



Certificate of Advanced Studies

Regulatory Affairs in Life Sciences

The life sciences industry operates in a highly regulated environment where regulatory affairs, quality management, and risk management are critical to product success. The CAS Regulatory Affairs in Life Sciences provides a comprehensive understanding of the regulatory frameworks applicable to medical devices, in vitro diagnostic medical devices (IVDs), and medical software. Guided by experienced industry experts, participants gain practical knowledge and skills to support product development, market access, lifecycle management, and regulatory compliance throughout the product life cycle.

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1 Environment

Medical devices, in vitro diagnostic medical devices, and medical software are developed, manufactured, and marketed within a highly regulated environment. Their successful lifecycle management requires expertise in regulatory affairs, quality management, and risk management. In this CAS, you develop an understanding of the applicable standards, regulations, and industry practices, and learn how regulatory affairs, quality management, and product development interact throughout the product lifecycle.

For a deeper understanding of pharmaceutical product regulations, we recommend the [CAS Regulatory Affairs Pharma | BFH](#).

2 Target audience

You are involved in the development, manufacture, market access, or lifecycle management of medical devices, in vitro diagnostic medical devices, or medical software. This CAS is particularly relevant if you wish to strengthen your expertise in regulatory affairs and gain a deeper understanding of quality management, risk management, compliance requirements, and emerging technologies such as artificial intelligence within the regulated healthcare environment.

3 Career opportunities

Typical positions include Regulatory Affairs Specialist, Regulatory Affairs Manager, Regulatory Affairs Consultant, and Regulatory Compliance Specialist.

The knowledge gained in this CAS is also relevant for professionals working in product development, engineering, manufacturing, project management, and other functions involved in the development, market access, and lifecycle management of healthcare products. It enables you to communicate effectively across multidisciplinary teams and to contribute to regulatory compliance throughout the product lifecycle.

Depending on your professional background and experience, you may also support or assume responsibilities associated with the Person Responsible for Regulatory Compliance (PRRC) as defined in Article 15 of the EU Medical Device Regulation (MDR).

4 Education goals

Upon completion of the CAS, you will be able to:

- Apply the key regulatory requirements governing medical devices, in vitro diagnostic medical devices (IVDs), and medical software, including relevant frameworks in Switzerland, the European Union, and the United States.
- Establish and maintain compliant quality management and risk management processes, taking into account standards such as ISO 13485 and related regulatory requirements.
- Apply principles of design control, usability engineering, validation, and post-market activities to support the development, market access, and lifecycle management of medical devices.
- Evaluate regulatory, quality, and cybersecurity requirements for digital health technologies, connected medical devices, and medical software.
- Understand the fundamentals of artificial intelligence in the life sciences industry, including current applications, regulatory considerations, and how to turn Trustworthy AI principles into practice.

5 Requirements

- You have a degree in engineering, medical technology, medical informatics, life sciences, pharmacy, medicine or veterinary medicine.
- You have relevant professional experience in the medical device or related regulated healthcare industries.

6 Teaching format and language

The CAS is designed to accommodate the needs of working professionals and offers different teaching formats throughout the program:

- Hybrid: Classes are delivered on-site in Biel and can also be attended remotely. If the majority of participants register for remote attendance, the session will be conducted fully online.
- Remote: Classes are held entirely online.
- On-site: Classes take place exclusively on-site in Biel.

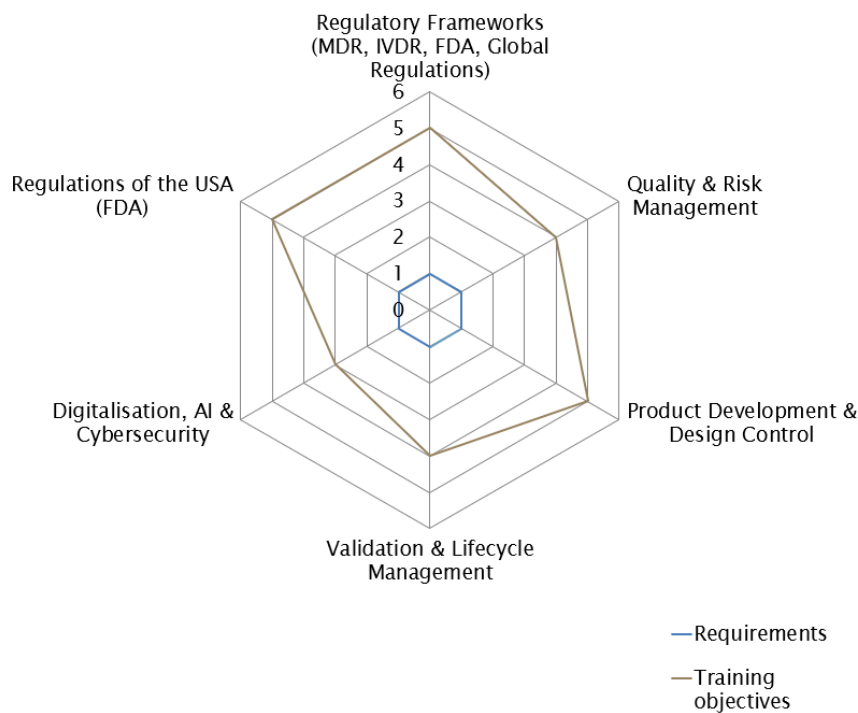
The teaching format for each session is indicated in the timetable.

The teaching language and the course materials are in English.

7 Location

Bern University of Applied Sciences, School of Engineering and Computer Science
Continuing Education, Aarbergstrasse 46 (Switzerland Innovation Park Biel/Bienne), CH-2503 Biel
Phone +41 31 848 31 11, E-Mail weiterbildung.ti@bfh.ch.

8 Skills 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. Appraisal: Critically evaluate what has been learned according to (mostly self-) chosen criteria.

The skill levels shown in the diagram reflect the competencies addressed within the individual course modules. Depending on the selected topic and scope of the semester project (Living Case), participants may achieve higher levels of competence (Levels 5–6: Synthesis and Appraisal) in specific subject areas.

9 Course outline

The learning concept of this CAS combines theoretical knowledge with practical application. Participants acquire competencies through contact studies, individual self-study, a semester project (Living Case), and an expert discussion at the end of the program.

9.1 Teaching methods

Table 1: Overview of learning units and teaching methods

Learning unit		Duration	Description
	Contact studies	~ 130 lessons (20-21 course days)	Classroom-based learning delivered in on-site, remote, or hybrid format. Contact studies include lectures, workshops, case studies, practical exercises, and discussions led by experienced industry experts.
	Semester project	115 hours	Application of acquired knowledge to a real-world regulatory challenge from your professional environment or an independently selected topic. The semester project is typically conducted in small groups and supervised by industry experts with expertise in the respective project area. The project culminates in a written report and project presentations.
	Individual self-study	45-60 hours	Self-directed learning to prepare for classes, consolidate acquired knowledge, review course materials, and prepare for assessments.
	Expert discussion	~ 1 lesson	At the end of the CAS, you analyse and defend selected aspects of your semester project in a discussion with your industry expert and the CAS lead, drawing on the knowledge and competencies acquired throughout the program.
CAS = 12 ECTS credits (360 hours)			

The next chapter provides a visual representation of the program structure and its alignment with the regulatory lifecycle.

9.2 Course outline

The CAS combines Swiss, European, global, and U.S. regulatory requirements. The programme structure and the relationship between the individual course modules are illustrated in Figure 1.

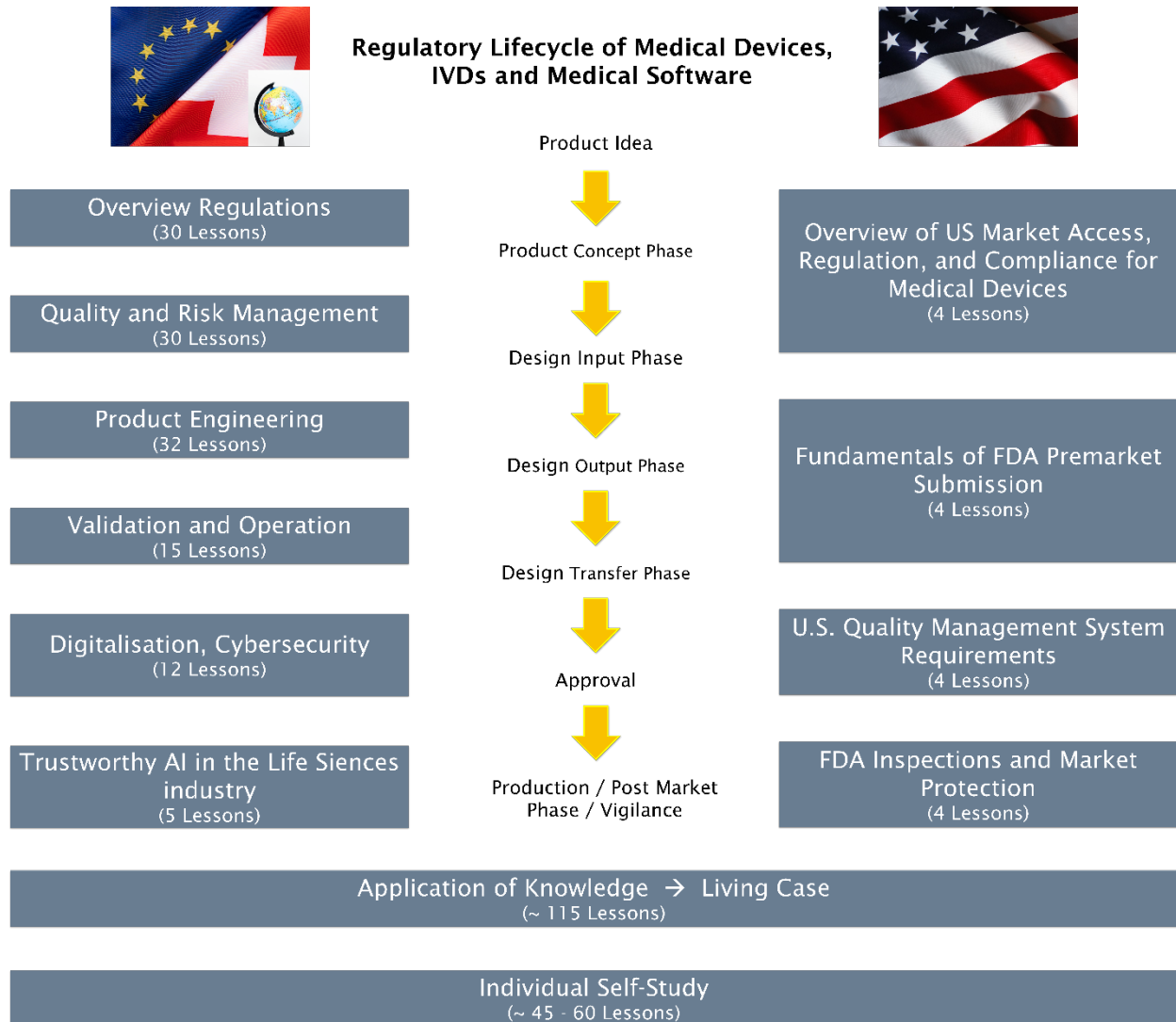


Figure 1: Course overview

Detailed descriptions of the individual subject areas are provided in the subsequent chapters.

9.3 Overview regulations

Course	Lessons	Lecturers
Introduction to the Medical Device Regulation (MDR)	3	Holger Kloess
Introduction to the General Data Protection Regulation (GDPR)	3	Muriel Künzi
Introduction to the In Vitro Diagnostic Medical Devices Regulation (IVDR)	6	Sandra Soniec
Swiss Regulations	6	Holger Kloess
International Regulations	6	Sandra Item
Global RA Strategy	6	Michael Maier
Total	30	

9.4 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	

9.5 Quality- and risk management

Course	Lessons	Lecturers
Risk management for medical products	7	Christina Degen - Wendlinger
QMS ISO 13485	4	Christina Degen - Wendlinger
Human centered product development	9	Andrea Schuetz Frikart
Documentation	3	Markus Angst
Biomaterials and biocompatibility	3	Nadine Schwarz
Biological evaluation of medical devices ISO 10993	4	Nadine Schwarz
Total	30	

9.6 Product engineering

Course	Lessons	Lecturers
Software lifecycle of a medical device IEC 62304	5	Erich Studer
Product engineering – practical implementation (1+2)	10	Erich Studer
From requirement to design transfer	4	Beat Steffen
From design transfer to phase-out	5	Markus Angst
Software as a Medical Device (SaMD)	2	Erich Studer

Packaging and labelling	5	Lutz Stehling
Total	32	

9.7 Validation and operation

Course	Lessons	Lecturers
Medical device audits	5	Holger Kloess
Clinical evaluation	3	Dr. med. Katharina Friedrich
Computer system validation	4	Erich Studer
Implementation in the market (vigilance)	3	Michael Maier
Total	15	

9.8 Digitalization and cybersecurity in life sciences

Course	Lessons	Lecturers
Digitalization and cybersecurity in life sciences (1+2)	8	Dr. Larissa Naber
Total	8	

9.9 Trustworthy AI in the Life Sciences industry

Course	Lessons	Lecturers
Trustworthy AI in the Life Sciences industry	5	Marco Cuomo, Darlene MacDonald
Total	5	

9.10 Semester project (living case)

Course	Lessons	Hours	Lecturers
Semester work	~ 15	100	Various experts
Total	~ 15	100	

10 Course description

The following sections provide an overview of the topics covered in the study program. Throughout this study guide, the term course is used as a collective term for the different program components, including lectures, case studies, living cases, study trips, assignments, and term papers.

10.1 Overview regulations

The healthcare industry operates within a complex regulatory environment. This course provides an overview of the key regulatory frameworks governing medical devices and medical software, as well as data protection requirements and international regulatory strategies that support market access and compliance.

Learning objectives	- You understand the key regulatory requirements applicable to medical devices and in vitro diagnostic medical devices, including the Swiss Therapeutic Products Act (TPA), the Medical Devices Ordinance (MedDO), the Medical Device Regulation (MDR), and the In Vitro Diagnostic Medical Devices Regulation (IVDR). - You understand the key principles and regulatory requirements of the General Data Protection Regulation (GDPR). - You understand the fundamentals of international regulatory frameworks and global regulatory affairs strategies, including their role in supporting worldwide product registration, market access, and lifecycle management.
Topics	- CH and EU regulations - Introduction to the MDR - Introduction to the IVDR - Introduction to the GDPR - International regulations - Global RA strategy
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

10.2 Regulatory requirements for medical devices in the USA

The United States is one of the world's largest markets for medical devices. This course introduces the regulatory framework of the U.S. Food and Drug Administration (FDA) and provides an overview of the key requirements and regulatory pathways for placing medical devices on the U.S. market.

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 insight 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	Overview of US Market Access, Regulation, and Compliance for MDs - 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 Fundamentals of FDA Premarket Submission - 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 U.S. Quality Management System Requirements - 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 FDA Inspections and Market Protection - FDA Inspections - Quality System Inspection Technique (QSIT) - Practical tips for FDA inspection preparation - Market protection
Form of teaching and teaching materials	- Online teaching - Teaching materials: Slides

10.3 Quality- and risk management

The development and manufacture of medical devices require robust quality and risk management processes to ensure product safety, performance, and compliance. This course provides an overview of key quality management, documentation, biocompatibility, and usability engineering principles, with a focus on the practical application of relevant international standards.

Learning objectives	- You have a general understanding of ISO 13485 and its requirements. - You understand the principles and requirements for the biological evaluation of medical devices and materials in accordance with ISO 10993. - You understand the key principles of document control and technical documentation and are able to prepare and maintain compliant documentation for medical devices. - You know how to apply user-centred design principles, understand the fundamentals of usability engineering according to IEC 62366, conduct usability evaluations, and identify and manage use-related risks.
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Topics	- QMS ISO 13485 - Biomaterials and biocompatibility - Biological evaluation of medical devices according to ISO 10993 - Risk management for medical products - Documentation - Human centered product development
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

10.4 Product engineering

Bringing a medical device from concept to market requires a structured development process that integrates engineering, software, and design control activities. This course provides an overview of key product engineering principles, from requirements engineering and product design to design transfer and market introduction. Participants also gain an understanding of software lifecycle management, design control, and packaging and labelling requirements for medical devices.

Learning objectives	- You understand the key stages of the medical device development process, from requirements engineering and product design to design transfer, market introduction, and product phase-out. - You can apply the principles of software lifecycle management and interpret software safety classifications according to IEC 62304. - You can explain how design control is implemented in the development of medical devices and combination products. - You can identify and interpret packaging and labelling requirements for medical devices.
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

10.5 Validation and operation

The successful operation of medical devices relies on effective quality assurance activities throughout their lifecycle. This course provides an overview of auditing practices, process and computer system validation, and post-market surveillance activities that support regulatory compliance, product quality, and patient safety.

Learning objectives	- You are familiar with the principles of auditing and the application of ISO 19011:2018 for auditing management systems. - You understand the principles and regulatory requirements for validating medical device manufacturing processes in Europe and the United States. - You are familiar with the requirements and key principles of computer system validation.
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	- You understand the roles of Competent Authorities and Conformity Assessment Bodies in market surveillance and the ongoing monitoring of product compliance.
Topics	- Medical device audits according to ISO 19011:2018 - Computer system validation - Implementation in the market (vigilance)
Form of teaching and teaching materials	- Face-to-face and online teaching (use of hybrid technology) - Teaching materials: Slides

10.6 Digitalization and cybersecurity in life sciences

Digital technologies are transforming the life sciences industry, creating new opportunities for innovation, efficiency, and patient care. At the same time, they introduce new regulatory, quality, and cybersecurity challenges. This course provides an overview of digitalization, cybersecurity, and artificial intelligence (AI) and explores their application in regulated healthcare environments.

Learning objectives	- You understand the opportunities, challenges, and risks associated with digitalization in the life sciences industry. - You understand the regulatory, quality management, and cybersecurity requirements relevant to digitalized healthcare environments. - You can assess cybersecurity risks and understand their implications for product quality, patient safety, and regulatory compliance. - You can explain the fundamental concepts of artificial intelligence and machine learning and evaluate their current and potential applications in the life sciences industry.
Topics	- Digitalization in Life Sciences - Cybersecurity - Artificial Intelligence (AI) and Machine Learning (ML)
Form of teaching and teaching materials	- Form of teaching: Online teaching - Teaching materials: Slides

10.7 Trustworthy AI in the Life Sciences industry

AI has the potential to fundamentally reshape business processes. How can we balance rapid innovation with the trust we expect? Trustworthy AI is the key to establishing accountability, transparency, fairness and governance.

Learning objectives	- You understand the core principles and requirements of Trustworthy AI and relevance for organizational and regulatory practice. - You recognize the relevance of Trustworthy AI and creating the necessary awareness in your professional context. - You know how to embed Trustworthy AI into the organizations existing ways of working — from scoping to retirement. - You can identify assets/tools that can be used to support the implementation of Trustworthy AI systems. - You can analyze concrete use cases from your organization and identify relevant Trustworthy requirements and potential next steps.
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	- You are equipped with a shared language, practical tools, and lifecycle know-how enabling you to put Trustworthy AI into practice.
Topics	Analyze – Clarify the Trustworthy AI Landscape - Why Trustworthy AI: Fundamental concepts (e.g. EU HLEG- Ethics Guidelines for Trustworthy AI, NIST AI RMF) Architect – Design for Trust - Integrating Trustworthy AI into your ways of working on an organizational and project level Anchor – Make Trust Operational - Validation strategies, acceptance criteria, and evidence for release decisions
Form of teaching and teaching materials	- Form of teaching: Face- to -Face - Group work - Real life examples - Teaching materials: Slides

10.8 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.

11 Proof of proficiency

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	Written exam, closed book	0 – 100 %
Semester project	2.5	Living Case	0 – 100 %
Expert Discussion	5.0	Oral exam	0 – 100 %
Weight overall	10.0		0 – 100 %
ECTS-Note			3 – 6

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 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 and 6 (averaged pass rate between 50 % and 100 %) are sufficient.

12 Lecturers

Name/First name	Company	E-Mail
Angst Markus	AtlantiQ Consulting Markus Angst, unipessoal LDA	markus@atlantiq.pt
Cuomo Marco	Cuomo IT Consulting GmbH	marco@cuomo.ch
Degen-Wendlinger Christina	Inmedis AG	c.degen@inmedis.ch
Friedrich Katharina	Katylistic, Medical Writing and Consulting	k.friedrich@katylistic.com
Item Sandra	ISS Integrated Scientific Services AG	sandra.item@iss-ag.ch
Kloess Holger	QUNIQUE GmbH	holger.kloess@quniquegroup.com
Künzi Muriel	BKS Rechtsanwälte AG	muriel.kuenzi@torneys.ch
MacDonald Darlene	Cuomo IT Consulting GmbH	darlene@cuomo.ch
Maier Michael	MMEX GmbH	mmex.gmbh@bluewin.ch
Naber Larissa	PROREGIA AG	larissa.naber@proregia.ch
Schuetz Frikart Andrea	GS1 Switzerland	andreaschuetz@frikart.com
Schwarz Nadine	meditec Consulting	schwarz@meditec-consulting.ch
Shcherba Valentina	QUNIQUE GmbH	valentina.shcherba@quniquegroup.com
Soniec Sandra	meditec Consulting	soniec@meditec-consulting.ch
Steffen Beat	Confinis AG, Project Management & Consulting	beat.steffen@confinis.com
Stehling Lutz	inmedis AG	l.stehling@inmedis.ch
Studer Erich	Mecomis GmbH, Medical Device Engineering & Consulting	erich.studer@mecomis.ch
Weiss Fabienne	Berner Fachhochschule	fabienne.weiss@bfh.ch

+ Further experts and supervisors for the semester work.

13 Organisation

Head of the CAS:

Fabienne Weiss

Phone: +41 31 848 32 15

E-Mail: fabienne.weiss@bfh.ch

CAS-Administration:

Miriam Patwa

Phone: +41 31 848 58 68

E-Mail: miriam.patwa@bfh.ch

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.

Bern University of Applied Sciences

School of Engineering and Computer Science

Continuing Education

Aarbergstrasse 46 (Switzerland Innovation Park Biel/Bienne)

2503 Biel/Bienne

Phone: +41 31 848 31 11

Email: weiterbildung.ti@bfh.ch

bfh.ch/ti/weiterbildung