and validation, regulatory approvals for key markets, quality requirements, traceability, and market surveillance.

Objectives

- You become familiar with the EU Medical Device Regulation (MDR) and EU In Vitro Diagnostic Medical Device Regulation (IVDR).
- You gain the expertise you need to set up a medical device quality management system (QMS) according to ISO 13485.
- You learn how to integrate risk management, usability engineering, reviews, and design and process validation.
- You learn how to report serious incidents and take corrective action.
- 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 medical device or life sciences industry.
- You are responsible for the early detection and analysis of risks in the areas of medical technology, medical informatics or in the life sciences 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/cas-ra

Factsheet

Degree/Certificate
Certificate of Advanced Studies in «Regulatory Affairs in Life Sciences»

ECTS-Credits
12 ECTS-Credits

Costs
CHF 7 500

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

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