

Registration, contact and further information

Website and registration

Please register before September 7, 2016 at www.ihk-schleswig-holstein.de/lisa
Programme details may be subject to change.

Contact

IHK zu Lübeck
Dirk Hermsmeyer
Phone +49-451-6006-191
hermsmeyer@ihk-luebeck.de

Attendance fee

50 EUR (including refreshments and lunch).

Discounts

Attendance fee is 30 EUR for representatives of member organisations of the BioMedTec Science Campus.
Students are exempt from fees.
A valid student-ID is required at registration.
All participants must register.

Life Science Nord e.V.

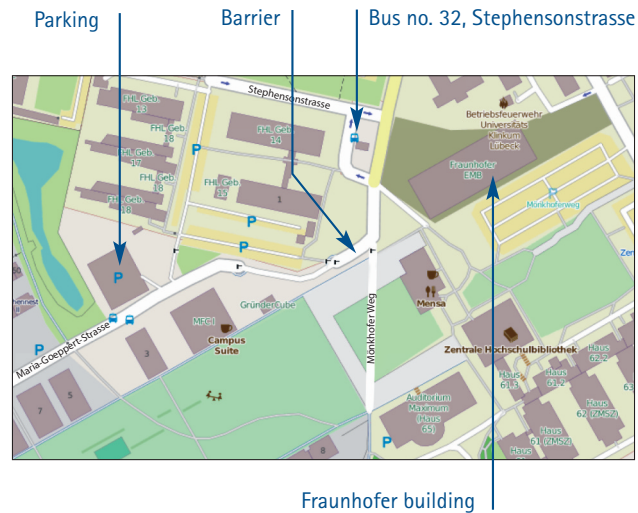
is one of the leading life science networks in Europe. In over 500 biotech/pharma and medical technology companies and numerous research institutes, 20,000 highly qualified professionals develop innovative medicines, medical products and services in Hamburg and Schleswig-Holstein. More than 220 of these companies and organisations are members of Life Science Nord e.V. In cooperation with the cluster management, the association offers its members additional advantages by means of a partner programme.

www.lifesciencenord.de

Note: With registration I agree to the organisers using and storing my personal data for the organisation of this event.
Personal data will not be forwarded to third parties.

Location

Fraunhofer Research Institution for Marine Biotechnology
(Fraunhofer EMB)
Mönkhofer Weg 239a
23562 Lübeck (Germany)



Directions

A limited number of parking spaces is available in front of the building (access via Mönkhofer Weg). Further free parking (from 8 o'clock) is available in the parking deck opposite Maria-Goeppert-Strasse 1 (about 200 m walk from the Fraunhofer building). Please use the password "Lübecker Sommerakademie Medizintechnik" at the parking deck gate. **PLEASE NOTE:** Car access from Mönkhofer Weg to Maria-Goeppert-Strasse is blocked. The parking deck is accessible from Berliner Allee (B 207, west of the campus) via Maria-Goeppert-Strasse.

Further parking is available on campus where indicated in the above map (P), but may be busy.

Bus no. 32 goes from Lübeck central bus station to bus stop Stephensonstrasse (200 m walk from the conference building, the bus ride takes about 16 min).

Accommodation

Hotel Excelsior Lübeck
www.hotel-excelsior-luebeck.de

Klassik Altstadt Hotel Lübeck
www.klassik-altstadt-hotel.de

Atlantic Hotel Lübeck
www.atlantic-hotels.de/luebeck

Park Inn by Radisson Lübeck
www.parkinn.de/hotel-luebeck



LSA2016

Lübeck Summer Academy on Medical Technology Medical Devices – How Do We Ensure Patient Safety?

September 14, 2016
BioMedTec Wissenschaftscampus
Lübeck, Germany

Venue: Fraunhofer Research Institution for Marine Biotechnology



In cooperation with



Welcome to LSA2016!

Medical Devices – How Do We Ensure Patient Safety?



It started with the so-called breast implant scandal. The founder of Poly Implant Prothèse (PIP) was convicted of aggravated fraud. Four other defendants, former PIP executives or managers, were also found guilty and given jail sentences. The PIP scandal had an immense impact on the revision of the regulatory framework for medical devices in the EU in order to avoid any harm for patients and users of medical devices in future. Manufacturers, Notified Bodies and competent Authorities are directly affected by the revision and implementation of first immediate actions concerning the control of Notified Bodies and their cooperation with manufacturers. Now that the Regulation on medical devices will enter into force and will be legally binding for all manufacturers of medical devices we discuss how the new requirements may ensure and improve patient safety. During LSA2016 we collect statements from stakeholders with all relevant backgrounds and discuss the important aspect of patient safety from different perspectives in two panel discussions.

In its fifth year, LSA gathers expert speakers to shed light on and discuss regulatory affairs around medical devices. They are of utmost importance to manufacturers, dealers, and importers, as well as to developers and medical research.

For those among you who are participants of the online course 'Regulatory Affairs for Medical Technology' (www.oncampus.de/medizintechnik) LSA2016 provides an excellent opportunity to meet your classmates face-to-face in the 'real world'. You are most cordially invited!

Heike Wachenhausen
Conference Chair
(Head of Working Group for Regulatory Affairs of Life Science Nord e.V.)

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Agenda

- 8.30 Registration and coffee
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- 9.00 **Welcome**
Charli Kruse
Director, Fraunhofer Research Institution for Marine Biotechnology
- Henrik Botterweck**
Vice-President, Lübeck University of Applied Sciences
Member of the Board, Lübeck BioMedTec Science Campus
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- 9.15 **The new Regulation on Medical Devices and its Impact on Patient Safety – A German Perspective**
Almut Fröhlich
German Federal Ministry of Health (BMG), Berlin
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- 10.00 **Market Surveillance Under the New Regulation on Medical Devices – A Regional Competent Authority's Point of View**
Niels Petersen
Free and Hanseatic City of Hamburg – Behörde für Gesundheit und Verbraucherschutz, BGV
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- 10.45 **The New Medical Device Regulation and its Impact on European Industry**
Dario Pirovano (tbc)
MedTech Europe (an alliance of the European Diagnostic Manufacturers Association, EDMA, and Eucomed), Brussels
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- 11.30 **Panel discussion (1)**
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- 12.00 Lunch
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- 13.00 **Patient Safety and Medical Devices: Challenges for Manufacturers, Operators and Legislative Authorities**
Uvo Hölscher
University of Applied Sciences, Münster
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- 13.45 **Medical Devices – Some Aspects of How a Notified Body Ensures Patient Safety**
Bent Buus
Presafe Denmark A/S, Copenhagen
-
- 14.30 **Improvement of the Cooperation Between Notified Bodies and Manufacturers – A Question of Patient Safety?**
Angela Graf
German Medicines Manufacturers' Association, Bundesverband der Arzneimittel-Hersteller e.V. (BAH), Bonn
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- 15.15 **Overview on the New European IVD Regulation and Requirements with Regard to Patient Safety**
Folker Spitzenberger
University of Applied Sciences, Lübeck
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- 16.00 **Panel discussion (2)**
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- 16.30 Get together, refreshments



Source: BWMed Bilderpool