Diploma of Advanced Studies

Regulatory Affairs

Regulatory Affairs is the discipline of applying regulations and standards in the development, approval and marketing of medical devices and pharmaceutical products with the aim of ensuring the safety and efficacy of these products. This programme will provide you with the necessary expertise to work as a regulatory affairs Professional in the highly regulated environment of the medical technology, pharmaceutical and biotechnology industries.

Berner
Fachhochschule

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1 Setting

The healthcare industry has evolved significantly over the last 10 years. As a result, the roles of regulatory affairs professionals have changed accordingly. New technologies such as personalised medicine, advanced therapy medicinal products, artificial intelligence and machine learning (e.g. decision support systems), home virus detection kits, wearable patient monitoring devices and improved patient management are already in use. In the wake of such innovations and the resulting revision or creation of new regulations, regulatory affairs professionals need to continually expand their knowledge.

In the medical technology sector, the Medical Devices Regulation (MDR) and the In Vitro Diagnostics Medical Devices Regulation (IVDR) are in force since May 2021 and May 2022 respectively. In addition to stricter regulatory requirements at each stage of the lifecycle of medical devices, medical software, and in vitro diagnostics, the two regulations also require companies to have at least one person responsible for regulatory compliance. The qualification of this person must be demonstrated by a university degree or by a course of study recognised as equivalent in law, medicine, pharmacy, engineering, or another relevant scientific discipline and at least one year's professional experience in the field of regulatory affairs or quality management related to medical devices and in vitro diagnostics.

To obtain and maintain regulatory approval of healthcare products, regulatory affairs professionals must fulfill the following core tasks:
- Regulatory strategies
- Implementing regulatory measures
- Adhering to quality management
- Solving trade-related issues
- Negotiating/communicating with authorities
- Management strategies

The MAS in Regulatory Affairs lays the foundation for entering the healthcare industry as a regulatory affairs professional by providing the above expertise and knowledge of the ever-changing regulations.

2 Target audience

The programme is designed for people from the fields of medical technology and informatics, pharmacy/chemistry, and life sciences as well as medicine or law who wish to work in the highly regulated environment of the medical technology, pharmaceutical and biotechnology industries or who wish to work as regulatory affairs professionals in these areas.

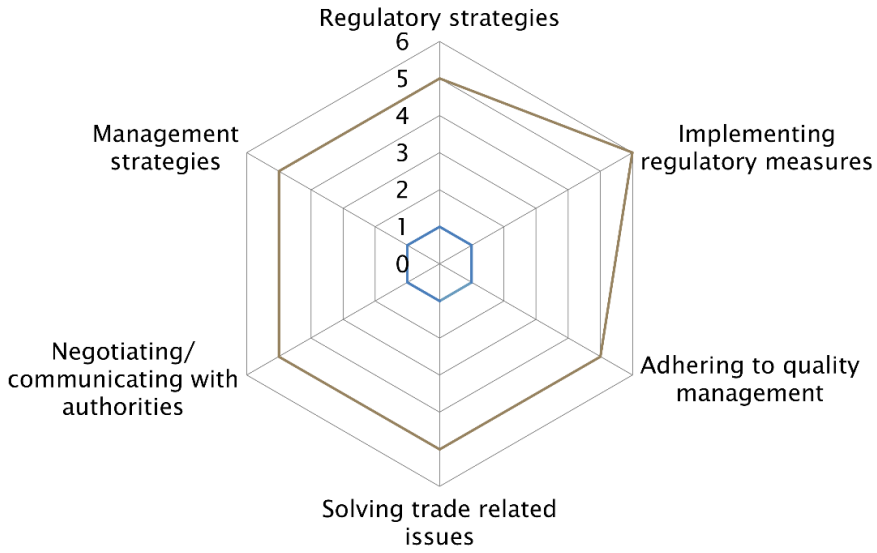
3 Training objectives

Regulatory strategies
– You learn about the regulatory strategies in Switzerland, in the EU and around the world. – You understand the relevant regulatory bodies and how they operate.
Implementing regulatory measures
– You become familiar with the EU Medical Devices Regulation (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation (IVDR). – You learn about the structure and function of regulatory bodies. – You know the different regulatory pathways for obtaining marketing authorization. – You know what clinical evaluation is and how it is done. – You understand the principles and requirements of GxP guidelines in relation to quality assurance, compliance and regulatory standards in the pharmaceutical, biotechnology and medical device industries. – You understand the market surveillance procedures to ensure the safety of pharmaceutical products and medical devices. – You know which product classes have special regulations. – You gain basic IT and data science skills to effectively analyse and interpret data and make data-driven decisions in your field.
Adhering to quality management
– You understand the structure and requirements of the ISO 13485 and ISO 9001 standards for the medical device industry. – You understand the structure and requirements of the ICH Q10 pharmaceutical quality system. – You learn how to integrate risk management, usability engineering, reviews and design and process validation.
Solving trade-related issues
– You understand the key elements of (digital) supply chain management for medical devices and pharmaceutical products, including optimising logistics processes and ensuring product integrity form manufacturing to the end consumer. – You are aware of the risks and challenges associated with the counterfeiting of medical devices and pharmaceutical products. – You develop (digital) marketing skills to create effective strategies and campaigns for medical devices and pharmaceutical products, considering industry-specific regulations and ethical standards.
Negotiating/communication with authorities
– You understand the processes and best practices for interacting with the regulator, including the preparation and conduct of meetings between the applicant and the regulatory authorities.
Management strategies
– You develop management skills to make strategic decisions and achieve organisational goals in your working environment.

4 Requirements

Bachelor's/Master's degree in life sciences, medicine, pharmacy, engineering, law, computer science or another relevant scientific field and usually two years of professional experience.

5 Skills

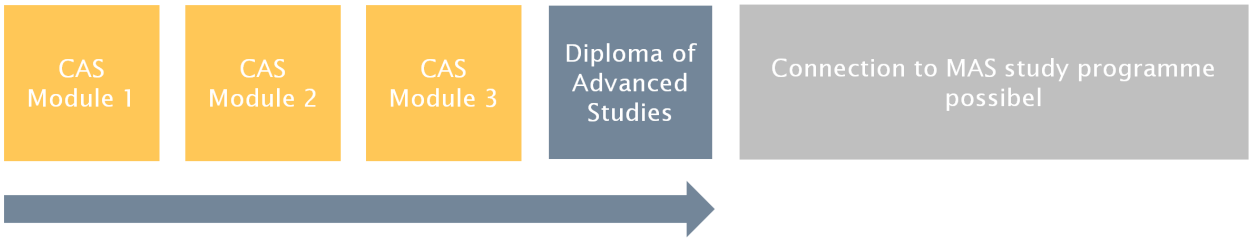


Levels of competence

1. Knowledge of terms, definitions, and regulations; factual knowledge.
2. Understanding the context, ability to explain complex matters.
3. Applying knowledge in simple situations.
4. Analysing one's own solution method.
5. Synthesis of new solutions and application in complex situations.
6. Assessing applicability for specific problems and situations, evaluating of methods and of alternatives, connections with other fields of expertise.

6 Structure of the programme

- The programme has a modular structure. Each module is thematically self-contained and lasts one semester. One module is a Certificate of Advanced Studies (CAS) and can also be taken as a stand-alone continuing education course. It corresponds to a workload of 12 ECTS (360 hours).
- The programme consists of three CAS modules. The modules can be taken in any order, but two of the three specific Regulatory Affairs CASs must be completed. An additional CAS from the TI continuing education portfolio can be taken (e.g. Digital Health, Informatics or Management).
- The study load is designed to allow students to work around 80% of the time.



7 Description of the key CAS

Regulatory Affairs in Life Sciences (CAS RA)	Medical devices, medical software, pharmaceuticals and combination products are subject to national and international regulations. The CAS in Regulatory Affairs in Life Sciences provides you with the necessary tools to operate in the highly regulated environment of the medical technology and life sciences industry. This CAS is taught in English.
Regulatory Affairs Pharma (CAS RAPHARMA)	Pharmaceutical products are developed, manufactured, controlled, and distributed under strict legal regulations to ensure that they are safe, effective and of high consistent quality. In this CAS you will gain 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 CAS is taught in English.
From autumn semester 2024: **Regulatory Affairs Mastery (CAS RAM)** (This CAS is taught in English)	This CAS equips you with the practical skills essential for a regulatory affairs professional in the pharmaceutic and medical industries. You will develop strategic negotiation skills for interactions with regulatory authorities, acquire the ability to analyse statistical data and generate meaningful documentation. Additionally, you will learn how to effectively incorporate artificial intelligence into your daily work.
Elective CAS	Other elective modules specified in the BFH-TI Masterplan may be taken: – CAS Leadership – CAS eHealth – CAS Data Analysis

The DAS in Regulatory Affairs consists of three CASs. Two of the specific Regulatory Affairs CASs are compulsory and then you can choose an additional elective CAS.

8 Costs

The costs can be found on the price list on our website.

9 Location

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During the programme, adjustments may be made to the content, learning objectives, lecturers, and assessments. It is up to the lecturers and the course guidance to make changes to the programme based on current developments in a field, the current knowledge and interests of the participants, and for pedagogical and organisational reasons.

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