Certificate of Advanced Studies

Regulatory Affairs Pharma

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.

bfh.ch/ti/cas-rapharma

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Date: 04.01.2023

1 Setting

Regulatory Affairs Pharma		Modules	Content
	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	Orphan drugs and Paediatric Medicines
			Advanced Therapy Medicinal Products
			Vaccines
			Blood and blood products

The CAS begins with general biology skills. This knowledge is important to understand the modules that follow. The CAS will end with the module 'New trends and challenges' thematising topics like Real World Data (RWD)/Real World Evidence (RWE) and Digital Transformation in the Pharmaceutical Industry.

2 Target audience

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

3 Training objectives

- You get insight into global regulatory strategies e.g. ICH (International Harmonization).
- You gain knowledge about the structure and function of relevant Regulatory Bodies.
- You learn the different regulatory pathways for the Marketing Authorization.
- You know how to develop the Scientific Technical Dossier to accompany a Marketing Authorization Application.
- You become familiar with GxP.
- You learn how post-approval changes are regulated and how pharmacovigilance is performed.
- You learn about product classes that are subject to special regulation.
- You learn how to interact with regulators e.g. how meetings between applicant and regulator take place.
- In a case study you work on a real project or question from your company or from your own interest.

4 Requirements

Ideally you have a medical, pharmacy or science degree, an engineering education, legal studies, a higher education in material science, a degree in Business Administration or in a related field.

5 Registration and location

Registration deadline is one month before the program starts.

Continuing Education, Bern University of Applied Sciences, Aarbergstrasse 46, 2502 Biel
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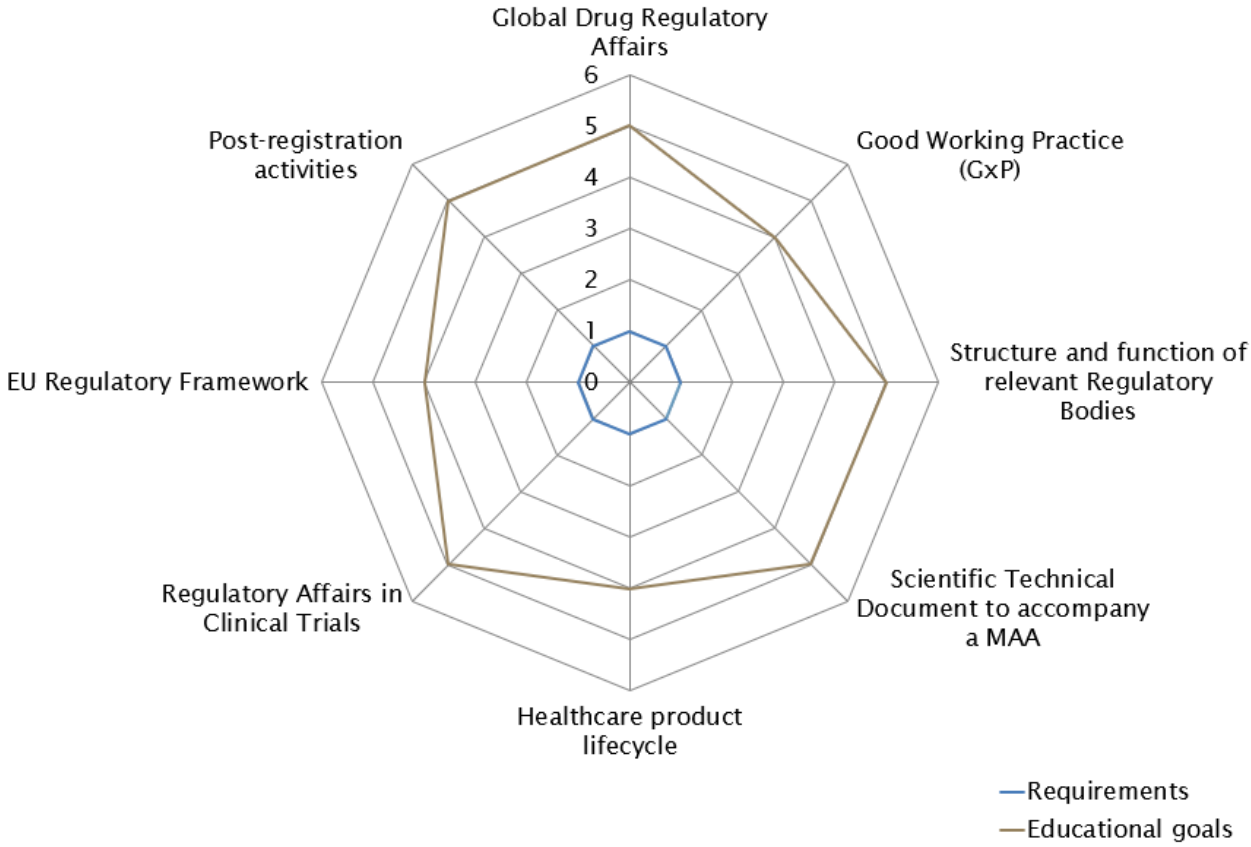
6 Skills



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.

7 Course overview

Module/Teaching unit	Lessons	Lecturers
Starting knowledge:		
Introduction to RA	2	Fabienne Weiss
Bio-Principles: Basics of the life cycle and bioinformatics	4	Prof. Dr. Joachim Frey
Bio-Principles: Pharmacogenetics	4	Prof. Dr. Carlo Largiadèr
Bio-Principles: Nanotechnology in Medicine	4	Dr. Tino Matter
Global drug regulatory affairs + structure and function of regulatory bodies:		
Falsified Medicines	3	Ruth Mosimann
Global drug regulatory affairs (1+2)	8	Dr. Barbara Jentges
Pharmaceutical Legislation & Regulations	2	Noëmi Müller
Structure and function of relevant Regulatory Bodies: EU and USA	4	Dr. Barbara Jentges
Structure and function of relevant Regulatory Bodies: CH (Swissmedic)	2	Dr. Andreas Pfenninger
Pricing and reimbursement	4	Andrea Ritzi
Lifecycle Management 1 (from R&D to Clinical Development):		
Research ethics	2	Dr. Salome Adam
Regulatory Affairs in Clinical Trials	3	Dr. Kathrin Bieri
Introduction to EU Regulatory framework	3	Dr. Elyse Drouyer
GLP	2	Corinne Meier
Patient involvement in the lifecycle of therapeutic products	3	Cordula Landgraf Prof. Dr. Cristiana Sessa Rosine Mucklow
Lifecycle Management 2 (from marketing authorization and launch to pharmacovigilance and withdrawal from the market):		
Healthcare product lifecycle + post-registration activities	2	Dr. Tamara Markovic
GMP	2	Corinne Meier
Pharmacovigilance	2	Dr. Th. Stammschulte
Interacting with regulators and how to prepare a scientific advice meeting	4	Dr. Barbara Jentges
Labelling	4	Corinne Meier
Scientific Technical Dossier to accompany a MAA	2	Dr. Barbara Jentges
Post-Approval Change Management Protocol	2	Sabine Rohner
Pharmacovigilance: Examples from CSLB	2	CSLB Pharmacovigilance Team
CTA process in EU	2	Dr. Julia Groeger
GVP	2	Corinne Meier

GDP	2	Corinne Meier
Packaging	6	Cathlyn Carley
Product classes with special regulations:		
Orphan Drugs and Paediatric Medicine / Advanced Therapy Medicinal Products / Vaccines / Blood and blood products (plasma)	5	Dr. Jens Rehbein and other lecturers from CSL Behring
New trends and challenges:		
Real-world data (RWD) and real-world evidence (RWE)	2	Dr. Salome Adam
Digital Transformation in Pharma Industry	2	Dr. Tamara Markovic
Drug-Device Combination Products	4	Dr. Barbara Jentges Mathias Eng
Total	**95**	

Course/Teaching unit	Lessons	Hours	Lecturers
Semester work (Living Case)	16	100	Diverse experts
Total	**16**	**100**	

The CAS comprises a total of 12 ECTS points. For each module/teaching unit you must add additional time for self-study, exam preparation, etc.

8 Module descriptions

In this chapter, the individual teaching modules are presented in detail.

8.1 Starting knowledge

8.1.1 Introduction to RA

Topics and content	After a historical outline, in which you will learn why regulatory affairs in life sciences and pharma is an important topic today, you will gain insight into the requirements for a career in this field.
Learning goals	– You know the reasons why regulatory affairs was developed and why this topic is of big importance today. – You know the requirements for a career in regulatory affairs in life sciences and pharma. – You get an overview over the contents of the CAS.
Teaching material	– Slides

8.1.2 Bio-Principles

Topics and content	When addressing the regulation of ATMPs (Advanced Therapy Medicinal Products), personalized medicine, or vaccines, it is expected that you are familiar with basics of gene technology, pharmacogenetics, and nanotechnology. The first few lessons in this CAS will provide you with this knowledge.
Learning goals	– You are familiar with the basics of genetics, gene technology and understand the principles of personalized medicine. – You know how a molecule of certain interest can be administered and directed to tumour cells with nanoparticles.
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, authorized medicines”. Such medicines lack active ingredients, contain dangerous contents, incorrect doses or are labelled inappropriately. This module will introduce you to the problems caused by falsified medicines and you will learn which initiatives the CH, EU and the rest of the world take, 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 are detecting and managing falsified medicines.
Teaching material	– Slides

8.2.2 Global drug regulatory affairs

Topics and content	This module starts with an economic perspective where potential conflicts of drug pricing, statistics about global sales, revenues and the economists' perspectives are discussed. Then you will become familiar with the major milestones of the regulatory life cycle of medicinal products for human use. In this module you will also learn about the pharma supply chain in a global context, and you will understand why there is a risk of drug shortages. The last two topics of this module are dedicated to the pharmacopoeias as significant standards and the ICH Q12 Lifecycle management as an example for a non-harmonised implementation of an ICH guidance document and the resulting regulatory consequences for marketing authorisation holders.
Learning objectives	– You get insight into the economic situation of 'global pharma' sales and revenues with focus on pharma's problem with growing R&D costs. – You know the general regulatory life cycle of a medicinal product for human use and its major regulatory milestones. – You understand the phases of drug development and the legislative provision that apply in the EU considering the revisions of the clinical trials provisions. – You understand the need for international harmonisation. – You get an insight into the particularities of the EU's pharmaceutical legislation. – You understand the challenge for regulatory compliance in a global economy. – You understand the risk of drug shortages in a global supply chain. – You understand the significance of pharmacopeial standards and pharmacopeial compliance. – You get insight into activities for pharmacopeial harmonisation. – You know what the Certificate of Suitability (CEP) is. – You understand the significance for a non-harmonised implementation of an ICH guidance document and become aware of the resulting regulatory consequences for marketing authorization holders.
Teaching material	– Slides – E-Learning courses

8.2.3 Pharmaceutical Legislation and Regulations

Topics and content	In Regulatory Affairs you are expected to work with laws, standards, norms, and guidelines. Reading such documents might be tricky. 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 will 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, EMA, US-FDA and other regulatory bodies.
Learning objectives	– You know the term “Regulatory Body”. – You discuss structure, responsibilities, and various activities of EMA, 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 respect of the European Pharmacopoeia (Ph. Eur.) and the Certificate of Suitability (CEP).
Teaching material	– Slides – Hands-on exercise

8.2.5 Pricing and reimbursement in CH

Topics and content	Swissmedic approval is a pre-condition for granting reimbursement of medicinal products for human use. In this module you will see how pharmaceuticals are priced and how they are reimbursed by the healthcare system in Switzerland.
Learning objectives	– You are familiar with the health insurance system in Switzerland. – You know the List of Pharmaceutical Specialties (SL). – You know how the public price of pharmaceuticals is composed. – You can explain the legal basis for reimbursement of pharmaceuticals in Switzerland. – You know the role and responsible sections of the Federal Office of Public Health (FOPH) in 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 are interlinked with pricing and reimbursement.
Teaching material	– Slides

8.3 Lifecycle Management 1 (from R&D to Clinical Development)

8.3.1 Research ethics

Topics and content	Ethical norms in research are important because such norms promote truth and minimize error by prohibiting fabricating, falsifying, or misrepresenting research data. This module will provide you with the ethical requirements for research projects.
Learning objectives	– You know the definition of research ethics. – You are familiar with the ethical requirements for planning and implementing 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 of Human Rights and Biomedicines, Human Research Act, Therapeutic Products Act, etc.)
	– Slides

8.3.2 Regulatory affairs in clinical trials

Topics and content	Clinical trials can be explained as investigations in humans to discover or verify the effects of one or more investigational medicinal products (IMPs). In clinical trials essential data are generated to evaluate product's safety, efficacy, and ability to improve or optimize existing therapies and medical treatments. This module provides you with the regulatory requirements for conducting clinical trials.
Learning objectives	– You know how to obtain authorization for a clinical trial. – You know the clinical trial application submission process. – You are familiar with trial safety reporting and regulatory notification requirements. – You are familiar with the clinical trial data discloser requirements. – You know about the revisions of the EU Clinical Trial Provisions (upcoming replacement of the Clinical Trials Directive with the Clinical Trials Regulation).
Teaching material	– Slides – Practical example

8.3.3 Introduction to EU regulatory framework

Topics and content	In the EU, medicinal products are covered by the principle of the free movement of goods within the internal market. However, before being placed on the EU market, products must have a valid marketing authorisation (MA) granted by the appropriate competent authorit(ies). This module provides you with an overview of the EU legal framework for medicinal products for human use and the different procedures used to authorise medicinal products before their introduction to the EU market. At the end of this module, you will learn what needs to be done to maintain the MA.

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

8.3.4 GxP

Topics and contents	In short, the lifecycle of medicines starts with research and development (R&D), the clinical trial phase, the marketing authorization phase and launch before the commercial (post-approval) phase begins. The lifecycle ends with the drug's withdrawal from the market and the termination or revocation of the marketing authorization. The good practice regulations, often abbreviated as GxPs govern the different lifecycle stages. This teaching module provides you with the basics of GMP, GDP GLP and GPvP.
Learning objectives	– You know 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 (GPvP) in CH and EU.
Teaching material	– Slides – Hands-on exercise

8.3.5 Patient involvement in the lifecycle of therapeutic products

Topics and contents	Thanks to the development of a patient-centered 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	– General introduction to the Patient and Public Involvement (PPI) concept and Swiss landscape, given by Cordula Landgraf, Communications and Stakeholder Engagement Director, SCTO, with integrated questions by expert patient and EUPATI Fellow Rosine Mucklow. – Presentation of the European Patients' Academy on Therapeutic Innovation (EUPATI) and EUPATI Switzerland, given by Prof. Dr. med. Cristiana Sessa, Ente Ospedaliero Cantonale (EOC) in Ticino. – Mock examples of patient involvement with expert patient and EUPATI Fellow Rosine Mucklow.
Teaching material	– Part 1 and 3 will be designed in an interactive format and not only as pure lectures to provide the students with opportunities to get involved. – Slides

8.4 Lifecycle Management 2 (from launch to pharmacovigilance to withdrawal from market)

8.4.1 Healthcare product lifecycle + post-registration activities

Topics and contents	The regulatory lifecycle of a medicinal product for human use consists of different phases. In this module you will gain detailed insight in how each of these phases is regulated. At the end of this module, you will be able to apply the knowledge you gained in a case study. A medicinal product for human use requires a marketing authorization (MA), which when granted, is valid for five years from the date of notification. It is renewable and once renewed, will be valid for an unlimited period. The focus of this module lies on the purpose and regulatory tools required for post-registration activities.
Learning objectives	– You know the various phases of drug development pre- and post-approval and describe the major regulatory milestones. – You know the basic pharmaceutical concepts and terminology related to license maintenance, following the approval. – You understand the product life cycle from the RA perspective and its importance. – You get an overview of the stages in life cycle management (LCM) and core activities in each stage. – You get the awareness of the tight link between RA and quality systems. – You know the importance and activities under the change management process. – You get an introduction to Chemistry, Manufacturing and Control (CMC) dossier sections and their maintenance activities. – You prepare an example filing, from receipt of a manufacturing change notification to its classification and reporting to HA authority.
Teaching material	– Slides – Hands-on exercise

8.4.2 Pharmacovigilance

Topics and content	According to the European Commission, Pharmacovigilance (PV) is called '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, detecting adverse reactions that occur after the product is placed on the market are conducted systematically. This module addresses the requirements and standards of Pharmacovigilance.
Learning objectives	– You will get a brief background on pharmacovigilance. – You will become familiar with the regulations and directives that define EU and CH requirements. – You will learn about the processes using product examples from CSL Behring.
Teaching material	– Slides

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

Topics and content	For companies seeking authorisation to market a medicinal product for human use in the EU, effective communication with the EMA throughout product development is important. There are several opportunities to engage with and receive valuable input from EMA in the months leading up to a Marketing Authorisation Application (MAA) submission. It is crucial that companies have a solid understanding of the different types of meeting procedures and know how to prepare carefully for these important interactions. At the end of this module, you will be familiar with the different types of advice provided to developers and applicants of (new) medicines in the European Union.
Learning objectives	– You know the different types of European Medicines Agency (EMA) meeting procedures that support 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

8.4.4 Packaging

Topics and content	Product packaging and labelling is an important part of product development. This module provides you with an overview of packaging processes in CH, the EU and USA.
Learning objectives	– You are familiar with the CH Packaging Regulatory framework. – You are familiar with the EU Packaging Regulatory framework. – You are familiar with the FDA Packaging Regulatory framework.
Teaching material	– Slides

8.4.5 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 which support the quality of the product. In this module you will become familiar with the labelling processes in CH, the EU and USA.
Learning objectives	– You are familiar with the legal framework of labelling in CH, the EU and the USA.
Teaching material	– Slides – Examples for labelling by practical exercise.

8.4.6 Scientific Technical Dossier to accompany a Marketing Authorisation Application

Topics and content	A Marketing Authorisation Application must be prepared and submitted in Common Technical Document (CTD) format. The CTD was developed by the International Council on Harmonisation (ICH). It is a format for preparing well-structured applications, organised in five modules. This course provides you with the knowledge needed to work on a CTD and on an eCTD, respectively.
Learning objectives	– You are familiar with the structure and content of the ICH Common Technical Document (CTD). – You know the nationally/regionally different CTD modules and are familiar with exemplary specific requirements for the EU-CTD Module 1. – You know the general features of an Electronic Common Technical Document (eCTD) and the nationally/regionally differing eCTD validation criteria and electronic submission gateways. – You are familiar with the elements of a 'good dossier' with respect to compliance, design and content and you know about the features of technical (regulatory) writing for submissions to regulatory authorities.
Teaching material	– Slides – Hands-on exercise – E-Learning course

8.4.7 Post-approval Change Management Protocol

Topics and content	According to the EU/EMA a Post-approval Change Management Protocol (PACMP) describes specific changes that a company would like to implement during the lifecycle of the product and how these changes would be prepared and verified. The PACMP allows a stepwise approach in the assessment of changes.
Learning objectives	– You know the importance and activities under the change management process. – You know the advantages of the use of PACMPs. – You know the limitations in the use of PACMPs. – You know the countries in which PACMPs are currently accepted. – You know how a PACMP submission works.
Teaching material	– Slides

8.4.8 CTA process in EU

Topics and content	The EU Clinical Trials Regulation entered into application on 31 January 2022. Its aim is to ensure that the EU offers an attractive and favourable environment for carrying out clinical research on a large scale with high standards of public transparency and safety for those who participate in clinical trials.
Learning objectives	– You will get a brief overview of clinical trials in the EU.

	– You will get familiar with the EU Clinical Trial Regulation and know 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 know a real case example of challenges for a trial sponsor.
Teaching material	– Slides

8.5 New trends and challenges + Product classes with special regulation

8.5.1 Product classes with special regulation

Topics and content	In this module you become familiar with regulatory requirements that apply for specific medicinal products for human use.
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

8.5.2 Real-world data and real-world evidence

Topics and content	Health-related data gathered and stored by computers, mobile devices, wearables, and other biosensors play an increasing role in healthcare decisions. Real-world data (RWD) and real-world evidence (RWE) are used to monitor post-market safety and adverse events and they are involved in regulatory decisions.
Learning objectives	– You can explain the meaning of RWD and RWE. – You know how RWE can support regulatory decision making and drug effectiveness. – You know how electronic health records are used in clinical investigations.
Teaching material	– Slides

8.5.3 Digital Transformation in the Pharmaceutical Industry

Topics and content	In recent years, digitalisation has made its way into the pharmaceutical industry. Data collections are important sources of information, and for the purpose of drug approval the eCTD (electronic common technical document) is used for the electronic transmission of the MAA (Marketing Authorization Application) from drug manufacturers to regulatory authorities.

Learning objectives	– You can give examples of digital transformation of processes in the pharmaceutical industry. – You know the challenges that digitalisation brings in the pharmaceutical industry.
Teaching material	– Slides

8.5.4 Drug-Device Combination Products

Topics and content	The conceptual delineation between medicinal products and medical devices is important because this determines the required regulatory pathway. Together with the class from the CAS Regulatory Affairs in Life Sciences you will discuss the regulatory requirements for combination products (DDCs) and practice your knowledge on product examples.
Learning objectives	– You know the difference between combination products as ‘medical devices’ and combination products as ‘medicinal products’. – You can classify combination products.
Teaching material	– Slides

8.6 Semester work (Living Case)

Objectives and Topic	In the Living Case you will work on a project or a question from your company or a topic of personal interest about regulatory affairs for medicinal products for human use. The case study should cover the full cycle of a typical master's thesis, from the formulation of the problem/question to the evaluation of the results. A special focus may be put on specific process stages.
Procedure	The Living Case is about 100 hours of work and includes the following milestones: 1. Looking for a topic within the company and preferably find a contact or supervisor within the company. 2. Preparing a topic proposal (1 to 2 pages) a. Title and details of the participants (front page) b. Initial situation c. Research question/presentation of the problem d. Methods e. Limitations f. Framework g. Deliverables h. Results 3. Short presentation of the topic in front of a panel of lecturers. Feedback by the lecturers in charge. 5-10 minutes presentation, 5-10 minutes discussion. 4. Revision of topic proposal if required, according to feedback. 5. Assignment of an expert by the CAS management. 6. Completing your work and writing the report according to your own planning. 7. Review: Short presentation of the topic to a panel of experts. Feedback by the responsible experts. 5-10 minutes presentation, 5-10 minutes questions/discussion. 8. Two to three meetings with the expert (you organize it by yourself). 9. Final presentation in front of the class, experts, and lecturers. 15 minutes for the presentation, 5-10 minutes for the discussion. 10. Submission of the deliverables to the expert and the CAS management (by email to the expert and upload on the learning management system Moodle for the CAS management).
Result and assessment	The report must be submitted to the expert (E-Mail) and the CAS management (upload on Moodle). Report: approx. 20-30 pages. The case study is assessed using the following criteria: – Submission of the topic proposal and presentation of the topic – Interim review – Methodology and implementation – Results – Report – Final presentation and poster session
Confidentiality	Case studies can be treated as confidential. The relevant framework is determined by the study regulations.

9 Assessment

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

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 %
Project work	5	Case study	0 – 100 %
Weight overall	10		0 – 100 %

The weighted average of the success rates for each assessment is converted to a grade between 3 and 6. The grade 3 (averaged success rate less than 50%) means failed. Grades 4, 4.5, 5, 5.5 and 6 (averaged success rate between 50% and 100%) are passing grades.

10 Teaching material

The following books are recommended for reading. You decide for yourself whether you want to purchase this teaching material.

Nr	Title	Author	Publisher	Year	ISBN Nr.
1.	Fundamentals of EU Regulatory Affairs, Ninth Edition	RAPS Publication	RAPS, USA	2020	978-1-947493-43-8
2.	Strategic Scientific and Medical Writing. The Road to Success	Peter H. Joubert und Silvia M. Rogers	Springer	2015	978-3-662-48316-9
3.	Wissenschaftliches Arbeiten in Psychologie und Medizin	Michael Trimmel	UTB	2009	978-3-8252-3079-1

11 Lecturers

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12 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 program, based on current developments in a field, participants' current prior knowledge and interests as well as for teaching and organizational reasons.

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