Master of Advanced Studies

Master of Advanced Studies in Regulatory Affairs (MAS RA)

Regulatory Affairs is the discipline of applying regulations and standards in the development, approval and marketing of medicinal products and medical devices 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 biotech industries.

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1 Setting

The healthcare industry evolved greatly over the last 10 years. As a result, the tasks of regulatory affairs professionals have changed accordingly. New technologies such as artificial intelligence and machine learning (e.g., decision support systems), home virus detection kits, wearable patient monitoring devices and improved patient management are already being used today. In the wake of such innovations and the resulting revision or creation of new regulations, Regulatory Affairs Professionals must continually expand their knowledge.

In medical technology, the Regulation on Medical Devices (MDR) and the Regulation on In-vitro Diagnostic Medical Devices (IVDR) are in force since May 2021 and May 2022 respectively. In addition to stricter regulatory requirements along the individual phases of the life cycle of medical devices, medical software, and in vitro diagnostics, the two regulations also require that manufacturers have at least one person in their organisation with the necessary regulatory expertise in the corresponding field. The qualification must be demonstrated by a university degree or by a course of study recognized as equivalent in law, medicine, pharmacy, engineering, or another relevant scientific discipline and at least one year of professional experience in the regulatory field 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:
- Developing regulatory strategies
- Implementing regulatory measures
- Adhering to quality management
- Solving trade-related issues
- Negotiating/communicating with authorities
- Crisis management

With the imparting of the above-mentioned expertise and the knowledge of the ever-changing regulations, the MAS Regulatory Affairs lays the foundation for entering the healthcare industry as a Regulatory Affairs Professional.

2 Target audience

The programme is aimed at people from the fields of medical technology and computer science, pharmacy/chemistry, and life sciences as well as medicine or law who would like to work in the highly regulated environment of the medical technology, pharmaceutical and biotech industries or who would like to work as Regulatory Affairs Professionals in these areas.

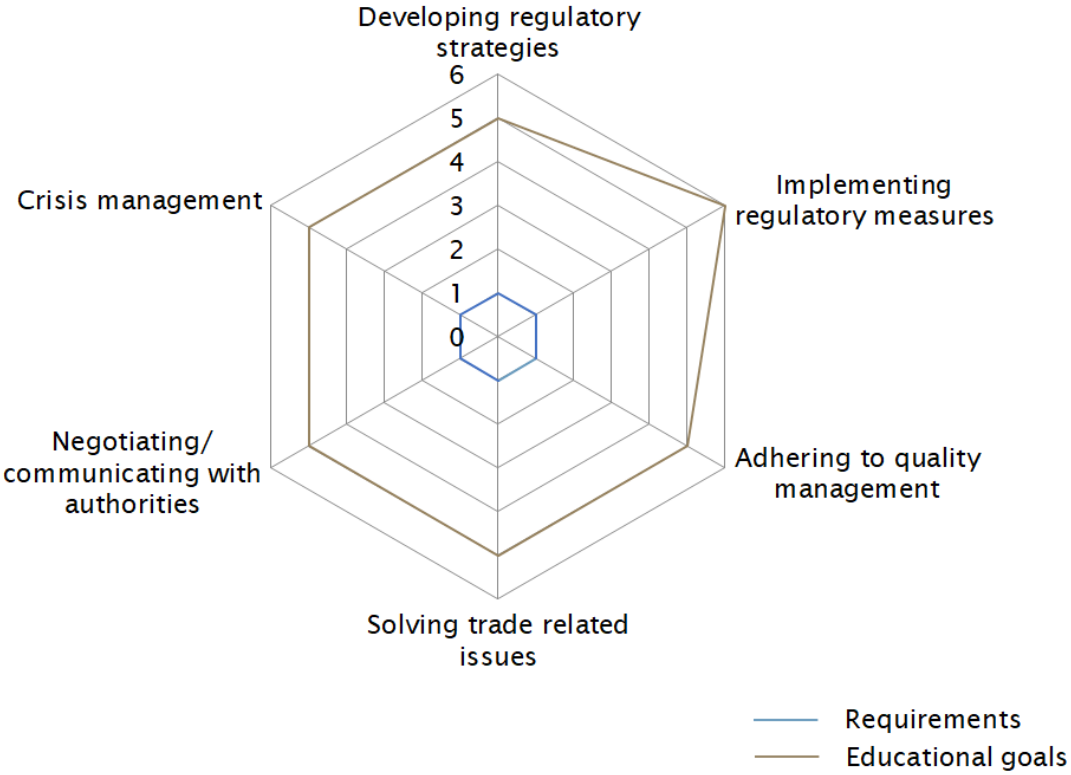
3 Training objectives

Developing regulatory strategies
– Global regulatory strategies, e.g., ICH (International Harmonisation) – Structure and function of the relevant regulatory authorities
Implementing regulatory measures
– EU Medical Device Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) – Marketing authorisation, including the preparation of the scientific and technical dossier – Clinical evaluation – GxP – Market surveillance (pharmacovigilance/materiovigilance) – Knowledge of IT and data sciences – Product classes subject to special regulation (e.g. combination or blood plasma)
Adhering to quality management
– Quality management system according to ISO 13485 and ISO 9001 – Pharmaceutical Quality System according to ICH Q10 – Interfaces to processes such as risk management, usability engineering, reviews, design verification, design validation and process validation
Solving trade-related issues
– (Digital) supply chain management of medical and pharmaceutical products – Most important methods of traceability – Falsified products – Marketing and digital marketing
Negotiating/communication with authorities
– Interaction with regulatory authorities, e.g., how meetings between applicant and regulatory authority are conducted
Crisis management
– Leadership and management skills

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

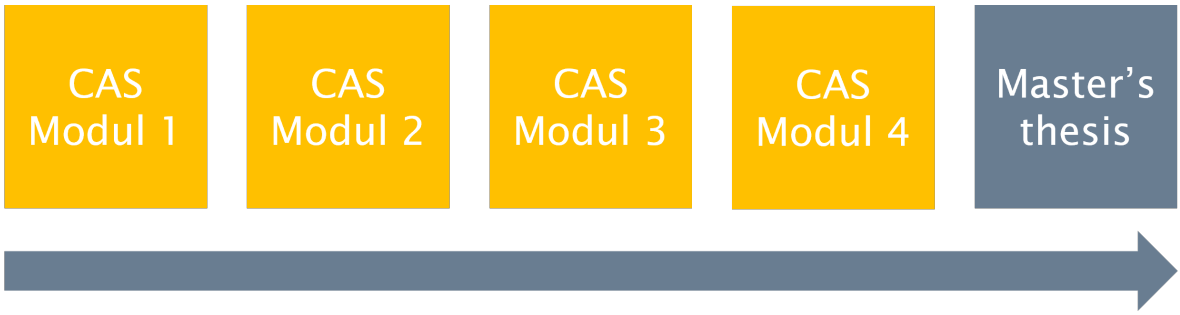


Levels of competence

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 study 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 attended as an independent continuing education course. It corresponds to a workload of 12 ECTS (360 hours).
- The programme lasts 5 semesters and consists of four CAS modules and a Master's thesis. The sequence of the modules can be freely chosen, but at least two modules must be completed from the MAS Regulatory Affairs area (see Master Plan CAS Modules).
- The study load is designed in such a way that a professional activity of approximately 80% is possible.



7 Description of the main CAS

Regulatory Affairs in Life Sciences (CAS RA)	Medical devices, medical software, pharmaceuticals, and combination products are subject to national and international standards. The CAS 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.
Regulatory Affairs Pharma (CAS RAP)	Pharmaceutical products are developed, manufactured, controlled, and distributed in compliance with strict statutory regulations to make sure that they are safe, effective and of high consistent quality. 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.
Digital Transformation in Life Sciences (CAS DTLS)	Digitalisation is influencing product development in the life sciences industry. In the CAS Digital Transformation in Life Sciences you will learn about the digital transformation of processes along the value chain of the medical technology, pharmaceutical and biotech industry.
Optional CAS from the TI Continuing Education portfolio	Other elective modules as specified in the BFH-TI Master Plan may be attended, in particular: – CAS Leadership – CAS eHealth – CAS Data Analysis

8 Master's thesis

The Master's thesis serves to methodically deepen and practically implement learning content acquired during the study programme, with a focus on a university-oriented, scientific approach. The entire time spent on the Master's thesis usually extends over the last module and the implementation semester and comprises a workload of 12 ECTS (360 hours).

Preparatory semester	During the last CAS, the topic is defined, and the proposal/disposition is developed.
Implementation semester	Independent work on the Master's thesis with two reviews, submission of the report and defence.

The focus of the Master's thesis is on the identification and application of the correct regulatory requirements for the development, marketing and monitoring of complex medical devices (e.g. combination products) and advanced therapy medicinal products.

9 Costs

The total costs consist of the individual CAS and the Master's thesis. The costs per CAS are usually 6'600 Swiss francs, the costs for the Master's thesis are 4'000 Swiss francs.

10 Location

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During the study there may be adaptations concerning content, learning objectives, lecturers, and competency assessments. It is up to the lecturers and the management to make changes to the programme, based on current developments in a field, participants' current prior knowledge and interests as well as for teaching and organisational reasons.

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