Master of Advanced Studies

Regulatory Affairs

Regulatory affairs professionals are essential in ensuring that medical devices and pharmaceutical products meet stringent regulatory standards throughout their life cycle, thereby upholding product quality, safety, and efficacy. This program prepares you to navigate the complex regulatory landscape of the medical technology, pharmaceutical, and biotechnology industries with in-depth knowledge and practical skills.

Berner
Fachhochschule

Table of contents

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1 Career prospects

With a MAS in Regulatory Affairs, you will be qualified to take on a responsible position in the medical technology and pharmaceutical industry. The roles are not only critical for the success of companies – many of them are also legally required functions.

Table 1: Key professional roles

Role	Sector	Main Responsibilities
PRRC (Person Responsible for Regulatory Compliance)	Medical Devices	Compliance with regulatory requirement, technical documentation, PMS/Vigilance obligation, QMS oversight
RA (Regulatory Affairs Manager)	Pharmaceuticals	Regulatory submissions, communications with authorities, lifecycle management of approvals
QP (Qualified Person)	Pharmaceuticals	Batch release, ensuring GMP compliance, responsibility for manufacturing conformity
QPPV (Qualified Person for Pharmacovigilance)	Pharmaceuticals	Establishment and oversight of the PV system, evaluation of safety data, authority communication

While these roles often require additional practical experience in the industries before you can take them on in full, the MAS Regulatory Affairs provides you with the essential regulatory knowledge and qualifications to grow into these roles step by step.

2 Target audience

- Professionals who are already working in the regulated environment in the pharma and medical technology industries and want to broaden their regulatory knowledge.
- Individuals aiming to enter the field of regulatory affairs, seeking a solid academic foundation and practical orientation for their career start.
- Regulatory affairs specialists who are already active in the field and wish to keep up to date with constantly evolving national and international regulations.

3 Requirements

- Bachelor's/Master's degree or PhD in life sciences, medicine, pharmacy, engineering, law, computer science or another relevant scientific field.
- Five years of professional experience in the life sciences environment or in a comparable regulated field.

4 Training objectives

Table 2: Training objectives

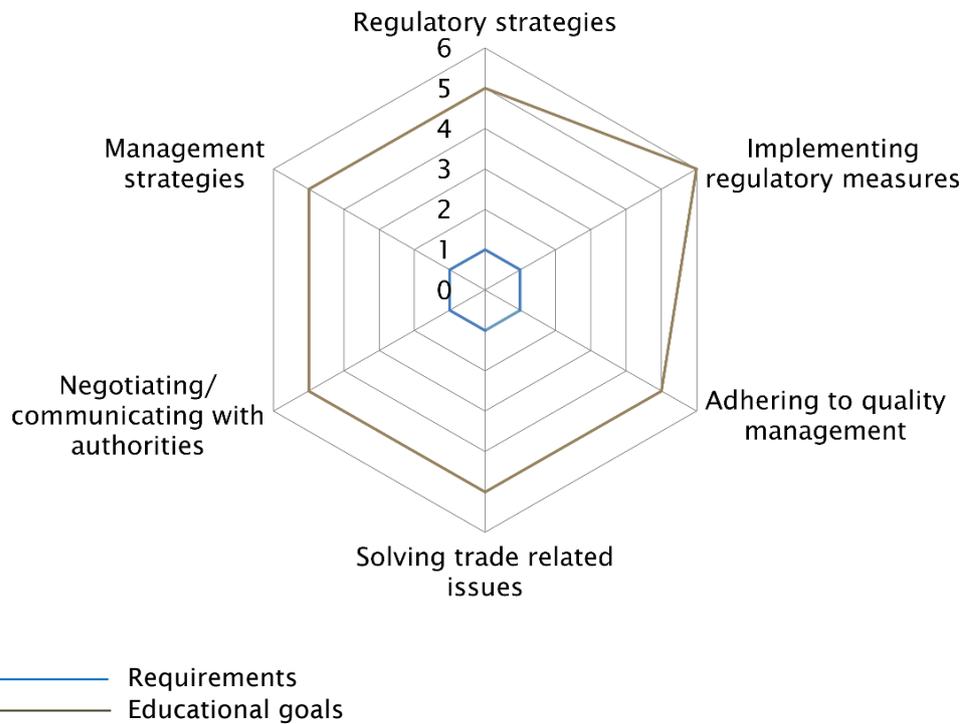| Training objective	Details
Regulatory strategies	– You learn about the regulatory strategies in Switzerland, in the EU and around the world. – You understand the relevant regulatory bodies and how they operate.
Implementing regulatory measures	– You become familiar with the EU Medical Devices Regulation (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation (IVDR). – You learn 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.
Adhering to quality management	– You understand the structure and requirements of the ICH Q10 pharmaceutical quality system. – You understand the structure and requirements of ISO 13485 quality management for medical devices. – You learn how to integrate risk management, usability engineering, reviews and design and process validation.
Solving trade-related issues	– You know the key elements of (digital) supply chain management for medical devices and pharmaceutical products, including optimising logistics processes and ensuring product integrity from manufacturing to the end consumer. – You are aware of the risks and challenges associated with the counterfeiting of medical devices and pharmaceutical products.
Negotiation/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 learn how to interact (speaking and writing) with a global audience, including manufacturers, authorities, and Notified Bodies. – You learn the language of statistics and what questions to ask the statistician when you need to write your regulatory documents. – You can analyse and evaluate how AI technology transforms regulatory processes, enhances data-driven decision making, and improve patient safety.

5   Competencies

Figure 1: Initial and final competencies

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 program

- The program lasts **five semesters and consists of four CAS modules and a Master's thesis**.
- The program 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 modules can be taken in any order, **but two of the three specific Regulatory Affairs CAS modules must be completed**. You have the option to specialize in Pharma, MedTech, or a combination of both (see Figure 2).
- Additional CAS modules from the TI continuing education portfolio can be taken (elective CAS).
- The study load is designed to give you the flexibility to work about 80 % while completing your studies.
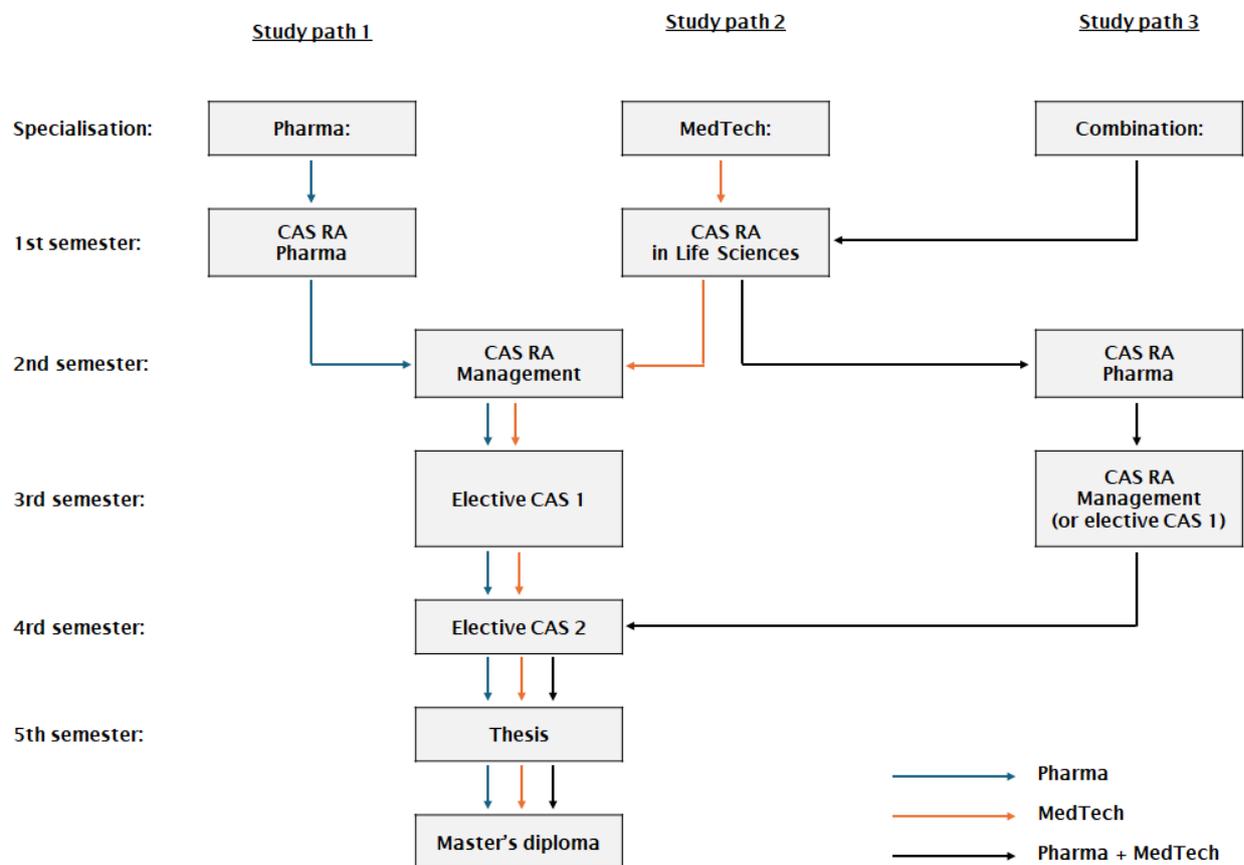

Possible study paths

Figure 2: Your possible study paths: You can specialize in regulatory affairs in Pharma, in MedTech, or combine both

7 Description of the key modules

To achieve the learning objectives outlined in Chapter 4 and align with the competency frameworks of the two leading professional associations in regulatory affairs – RAPS and TOPRA – we have developed three specific regulatory affairs modules. These can be complemented by other modules from the TI continuing education portfolio, allowing the master's program to be tailored to induvial professional needs (see Figure 3).
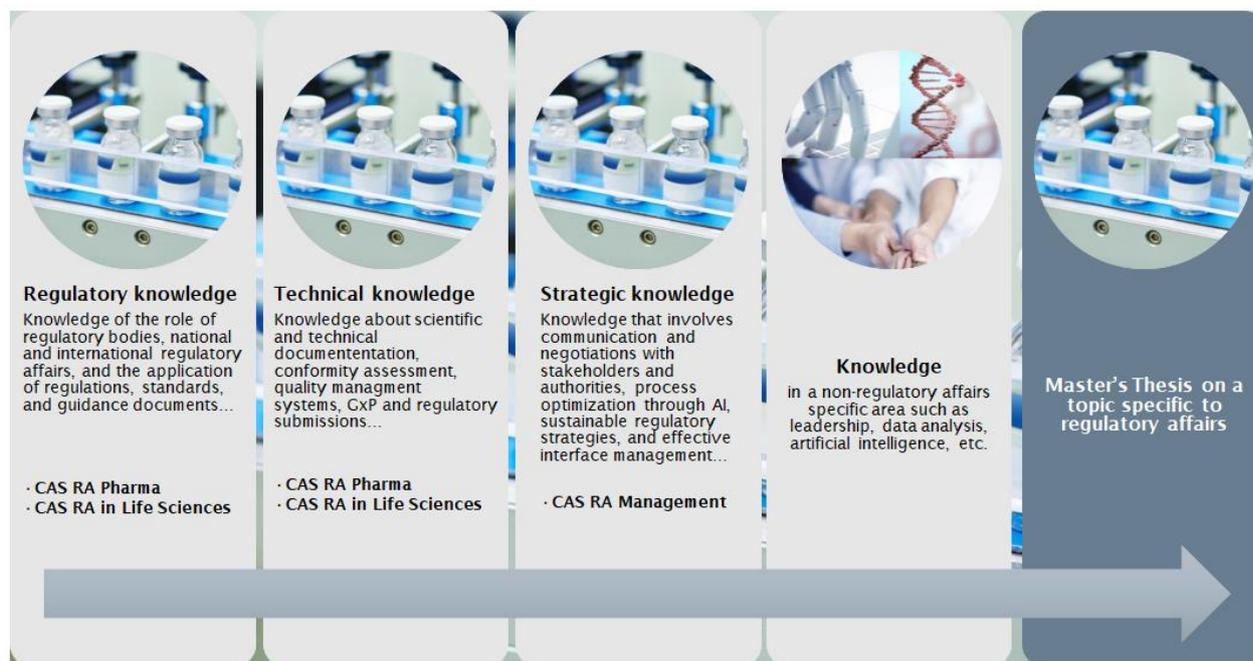

Figure 3 : The regulatory affairs knowledge condensed into four CAS modules complemented by a practice-oriented master's thesis

The regulatory affairs specific CAS modules
The table below shows the three modules focused on regulatory affairs. Two of these modules must be completed to obtain the MAS in Regulatory Affairs.

Table 3: CAS modules with focus on regulatory affairs

Modules	Description
CAS Regulatory Affairs in Life Sciences	This CAS provides you with a comprehensive understanding of the regulatory framework governing medical devices, medical software, and combination products. It focuses on the application of Swiss and international regulations and quality management standards throughout the product lifecycle. The program further addresses human-centred product development, design control, packaging, labelling, and key validation processes, clinical evaluation, and medical device audits. More information is available here: CAS Regulatory Affairs in Life Sciences | BFH
CAS Regulatory Affairs Pharma	This CAS provides you with the competencies required to navigate the complex regulatory environment of the pharmaceutical industry. It focuses on global regulatory frameworks and the roles of key authorities such as Swissmedic, the FDA, and the EMA, covering the entire product lifecycle from development to post-

Modules	Description
	approval. The program also examines current developments including real-world evidence, digital transformation, and regulatory requirements for specific product classes such as human plasma, advanced therapies, and vaccines. More information is available here: CAS Regulatory Affairs Pharma | BFH
CAS Regulatory Affairs Management	This CAS provides you with the practical skills required to manage regulatory activities in the pharmaceutical and medical device industries. It focuses on developing strategic communication and negotiation skills for interactions with regulatory authorities, the ability to evaluate statistical data, and the application of artificial intelligence and digital tools to streamline regulatory processes. The program also addresses sustainability and ethical aspects across the product lifecycle. You have the option to specialize in either pharmaceuticals or medical devices. More information is available here: CAS Regulatory Affairs Management | BFH

The elective CAS modules
Depending on your individual learning path, you may complete one or two elective CAS modules. These electives can be freely chosen and should ideally align with your professional goals. The table below provides five examples of how you can complement your master's degree.

Table 4: Possible elective CAS programs

Modules	Description
CAS eHealth	This CAS provides you with the technical and strategic competencies required to lead healthcare organisations through the digital transformation associated with the Electronic Patient Record (EPR). It focuses on the planning and implementation of eHealth projects, addressing both development and project management perspectives, as well as the emerging challenges of ongoing EPR evolution. Key topics include medical documentation and digital medicine, medical software, interoperability, and the legal and practical dimensions of electronic patient records. More information is available here: CAS eHealth | BFH
CAS Lean and Digital in Healthcare	This CAS provides you with the knowledge and practical tools to address the challenges of digitalisation, cost pressure, and rising quality expectations in healthcare. It focuses on the application of lean healthcare and lean management principles, enabling participants to analyse and optimise digital processes and to lead process improvement and transformation initiatives within healthcare organisations. More information is available here: CAS Lean and Digital in Healthcare | BFH
CAS Enabling and Managing Hospital at Home	This CAS provides you with the knowledge and practical skills to plan and implement hospital at home models that promote patient-centred care. It focuses on the integration of telemedicine,

	interdisciplinary collaboration, and technology-supported home monitoring. The program also addresses change management and prepares participants to contribute to the transition toward flexible, technology-driven healthcare delivery. More information is available here: CAS Enabling and Managing Hospital at Home | BFH
CAS Datenanalyse	This CAS provides a practical foundation in data analysis, focusing on how to describe, analyse, and draw meaningful conclusions from data. Participants will become familiar with scientific methods and user-friendly software tools for processing, analysing, and visualising data, enabling them to turn complex datasets into actionable insights for evidence-based decision-making. More information is available here: CAS Datenanalyse | BFH
CAS Führung	This CAS provides participants with a comprehensive framework for developing leadership competencies. It focuses on strategic thinking, communication, and interpersonal skills needed to lead diverse teams, manage change, and foster collaboration. The program also addresses personal development, negotiation, and methods to inspire and engage people in an increasingly digital and agile (healthcare) environment. More information is available here: CAS Führung | BFH

8 Master's thesis

The Master's thesis allows you to deepen and apply the knowledge gained across the four CAS modules using a practical, research-based approach. It emphasizes the use of sound scientific methods at a university level. The thesis is typically completed during the final CAS (preparatory semester) and the subsequent implementation semester, corresponding to a total workload of 12 ECTS credits (approximately 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 at least two reviews, followed by submission of the written report, and a final defence.

Topic
The Master's thesis emphasizes the identification and application of relevant regulatory frameworks for the development, commercialisation, and lifecycle of complex medical devices (such as combination products) and novel or challenging pharmaceutical products.

9   Costs

The costs can be found on the [price list on our website](#).

10 Location

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11 Contact

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During the program, 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 program 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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