Training purpose

The use of medical products is subject to legal requirements throughout the entire product life cycle. Knowledge of the increasingly complex subject matter of medical device law is indispensable from the very first implementation of the idea, during development, operation and service.

Aims of the course

In the certificate course on medical device law you will learn about the regulatory framework for medical device products. You will understand the conditions, interrelationships and dependencies between the corresponding directives, laws and standards.

You will be enabled to successfully and timely take necessary measures to comply with the legal requirements.

In addition, the certificate course offers the opportunity to establish contacts with students as future professionals.

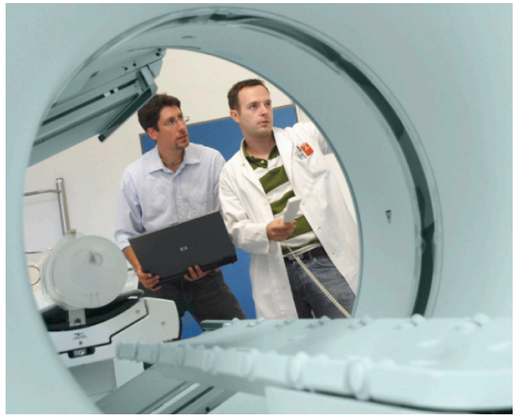
Structure of the course

The structure of the certificate course is based on the process that must be passed through in order to bring medical devices to market. It consists of 10 different seminar days, which can also be booked individually.

The seminar days consist of lectures and practical parts, e.g. group work. After successful participation in the separately held examinations on all seminar days, you will receive a certificate from FAU.

FRIEDRICH-ALEXANDER UNIVERSITÄT ERLANGEN-NÜRNBERG

ZENTRALINSTITUT FÜR MEDIZINTECHNIK



Sign up

via: www.zimt.fau.eu/wissenschaft/medical-devices-law-seminar/

Organizer

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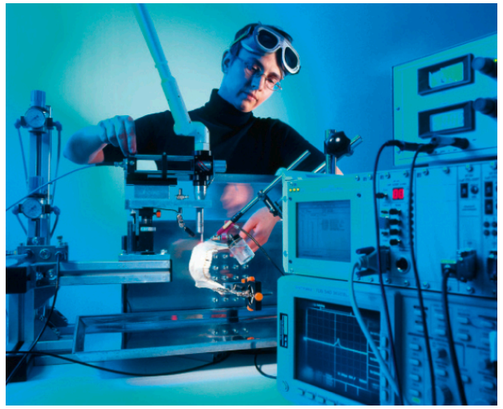
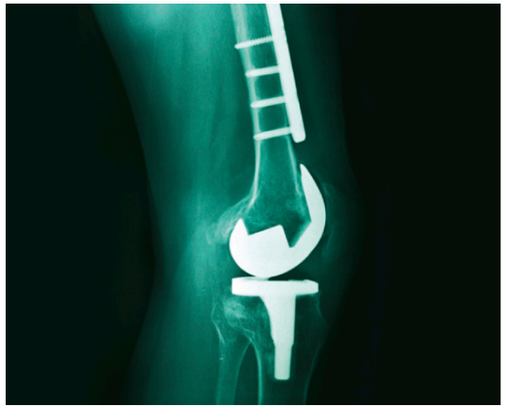
Certificate Course Medical Device Regulation





For further information visit:
www.zimt.fau.eu/wissenschaft/medical-devices-law-seminar/

Certificate course MDR Overall offer

The certificate course on medical device regulation offers you a comprehensive insight into medical device law in ten seminar days. The structure of the course is based on the process that must be passed through in order to bring medical devices to market.

Target groups

- Employees in the medical device industry
- Newcomers to the medical device industry
- Students of the Master's program in medical engineering

The certificate course in medical device law offers a combination of knowledge acquisition in a university environment with seminar character and the opportunity to establish contacts with students as future specialists.

Cooperation partners:

SIEMENS Healthineers

MEDICAL VALLEY
Europäische Metropolregion Nürnberg

Kontaktstelle für Wissens- und Technologietransfer

Forum MedTech Pharma

FRIEDRICH-ALEXANDER UNIVERSITÄT ERLANGEN-NÜRNBERG

ZiMT ZENTRALINSTITUT FÜR MEDIZINTECHNIK

Registration

The binding registration takes place online under www.zimt. fau.eu/wissenschaft/medical-devices-law-seminar/ and will be processed in the order of receipt. The number of participants is limited. It is recommended to start the certificate course with „Introduction to Medical Device Law“ and „Risk Management System in Medical Engineering", for students these are mandatory. Attendance of all 10 courses must take place within two years.

Registration deadline is one week before the course at the latest.

Introduction to the Medical Device Law
(winter and summer semester)

The introduction to medical device law provides an overview of the national legal basis and the European directives for medical devices. The path to CE marking is presented and supplemented with information on the distribution and operation of medical devices. A look beyond the European horizon rounds off the se-minar day.

Risk Management in Medical Engineering
(winter and summer semester)

The seminar day Risk management in medical techno-logy provides an overview of the contents of ISO 14971 and supplements this with methods and procedures for risk analysis and risk assessment as well as for risk management in the product life cycle.

Clinical Evaluation (winter semester)

A clinical evaluation is required for every medical de-vice to be placed on the European market. The Clinical Evaluation seminar day will deal with the approach and will also cover clinical trials according to ISO 14155.

Software for Medical devices (winter semester)

Software cannot be touched and tested like medical devices, but can still be a medical device. The seminar day Software as a medical device presents the special features of software and introduces the IEC 62304.

Introducing eMaps - our online market access guide for innovators (winter semester)

eMaps (emaps.co), a digital knowledge hub for life science innovators, is a unique ‘one stop shop’ for advice and information on key areas of market access including regulatory approval, pricing and reimbursement. It provides tailored, market specific support through adoption pathways for digital health, medtech and biotech products. The platform equips users to understand how the systems and pathways are likely to impact their innovation and helps define value pro-position. The suite of UK modules has just launched, shortly to be followed by USA and Germany.

Digital Health (summer semester)

The Digital Health seminar day will highlight current trends in networking in the healthcare sector from a medical law perspective. In addition to political and regulatory aspects, normative requirements will be examined. Using examples from the industry, the seminar day offers an attempt to distinguish and classify between software and medical devices.

Medical Devices in the Field (summer semester)

Even after fulfilling the requirements to bring medical products to the European market, there are still various regulations to be considered. The seminar day Medical devices on the market, in operation and application introduces the requirements for manufacturers, operators and users in this phase of the product life cycle.

Other Countries, other Customs (summer semester)

A medical device manufacturer must have a thorough knowledge and understanding of the regulatory requirements of the target markets to ensure that its products are compliant and that market access is guaranteed. Although the requirements vary from country to country, there are also many similarities that become apparent when medical device manufac-turers are introduced to the main markets.

Medical Device Regulation - MDR (summer semester)

The seminar day gives an overview of the conditions of the MDR and which legal aspects have to be fulfilled. The requirements for safety and performance, clinical data collection, product registration, product classifi-cation and the necessary procedures will be discussed.

Usability Engineering for Medical devices (Winter Semester)

This seminar day for medical devices is an introduction to usability engineering: describing the definition, concept, standard requirements and steps of the usability engineering process in accordance to DIN EN 62366-1 (IEC 63266-1) and IEC 60601-1-6. Furthermore, the seminar will also focus on the methods of the usability engineering.

Pricing information

8 teaching units per single seminar topic:

346,00 Euro (incl. VAT)

90 teaching units (complete course, including exami-nation fee):

3.300,00 Euro (incl. VAT)

Discount

25% discount for members of ZiMT, ASQF e.V. and Medical Valley EMN e.V. or 10% discount for members of Forum MedTech Pharma e.V. For Doctoral students a fee of 70 Euros per course is required. Doctoral students enrolled at FAU receive a 50% discount.

HMDA students participate in all 10 teaching units free of charge. The other students of the Master’s program in medical engineering are allowed to particpate in 6 teaching units free of charge. For each additional course a fee of 35 Euros is required.

Examination

one time: 186,00 Euro

For the university certificate, all 10 seminar days must be attended within 2 years, the exams are taken separately.

Cancellation

Cancellation is possible free of charge up to one week before the start of the event. After that or in case of non-appearance of the participant, the entire partici-pation fee must be paid.
Students can only rebook a free seminar day once for the obligatory events.
The organizer is entitled to cancel the seminar for eco-nomic or organizational reasons. In this case, partici-pation fees already paid will be refunded.

Certificate Course Medical Device Regulation