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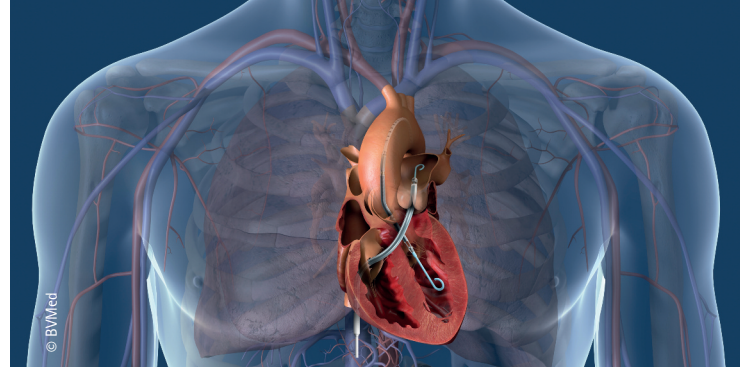


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## Networking Partners



## Registration, contact and further information

LSA2019 website and online registration  
Please register before 19 June 2019 at [www.ihk-sh.de/lisa](http://www.ihk-sh.de/lisa)  
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](http://www.hotel-excelsior-luebeck.de)  
Klassik Altstadt Hotel Lübeck [www.klassik-altstadt-hotel.de](http://www.klassik-altstadt-hotel.de)  
Atlantic Hotel Lübeck [www.atlantic-hotels.de/luebeck](http://www.atlantic-hotels.de/luebeck)  
Park Inn by Radisson Lübeck [www.parkinn.de/hotel-luebeck](http://www.parkinn.de/hotel-luebeck)

**Contact**  
IHK zu Lübeck  
Dirk Hermsmeyer  
Fackenburger Allee 2  
23558 Lübeck, Germany  
Phone +49-451-6006-191  
[hermsmeyer@ihk-luebeck.de](mailto: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.



# 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

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**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

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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

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

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10.20 **Discussion**

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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

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

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13.00 Lunch and exhibition

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

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

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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

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16.00 **Panel Discussion: Regulatory Affairs for Medical Devices**

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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

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

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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

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

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15.00 Refreshments and exhibition

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

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

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16.30 Get-together: Refreshments and exhibition