Certificate of Advanced Studies

Regulatory Affairs Mastery

This CAS focuses on the practice and day-to-day work of regulatory affairs professionals. You will develop strategic negotiation skills for interactions with regulatory authorities, acquire the ability to analyse statistical data, learn the phases of clinical trials and generate meaningful documentation. Artificial Intelligence (AI) has also found its way into the daily work of regulatory affairs professionals. In the second part of this program, you will learn where AI can assist regulatory affairs professionals. The second part of the program also covers ethics and sustainability in the development, production, use and disposal of pharmaceutical products and medical devices.

Berner
Fachhochschule

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1 Setting

- This program emphasises communication (speaking and writing) as a critical skill, particularly for regulatory professionals who interact with a global audience, including manufacturers, authorities, and Notified Bodies.
- An understanding of statistical methods and data interpretation is essential. You will learn the language of statistics and what questions to ask the statistician when you need to write your documents.
- The integration of Artificial Intelligence (AI) is transforming the regulatory landscape. This program explores how AI can streamline processes, enhance data analysis, and improve decision making. You'll learn how to use AI to automate routine tasks, allowing you to focus on strategic activities and increase productivity.
- Ethics underpins laws and regulations. This CAS addresses the ethical challenges faced by regulatory affairs professionals and the importance of ethical practices in clinical trials, product development and regulatory compliance. Linked to ethics is sustainability: You will also learn about environmental management, recycling, and waste disposal, and best practices for sustainability and environmental compliance.
- Marketing principles and marketing regulation are also included in this program.

2 Target audience

- You work in regulatory affairs and don't want to miss out on the latest developments in Artificial Intelligence (AI) in this area.
- You work in the medical technology or pharmaceutical industry and would like to learn more about topics like "Green Hospital" and sustainability.
- You work in development, manufacturing, quality management or regulatory affairs and would like to improve your skills in
    - communication and medical/technical writing in regulatory affairs.
    - the principles of clinical trial design and understanding and evaluating statistics in medicine.
    - the challenges of ethics that are faced by regulatory affairs professionals.
    - regulation of the marketing of medicinal products and medical devices.

3 Requirements

- Ideally you have a degree in medicine, pharmacy, chemistry or life science, engineering, law, materials science, business studies or a related field, along with a fundamental understanding of regulatory affairs in the medical technology or pharmaceutical industry.

4 Language

- Classes and course materials are in English.

5 Location

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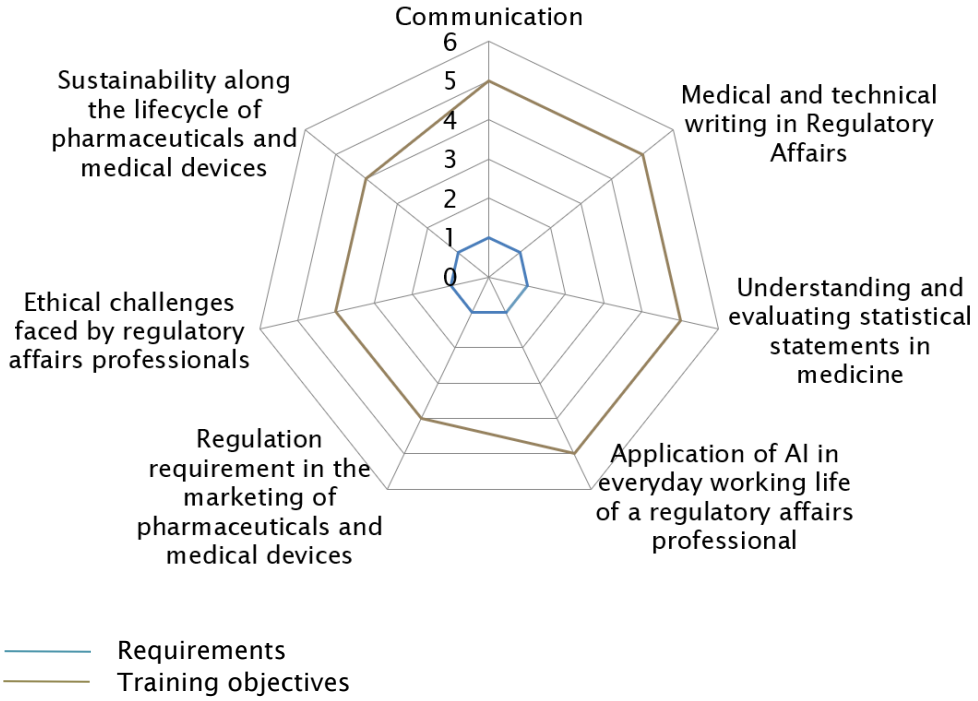
6 Competency profile



Bloom's taxonomy of learning objectives

1. Knowledge: Reproduce what has been learned by heart, perform routines.
2. Comprehension: Explain, reformulate, or paraphrase what has been learned.
3. Application: Apply what has been learned in a new context/situation.
4. Analysis: Break down what has been learned into components, explain structures.
5. Synthesis: Reassemble what has been learned or generate new content.
6. Judgement: Critically evaluate what has been learned according to (mostly self-) chosen criteria.

7 Course overview

Module/Teaching Unit	Lessons	Lecturers
Communication / Medical and technical writing in Regulatory Affairs		
Introduction	2	
Developing a communication strategy	5	
Effective communication techniques	14	
Medical and technical writing for regulatory affairs professionals	5	
Technical writing: Medical devices	7	
Medical writing: Pharmaceuticals	7	
Understanding and evaluating statistical statements in medicine		
Principals of clinical design / phases of clinical studies	7	
Statistical Methodologies	11	
Regulation requirement in the marketing of pharmaceuticals and medical devices:		
Delivery, consulting and presales roles	7	
Regulation requirement in digital marketing of pharmaceuticals and medical devices	7	
Application of artificial intelligence (AI) in the healthcare industry		
Challenges of using AI in the healthcare industry	7	
AI for regulatory affairs professionals	7	
AI for regulatory affairs (examples from industry and government)	4	
Sustainability & ethics in the development, production and disposal of medicinal products and medical devices		
Ethical challenges in regulatory affairs	7	
Sustainability in the lifecycle management of medical devices and pharmaceuticals	7	
Total	**104**	

Course/Teaching Unit	Lessons	Hours	Lecturers
Semester work (Living Case)	24	100	Diverse Experts
Total	**24**	**100**	

The CAS program consists of a total of 12 ECTS credits. Additional time for self-study, exam preparation etc. must be planned for the individual courses.

8 Course description

In this chapter, each of the teaching modules will be presented in more detail.

8.1 Communication / Medical and technical writing in Regulatory Affairs

Communication is critical for regulatory affairs professionals due to their responsibility to interact with a global audience, including manufacturers, global regulatory authorities, and Notified Bodies. The ability to discuss matters with internal management and communicate effectively during due diligence processes further underlines the need to be skilled communicators.

8.1.1 Developing a communication strategy

Topics and content	Communication involves a complex interaction between the communicator and the audience, aiming for a common understanding and agreement. Key aspects include: - Message awareness - Targeted messaging
Learning objectives	- You understand and identify the needs of your audience. - You learn the essential components of effective communication. - You can choose the right medium to convey your message. - You learn the key components of successful presentations.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.1.2 Effective communication techniques

Topics and content	Effective communication is a skill that improves with knowledge and experience. Regulatory affairs professionals must be able to communicate clearly with a variety of audiences, including engineers, statisticians, chemists, biologists, marketing teams, and regulatory agencies.
Learning objectives	- You develop active listening skills to improve overall communication effectiveness. - You are aware of the importance of relationship building in effective communication. - You understand the key elements of successful negotiation. - You understand how to run efficient and productive meetings. - You understand the differences between virtual and face-to-face meetings and adapt your communication style accordingly.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.1.3 Medical and technical writing for Regulatory Affairs Professionals

Topics and content	Technical and medical writing is critical to the approval process, ensuring that new product submissions are well-organised, accurate and easy to review. Regulatory affairs professionals produce detailed documents that are essential for the approval and marketing of healthcare products worldwide. This course covers tips and tricks for effective writing, quality control techniques, and factors that influence the quality of regulatory documents.
Learning objectives	- You learn how to prepare regulatory documents effectively. - You understand how to write for an international audience. - You learn how to write key messages clearly and effectively. - You learn techniques for quality control of regulatory documents. - You know how to prepare a team to contribute effectively to a regulatory submission. - You understand the importance of templates, style guides and timelines.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.1.4 Technical writing: Medical Devices

Topics and content	In this course you will develop skills to create an outline, template and guide for premarket approval (PMA) submission content. You will also understand the process for 510(k) submission and review. This course includes also detailed guidance on writing the Technical Documentation (TD) to achieve market access for medical devices in the EU.
Learning objectives	- You know when a PMA is required for a new medical device. - You can outline the regulatory process involved in PMA submission and review. - You learn how to create an outline, template, and guide for developing the content of a PMA application. - You will practise filling in the 510(k) premarket notification form using the electronic Submission Templates And Resources (eSTAR). - You will practice writing the Technical Documentation (TD) required to gain market access in Switzerland and EU.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.1.5 Medical writing: Pharmaceuticals

Topics and content	This course provides an overview of the complex documents prepared by regulatory and medical writers, focusing on the Common Technical Document (CTD/eCTD). You will learn about region-specific considerations for the clinical sections of US New Drug Applications (NDA), US Biologics License Applications (BLA) and EU Marketing Authorisation Applications (MAA).
Learning objectives	- You know, which sections of the CTD are typically assigned to the regulatory affairs or medical writer. - You know the guidance documents for the CTD. - You learn the region-specific consideration associated with preparing a CTD. - You know the relevant guidance documents needed to develop an MAA. - You know the relevant guidance documents needed to develop an NDA. - You know the relevant guidance documents for developing a BLA.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.2 Understanding and evaluating statistical statements in medicine

Understanding statistical methodology and data interpretation is essential in regulatory affairs. To know which and how many clinical trials are required for medical devices and pharmaceuticals, it is advantageous if you speak the same language as the statistician. Knowledge of (bio)statistics and its terminology ensures consistency of documentation and clarity of communication.

8.2.1 Clinical study design

Topics and content	The objective of a clinical study is to evaluate the safety, efficacy, and/or mechanism of action of new pharmaceuticals or devices that are in development but have not yet been approved by a health authority. Clinical studies may also be conducted to investigate a drug, device or procedure that has already been approved but is still in need of further investigation, typically with respect to long term effects or cost-effectiveness.
Learning objectives	- You learn the different types of designs for clinical studies.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides.

8.2.2 Statistical methodologies

Topics and content	In this course you will learn how to find and understand information about statistical methods used in clinical research. You will also be able to identify the types of data sets commonly included in clinical trial reports. Finally, you will describe and apply common statistical methods used in clinical trials.
Learning objectives	- You learn how to find information about statistical methods used in the clinical development. - You can identify the types of data sets commonly included in clinical trial reports. - You can describe and apply the common statistical methods used in the clinical development.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises

8.3 Regulation requirements in the marketing of pharmaceuticals and medical devices

What marketing strategies are currently used in the healthcare industry and how is the market for pharmaceutical and medical products regulated? These are the questions to be explored in this course.

Topics and content	In the first part of this course, you will learn the theories, principles and concepts of marketing that are common in general business practice, be able to analyse simple market situations, select appropriate digital methods and tools and use them in a targeted manner. In the second part of this course, you will take a closer look at supply chain management and familiarise yourself with the main traceability methods.
Learning objectives	- You can define marketing and describe the development of marketing. - You can describe the six steps of the marketing concept and explain the market as a system. - You can explain how to proceed with market definitions and delineation and show how to analyse the market, one's own company and the environment. - You can explain what market research is and list its uses in marketing. - You can describe the methods of market research and the phases of the market research and process. - You can describe the contents and sub-steps of the PR concept. - You will be able to explain the instruments and objectives of distribution. - You can analyse and select international markets and explain the types of international market entry. - You know how digital marketing is used in medicine.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides.

8.4 Application of Artificial Intelligence (AI) in everyday working life of a regulatory affairs professional

Artificial Intelligence (AI) is also an increasingly important topic for the healthcare industry. This also includes the field of regulatory affairs. In this course you will explore how AI tools can streamline regulatory processes, enhance data analysis, and improve decision-making. By automating routine tasks, AI allows professionals to focus on more complex and strategic activities, increasing efficiency and productivity. However, the integration of AI in the healthcare industry is not without its challenges. Issues such as privacy, ethical considerations, and the need for regulatory frameworks to keep pace with technological advances need to be addressed. Understanding the potential and limitations of AI will enable you to use these technologies effectively while addressing the challenges they present.

8.4.1 Challenges of using AI in the healthcare industry

Topics and content	The balance between innovation and compliance remains a significant challenge for the healthcare industry when using AI. This includes privacy concerns, ethical considerations, and the need for a robust regulatory framework. Regulations such as the AI Act and the General Data Protection Regulation (GDPR) in Europe and the Health Insurance Portability and Accountability Act (HIPAA) in the United States govern the use of patient data, ensuring confidentiality and security. Navigating these regulations and maintaining ethical standards is critical to the successful integration of AI in healthcare.
Learning objectives	- AI Act - General Data Protection Act (GDPR) - Health Insurance Portability and Accountability Act (HIPPA)
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides.

8.4.2 AI for Regulatory Affairs

Topics and content	AI-powered tools can analyse vast amounts of regulatory data and improve decision-making. AI can help interpret complex regulatory guidelines and generate submission documents, ensuring accuracy and consistency. By leveraging AI, regulatory affairs professionals can increase efficiency, reduce errors, and stay ahead of the rapidly evolving regulatory landscape.
Learning objectives	- You will learn where and how AI is used in the work of regulatory affairs professionals. - You will see examples of AI tools from the medical technology and pharmaceutical industries. - You can work with AI programs yourself.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and exercises.

8.5 Ethics & sustainability in the development, product and disposal of pharmaceuticals and medical devices

In which country should clinical trials be conducted? Will a patient still receive the drug after the clinical trial, even if he or she cannot to pay for it? Such ethical challenges are also part of the daily work of regulatory professionals. In addition to this area of medical ethics, the industry is also confronted with environmental ethics. In the face of climate change, sustainability permeates the entire medical technology and pharmaceutical industry. To achieve the goal of net zero emissions, the manufacturers need to apply sustainability strategies along the product life cycle from raw material extraction to waste disposal.

Topics and content	The first part of this course explains the ethical challenges faced by regulatory affairs professionals and introduces concepts, principles, and theories to solve such challenges. In the second part of the course, you will learn about sustainability strategies along the life cycle of pharmaceutical products and medical devices to achieve net zero emissions.
Learning objectives	Ethics: - You will understand the ethical and scientific considerations involved in the design of clinical trials and know where and how to obtain approval from the ethics committee. - You will discuss the responsibilities of clinical study sponsor and investigators. - You learn how to identify common compliance and ethical issues that arise. Sustainability: - You will understand the importance of the circular economy and how it interacts with the supply chain. - You will know the basics of operational environmental protection. - You can formulate concrete and feasible measures to avoid and reduce waste. - You can describe the possibilities and limitations of waste recycling. - You can explain environmental management systems. - You can apply the laws and regulations on waste disposal and recycling. - You recognize the hazard potential of (hazardous) waste, design appropriate precautionary and protective measures and ensure that it is handled in accordance with the regulations.
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology). - Teaching materials: Slides and examples from medical technology and pharmaceutical industries.

8.6 Semester project (Living Case)

The semester project (Living Case) is carried out as a group work within the context of your professional environment. On average, each group member invests approximately 100 working hours, but this may vary depending on the preparation phase and the complexity of the task.
If necessary, semester projects can be treated confidentially. The framework is determined by the study regulations. It is important to stress that, while maintaining confidentiality, it is imperative to respect the pedagogical framework. This means that presentations and in-depth discussions on the chosen topic should remain possible in the classroom.

Objectives and topic	In the semester project (Living Case), you carry out a project or a question from your company on the topic of regulatory affairs. Instead of a question from the company, you can also define and work on topics of your own interest. The semester work should cover the entire cycle of a typical Master's thesis, from formulating the question to evaluating the results. However, you may choose to focus on specific steps in the process.
Procedure	The semester work includes the following milestones: 1. You look for a topic within the company and preferably find a contact or supervisor within the company. 2. You prepare a proposal (2 to 4 pages) 2.1 Title and information on the persons concerned (title page) 2.2 Initial situation and motivation 2.3 Objective or question 2.4 Material and methods 2.5 Limits 2.6 Framework conditions 2.7 Deliverables/Results 2.8 Supplements 2.9 Annex 3. You present the topic to a panel of lecturers. 5-10' for the presentation, 5-10' for questions/discussion. 4. You revise the proposal if necessary, according to the feedback. 5. You will be assigned to an expert by the head of the CAS programme. 6. You do the work required for the semester work according to your own schedule. 7. You organise two or three meetings with your expert. 8. In a review, you present the state of your work to the experts and to the class. 10' presentation, 5-10' questions/discussion. 9. You submit the report to the experts and upload it to Moodle. 10. You give a final presentation to the class, experts, and lecturers. 15' for the presentation, 10' for the discussion. 11. You will be available to answer questions from interested participants in a poster session following the final presentation.
Result and assessment	The report is to be sent to the experts in electronic form as a PDF document and posted on the Moodle platform. Report: approx. 20-30 pages. The semester work (Living Case) will be assessed according to the following criteria: – Submission of the topic and topic presentation – Review – Methodology and execution

	– Results – Report, documentation – Final presentation You will receive a detailed evaluation sheet at the beginning of the CAS.

9 Competency assessment

For the 12 ECTS credits to be recognised, successful completion of the competency assessment is required (exams, project work), according to the following list:

Competency assessment	Weight	Type of assessment	Student's success rate
Multiple Choice Exam	2.5	Written exam, closed book	0 – 100 %
Expert discussion	2.5	Oral exam	0 – 100 %
Semester work	5	Living Case	0 – 100 %
Weight overall	10		0 – 100 %
ECTS-Note			**A - F**

The exams cannot be repeated.

The weighted average of the pass rates of the individual competency assessments is converted into a grade between 3 and 6. Grade 3 (averaged success rate is less than 50%) is insufficient.
Grades 4, 4.5, 5, 5.5 and 6 (averaged pass rate between 50% and 100%) are sufficient.

10 Lecturers

Name/Prename	Company	E-Mail

+ Further experts and supervisors for the semester work.

11 Organisation

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

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