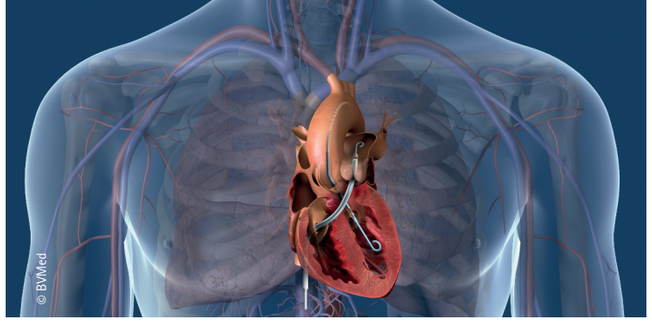
Organisers

IHK zu Lübeck
www.ihk-sh.de/lsa



Supported by

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www.bio-med-tec.de

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www.mevis.fraunhofer.de

Life Science Nord e.V.
www.lifesciencenord.de

VDMA Arbeitsgemeinschaft Medizintechnik
https://medtec.vdma.org

Universität zu Lübeck
www.uni-luebeck.de

Networking Partners

B.A.H. e.V.
www.bah-bonn.de

DGBMT
www.vde.com/de/dgbmt/

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http://diagnostiknet-bb.de/

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www.ffm-luebeck.com

Initiative Bildverarbeitung e.V.
www.initiative-bildverarbeitung.de

VDI Lübecker Bezirksverein
www.vdi.de/ueber-uns/vdi-vor-ort/bezirksvereine/luebecker-bezirksverein/

Registration, contact and further information

LSA2019 website and online registration
Please register before 19 June 2019 at www.ihk-sh.de/lsa
Programme details may be subject to change.

Fees and discount fees
All participants must register. Attendance fee is 60 EUR. Discount fee is 40 EUR. Representatives of member organisations of the BioMedTec Science Campus, Life Science Nord, and VDMA are eligible for discount fees. Students are exempt from fees.
A valid student-ID is required at registration.

Table-top exhibition
Room MF 500
Fees for table-top stands are 300 EUR plus 19% V.A.T. per stand, including catering and free access to the conference presentations for two staff of the exhibitor's organisation. Stands include a stand-up table and space for one roll-up display. Further details and a service package leaflet are available from IHK zu Lübeck (see below for contact details).

Location
MediaDocks, Willy-Brandt-Allee 31, 23554 Lübeck / Germany
For directions see http://www.media-docks.de/lage-anfahrt.php

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

Contact
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hermsmeyer@ihk-luebeck.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.

IHK Lübeck

LSA2019

Lübeck Summer Academy on Medical Technology

- Regulatory Affairs
- Artificial Intelligence / Deep Learning

June 26, 2019, 8.30 am to 5.30 pm
MediaDocks, Lübeck

Welcome to LSA2019!

Our topics are regulatory affairs for medical devices, and artificial intelligence / deep learning.

Transition to the Medical Device Regulation (MDR) until May 2020 (end of transition period) continues to be the dominating topic in the medical device industry. The designation process of notified bodies (NB) in accordance with the MDR remains ongoing. In our session on **Regulatory Affairs** we will try to give you an overview on the state of play, and will examine a number of particular aspects, including the role of the new qualified person and the impact of the MDR on Over-the-Counter (OTC, or borderline) products. Also included is a report on experiences of a medical device start-up with European and US regulations. The session is organised by **Life Science Nord's Working Group on Regulatory Affairs**.

In 2017 we first included **Artificial Intelligence (AI)** as a session into the Lübeck Summer Academy. Since then, IHK zu Lübeck's Working Group on AI has discussed both emerging and already implemented applications of AI and Deep Learning (DL) in the regional industry, research organisations and universities. Besides technological aspects, ethical issues remain an important matter of the discussion, particularly when health applications come into play. This year's AI session at LSA describes a number of novel AI-based medical applications, and highlights how ethical concerns in system design gradually advance into legal guidelines and industry standards. The session is co-organised by **Fraunhofer MEVIS** and the **Institute for Electrical Engineering in Medicine** of the University of Lübeck.

A common introductory session with key notes, panel discussions in both sessions, and a table-top industry exhibition will complete LSA2019.

You are most cordially invited!

Heike Wachenhausen, Conference Chair
(Head of Life Science Nord Working Group on RA)

Programme

8.30 Registration and coffee

Plenum Session: Welcome and Introductory Key Notes
Room MF 500

9.00 Welcome
Heike Wachenhausen
Life Science Nord Working Group on Regulatory Affairs and Wachenhausen Law, Lübeck

9.10 Key note 1:
AI and Medical Devices – The Point of View of the Federal Institute for Drugs and Medical Devices
Wolfgang Lauer
Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM, Bonn

9.40 Key note 2:
The Future of AI in Radiology
Mathias Goyen
Universitätsklinikum Hamburg-Eppendorf, Hamburg and GE Healthcare, Solingen

10.20 Discussion

10.50 Refreshments and exhibition

Parallel Session 1: Regulatory Affairs
Room MF 500

11.30 Transition to the MDR/IVDR – Update
Folker Spitzenberger
Technische Hochschule Lübeck

12.15 EU-MDR: Challenges for "Other" Economic Operators – Authorised Representatives, Importers and Distributors
Frank Wilmerstädt
PENTAX Medical, Hamburg

13.00 Lunch and exhibition

14.00 Legal Responsibility and Liability of the New Qualified Person
Susanna Dienemann
Wachenhausen Rechtsanwälte, Lübeck

14.30 Software to Support Medical Practice – Applications, Legal Aspects / MDR
Ulrich Juknat
Johnson & Johnson Medical GmbH, Norderstedt

15.00 Refreshments and exhibition

15.30 Impact of the MDR on Over-the-Counter (OTC) Medical Devices
Guido Middeler
Diapharm GmbH & Co. KG, Lübeck

16.00 Panel Discussion: Regulatory Affairs for Medical Devices

16.30 Get-together: Refreshments and exhibition

Parallel Session 2: Artificial Intelligence and Deep Learning
Technological and Ethical Aspects of AI- and DL-Based Products
Room MF 100-1

11.30 Deep Learning – A Game Changer for Radiotherapy Planning?
Jonas Honegger
Varian Medical Systems, Baden, Switzerland

12.15 Experiences of ThinkSono – The Implications of using Deep Learning in Diagnostic Care
Sven Mischkewitz
ThinkSono, Potsdam

13.00 Lunch and exhibition

14.00 IEEE-SA, Ethically Aligned Design, Supporting Standards and Certification Programme
Ali G. Hessami
Chair, IEEE P7000 Ethics in Design Standard, London, UK

14.30 Legal Challenges Regarding the Use of AI in Medical Technology
Peter Schüller
Christian Dierks & Co., Berlin

15.00 Refreshments and exhibition

15.30 Human-Centred Pattern Recognition for Assistive Technologies
Marcin Grzegorzek
Lübeck University, Lübeck

16.00 Panel Discussion: Technological and Ethical Aspects of Health-AI

16.30 Get-together: Refreshments and exhibition