Swiss Institute for Translational and Entrepreneurial Medicine

sitem-insel

UNIVERSITÄT BERN

MAS / DAS

Medical Device Regulatory Affairs and Quality Assurance

sitem-insel School for Translational Medicine and Biomedical Entrepreneurship

sitem-insel School
Connecting the best minds.

sitem-insel School offers continuing education programs to specialists in industry, hospitals and academia in the field of translational medicine and biomedical entrepreneurship. We share our expertise in medical device regulatory affairs and provide medical doctors with the necessary skills to take a leading role in the artificial intelligence-driven transformation of medicine.

Science meets Entrepreneurship
In an unique collaboration between the University of Bern and sitem-insel AG, sitem-insel School was founded to address unmet professional needs in the medical industry and to elevate the expertise in knowledge transfer from scientific and medical fields, as well as entrepreneurial skills. This partnership, in collaboration with other experts in the field of entrepreneurship, translational medicine and life science, provides you with access to an excellent network.

Learning Environment
All study programs are conceptualized as extra-occupational programs that can be reconciled with professional work. The program is taught in a blended learning environment and utilises e-learning, peer learning and interactive discussions with experts, on site lectures, workshops and case studies.

Small class sizes allow for large flexibility while at the same time permitting participants to profit from the lecturers expertise.

Connecting the Best Minds
Our programs are targeted at graduates and professionals who would like to advance their expertise and contribute to the success of the patient care and medical industry. Our highly specialised lecturers and module leaders come from various backgrounds: research and development orientied private companies, scientists from universities, ETHs and FHS, collaborators from regulatory agencies, financial experts and clinicians.

The study program

Regulatory specialists are integral to bringing novel medical devices to market. They require a breadth of managerial and interpersonal skills in addition to technical, clinical and legal knowledge. The program of Advanced Studies in Medical Device Regulatory Affairs (RA) and Quality Assurance offers career specialised training for graduate students based on the newly implemented European Medical Device Regulations (MDR). In addition, the course provides participants with comprehensive knowledge and practical experience in: international RA, quality management, risk management and usability, the clinical evaluation of medical devices, technical writing, cybersecurity and the regulation of medical software and market access.

Participants
The program addresses university graduates interested in commencing a career in the regulation or quality control of medical devices. The program prepares 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.

Learning Environment
The program is taught in a blended learning environment, allowing for flexible education that complements part time professional work. The courses utilise e-learning, peer learning and interactive discussions with experts, on site lectures, workshops and case studies. The MAS program includes an optional industry based learning placement in the second year of study. Class sizes are limited to ensure high quality personal education that fosters communication and professional networking. It is possible to complete the program remotely.

The modules

Core Studies

M1 Research and Development Processes
Module 1 provides an overview of medical device research, development and verification processes in order to provide understanding of the regulatory environment.

M2 EU Medical Device Regulations Part A
Module 2 introduces the regulatory landscape and the European Medical Device Regulations (MDR). It focusses on the structure, interpretation and application of the MDR and includes a complex study of medical device classification.

M3 EU Medical Device Regulations Part B
Module 3 focusses on the interpretation and practical application of the general safety and performance requirements and technical documentation requirements as outlined in the MDR.

M4 EU Medical Device Regulations Part C
Module 4 is comprised of three submodules covering the regulation of labelling and instructions for use, conformity assessment and product registration, and post market surveillance and post market clinical follow-up.

M5 Quality Management
Module 5 provides a comprehensive and practical study of quality assurance as it pertains to medical devices.

M6 Risk Management and Usability Engineering
Module 6 teaches 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.

Advanced Studies

M7 Clinical Evaluation for Medical Devices
Module 7 concentrates on the clinical evaluation required to demonstrate the device's intended purpose without exposing users and patients to unnecessary risk. The module covers the collection and reporting of pre- and post-market clinical data including safety reporting.

M8 Digitalisation, Software and Cybersecurity
Module 8 focuses on the regulatory framework for medical device software. It provides an overview of the software development lifecycle and the management of software quality. The module additionally covers cybersecurity and the regulation of devices based on artificial intelligence.

M9 International Regulatory Affairs
Module 9 provides an overview of international regulatory affairs with a particular focus on the US and Asian medical device regulations and path to market.

Elective Studies

M10 Combination Products
Combination products include a combination of a medical device, and/or drug and/or biologic. Module 10 will cover the corresponding regulatory requirements for each component, their similarities and differences. The market launch of a combination product on the market will be discussed.

M11 Market Access and Pricing
Module 11 introduces 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.

M12 Leadership, Team and Project Management for Regulatory Experts
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.

Admission

Applications are accepted throughout the year until 31 August 2021 or until all available places are filled.

Requirements
The requirements are those of the University of Bern. Admission *sur Dossier* by the study commission is possible.

DAS and MAS
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.

Fees
The fee for the MAS in Medical Device Regulatory Affairs and Quality Assurance is CHF 31'500.00 and for the DAS program CHF 23'100.00.

Additional Information
The study program starts in September 2021 and is designed for a duration of minimum 4 semesters (MAS) and 14 to 20 months (DAS). The course language is English. On-sight classes are held at sitem-insel, the Swiss Institute for Translational and Entrepreneurial Medicine in Bern, Switzerland. E-learning courses may be performed at home. In case of University closures due to Covid-19, planned on-sight lessons will be held in virtual classrooms.

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

Faculty
The faculty is comprised of leading experts from industry and academics, and includes specialists from regulatory agencies with extensive international experience in the regulation and quality assurance of medical technologies.

Contact

Whether you are yet to decide, are already set on your choice, or have a general inquiry - we welcome you to contact us anytime. We understand the importance of continuing education and help you to make sure we are your right choice.

Point of contact

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