

MAS/DAS

Medical Device Regulatory Affairs and Quality Assurance

sitem-insel School for Translational Medicine and Biomedical Entrepreneurship

Registration Deadline:
15th July



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sitem-insel School

Connecting the best minds.

University of Bern and sitem-insel AG, in a unique collaboration, offer continuing education programs to address unmet professional needs in the medical industry and to elevate expertise in the knowledge transfer from scientific and medical needs. The MAS in Medical Device Regulatory Affairs and Quality Assurance connects students with experts in the medical device industry, and helps them carve out a spot in a growing field where professionals are highly in-demand.

Connecting the Best Minds

The ambitious association between the University of Bern and sitem-insel AG connects with other experts in the field of translational medicine, life science and medical device regulations, providing you with admission to an excellent network.

Lecturers and supervisors of this study program are professionals with high expertise – they bring many years of experience from industry, research, academia and life sciences. In addition, you gain access to hightech facilities and services.

The program targets graduates and professionals who would like to advance their career in the medical device regulatory industry.



The study program

Regulatory specialists play a key role in bringing novel medical devices to the market. They require a breadth of managerial and interpersonal skills in addition to technical, clinical and also legal knowledge.

The study program offers specialized training for graduates who are interested in increasing their career prospects in the regulation or quality control of medical devices.

It also provides extensive in-depth expertise for mid-level professionals looking to raise their proficiency to the next level, while allowing them to explore different career options.

Master and Diploma of Advanced Studies

The program offers two pathways, allowing to specialise according to your own professional background and desired career path.

Due to its modular-designed structure, you are further able to change inbetween courses and pursue a higher degree.

Upon successful completion, you will gain a MAS or DAS of the University of Bern, an internationally accredited degree.



Learning Environment

All study programs are conceptualized as extra-occupational, so that students can combine professional work with their studies. The program is taught in a blended learning environment and utilises e-learning, peer learning and interactive discussions with experts, guest lecturers, workshops and case studies.

Through a customised-designed approach and individualized support, you can expect large flexibility navigating your studies with your professional and private life.

Small class sizes allow for large flexibility while permitting participants to closely profit from the teachers and supervisors expertise.

Industry-Based Learning: Work placement

The MAS study program includes an optional work experience during the second year, where you can put theory into practice and gain hands-on experience at a top company in the medical device industry.

University of Bern

Located in Switzerland's capital and part of the UNESCO world heritage, the University of Bern is internationally recognised and can trace its roots back to 1528. The University of Bern provides a high quality infrastructure, while sitem-insel AG is located close to the Inselspital - the University Hospital.

Switzerland is one of the most important research nations in the world. **Become part of the medical future.**

Diploma of Advanced Studies

The Diploma of Advanced Studies (DAS) focuses on modules 1 to 6 and one additional one chosen from module 7 to 9 over a minimum duration of 14 months.

While the core studies provide a solid foundation, the advanced studies give the opportunity to specialise within your professional goals.

Core Studies

- Module 1 - Research and Development Process
- Module 2 - EU Medical Device Regulations Part A
- Module 3 - EU Medical Device Regulations Part B
- Module 4 - EU Medical Device Regulations Part C
- Module 5 - Quality Management
- Module 6 - Risk Management and Usability Engineering

Advanced Studies

Choose one out of three modules

- Module 7 - Clinical Evaluation for Medical Devices
- Module 8 - Digitalisation, Software and Cybersecurity
- Module 9 - International Regulatory Affairs

DAS Thesis



Master of Advanced Studies

The Master of Advanced Studies (MAS) is an extensive and in-depth course that builds on the foundation of medical device regulations and elevates to proficiency through advanced studies.

With three additional electives, this 24-month course will provide you with the knowledge and confidence to build and progress your career and an industry where professionals are sought after.

Core Studies

- Module 1 - Research and Development Process
- Module 2 - EU Medical Device Regulations Part A
- Module 3 - EU Medical Device Regulations Part B
- Module 4 - EU Medical Device Regulations Part C
- Module 5 - Quality Management
- Module 6 - Risk Management and Usability Engineering

Advanced Studies

- Module 7 - Clinical Evaluation for Medical Devices
- Module 8 - Digitalisation, Software and Cybersecurity
- Module 9 - International Regulatory Affairs

Elective Studies

Choose two out of three modules

- Module 10 - Combination Products
- Module 11 - Market Access and Pricing
- Module 12 - Leadership, Team and Project Management for Regulatory Experts

MAS Thesis

The MAS Thesis will be written during the optional industry based learning placement or within your own professional environment

Industry-Based Learning (IBL) Work placement

The IBL is a unique program that allows for a hands-on experience within the medical device regulation industry during the second year of the MAS Medical Device Regulatory Affairs and Quality Assurance.

For this purpose, we work together with top companies in Switzerland - so you have the opportunity to take a paid internship to apply theory into practice.

Partner Companies in 2023

Novartis

Johnson & Johnson

Straumann Group

Mathys Ltd Bettlach

SQS - Swiss Association for Quality and Management
Systems

Ypsomed AG

Decomplex

confinis

ISS AG, Integrated Scientific Services

Depuy Synthes



Admission

Applications are accepted throughout the year until 15th August or until all available places are filled.

Requirements

Applicants must hold a BSc or higher degree in engineering, computer science, pharmacy, life science, health management, medicine, law or other relevant scientific discipline. No professional experience is required. Admission *sur Dossier* by the study commission is possible.

Fees

Diploma of Advanced Studies	CHF 23 100.–
Master of Advanced Studies	CHF 31 500.–

Instalment plans are available.

Additional Information

The study program is designed for a duration of 14 to 24 months. The course language is English. On-site classes are held at sitem-insel, the Swiss Institute for Translational and Entrepreneurial Medicine in Bern, Switzerland. The program allows for flexibility in terms of distance learning and on-line participation.

Some of the nationalities represented in the program: Switzerland, UK, Germany, France, Italy, Russia, Malaysia, Greece, India, Spain, China, etc.

Participants will be registered at the University of Bern. Upon successful registration, the participants will get a campus account. MAS students will receive a UNICARD and have access to sports, childcare and counselling facilities offered by the University of Bern.

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May 2023