Appendix to the curricula of the study programs

a CAS in Regulatory Affairs, University of Bern (CAS RA UniBE),

b CAS in Quality Management in Translational Medicine, University of Bern (CAS QM UniBE),

c CAS in Advanced Regulatory Affairs, University of Bern (CAS ARA UniBE),

e DAS in Regulatory Affairs and Quality Management, University of Bern (DAS RAQM UniBE),

f DAS in Advanced Regulatory Affairs, University of Bern (DAS ARA UniBE),

g MAS in Regulatory Affairs and Quality Management, University of Bern (MAS RAQM UniBE).

Catalogue of modules (descriptions)

Module RA1: Introduction to Regulatory Affairs with focus MD/IVD

ECTS-points	**4 ECTS-points** (incl. self-study and performance review)	**Scope**	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	Navigating the healthcare sector requires compliance with stringent regulations, underscoring the importance of a thorough understanding of regulatory affairs for medical devices. RA Module 1 introduces the regulatory landscape and provides an overview of European legislation. It covers the history, structure, interpretation, and application of the regulation and provides a comprehensive study of product qualification and classification.		
Learning objectives	The participant: • gains a basic understanding of regulatory concepts and CE-marking processes, • understands the structure of the EU Regulations on medical devices (Reg. 2017/745, MDR) and on in-vitro diagnostic devices (Reg. 2017/746, IVDR), as well as the role of harmonized standards, common specifications, and guidelines, • understands the specifics of device qualification and is enabled to perform comprehensive qualification assessments, • is familiar with the principles of MD/IVD classification and able to apply them, • is able to evaluate and select appropriate conformity assessment routes based on specific device classification and characteristics, • understands the role and responsibilities of various regulatory stakeholders, including notified bodies and economic operators.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	No prior knowledge required.		
Language	English		

Module RA2: Pre-Submission Regulatory Affairs with focus MD/IVD

ECTS-points	**6 ECTS-points** (incl. self-study and performance review)	**Scope**	150-180 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	RA Module 2 delves into the regulation of all life cycle phases from research and development to submission of a medical device with a focus on the European market. The module aims to provide participants with the skills and knowledge to identify and apply quality, safety, and effectiveness requirements of a medical device and to provide them with comprehensive knowledge on documentation requirements.		
Learning objectives	The participant: • is able to identify the applicability of individual General Safety and Performance Requirements (GSPR) for a given type of device, and to determine the type of evidence of conformity required to fulfil such GSPRs, • demonstrates proficiency in the structure and contents of technical documentations required under the EU MDR and IVDR, • can identify and apply European regulatory requirements for specific types of devices, including Companion Diagnostic IVDs, Custom-made devices (CMD), and products without medical device purpose covered by MDR Annex XVI.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A.		
Prior knowledge required	This module builds up on knowledge taught in module “Introduction to Regulatory Affairs”.		
Language	English		

Module RA3: Post-Submission Regulatory Affairs with focus MD/IVD

ECTS-points	**5 ECTS-points** (incl. self-study and performance review)	**Scope**	125-150 working hours (incl. appr. 20-25 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	Following on from the module on pre-submission regulatory affairs, RA Module 3 deals with the stages of the lifecycle of a medical device from submission to discontinuation. It provides participants with the regulatory skills necessary to introduce a medical device to the European market and to effectively monitor and manage its performance. The module also addresses the regulatory considerations and processes involved in implementing post-market changes to therapeutic products.		
Learning objectives	The participant: • is able to identify and apply MDR and IVDR requirements and best practices associated with product labeling, • understands the requirements and challenges of managing Unique Device Identification (UDI) requirements, • acquires the skills to successfully navigate the EUDAMED (European Database on Medical Devices) registration process, • understands the principles and practices of post-market surveillance (PMS) and vigilance under the MDR and IVDR, • is enabled to develop strategies for managing post-market changes while ensuring compliance and product safety.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	This module builds up on knowledge taught in modules “Introduction to Regulatory Affairs” and “Pre-Submission Regulatory Affairs”.		
Language	English		

Module QM1: Introduction to Quality Management with focus MD/IVD

ECTS-points	**5 ECTS-points** (incl. self-study and performance review)	**Scope**	125-150 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	QM Module 1 provides fundamental knowledge of systematic quality management processes and practices to ensure that a medical device meets the level of excellence required by customers and regulatory agencies throughout its entire life cycle. Participants will gain comprehensive insight into quality assurance principles and procedures applied through all life cycle phases of a medical device in accordance with ISO9001 and industry specific standards.		
Learning objectives	The participant: • gains a general understanding of quality management and its distinction from product compliance, • understand the principles and best practices in medical device industry for quality management systems and to be able to build up a QM-documentation, • develops proficiency in assessing, optimizing, and ensuring the quality of the entire value chain on the production side, including suppliers and manufacturing processes (auditing), • is able to articulate and apply key concepts in quality management, including process management and continuous product safety (ISO 13485), • demonstrates in-depth understanding of the ISO13485, MDSAP and FDA standards, • acquires the knowledge and skills to identify and manage defects within a quality management framework and product quality and systematically apply Corrective and Preventive Actions (CAPA).		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Basic understanding of process management in regulated industry or one/two years of working experience in MD/IVD field.		
Language	English		

Module QM2: Design Control with focus MD/IVD: from input to validation

ECTS-points	**5 ECTS-points** (incl. self-study and performance review)	**Scope**	125-150 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	QM Module 2 focusses on the legal and normative frameworks that ensure that medical devices meet the necessary quality, safety and efficacy standards through all phases from design to manufacturing. Participants are introduced to the critical processes that ensure that medical devices are designed, developed, and validated in a systematic and controlled manner. The module also introduces relevant principles facilitating a structured and effective approach to implementing changes in the development and manufacturing processes.		
Learning objectives	The participant: • understands the applicable requirements for an effective design process, • knows the relevant phases of design control and the respective requirements that apply, • is able to set out a plan for design and development activities and to identify the requirements the product must meet, • acquires the skills and knowledge to define, reflect and verify the output of a design process, • becomes familiar with specific approaches and analytical methods for design verification and validation, • understands the relevant principles of Change Management to implement changes in the design and manufacturing of a medical device, • is enabled to ensure a smooth transition of the design output to manufacturing (design transfer).		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	This module builds up on knowledge taught in module “Introduction to Quality Management”.		
Language	English		

Module QM3: Risk Management and Usability Engineering

ECTS-points	**5 ECTS-points** (incl. self-study and performance review)	**Scope**	125-130 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	QM Module 3 provides participants with an understanding of the purpose, methodology and regulation of risk identification, assessment and mitigation in the context of the development of medical devices. It includes a comprehensive study of relevant risk management principles, various risk analysis methods and usability regulation.		
Learning objectives	The participant: • understands the principles of usability engineering, • knows the fundamental principles and practices of risk management, • explores and applies risk-based approaches, • conducts a comprehensive study of risk analysis methodologies applicable to various domains, including product, process, and organizational aspects, • understands how to integrate risk considerations into decision-making processes, • is familiar with different risk management techniques and able to perform Failure Mode and Effects Analysis (FMEA) and Risk-Benefit-Analysis.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	This module builds up on knowledge taught in module “Introduction to Quality Management”.		
Language	English		

Module ARA1: Foreign Regulatory Affairs with focus MD/IVD

ECTS-points	**4 ECTS-points** (incl. self-study and performance review)	**Scope**	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	In this module participants will learn to navigate through foreign regulatory frameworks. The module provides an overview of the global regulatory landscape and current developments, including practical applications and best practices. The module in particular covers an introduction to the US FDA regulatory infrastructure and framework, with a focus on the expectations in pre-market submissions, including the different types of medical device submission pathways.		
Learning objectives	The participant: • acquires a high-level understanding of the global regulatory landscape including harmonization efforts, • is able to evaluate foreign legislation and regulations to ensure compliance with regulatory requirements and understands the roles of the various regulatory agencies and the regulatory framework in selected countries, • develops a fundamental understanding of how to navigate through and apply the US FDA regulations governing medical devices, • understands the different submission document types for US market access and can submit an application compliant to US FDA device regulations, • is able to draft a pre-submission packet and prepare for a pre-submission meeting, • understands the interdependency of regulatory and business considerations.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Module ARA2: Combination Products

ECTS-points	**3 ECTS-points** (incl. self-study and performance review)	**Scope**	75-90 working hours (incl. appr. 12-15 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	Combination products include a combination of a medical device, and a drug (and/or biologic – only US). ARA Module 2 aims to provide participants with knowledge of the regulatory requirements for each component of a combination product including their similarities and differences. The module will additionally provide participants with an understanding of combination product market launch considerations.		
Learning objectives	The participant: • understands the definitions in the EU and the US and familiarize with the regulatory frameworks, • understands regulatory requirements for each component of a combination product including their similarities and differences, • understands use cases of combination products (e.g. diagnostic or therapeutic), • understands the types and use cases of Combination Products, • understands important standards and guidelines, • knows how to categorize and distinguish different medical device software (e.g. standalone, embedded, accessory, etc.) familiar with new regulatory developments (e.g., AI Act EU), • sensitized to moral and ethical issues (algorithm bias, representative data, hallucination, etc.), • knows how to apply transition timelines in EU, • knows how to structure a technical documentation (eCTD vs. MDR Annex II, STED, ToC, etc.).		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Module ARA3: Digital Health Technologies and Security

ECTS-points	**4 ECTS-points** (incl. self-study and performance review)	**Scope**	100-120 working hours (incl. appr. 16-20 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	ARA Module 3 provides participants with specialized knowledge regarding the regulation of medical device software in Europe and the USA. Since it is difficult to regulate a technical domain one has scant knowledge of, the module will introduce the participants to the foundations of modern software engineering with a special focus on which aspects to watch for to ensure smooth approval of even the most complex software-based medical devices. The module offers an overview of the regulatory framework for medical device software, the software development lifecycle, and software quality management. Participants will also understand specialised regulations regarding the safety and cybersecurity of devices based on artificial intelligence.		
Learning objectives	The participant: • learns about digitalisation/digital transformation, cybersecurity, security by design approach, modern software engineering methods, European and US regulatory frameworks, and artificial intelligence. • becomes familiar with digitalisation/digital transformation and its impact on the medical device industry • becomes familiar with areas of application, opportunities, and risks of medical device software and digital health in general, • understands cybersecurity concepts (difference between connected and unconnected devices), including key cryptographic processes and techniques and their application areas, • understands the unique nature of cybersecurity risk and its assessment and mitigation, • understands modern approaches to software development and their application to ensure the cybersecurity of connected medical devices, • understands general trends, qualifications, and classification of medical device software, • understands the regulatory requirements in terms of cybersecurity and data protection (quality management system, risk management, software life cycle (e.g. IEC 62304), GDPR (privacy by design and default), FDA Cyber Security in Medical Devices Guideline, and data storage and management, etc. • understands the role of the legislator and the public authorities (Swissmedic, BACS, FOPH, FDPIC, notified bodies) within data protection and cybersecurity, but also the role of care providers (hospitals, etc.) • is familiar with basic terms, fundamental approaches and applications in the fields of Artificial Intelligence and Machine Learning in life sciences (e.g. prediction, classification, time series analysis, natural language processing, generative algorithms, robotics), • develops a comprehensive understanding of the business expert's role and the conditions relevant for success in Machine Learning/AI projects.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	Comprehensive knowledge of Swiss and EU regulatory affairs required.		
Language	English		

Module ARA4: Research and Development with focus MD

ECTS-points	**2 ECTS-points** (incl. self-study and performance review)	**Scope**	50-60 working hours (incl. appr. 8-10 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	Regulatory affairs and quality management are integral to the design and development throughout all phases of the product life cycle. This module focuses preclinical processes that the performance of a medical device is sufficiently robust so that clinical trials can be considered and are likely to be granted by an ethics commission and an office of regulatory affairs.		
Learning objectives	The participant: • knows the scientific aspects and principal steps of the research, discovery and development process, • understands the process of prototyping and its distinction to production, • knows the requirements for different product types, including material selection, biomarkers, and hit and lead compounds.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	A background in natural science, engineering or medicine, or, relevant fundamental scientific-medical knowledge required.		
Language	English		

Module ARA5: Clinical Trial Design and Performance

ECTS-points	**6 ECTS-points** (incl. self-study and performance review)	**Scope**	150-180 working hours (incl. appr. 24-30 in person hours)
Performance review	Quizzes and/or exercises and/or teamworks and written or oral final exam	**Attendance requirement**	80 %
Description and contents	Clinical trials are designed to test how well new medical approaches work in humans. The prerequisites for such scientific studies, the understanding of the pathophysiology of the underlying diseases and the definition of quantifiable endpoints by clinicians as well as the analyses of data by statisticians will be considered.		
Learning objectives	The participant: • knows the basics of clinical trial design and performance process, • understands relevant clinical endpoints and their differences, • understands the different study designs, the prevention of bias and the basic principles of statistics, • is familiar with the conduct of clinical trials and to know how to report results, • understands the structure of a study protocol, • understands the principles of data acquisition, data quality and data monitoring, • knows what regulatory and ethical issues need to be considered when requesting permission to perform a clinical trial, • recognizes the costs involved in a clinical trial and know how to estimate a budget, • understands the basic concepts of pharmacometrics and its impact in clinical trial designs.		
Didactic methods	Blended learning: face-to-face teaching, online lectures, self-study materials, group works, online activities, discussions, and Q&A		
Prior knowledge required	A background in natural science, engineering or medicine, or, relevant fundamental scientific-medical knowledge required.		
Language	English		