Certificate of Advanced Studies

Regulatory Affairs in Life Sciences

Products from the life sciences industry are subject to strict national and international laws and standards. The CAS Regulatory Affairs in Life Sciences focuses on the regulations concerning medical devices, in vitro diagnostics, and medical software. Experienced experts will guide you through the practice-oriented course content and equip you with the necessary knowledge to navigate the regulated environment of the life sciences industry.

Berner
Fachhochschule

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1 Environment

- Regulated environment in medical technology and the life sciences industry.
- Quality and risk management in medical technology and the life sciences industry.

Medical devices including software as a medical device, active pharmaceutical ingredients, and medicinal drug products as well as combination products (medical devices – drugs/biologics) are governed by diverse standards and regulations. This CAS specifically addresses the regulations for medical devices, in vitro diagnostics, and medical software.

For a comprehensive understanding of pharmaceutical product regulations, we recommend the CAS Pharma Regulatory Affairs | BFH.

2 Target audience

- You are planning to work in a regulated environment in the medical device- or in the life sciences industry.
- You are currently working in the areas of development, manufacturing, quality management or regulatory affairs.
- You are responsible for the early detection and analysis of risks in the areas of medical technology, medical informatics or in the life sciences industry.

3 Training objectives

- You gain comprehensive knowledge of the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) and demonstrate proficiency in their practical application.
- You acquire the necessary expertise to establish a quality management system (QMS) for medical devices, aligning with ISO 13485.
- You know the interfaces to processes such as risk management, usability engineering, reviews, design verification, design validation and process validations.
- You develop the capability to implement national regulations pertaining to reporting obligations and corrective measures in the event of serious incidents involving medical devices.

4 Requirements

- Ideally you have a degree in engineering, medical technology, or medical informatics, in medicine/veterinary medicine or in life sciences.
- You are active in the field of regulatory affairs in the healthcare sector, seeking to approach this topic systematically and comprehensively.

5 Language

The teaching language and the course materials are in English.

6 Location

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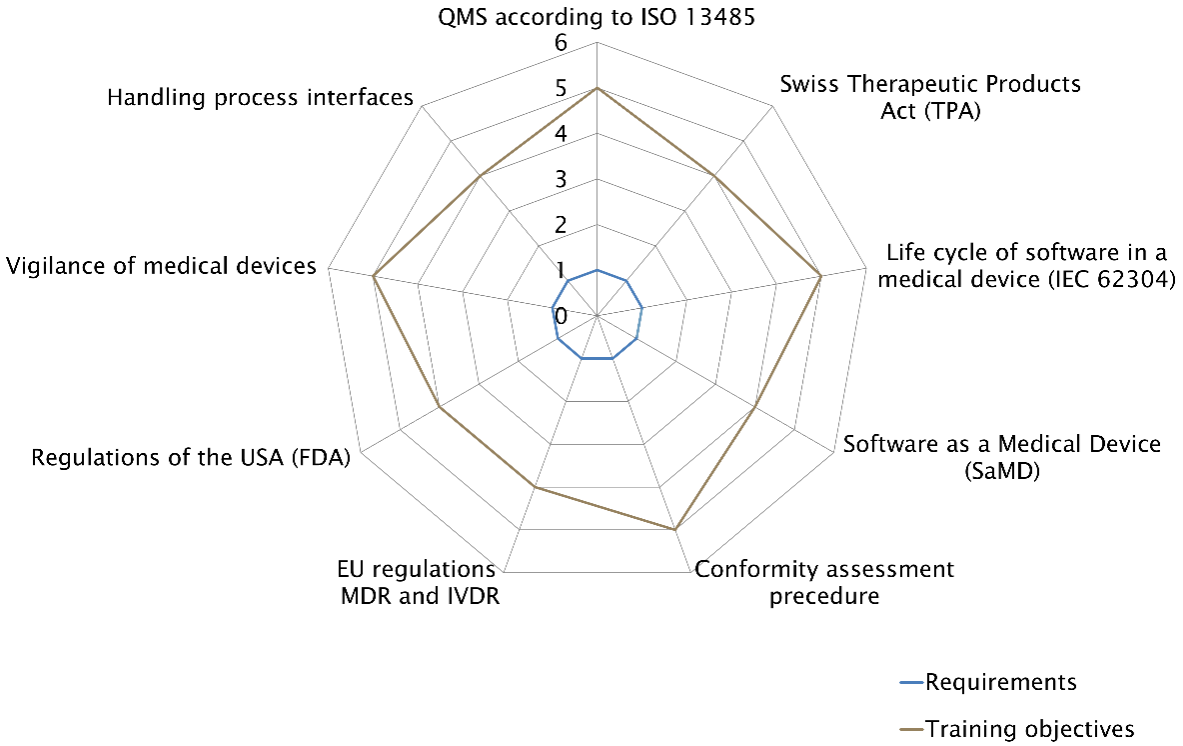
7 Competency profile



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.

8 Course overview

The CAS comprises a mandatory course block covering EU, CH, and global regulations. Since medical devices and in vitro diagnostics manufacturers must demonstrate product safety and effectiveness through clinical data, studies, or relevant sources, the course block also integrates statistics, including regulatory requirements for creating a statistical analysis plan. To enhance learning, participants carry out a semester work (Living Case) of a topic of their choice, preferably from their professional environment.

Additionally, there is an optional course block available on the regulatory requirements of medical devices of the USA (FDA).

Both course blocks follow the phases of the regulatory live cycle of medical devices, in vitro diagnostics, and medical software. Essential regulations, standards, norms, and guidelines relevant to each phase are thoroughly addressed during the teaching process.

Overview Regulations

Quality and Risk Management

1. Exam

Statistics und Living Case

Product Engineering

Validation and Operation

2. Exam

Overview Regulations

Quality and Risk Management

Product Engineering

Validation and Operation

Mandatory course block for EU, CH, and global regulations.

Optional course block for in-depth study of US regulatory requirements (FDA).

Overview Regulations

Course	Lessons	Lecturers
Organisation / Introduction	3	Prof. Michael Lehmann/ Fabienne Weiss
Swiss Regulations (national specialties)	3	
Introduction to the Medical Device Regulation (MDR)	5	P. L. Roka
Introduction to the In Vitro Diagnostic Medical Devices Regulation (IVDR)	6	Sandra Soniec (Mathias Eng)
International Regulation	6	Sandra Item
Introduction to the General Data Protection Regulation (GDPR)	3	Muriel Künzi
Total	**26**	

Quality- and Risk Management

Course	Lessons	Lecturers
Risk management for medical products	7	Serdar Gelebek
QMS ISO 13485	4	Serdar Gelebek
Documentation	3	Markus Angst
Biomaterials and Biocompatibility	4	Dr. Reto Lerf stellv. Nadine Schwarz
Biological evaluation of medical devices ISO 10993	4	Nadine Schwarz
Clinical risk management	4	Helmut Paula
Total	**26**	

Product Engineering

Course	Lessons	Lecturers
Software lifecycle of a medical device IEC 62304	7	Peter L. Roka
Product Engineering – practical implementation (1+2)	11	Michael Krieftewirth
Design Control for Combination Products	3	Michael Krieftewirth
Packaging and Labelling	5	Lutz Stehling
From requirement to design transfer	5	Beat Steffen
Software as a Medical Device (SaMD)	2	Peter L. Roka
From design transfer to phase-out	5	Markus Angst
Total	**38**	

Validation and Operation

Course	Lessons	Lecturers
Computer System Validation	4	Peter L. Roka
Clinical evaluation	3	Dr. Michel Weber
Regulations: Implementation in the market (vigilance)	3	Michael Maier
Global RA strategy	6	Michael Maier
Total	**16**	

Statistics

Course	Lessons	Lecturers
Introduction to statistics	4	Christophe Lesimple
Research design	4	Christophe Lesimple
Regulatory requirements	4	Christophe Lesimple
Practical considerations	4	Christophe Lesimple
Total	**16**	

Semester work (Living Case Aufgabe)

Course	Lessons	Hours	Lecturers
Semesterarbeit (Living Case Aufgabe)	16	100	Various experts
Total	**16**	**100**	

Regulatory requirements of medical devices of the USA (FDA)

Course	Lessons	Lecturers
Introduction to FDA Medical Device Regulation	4	
Quality-and Risk Management	12	
Product Engineering	8	
Validation and Operation	16	
Total	**40**	

Digitalisation + Cybersecurity in Life Sciences

Kurs / Lehreinheit	Lektionen	Dozierende
Digitalisation and Cybersecurity in Life Sciences (1+2)	8	Dr. Larissa Naber Mathias Eng
Total	**8**	

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.

9 Course description

The study program encompasses various individual topics, which are described below. The term "course" serves as a collective term for different event types, such as lectures, courses, case studies, living case, subject, study trip, term papers etc.

9.1 Overview Regulations

The healthcare industry operates under strict regulations, making it crucial to have a comprehensive understanding of regulatory affairs for medical devices and medical software. In this course you will gain insight into the key national and international regulations. This overview will equip you, as a Swiss medical device manufacturer, with the necessary knowledge to successfully market your products on the home market, on the European market and internationally.

Learning objectives	– Your knowledge encompasses a range of critical regulations, including the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), the Medicinal Devices Ordinance (MepDO), the Ordinance on the Prevention of Creutzfeld-Jakob Disease in Surgical and Medical Interventions (CJKV) as well as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). – You possess a comprehensive understanding of the regulatory requirements concerning the new Data Protection Act (GDPR).
Topics	– CH and EU regulations – Introduction to the MDR – Introduction to the IVDR – Introduction to the GDPR – International regulations
Form of teaching and teaching materials	Form of teaching: Face-to-face and online teaching Teaching materials: Slides

9.2 Quality and Risk Management

This course offers instruction on risk analysis methods applicable to both the medical device industry and clinical environments. You will acquire essential skills to analyse risks, ensuring safety and compliance in medical device development and clinical practice.

Learning objectives	– You understand the requirements of ISO 14971 standard and the significance of documentation in ensuring product conformity. – You possess a general understanding of ISO 13485 and its requirements. – You are acquainted with the biocompatibility testing of medical devices and materials following the ISO 10993 standard. – You have knowledge of the essential element for a controlled document, and you can prepare a simple documentation.
Topics	– Risk management concerning medical devices. – Clinical risk management – QMS ISO 13485 – Biomaterials and biocompatibility – Biological evaluation of medical devices according to ISO 10993. – Documentation
Form of teaching and teaching materials	– Form of teaching: Face-to-face – Teaching materials: Slides

9.3 Product Engineering

During this course you will gain an in-depth understanding of the product engineering process specific to the medical device industry. Emphasis will be placed on addressing legal and normative requirements concerning design control. Additionally, you will explore the life cycle of software in medical devices, as outlined in the harmonised and recognised standard IEC 62304.
Moreover, the course will cover the normative, legal, and practical fundamentals for packaging and labelling of medical devices as an integral part of product development.

Learning objectives	You will acquire the following skills and knowledge: – You will acquire knowledge about the process involved in the product design and comprehend their objectives. – You will be able to proficiently create requirement documents. – You will gain insight into the fundamentals of creating system architectures and system models. – You will become acquainted with the principles of design control for medical devices. – You will be well-versed in the three safety classifications for software according to IEC 62304. – You will understand the requirements for packaging systems and their practical implementations.
Topics	– Software life cycle process according to IEC 62304 – Product engineering – practical implementation – Design control for combination products – Packaging and labelling of medical devices – From requirement to design transfer – From design transfer to phase out

	– Software as a medical device (SaMD)
Form of teaching and teaching materials	– Form of teaching: Face-to-face and online teaching – Teaching materials: Slides

9.4 Validation and Operation

By the end of this course, you will have a solid understanding of the fundamentals of validating manufacturing processes for medical devices. Additionally, you will be well-versed in the basics of validating computer systems employed in the manufacturing process of medical devices. Another significant aspect covered will be post-marked surveillance and vigilance, along with the emphasis on the clinical evaluation of medical devices.

Learning objectives	– You possess a thorough understanding of the legal and normative fundamentals for validating manufacturing processes in Europe and the USA. – You are well-versed in the legal and normative requirements concerning the validation of computer systems. – You comprehend the intricacies of market surveillance conducted by competent authorities and monitoring functions carried out by conformity assessment bodies to ensure product compliance in the market. – You are familiar with the formal aspects of evaluating clinical data according to the European MEDDEV recommendation and can effectively apply them. – Based on clinical evaluation, you can make informed decisions regarding the necessity of conducting a clinical study.
Topics	– Design and validation of manufacturing processes – Computer system validation – Regulations – implementing in the market – Global RA strategy – Clinical evaluation
Form of teaching and teaching materials	– Form of teaching: Face-to-face and online teaching – Teaching materials: Slides

9.5 Statistics

Under the Medical Device Regulation (MDR), medical device manufacturers are required to establish the safety and effectiveness of their devices through clinical data, studies, or relevant sources. The "Technical Documentation" should include clear evidence of the statistical methods and results. This course serves as an introduction to statistics, research designs, and the regulatory demands for conducting clinical trials. Practical aspects, such as the role of statistics in clinical trials and effective communication with stakeholders, will also be covered.

Learning objectives	– Acquire a foundation in statistics, covering descriptive statistics, data representation, visualisation, p-values, confidence intervals, diagnostic measures, linear regression, logistic regression, and survival analysis.

	– Deepen your understanding of research design and study design, including repeated measurements, factorial designs, and identification of hypotheses such as superiority, non-inferiority, and equivalence. – Learn how to calculate sample sizes and comprehend the principle of randomisation. – Gain knowledge of regulatory applications, such as creating a statistical analysis plan and understanding clinical data management systems, their design, and validation. – Develop insights into data reporting, product validation, safety, and performance evaluation. – Understand the role of statistics in clinical trials, enhance communication with stakeholders, and optimise clinical research analysis planning.
Topics	– Introduction to statistics – Research design – Regulatory requirements – Practical considerations
Form of teaching and teaching materials	– Form of teaching: Face-to-face and online teaching – Teaching materials: Slides

9.6 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 slightly depending on the preparation phase and the complexity of the task.
If necessary, semester projects can be treated confidentially. The study regulations are decisive for the framework conditions. It is essential to emphasise that while maintaining confidentiality, it is imperative to uphold the pedagogical framework. This implies that presentations and comprehensive discussions about the selected subject should remain feasible within the classroom environment.

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 term paper should cover the entire cycle of a typical Master's thesis, from posing the question to evaluating the results. However, emphasis may be placed on certain process steps.
Procedure	The term paper 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 proposal (2 to 4 pages) 2.1 Title and information on the persons (title page) 2.2 Initial situation 2.3 Problem 2.4 Objectives 2.5 Delimitations 2.6 Methods 2.7 Procedure and timetable

	3. Short presentation of the topic before a panel of lecturers. Feedback by the lecturers in charge. 5-10' for the presentation, 5-10' for questions/discussion. 4. Revision of project outline if required, according to feedback. 5. You will be assigned to an expert by the head of the CAS programme. 6. Doing the work required for the paper according to your own schedule planning. 7. Two to three meetings with an expert (organised by students). 8. In an interim review, you present the status of your work to the experts and to the class. 10' presentation, 5-10' questions/discussion. 9. Submit the report to the experts and upload it in Moodle. 10. Final presentation in front of the class, experts, and lecturers. 15' for the presentation, 10' for the discussion. 11. You will be available to answer questions from interested participants at 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 deposited 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 – Interim review – Methodology and execution – Results – Report, documentation – Final presentation You will receive a detailed evaluation sheet at the beginning of the semester work.

9.7 Regulatory requirements of the USA (additional course)

The US is the world's largest consumer of medical devices. Manufacturers and distributors must ensure that their products comply with the strict regulations of the Food and Drug Administration (FDA) to be approved in the US market.
Knowledge of US regulatory requirements is crucial for Swiss regulatory affairs professionals to successfully operate in the international market, take advantage of export opportunities, and participate in global harmonisation efforts.

Learning objectives	– You attain a comprehensive understanding of the most important regulations and pivotal regulatory authorities governing medical devices within the United States. – You will acquire insights into the categorisation and risk assessment of medical devices. – You will learn about regulatory requirements for premarket submission and become familiar with the FDA clearance and approval process. – You will understand the principle of Good Manufacturing Practice (GMP) and Quality System Regulations (QRS) for medical device.

Topics	**Introduction to FDA Medical Device Regulations**
	– Overview of the FDA and its role in medical device regulation
	– Laws, regulations, and guidance documents governing medical devices
	– Regulatory pathways for medical devices
	– Pre-Market Submission
	  – Investigational Device Exemption (IDE) process
	  – 510(k) pre-market notification process
	  – Premarket Approval (PMA) process
	  – De Novo classification process
	  – Humanitarian Device Exemption (HDE) process
	
	Quality- and Risk management
	– Medical Device Classification and Risk Assessment
	  – Classification systems for medical devices (class I, II, and III)
	  – Risk assessment and risk-based classification
	  – Special controls and exemptions for low-risk devices
	
	Product Engineering
	– Good Manufacturing Practices (GMP) and Quality System Regulations (QSR)
	  – Introduction to GMP and QSR requirements
	  – Design controls and documentation
	  – Production and process controls
	  – Device labelling and packaging requirements
	  – Complaint handling and corrective actions
	– Labelling and Advertising Regulations
	  – Labelling requirements for medical devices
	  – Advertising and promotion regulations
	  – Off-label use and limitations
	
	Validation and Operation
	– Post-Market Requirement
	  – Post-market surveillance and adverse event reporting
	  – Medical device recalls and market withdrawals
	  – Medical Device Reporting (MDR)
	  – Unique Device Identification (UDI) system

Form of teaching and teaching materials	– Form of teaching: Online teaching – Teaching materials: Slides

9.8 Digitalisation and Cyber Security in Life Sciences

Digitalisation is also making its way into the life science industry. Digitalisation is on everyone's lips. But what exactly does this mean, what are the areas of application in the life science industry? What new opportunities does digitalisation bring, what activities are associated with it and what are the associated risks, how does the legislator deal with them?

Learning objectives	– You know the areas of application, activities, opportunities, and risks of digitalisation. – You are familiar with the regulatory requirements in connection with digitalisation and cybersecurity.

	– You know the requirements to the quality management system in connection with digitalisation and cybersecurity.
	– You understand risk management in the context of cybersecurity.
	– You understand the basics of AI / Machine Learning about
	  – Artificial Intelligence (AI) / Machine Learning,
	  – Natural Language Processing,
	  – Reinforcement Learning,
	  – Generative Adversarial Networks and
	  – Recommendation Systems
	– You understand key terms such as “neural networks”, “deep learning”, “supervised and unsupervised learning”.
	– You know current application areas of AI in the life science industry.

Topics	– Introduction to the topic, areas of application, activities, new possibilities, new risks.
	– Cybersecurity:
	  – Regulations
	  – Requirements for the quality management system, life cycle
	  – Security Risk Assessment
	– Artificial Intelligence (AI) / Machine Learning:
	  – Basics of AI
	  – Differentiation from statistics; differentiation between structured and unstructured data
	  – Application of machine learning to unstructured data, such as natural speech recordings, images, audio.
	  – Applications of AI in Life Sciences with examples.

Form of teaching and teaching materials	– Form of teaching: Online teaching – Teaching materials: Slides

10 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 %
Project work	5	Case study	0 – 100 %
Weight overall	10		0 – 100 %
ECTS-Note			**A - F**

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.

11 Lecturers

Name	Company	E-Mail
Angst Markus	AtlantiQ Consulting Markus Angst, unipessoal LDA	markus@atlantiq.pt
Eng Mathias	QUAREGIA GMBH, Quality and Regulatory Compliance	mathias.eng@quaregia.com
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Item Sandra	ISS Integrated Scientific Services AG	Sandra.item@iss-ag.ch
Krieftewirth Michael	Janssen Vaccines	michael.krieftewirth@gmx.ch
Künzi Muriel	BKS Rechtsanwälte AG	muriel.kuenzi@torneys.ch
Maier Michael	Medidee Services SA	michael.maier@medidee.com
Naber Larissa	PROREGIA AG	larissa.naber@proregia.ch
Paula Helmut	Stiftung Patientensicherheit Schweiz	paula@patientensicherheit.ch
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Soniec Sandra	meditec Consulting	soniec@meditec-consulting.ch
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+ Further experts and supervisors for the semester work.

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 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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