UNIVERSITY OF LÜBECK

LÜBECK UNIVERSITY
OF TECHNOLOGY

UNIVERSITY CERTIFICATE

Mr. Bastin Winkel

receives the

Universitycertificate Manager Regulatory Affairs

the University of Lübeck and the Technical University of Lübeck.

He participated in the following courses between January 15, 2024, and December 1, 2024, and successfully passed all exams. The workload for all three courses combined is 5 credit points (according to the European Credit Transfer System).

- Regulatory requirements for medical devices System
- requirements for medical devices
- Product-specific requirements for medical devices

The overall grade is 2.0 (good).

The certificate is valid with the attached supplement.

Lübeck, December 6, 2024

Folker Spitzenberger

Prof. Dr. Folker Spitzenberger, M.D.R.A.
Centre for Regulatory Affairs in Biomedical Sciences

Lübeck University of Applied Sciences

Thorsten M. Buzug Bezug

Prof. Dr. Thorsten M. Buzug Institute
of Medical Technology
University of Lübeck

Information about the university certificate Manager/in Regulatory Affairs of the Technical University of Lübeck and the University of Lübeck

Course content

After successfully completing all three courses, participants will be qualified for a career in regulatory affairs in medical technology. This includes basic and in-depth skills regarding regulatory requirements for medical devices for approval in the European Economic Area. Participants will be able to deal with regulatory requirements in a business context and plan and implement the necessary processes. They will be familiar with the key approval processes for medical devices and in-vitro diagnostics at the EU level and will be able to solve the associated complex problems in business practice. They will also be familiar with the essential requirements of Regulation 2017/745 (MDR) and Regulation 2017/746 (IVDR), as well as specifications for placing medical devices on the market in relevant international markets such as North and South America and Asia. Participants will have acquired skills regarding the requirements of a quality management system according to ISO 13485, risk management according to ISO 14971, and usability according to IEC 62366-1. Participants will gain an overview of the regulatory requirements for clinical trials and will be able to develop and structure a clinical evaluation based on the requirements of MEDDEV 2.7/1 Revision 4. They will understand the requirements for medical electrical devices and medical electrical systems based on the IEC 60601 family of standards and IEC 61010 for laboratory equipment. Furthermore, participants will have acquired the necessary skills with regard to the requirements of IEC 62304 medical device software and software lifecycle processes. Furthermore, participants will have acquired specialist knowledge of the health software requirements of IEC 82304-1 regarding software as a medical device, including medical mobile applications and other health software (outside the scope of the Medical Devices Act). They will be able to describe the fundamentals of the regulatory and legal requirements for sterilization and biocompatibility.

Main topics

Regulatory requirements for medical devices

1. Legal requirements for medical devices in the European Economic Area
2. Legal requirements for in vitro diagnostic medical devices in the European Economic Area
3. Authorisation and registration of medical devices outside the European Economic Area
4. Regulatory requirements for medical devices in the USA

System requirements for medical devices

1. Quality management systems for medical devices according to ISO 13485
2. Requirements for risk management systems according to ISO 14971
3. Requirements for the usability of medical devices according to IEC 62366-1
4. Clinical evaluation and clinical testing of medical devices

Product-specific requirements for medical devices

1. Electrical safety requirements according to IEC 60601 and IEC 61010
2. Requirements for software as a medical device according to IEC 62304
3. Requirements for health software according to IEC 82304-1
4. Requirements for the sterilization and biocompatibility of medical devices

Learning arrangement

All three Regulatory Affairs for Medical Devices courses were conducted entirely online.

Participants were supervised by a qualified team of experts using the Moodle learning environment.

Proof of performance

All three courses were successfully completed with a graded final test (online test without proof of identification). The overall result was calculated from the results of the three

Individual courses determined.