Certificate of Advanced Studies

Regulatory Affairs Pharma

Pharmaceutical products are developed, manufactured, controlled, and distributed under strict regulations to ensure that they are safe, effective and of high consistent quality. In this CAS you will gain the skills to work in this highly regulated environment and learn how to act as a liaison person between companies and regulatory authorities.

Berner
Fachhochschule

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27.02.2024

1 Setting

	Modules	Content
Regulatory Affairs Pharma	Semester work (You will work on a project or a question from your company about regulatory affairs for medicinal products for human use)	
	Introduction to the Topic	Regulatory Affairs – History
		Requirements for a Career in Regulatory Affairs
		Overview of the Content
		Introduction to the Semester Work (Living Case)
	Global Drug Regulatory Affairs	'Global Pharma' – An Economic Perspective
		Pharma Supply Chain in a Global Context
		Role of Pharmacopoeias
		ICH Q12 Lifecycle Management: Consequences of Non-harmonized Implementation
		Phases of Drug Development
	Structure and Function of Relevant Regulatory Bodies	Major Regulatory Bodies in the EU/EEA, Specific Role of the EDQM, Roles of FDA's CDER and CBER
		Swissmedic
	Scientific Technical Dossier to Accompany a Marketing Authorisation Application	CTD Modules 1 to 5 and eCTD
		Scientific Technical Writing
	GxP	GMP, GDP, GLP and GPvP
	Healthcare Product Lifecycle	R&D, pre-Authorisation Phase, Marketing Authorisation Procedure, Post-authorisation Phase
	Regulatory Affairs in Clinical Trials	Clinical Trial Application According to ClinO and Clinical Trials Regulation/Registration of a Clinical Trial
		Research Ethics
	Introduction to EU Regulatory Framework	Different Pathways of a Marketing Authorization
		Development Phase: Tools & Obligations in EU
		Changes to Marketing Authorization Application
		Maintaining the Marketing Authorization Application
	Post-Registration Activities	Post-approval Activities
		Change Reporting
	Pricing and Reimbursement (CH)	Legal Basis
		Reimbursement Procedures
	Interacting with Regulators (EU)	Scientific Advice/Protocol Assistance
		Pre-submission Meetings
	Packaging and Labelling	CH, EU and US Regulatory Framework
	Product Classes with Special Regulations	Advanced Therapy Medicinal Products
		Vaccines
		Blood and Blood Products

The CAS begins with general biology knowledge and ends with the new trends and challenges module, which covers topics such as Real-World Data (RWD)/Real-World Evidence (RWE) and Digital Transformation in the Pharmaceutical Industry.

2 Target audience

- You are interested in a career in regulatory affairs in the pharmaceutical industry.
- You work in the development, manufacturing, quality management or regulatory affairs and want to improve your knowledge of regulatory affairs for medicinal products for human use.

3 Requirements

Ideally you have a degree in medicine, pharmacy or science, engineering education, law, material science, business studies or a related field.

4 Language

Teaching and the course materials are in English.

5 Location

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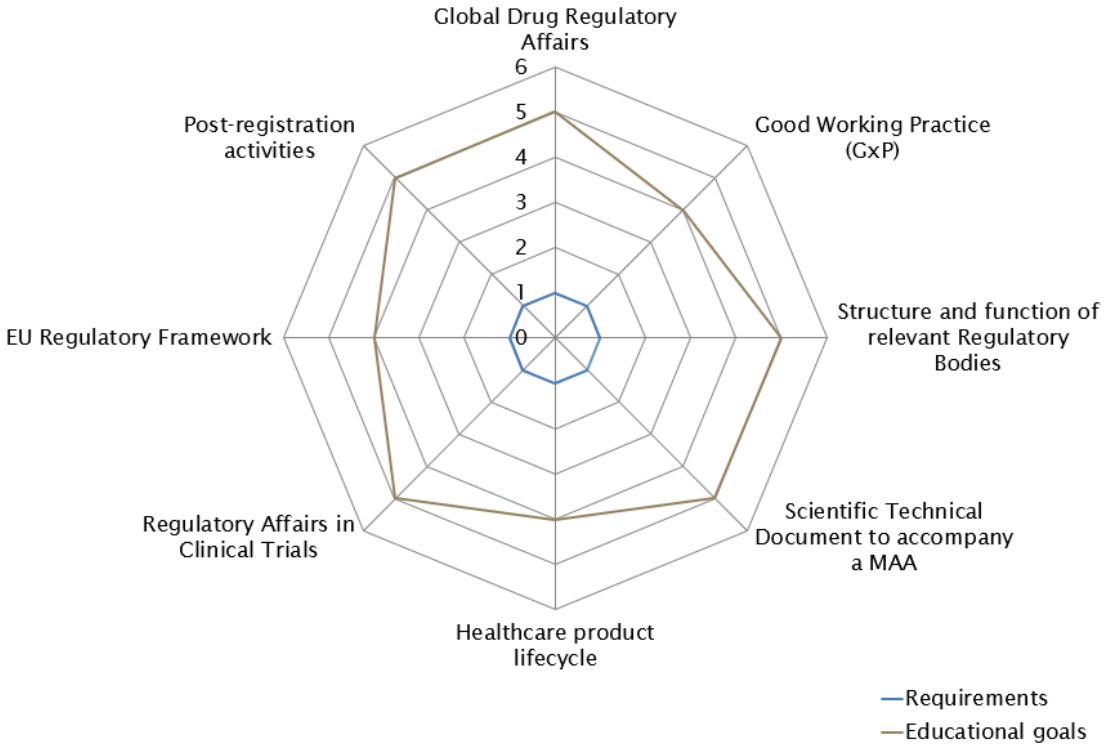
6 Competency profile



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
Starting Knowledge:		
Introduction to RA	2	Fabienne Weiss
Bio-Principles: Nanotechnology in Medicine	4	Dr. Tino Matter
Bio-Principles: Pharmacogenetics	4	Prof. Dr. Carlo Largiadèr
Bio-Principles: Basics of the Lifecycle and Bioinformatics	4	Prof. Dr. Joachim Frey
Global Drug Regulatory Affairs + Structure and Function of Regulatory Bodies:		
Structure and Function of Relevant Regulatory Bodies: EU and USA	4	Ogie Ahanor
Structure and Function of Relevant Regulatory Bodies: CH (Swissmedic)	2	Dr. Andreas Pfenninger
Introduction to EU Regulatory Framework	4	Speaker of the CSLB
Global Drug Regulatory Affairs	8	Ogie Ahanor
Falsified Medicines	3	Ruth Mosimann
Interacting with Regulators and How to Prepare a Scientific Advice Meeting	4	Ogie Ahanor
Pharmaceutical Legislation & Regulations	2	Noëmi Müller
Lifecycle Management		
Patient Involvement in the Lifecycle of Therapeutic Products	3	Prof. Dr. Cristiana Sessa Sabine Rütti Roch
Research Ethics	2	Dr. Salome Adam
Healthcare Product Lifecycle + Post-registration Activities	3	Dr. Tamara Markovic
GxP: GLP	2	Salieu Jalloh
GxP: GMP	2	Salieu Jalloh
Scientific Dossier to Accompany a MAA	3	Ogie Ahanor
GxP: GVP	2	Salieu Jalloh
GxP: GDP	2	Salieu Jalloh
Packaging	6	Cathlyn Carley
Pharmacovigilance	2	Dr. Thomas Stammschulte
Pharmacovigilance: Real Life Examples	2	Diff. speakers of CSLB
Pricing and Reimbursement	4	Dr. Muriel Grämer
Labelling	4	Corinne Meier
Post-approval Change Management Protocol	2	Speaker of the CSLB

CTA Process in EU	2	Speaker of the CSLB
New Trends and Challenges:		
Real-World Data (RWD) and Real-World Evidence (RWE)	4	Dr. Salome Adam
Digital Transformation in Pharma Industry	2	Dr. Tamara Markovic
Product Classes with Special Regulations:		
Human Plasma: A Special Starting Material	2	Dr. Jens Rehbein
Advanced Therapies	2	Dr. Ana Figueiredo
Vaccines	1	Speaker of CSLB
Total	**93**	

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. Each course is designed to provide ample time for self-study, exam preparation, and other essential activities.

8 Course description

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

8.1 Starting knowledge

8.1.1 Introduction to RA

Topics and content	After a historical overview of why regulatory affairs in life sciences and pharmaceuticals is so important today, you will gain an insight into the requirement for a career in this field.
Learning goals	– You understand why the field of regulatory affairs was developed and why it is so important today. – You know the requirements for a career in regulatory affairs in life sciences and pharmaceuticals. – You will get an overview of the contents of the CAS.
Teaching material	Slides

8.1.2 Bio-principles

Topics and content	When navigating the regulation of Advanced Therapy Medicinal Products (ATMPs), personalised medicine, or vaccines, a basic understanding of gene technology, pharmacogenetics, and nanotechnology is essential. The initial modules of this CAS are designed to provide you with the necessary knowledge in these areas.
Learning goals	– You know the basics of genetics and genetic engineering and understand the principles of personalised medicine. – You know how to use nanoparticles to deliver a molecule of particular interest to tumour cells.
Teaching material	Slides

8.2 Global drug regulatory affairs + Structure and function of regulatory bodies

8.2.1 Falsified medicines

Topics and content	The European Medicines Agency (EMA) defines falsified medicines as 'fake medicines that pass themselves off as real, authorised medicines'. Such medicines my lack active ingredients, contain dangerous ingredients, have the wrong dosage or be incorrectly labelled. This module will introduce you to the problems caused by falsified medicines and the initiatives being taken in Switzerland, the EU and the rest of the world to eliminate them.
Learning objectives	– You know the definitions of substandard, falsified, and counterfeit medicines. – You are familiar with the Falsified Medicines Directive (FMD). – You know how Switzerland, the EU and the rest of the world detect and deal with falsified medicines.
Teaching material	Slides

8.2.2 Global drug regulatory affairs

Topics and content	This module begins with an economic perspective, discussing potential conflicts in drug pricing, statistics on global sales, revenues, and economists' perspectives. You will then be introduced to the key milestones in the regulatory life cycle of human medicines. In this module you will also learn about the pharmaceutical supply chain in a global context and understand why there is a risk of drug shortages. The final two topics of this module are pharmacopoeias as important standards and the ICH Q12 lifecycle management as an example of a non-harmonised implementation of an ICH guidance document and the resulting regulatory consequences for marketing authorisation holders.

Learning objectives	– You gain an insight into the economic situation of global pharmaceutical sales and revenues, with a focus on the pharmaceutical industry's problem of rising R&D costs. – You know the general regulatory life cycle of a human medicine and its key regulatory milestones. – You understand the phases of drug development and the legislation that applies in the EU, considering revisions to clinical trials provisions. – You understand the need for international harmonisation. – You gain an insight into the specifics of EU pharmaceutical legislation. – You understand the challenge of regulatory compliance in a global economy. – You understand the risk of drug shortages in a global supply chain. – You understand the importance of pharmacopeial standards and compliance. – You gain an insight into pharmacopeia harmonisation activities. – You know what the Certificate of Suitability (CEP) is. – You understand the implications of a non-harmonised implementation of an ICH guidance document and the resulting regulatory consequences for marketing authorisation holders.
Teaching material	Slides

8.2.3 Pharmaceutical legislation and regulation

Topics and content	In Regulatory Affairs, you are expected to work with laws, standards, norms, and guidelines. Reading such documents can be difficult. In this module you will learn how to read legal documents.
Learning objectives	– You know the structure of legal documents and the relevance of their passages. – You know how to find specific information. – You learn how to find hidden reasonings in legal documents.
Teaching material	– Slides – Exercises

8.2.4 Structure and function of relevant Regulatory Bodies (with focus on CH, EU, USA)

Topics and content	In this module, you will become familiar with the structure and responsibilities of Swissmedic, the EMA, the US FDA and other regulatory bodies.
Learning objectives	– You know the term 'Regulatory Body'. – You discuss the structure, responsibilities and different activities of the EMA, the US-FDA and Swissmedic. – You learn about the European Directorate for the Quality of Medicines (EDQM) as a Directorate of the Council of Europe (COE) and its role in relation to the European Pharmacopoeia (Ph. Eur.) and the Certificate of Suitability (CEP).
Teaching material	Slides

8.2.5 Pricing and reimbursement in CH

Topics and content	In this module you will learn how medicines are priced and reimbursed by the Swiss healthcare system.
Learning objectives	– You are familiar with the Swiss health insurance system. – You are familiar with the List of Pharmaceutical Specialties (SL). – You know what the public price of medicines is made up of. – You can explain the legal basis for the reimbursement of medicines in Switzerland. – You know the role of the Federal Office of Public Health (FOPH) and the sections responsible for reimbursement and pricing. – You can name the three kinds of reimbursement procedures in Switzerland. – You can explain how and why Therapeutic Price Comparison is done. – You know why the Federal Office of Public Health (FOPH) conducts Health Technology Assessments (HTAs) and how HTAs relates to pricing and reimbursement.
Teaching material	Slides

8.3 Lifecycle management

8.3.1 Research ethics

Topics and content	Ethical standards in research are important because they promote truth and minimise error by prohibiting the fabrication, falsification, or misrepresentation of research data. In this module you will learn about the ethical requirements for research projects.
Learning objectives	– You understand the definition of research ethics. – You are familiar with the ethical requirements for planning and conducting research projects. – You know the legal framework of research ethics (Declaration of Helsinki, Guideline for Good Clinical Practice ICH E6 (R2), Clinical Trials on Medicinal Products for Human Use in the EU, European Convention on Human Rights and Biomedicine, Human Research Act, Therapeutic Products Act, etc.)
	Slides

8.3.2 Introduction to EU regulatory framework

Topics and content	In the EU, medicines are covered by the principle of free movement of goods within the single market. However, before products can be placed on the EU market, they must have a valid marketing authorisation granted by the relevant competent authority(ies). This module will give you an overview of the EU regulatory framework for medicinal products for human use and the different procedures for authorising medicinal products before they are placed on the EU market. At the end of this module, you will learn what needs to be done to maintain the marketing authorisation.

Learning objectives	– You gain an understanding of the regulatory framework that is required for a medicinal product to be granted access to the EU market. – You are familiar with the different marketing authorisation pathways (centralized, pure national, mutual recognition, decentralized). – You know the different procedures for post-approval changes and which guidance documents to use. – You will get an overview of how to maintain a marketing authorisation (renewals, periodic safety update report, sunset clause).
Teaching material	Slides

8.3.3 GxP

Topics and contents	In a nutshell, the drug lifecycle starts with research and development (R&D), the clinical trial phase, the regulatory approval phase and the launch before the commercial (post-approval) phase begins. The lifecycle ends with the withdrawal of the medicine from the market and the termination or revocation of the marketing authorisation. The good practice regulations, often abbreviated as GxPs, govern the different phases of the lifecycle. This module will provide you with the basics of GMP, GDP, GLP and GPvP.
Learning objectives	– You understand the basics of Good Manufacturing Practice (GMP) in CH, EU and ROW (rest of the world) – You know the basics of Good Distribution Practice (GDP) – You know the basics of Good Laboratory Practice (GLP) – You know the basics of Good Pharmacovigilance Practice (GVP) in CH and EU.
Teaching material	– Slides – Hands-on exercise

8.3.4 Patient involvement in the lifecycle of therapeutic products

Topics and contents	With the development of a patient-centred approach to medicine, more and more patients can participate in their own medical decisions. In this module, you will learn about the ways in which the level of information of patients and society can be promoted to encourage the formation of expert patients.
Learning objectives	– You will get a general introduction to the Patient and Public Involvement (PPI) concept and Swiss landscape. – You learn about the European Patients' Academy on Therapeutic Innovation (EUPATI) and EUPATI Switzerland.
Teaching material	– Interactive format – Slides

8.3.5 Healthcare products lifecycle + post-authorisation activities

Topics and contents	The regulatory lifecycle of a medicinal product for human use consists of different phases. In this module you will gain a detailed insight into how each of these phases is regulated. A medicinal product for human use requires a marketing authorisation which, once granted, is valid for five years from the date of notification. It is renewable and, once renewed, is valid indefinitely. This module also focuses on the purpose and regulatory tools required for post-authorisation activities.
Learning objectives	– You understand the different stages of drug development before and after marketing authorisation and be able to describe the key regulatory milestones. – You understand basic pharmaceutical concepts and terminology in relation to post-authorisation licence maintenance. – You understand the product life cycle from an RA point of view and its importance. – You get overview of the stages of Life Cycle Management (LCM) and the core activities at each stage. – You gain an awareness of the close links between the RA and the quality systems. – You understand the importance of, and activities involved in the change management process. – You get introduced to the Chemistry, Manufacturing and Control (CMC) dossier sections and how to maintain them.
Teaching material	– Slides – Hands-on exercise

8.3.6 Pharmacovigilance

Topics and content	According to the European Commission, pharmacovigilance (PV) is 'the process and science of monitoring the safety of medicines and taking action to reduce their risks and increase their benefits'. Since the Thalidomide disaster in the early 1960s, the detection of adverse reactions occurring after a product has been placed on the market has been systematic. This module addresses the requirements and standards of pharmacovigilance.
Learning objectives	– You get a brief background on pharmacovigilance. – You become familiar with the regulations and directives that define EU and CH requirements. – You learn about the processes using product examples.
Teaching material	Slides

8.3.7 Interacting with regulators and how to prepare a scientific advice meeting (focus EU)

Topics and content	For companies seeking authorisation to market a medicine use in the EU, effective communication with the EMA throughout the product development process is important. In the months leading up to the submission of a Marketing Authorisation Application (MAA), there are several opportunities

	to engage with the EMA and receive valuable input. It is essential that companies have a solid understanding of the different types of meeting procedures and know how to prepare carefully for these important interactions. By the end of this module, you will be familiar with the different types of advice available to developers and applicants of (new) medicines in the European Union.
Learning objectives	– You know the different types of European Medicines Agency (EMA) meetings that support the submission of a marketing authorisation application (e.g. Scientific advice, protocol assistance and pre-submission meeting). – You know the ITF briefing meetings for innovative medicines.
Teaching material	– Slides – Hands-on exercise

8.3.8 Packaging

Topics and content	Product packaging and labelling is an important part of product development. This module will give you with an overview of packaging processes in Switzerland, the EU and the USA.
Learning objectives	You are familiar with the CH, EU, and USA packaging regulatory frameworks
Teaching material	Slides

8.3.9 Labelling

Topics and content	Labels provide information about the known profile and proper use of a drug, and for the packaging materials it is crucial to choose those that support the quality of the product. In this module you will become familiar with the labelling processes in CH, the EU and the USA.
Learning objectives	You are familiar with the legal framework of labelling in CH, the EU, and the USA.
Teaching material	– Slides – Labelling examples based on practical exercises.

8.3.10 Scientific technical dossier to accompany a marketing authorisation application

Topics and content	A marketing authorisation application must be prepared and submitted in the Common Technical Document (CTD) format. The CTD has been developed by the International Council on Harmonisation (ICH). It is a format for the preparation of well-structured applications, divided in five modules. This course will provide you with the knowledge required to work on a CTD or eCTD.
Learning objectives	– You are familiar with the structure and the content of the ICH Common Technical Document (CTD).

	– You know the national/regional different CTD modules and are familiar with the specific requirements for the EU-CTD Module 1. – You understand the general characteristics of an Electronic Common Technical Document (eCTD) and the national/regional differences in eCTD validation criteria and electronic submission gateways. – You are familiar with the elements of a 'good dossier' in terms of compliance, design and content as well as the characteristics of technical (regulatory) writing for submissions to regulatory authorities.
Teaching material	– Slides – Hands-on exercise – E-Learning course

8.3.11 Post-approval change management protocol

Topics and content	A Post-Approval Change Management Protocol (PACMP) outlines the changes a company plans to make to a product over time and how to prepare and check these changes, allowing for a gradual assessment process.
Learning objectives	– You know the importance and activities of the change management process. – You know the benefits of using PACMPs. – You know the limitations of using PACMPs. – You know which countries currently accept PACMPs. – You know how a PACMP submission works.
Teaching material	– Slides

8.3.12 CTA process in EU

Topics and content	The EU Clinical Trials Regulation came into force on 31 January 2022. It aims to ensure that the EU provides an attractive and favourable environment for the conduct of large-scale clinical research, with high standards of public transparency and safety for clinical trial participants.
Learning objectives	– You get a brief overview of the clinical trials taking place in the EU. – You are familiar with the EU Clinical Trials Regulation the differences between the Directive 2001/20/EC and the EU Clinical Trials Regulation (key changes). – You know the Clinical Trial Information System (CTIS) – You get a real-life example of the challenges faced by a sponsor of a clinical trial.
Teaching material	– Slides

8.4 Product classes with special regulation + New trends and challenges

8.4.1 Product classes with special regulation

Topics and content	In this module you become familiar with regulatory requirements that apply for specific medicinal product classes.
Learning objectives	You are familiar with the basic EU regulatory requirements of – orphan drugs – paediatric medicines – advanced therapy medicinal products (ATMPs) – vaccines – blood and blood products with focus on blood plasma
Teaching material	– Slides

8.4.2 Real-world data and real-world evidence

Topics and content	Health-related data collected and stored by computers, mobile devices, wearables, and other biosensors are playing an increasing role in healthcare decisions. Real-World Data (RWD) and Real-World Evidence (RWE) are used to monitor post-marketing safety and are also involved in other regulatory decisions.
Learning objectives	– You can explain what RWD and RWE means. – You understand how RWE can support regulatory decision making and the efficacy of medicinal products. – You know how electronic health records are used in clinical trials.
Teaching material	– Slides

8.5 Semester work (Living Case)

The semester work (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 work (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	Online exam, closed book	0 – 100 %
Multiple Choice Exam	2.5	Online exam, closed book	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

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+ 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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