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

Table of contents

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 the 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 the EU 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, design verification, design validation, process validations and reviews.
- You will develop the ability to implement national regulations on 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, in pharmacy or in life sciences.
- You work in the field of healthcare regulatory affairs and want to keep up to date with the latest changes.

5 Language

The teaching language and the course materials are in English.

6 Location

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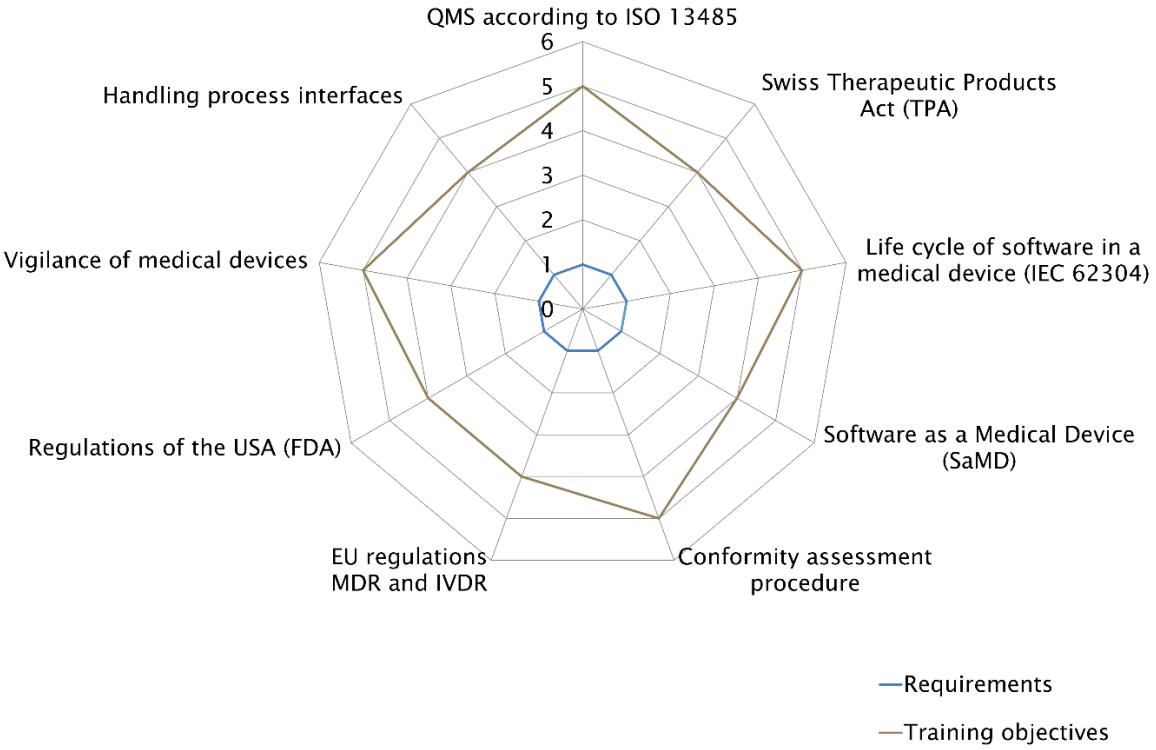
7 Competency profile



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

This CAS comprises a mandatory course block covering EU, CH, and global regulations. To enhance learning, participants carry out a semester project (Living Case) of a topic of their choice, preferably from their professional environment. Since medical devices and in vitro diagnostics manufacturers must demonstrate product safety and effectiveness through clinical data, studies, or relevant sources, the CAS also integrates an optional module in statistics.

In addition, there is an optional course block on the US regulatory requirements for medical devices (FDA).

Both course blocks follow the phases of the regulatory life 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

Product Engineering

Validation and Operation

2. Exam

Living Case

Statistics

Overview of US Market Access, Regulation, and Compliance for Medical Devices

Fundamentals of FDA Premarket Submission

U.S. Quality Management System Requirements

FDA Inspections and Market Protection

Mandatory course block for EU, CH, and global regulations and Living Case (including optional statistics module).

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

8.1 Overview Regulations

Course	Lessons	Lecturers
Organization/Introduction	1	Fabienne Weiss
Introduction to the Medical Device Regulation (MDR)	3	Dr. Anca Tigan
Introduction to the General Data Protection Regulation (GDPR)	3	Muriel Künzi
Introduction to the In Vitro Diagnostic Medical Devices Regulation (IVDR)	6	Sandra Soniec (Mathias Eng)
Swiss Regulations	6	Holger Kloess
International Regulations	6	Sandra Item
Global RA strategy	6	Michael Meyer
Regulation of Nanotechnology in Medicine	4	Dr. Tino Matter
Total	**35**	

8.2 Quality- and Risk Management

Course	Lessons	Lecturers
Risk management for medical products	7	Serdar Gelebek
QMS ISO 13485	4	Serdar Gelebek
Clinical evaluation	3	Dr. med. Katharina Friedrich
Clinical risk management	4	Helmut Paula
Documentation	3	Markus Angst
Biomaterials and Biocompatibility	3	Dr. Reto Lerf
Biological evaluation of medical devices ISO 10993	4	Nadine Schwarz
Medical device audits	5	Holger Kloess
Total	**33**	

8.3 Product Engineering

Course	Lessons	Lecturers
Software lifecycle of a medical device IEC 62304	5	E. Studer
Software as a Medical Device (SaMD)	2	E. Studer
Product Engineering – practical implementation (1+2)	11	Michael Krieftewirth
From Requirement to Design Transfer	4	Beat Steffen
From Design Transfer to Phase-out	5	Markus Angst
Design Control for Combination Products	3	Michael Krieftewirth
Packaging and Labelling	5	Lutz Stehling
Total	**35**	

8.4 Validation and Operation

Course	Lessons	Lecturers
Computer system validation	4	E. Studer
Implementation in the market (vigilance)	3	Michael Maier
Total	**7**	

8.5 Digitalization and Cybersecurity in Life Sciences

Course	Lessons	Lecturers
Digitalization and Cybersecurity in Life Sciences (1+2)	8	Dr. Larissa Naber, Dr. Anca Tigan and Mathias Eng
Total	**8**	

8.6 Semester project (Living Case)

Course	Lessons	Hours	Lecturers
Semester work (Living Case)	~ 16	100	Various experts
Total	**~ 16**	**100**	

8.7 Statistics

Course	Lessons	Lecturers
Introduction to statistics and research design	3	Christophe Lesimple
Regulatory requirements	3	Christophe Lesimple
Practical considerations	3	Christophe Lesimple
Total	**9**	

8.8 Regulatory requirements for medical devices in the USA

Course	Lessons	Lecturers
Overview of US Market Access, Regulation, and Compliance for Medical Devices	4	Valentina Shcherba
Fundamentals of FDA Premarket Submissions	4	Valentina Shcherba
U.S. Quality Management System Requirements	4	Valentina Shcherba
FDA Inspections and Market Protection	4	Valentina Shcherba
Total	**16**	

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.

9 Course description

The study program encompasses different topics, which are described below. The term “course” is used as a collective term for different types of events, 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 essential 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 course will provide you, as a Swiss medical device manufacturer, with the necessary knowledge to successfully market your products in the domestic, European, and international markets. At the end of this course, you will get a deeper insight into the field by learning about the regulatory aspects of nanomedicine as a practical example.

Learning objectives	- You will get familiar with 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). - You will gain an insight into the regulatory aspects of nanomaterials.
Topics	- CH and EU regulations - Introduction to the MDR - Introduction to the IVDR - Introduction to the GDPR - International regulations - Global RA strategy - Regulation of Nanotechnology in Medicine
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

9.2 Quality- and Risk Management

This course provides instruction in risk analysis methods applicable to both the medical device industry and clinical environments. You will gain essential skills in risk analysis to ensure safety and compliance in medical device development and clinical practice. The course ends with an introduction to the importance of auditing.

Learning objectives	- You have a general understanding of ISO 13485 and its requirements. - You are familiar with the biocompatibility testing of medical devices and materials according to ISO 10993 standard. - You will know the essential elements of a controlled document and be able to prepare a simple documentation. - You learn the definitions of clinical evaluation and know how to set up a clinical evaluation plan. - You will gain insight into the ISO 19011:2018 standard that provides guidance for auditing management systems, including the principles of auditing, managing an audit program and conducting management systems.

Topics	- Risk management for medical products - QMS ISO 13485 - Clinical evaluation - Clinical risk management - Documentation - Biomaterials and biocompatibility - Biological evaluation of medical devices according to ISO 10993 - Medical device audits according to ISO˚19011:2018
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

9.3 Product Engineering

In this course, you will start with gaining insight into the software lifecycle in medical devices according to the IEC 62304 standard. Then you will gain an understanding of the product engineering process specific to the medical device industry. Emphasis will be placed on addressing the requirements for design control. The course will also cover the normative, legal, and practical basis 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 know the safety classifications for software according to IEC 62304. - You get to know the product design process and understand its objectives. - You learn how to create requirement documents. - You gain insight into the fundamentals of creating system architectures and system models. - You will learn the principles of design control for medical devices. - You understand the packaging and labelling requirements.
Topics	- Software life cycle process according to IEC 62304 - Software as a medical device (SaMD) - Product engineering – practical implementation - Design control for combination products - From requirement to design transfer - From design transfer to phase-out - Packaging and labelling of medical devices
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

9.4 Validation and Operation

This course covers the validation of medical device manufacturing processes, including the basics of validation of computer systems in medical devices. Other important topics include clinical evaluation of medical devices, post-market surveillance and vigilance.

Learning objectives	- You understand the basics for validating manufacturing processes of medical devices in Europe and the USA. - You will be familiar with the requirements for validating computer systems. - You understand the intricacies of market surveillance carried out by Competent Authorities and the monitoring functions carried out by

	Conformity Assessment Bodies to ensure product compliance in the marketplace.
Topics	- Computer system validation - Regulations: Implementation in the market (vigilance)
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

9.5 Digitalization and Cybersecurity in Life Sciences

Digitalization is also making its way into the life science industry. Digitalization 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 digitalization 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 digitalization.
	- You are familiar with the regulatory requirements in connection with digitalization and cybersecurity.
	- You know the requirements to the quality management system in connection with digitalization and cybersecurity.
	- You understand risk management in the context of cybersecurity.
	- You understand the basics of AI/Machine Learning about
	  - 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.
	  - 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 recording, images, audio.
	  - Applications of AI in Life Sciences with examples.

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

9.6 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 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 project should cover the entire cycle of a typical Master's thesis, from formulating the question to discussing 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 Delimitations 2.5 Material and methods 2.6 Dependencies and risk factors 2.7 Deliverables/Results 2.8 Procedure and timetable 2.9 Literature list 2.10 Supplements 2.11 Appendix 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. According to your topic you will be assigned to an expert by the head of the CAS program. 6. You do the work required for the semester project according to your own schedule. 7. You organize 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.
Result and assessment	The report (approx. 20–30 pages) is to be sent to the experts in electronic form as a PDF document and posted on the Moodle platform. The semester project (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.

9.7 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	- You acquire a foundation in statistics, covering descriptive statistics, data representation, visualization, p-values, confidence intervals, diagnostic measures, linear regression, logistic regression, and survival analysis. - You will 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. - You learn how to calculate sample sizes and comprehend the principle of randomization. - You will gain knowledge of regulatory applications, such as creating a statistical analysis plan and understanding clinical data management systems, their design and validation. - You will understand the role of statistics in clinical trials, enhance communication with stakeholders, and optimize clinical research planning.
Topics	- Introduction to statistics - Research design - Regulatory requirements - Practical considerations
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides and exercises

9.8 Regulatory requirements for medical devices in the USA

The United States 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 market.
Knowledge of the regulatory requirements in the United States is critical for Swiss regulatory affairs professionals to successfully operate in the international market, take advantage of export opportunities, and participate in global harmonization efforts.

Learning objectives	- You attain an understanding of the most important regulations and pivotal regulatory authorities governing medical devices within the United States. - You will acquire insights into the classification of medical devices. - You will learn about regulatory requirements for premarket submissions and become familiar with the FDA approval processes. - You will understand the principle of Good Manufacturing Practice (GMP) and Quality System Regulations (QSR) respectively Quality Management System Regulation (QMSR) for medical devices.
Topics	**Day 1** - Market access in the United States, legislation, and organization of the FDA. - Medical devices in the United States. - Medical device definition

	- Product classification - Workshop - Marketing and distribution, establishment registration and device listing. **Day 2** - Premarket submissions (overview) - Premarket Notification 510(k) - Investigational Device Exemption (IDE) - Premarket Approval (PMA) - De Novo classification request - Humanitarian Device Exemption (HDE) - Q-Submission Program - Considerations preparing Premarket submissions, FDA guidance documents and databases - Premarket Notification 510(k) (in detail) - 510(k) types and FDA processing - Structure of the traditional 510(k) - Workshop **Day 3** - U.S. FDA requirements to QMS (basics) - QSR/QMSR - 21 CFR Part 11 e-records, e-signatures - MDR, correction and removals, recalls - 21 CFR Part 803 Medical Device Reporting (MDR) - 21 CFR Part 806 Reports of corrections and removals - 21 CFR Part 7 Recalls/Part 810 **Day 4** - FDA Inspections - Quality System Inspection Technique (QSIT) - Practical tips for FDA inspection preparation - Market protection
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology), workshop - Teaching materials: Slides

10 Competency assessment

For the 12 ECTS credits to be awarded, successful completion of the competency assessment is required, as listed below:

Competency assessment	Weight	Type of assessment	Student's success rate
Mid-semester exam	2.5	Online exam, closed book	0 – 100 %
Expert Discussion	2.5	Oral exam	0 – 100 %
Semester project	5	Living Case	0 – 100 %
Weight overall	10		0 – 100 %
ECTS-Note			**6 – 3**

The mid-semester exam consists of multiple-choice questions. In the Expert Discussion at the end of the CAS, selected aspects of the semester project are discussed and justified by using arguments and the specialist knowledge acquired in the CAS. 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.

11 Lecturers

Name/First 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
Friedrich Katharina	Katylistic, Medical Writing and Consulting	k.friedrich@katylistic.com
Gelebek Serdar	CONSYS AG	serdar.gelebek@consys.ch
Item Sandra	ISS Integrated Scientific Services AG	sandra.item@iss-ag.ch
Kloess Holger	QUNIQUE GmbH	holger.kloess@quniquegroup.com
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Lesimple Christophe	Sonova AG	Christophe.Lesimple@sonova.com
Maier Michael	Medidee Services SA	michael.maier@medidee.com
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Soniec Sandra	meditec Consulting	soniec@meditec-consulting.ch
Steffen Beat	Confinis AG, Project Management & Consulting	beat.steffen@confinis.com

Stehling Lutz	inmedis GmbH	l.stehling@inmedis.ch
Studer Erich	QUAREGIA GMBH, Quality and Regulatory Compliance	erich.studer@quaregia.com
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+ Further experts and supervisors for the semester work.

12 Organization

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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 particular field, participants' current prior knowledge and interests as well as for teaching and organizational reasons.

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