

# Study Plan for the Study program Medical Device Regulatory Affairs and Quality Assurance



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**UNIVERSITÄT  
BERN**

20.03.2020

The study program Medical Device Regulatory Affairs and Quality Assurance is a continuing education program leading to the award degrees, "Diploma of Advanced Studies in Medical Device Regulatory Affairs and Quality Assurance, University of Bern (DAS MDRAQA)", and "Master of Advanced Studies in Medical Device Regulatory Affairs and Quality Assurance, University of Bern (MAS MDRAQA)".

The legal basis is the Regulations of the Faculty of Medicine for Continuing Education and the Reglement für die Weiterbildungsstudiengänge in the Regulation of Medical Devices and In-Vitro Diagnostic Medical Devices from 22.04.2020.

## 1. Objectives of the Study Programs

Objectives

**DAS MDRAQA:** The program is designed to provide participants with comprehensive knowledge of the principle and general European medical device regulations and their application, in addition to medical device design and development processes, quality assurance, risk management. The program additional aims to provide participants with comprehensive knowledge in one specialty area of medical device regulation such as the regulation of software, the regulation of combination products, the clinical evaluation of medical devices or international regulatory affairs.

**MAS MDRAQA:** The program is designed to provide participants with comprehensive knowledge of the European medical device regulations and their application, including the specialty areas of: the regulation of software, the regulation of combination products, the clinical evaluation of medical devices or international regulatory affairs. The program aims to provide participants with an introduction to medical device design and development processes and comprehensive understanding of medical device quality assurance and risk management. Additionally the program aims to provide participants with complementary skills in leadership and management.

## 2. Scope, objectives and content of the programme elements

Scope	<p>The program of Advanced Studies in Medical Device Regulatory Affairs and Quality Assurance offers career specialised training for graduate students based on the newly implemented European Medical Device Regulations (MDR). The program aims to prepare students to work as a regulatory officer or quality manager within a medical device company or regulatory body. The program also targets those from complementary disciplines such as entrepreneurship, research and development, and management, seeking comprehensive and practical knowledge of the regulation of medical devices according to the new European MDR. Participants are expected to acquire the knowledge and skills necessary to manage the regulation and quality assurance process of a medical device throughout its lifecycle and to produce the documentation required to obtain regulatory approval within the EU.</p> <p>The DAS MDRAQA program includes a minimum of 37 ECTS-Credits and is composed of at least 33 ECTS-Credits from course work and a DAS-thesis of 4 ECTS-Credits. The program requires the completion of Modules 1-6 and at least one of Modules 7 – 10.</p> <p>The MAS MDRAQA program includes a minimum of 60 ECTS-Credits and is composed of at least 44 ECTS-Credits from course work and a MAS-thesis of 16 ECTS-Credits. The program requires the completion of Modules 1 -10 and at least one of Modules 11-12.</p> <p>Each module commences with preliminary online learning and introductory presence lectures. The contents are thereafter deepened via E-Learning in the form of theoretical documents, Podcasts, interactive exercises, case studies, group works as well as forums. Case studies introduced in modules 1 and 2 are used as teaching examples throughout the following Modules. Additional presence lectures and presence workshops are held throughout the course (total duration of 1.5 – 6 course days) to facilitate participants learning and to encourage collaborative work.</p>
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Language	<p>The language of instruction in all modules is English. All performance assessments (performance tests, written work, presentations) are conducted in English.</p>
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## 3. Module descriptions

MAS MDRAQA:	<p>Modules M1–M9 are mandatory. Two modules out of M10–M12 have to be selected.</p>
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DAS MDRAQA:	<p>Modules M1–M6 are mandatory. One modules out of M7–M10 has to be selected.</p>
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Module 1

### **Research and development Processes**

2 ECTS points

Module 1 provides an overview of medical device research, development and verification processes in order to provide an understanding of the regulatory environment.

Module 2

### **EU Medical Device Regulations Part A**

6 ECTS points

Module 2 introduces the regulatory landscape and the European Medical Device Regulations (MDR). It presents the history, structure, interpretation and application of the MDR and provides a complex study of medical device classification. The Module is divided into two submodules:

- Submodule 1: Introduction to the medical device regulations (3 ECTS)
- Submodule 2: Product description and classification (3 ECTS)

Module 3

### **EU Medical Device Regulations Part B**

6 ECTS points

Module 3 focuses on the content, interpretation and practical application of the general safety and performance requirements (GSPR) and technical documentation requirements as outlined in the MDR. The module aims to provide participants with the skills and knowledge to identify the applicable GSPRs for a given device and to provide them with comprehensive knowledge of medical device documentation requirements and technical file preparation skills. The Module is divided into two submodules:

- Submodule 1: General Safety and Performance Requirements (3 ECTS)
- Submodule 2: Technical Documentation (3 ECTS)

Module 4

### **EU Medical Device Regulations Part B**

6 ECTS points

Module 4 aims to complete the study of the general EU medical device regulations. The module is comprised of three submodules

- Submodule 1: Labelling and instructions for use (2 ECTS)
- Submodule 2: Conformity assessment and product registration (2 ECTS)
- Submodule 3: Post market surveillance and post market clinical follow up (2 ECTS)

Module 5

### **Quality Management**

5 ECTS points

Module 5 provides a comprehensive and practical study of quality assurance as it pertains to medical devices. It aims to provide participants with knowledge of the quality management standardizing documents, quality management systems, quality certification, and quality processes.

Module 6

### **Risk Management and Usability Engineering**

5 ECTS points

Module 6 aims to provide participants with an understanding of the purpose, methodology and regulation of medical device risk identification, assessment and mitigation. The module includes a comprehensive study of usability regulation, assessment and risk assessment.

Module 7

### **Clinical Evaluation for Medical Devices**

4 ECTS points

Module 7 aims to provide participants with an understanding of the clinical evaluation required to demonstrate the device's intended purpose without exposing users and patients to unnecessary risks. The module covers the collection and reporting of pre- and post-market clinical data including safety reporting. The module additionally aims to provide participants with knowledge of good clinical practice.

Module 8

### **Digitalisation, Software and Cybersecurity**

3 ECTS points

Module 8 aims to provide participants with specialized knowledge pertaining to the regulation of medical software. Module 8 focuses on the regulatory framework for medical device software. The module provides an overview of the regulatory framework for medical software, software development lifecycle and the management of software quality. The module additionally provides participants with an understanding of specialized regulations and safety considerations pertaining to cybersecurity and devices based on artificial intelligence.

Module 9

### **International Regulatory Affairs**

3 ECTS points

Module 9 aims to provide participants with an overview of international regulatory affairs with a particular focus on the US and Asian medical device regulations and path to market.

Module 10

### **Combination Products**

3 ECTS points

Combination products include a combination of a medical device, and/or drug and/or biologic. Module 10 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.

Module 11

### **Market Access and Pricing**

2 ECTS points

Module 11 aims to introduce participants to the complementary topics of health economics & outcomes research, pricing & reimbursement and health policy, including health technology evaluation. In a case study, the optimal price level for a product as well as a launch sequence to optimise profitability will be developed.

Module 12

### **Leadership, Team and Project Management for Regulatory Experts**

2 ECTS points

Regulatory and quality experts inhabit critical roles that rely on successful intra- and inter-department communication, the management and motivation of teams and the management of tasks and projects. Module 12 aims to provide students with the skills and confidence to work successfully within a regulatory team and within a regulatory managerial position.

Master thesis

### **MAS MDRAQA**

16 ECTS points

In the MAS MDRAQA thesis, participants will describe an in depth critical evaluation of a medical device regulation, its implementation or of a quality assurance regulation, strategy or activity, or, provide a description of the application of medical device regulations to a novel medical device or new technology.

Details are provided in the document "Guidelines.MAS MDRAQA.Thesis")

Diploma thesis

### **DAS MDRAQA**

4 ECTS points

In the DAS MDRAQA thesis, participants will provide a critical evaluation of a medical device regulation, its implementation or of a quality assurance regulation, strategy or activity, or, provide a description of the application of medical device regulations to a novel medical device or new technology.

Details are provided in the document "Guidelines.DAS MDRAQA.Thesis")

#### 4. Performance Assessment in the Study Program

Performance Assessment      The performance assessment for each module will be conducted either on site or via the e-learning platform. Performance assessments will include the following elements:

- Oral or written final examination and
- Quizzes and/or
- Exercises and/or
- Presentations

A final grade will be given for each of the modules.

The Study Commission decides on the passing and awarding of the certificate on the basis of the evaluation of the performance certificates and the fulfilment of further performance requirements.

Further details are regulated by the guidelines of the Study Commission on performance assessment.

#### 5. Final Provisions

Entry into force      This study plan comes into effect on 1 May 2020.

20.03.2020      Decided by the study commission:

The Chairman



Prof. Dr. Jürgen Burger

22.04.2020      Approved by the Faculty of Medicine:

The Dean



Prof. Dr. Hans-Uwe Simon