Module 4
12 September, 2013 – Morning

Regulatory Challenges for Software as Medical Device or Component of Medical Devices

08:15 ***Registration, coffee***

08:45 **Welcoming address**
Prof. Dr. Stefan Bartels, President,
Lübeck University of Applied Science

08:55 **Introduction and Current Status**
Dr. Heike Wachenhausen (Chair),
Forum für Medizintechnik (FFM e.V., Lübeck)

09:30 **Qualification of Software as Medical Device: From Healthcare Applications to Embedded Software**
Prof. Jürgen Stettin, Hochschule für Angewandte Wissenschaften, HAW (Hamburg)

10:15 **Development and Clinical Evaluation: Potential Development Strategies for Software**
Arne Briest, VISAMED GmbH (Karlsruhe)

10:45 ***Refreshments***

11:00 **Conformity Assessment and Risk Management under Consideration of Applicable Harmonized Standards**
Dipl.-Ing. Sven Wittorf,
Institut für IT im Gesundheitswesen (Konstanz)

11:30 **Market Surveillance and Product Liability: What if Software Fails?**
Dr. Heike Wachenhausen, FFM e.V.

12:00 **Development and Maintenance of Medical Software and Computer-Assisted Medical Diagnosis and Therapy Tools: Introduction and Application of EN ISO 9001:2008 and EN ISO 13485:2012 at Fraunhofer MEVIS**
Till Kipshagen and Dr. Nils Papenberg, Fraunhofer MEVIS Project Group Image Registration (Lübeck)

12:30 **Discussion**

12:45 ***Lunch***

Module 5
12 September, 2013 – Afternoon

Medical Technology in the Focus of the X-Ray Microscope

13:25 **Welcome**

13:30 **Synchrotron Radiation for Life Science and MedTech: Introduction and Overview**
Dr. Frank Lehner, DESY, Hamburg

13:55 **Brilliant Technology for Life Beyond the Limits of Standard Laboratory Methods with Synchrotron Radiation at DESY**
Dr. Thomas Wroblewski, DESY (Hamburg)

14:20 **Implants and Joint Fluids – Synergies of Medical Technology and Materials Research at the German Engineering Materials Science Center (GEMS) of Helmholtz-Zentrum Geesthacht (HZG)**
Dr. Florian Wieland, HZG (Geesthacht)

14:45 **Integrated Facilities for Life Sciences at European Molecular Biology Lab (EMBL)**
Johanna M. Kallio (née Hakanpää), Ph.D.,
EMBL (Hamburg)

15:10 ***Refreshments***

15:35 **Present and Future Opportunities at the MAX IV Laboratory**
Andreas Lassesson, Ph.D., MAX IV Laboratory (Lund, SE)

16:10 **ESS (European Spallation Source) – Neutron Radiation Facility in Lund**
Juan Tomás Hernani, ESS (Lund, SE)

16:35 **The European Science Link Project – An excellent First Access for Novel Users of Synchrotron and Neutron Facilities**
Dr. Graham Appleby, Science Link (Hamburg)

17:00 **Practical Example of an SME as Synchrotron User in the Science Link Project**
Anna Stenstem, Ph.D.,
CEO, Colloidal Resource (Lund, SE)

17:30 ***Refreshments & free networking***

Registration, Contact and Further Information

Website and Registration:
Please register before 3 Sep. 2013 at
www.biomedtec-campus.de/summeracademy

Programme details may be subject to change.

Fees:
Attendance fee for a single module (half day) is 50 EUR per module. Attendance fee for the Summer Academy (five modules) is 200 EUR.

Discounts:
Attendance fee for the Summer Academy (five modules) is 150 EUR for members of Life Science Nord e.V. Students are exempt from fees. A valid student-ID is required at registration.

Conference location:
Fachhochschule Lübeck, FB Maschinenbau und Wirtschaft,
Mönkhofer Weg 239, Gebäude 2, 1. Stock, Hörsaal 2
(Building 2, 1st floor, lecture hall 2)
D-23562 Lübeck / Germany
Parking is available in front of the building.

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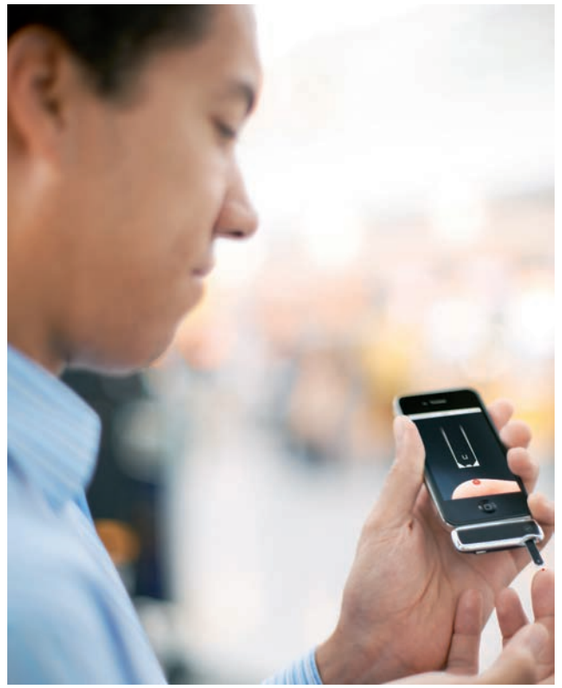

Lübeck 2013 Summer Academy on Medical Technology

10-12 September 2013
BioMedTec Wissenschaftscampus Lübeck, Germany

In cooperation with

Medisert
Technologie- und Wissenstransfer BioMedTec Wissenschaftscampus

F.F.M.

Welcome to Lübeck!

'Lübeck Summer Academy on Medical Technology' was introduced in 2012. Instantly, it was a well-visited networking platform for stakeholders from industry and research organisations around the Lübeck BioMedTec Science Campus – including the 'Fehmarnbelt-Öresund corridor' from Hamburg and Lübeck to Copenhagen, Malmö and Lund as its region. Top motivation for the Summer Academy's organisers to continue the format in 2013!

The 2012 Summer Academy's most popular workshop was 'Regulatory Affairs in Medical Technology – New Developments in Europe'. Much has happened since: In September 2012, the European Commission published its proposal for a new Medical Device Regulation. In April 2013, the draft report on the Commission's proposal was circulated by the Committee on the Environment, Public Health and Food Safety. Discussions around European medical device regulations are ongoing. Manufacturers, small and large, are concerned about legal conditions that may apply three to five years from today. Lübeck 2013 Summer Academy on Medical Technology gives orientation on this important topic in three workshops: on **'Regulatory Affairs',** on **'Regulatory Affairs & Software'**, and on the practical development of medical devices **'From Idea to Market'.**

Moreover, the 2013 Summer Academy covers technical topics. Module 1 highlights **'Imaging Technologies in the Life Sciences'**, a stronghold within the Lübeck medtech industry. Important organisations among many others are the Fraunhofer MEVIS Group for Image Registration, and the University's Institute for Biomedical Optics (BMO).

Module 5, on **'Medical Technology in the Focus of the X-Ray Microscope'** emphasizes the fact that Lübeck is in the midst of several top European research facilities. These offer extremely high potential and excellent services for innovation and the development of new materials and products. DESY and EMBL in Hamburg, HZG in Geesthacht, as well as MAX IV and ESS in Lund are all just a few hours away.

'Lübeck 2013 Summer Academy on Medical Technology' is jointly organised by Lübeck BioMedTec Science Campus / Medisert, Forum für Medizintechnik (FFM e.V.), and Lübeck Chamber of Industry and Commerce (IHK zu Lübeck).
We wish you a successful Summer Academy and good networking!

Module 1
10 September, 2013 – Afternoon

Imaging Technologies in the Life Sciences

12:30 *Registration, lunch*

13:25 **Welcome**

Digital Pathology

13:30 **Histology in New Dimensions**
André Homeyer,
Fraunhofer MEVIS (Bremen)

14:00 **Quantitative Digital Pathology – A new Tool in Cancer Research**
Lars Pedersen, Ph.D.,
Stereology Visiopharm (Hørsholm, DK)

14:30 **High Resolution 3D Reconstruction of Differently Stained Histological Whole Slide Images**
Johannes Lotz, Fraunhofer MEVIS Project Group Image Registration (Lübeck)

15:00 *Refreshments*

Intravital Optical Imaging Technologies

15:30 **Intraoperative Optical Coherence Tomography**
Dr. Eva Lankenau,
Optomedical Technologies (Lübeck)

16:00 **Intravital 2-Photon Microscopy**
PD Dr. Gereon Hüttmann,
Institute for Biomedical Optics, BMO,
University of Lübeck

16:30 **Intravital Laser Nanosurgery and 2-Photon Microscopy Probing the Immune and Healing Response of Intestinal Mucosa**
Prof. Dr. Alfred Vogel, Inst. for Biomedical Optics, BMO,
University of Lübeck

17:00 *Refreshments & free networking*

Module 2
11 September, 2013 – Morning

Regulatory Challenges for Medical Device Manufacturers in Europe– What's Next?

08:15 *Registration, coffee*

08:45 **Welcoming address**
Lars Schöning, Acting CEO,
Lübeck Chamber of Industry and Commerce
Prof. Dr. Peter Dominiak,
Chairman of the Board, BioMedTec Science Campus;
President, Lübeck University

09:00 **Introduction – The Proposal for a Medical Device Regulation (MDR)**
Dr. Heike Wachenhausen (Chair),
Forum für Medizintechnik (FFM e.V., Lübeck)

09:30 **Product Liability – Court Proceedings, Case Law and Consequences from a Legal Perspective**
Stefan Todt, Legal Counsel, B. Braun Melsungen AG

10:00 **Potential Impact of the MDR on the German Market and the Development of Medical Devices – Current Situation**
Dr. med. Christian Schübel,
Head of Medical Affairs, i.DRAS GmbH (München)

10:30 *Refreshments*

10:45 **Living in Conformity with EN ISO 13485 – Best Practice Examples**
Dr. Martin Peters, Head of Quality and Regulatory Affairs, Olympus OSTE (Hamburg)

11:15 **Current Challenges for the Medical Device Industry – A Wish List**
Peter Schroeer, Group Director,
EMEA Regulatory Affairs,
Johnson & Johnson (Dülmen)

11:45 **Panel discussion: European Legislation on Medical Devices**

12:45 *Lunch*

Module 3
11 September, 2013 – Afternoon

From Idea to Market – Development of Medical Devices: A Question of Trust and Risk Management

12:45 *Registration, lunch*

13:25 **Welcome**

13:30 **From Idea to Market - Introduction and Overview**
Lars Seier Petersen,
DELTA (Hørsholm, DK)

14:00 **Agile Development in a Medical Device Regulatory Context**
Morten Elvang,
DELTA (Hørsholm, DK)

14:30 **Legsilative Requirements Beyond the Medical Device Regulation – Making Medical Devices Mobile**
Mads Marker,
HypoSafe (Kongens Lyngby, DK)

15:00 *Refreshments*

15:30 **Continua Health Alliance**
Brian Hedegaard,
Continua Health Alliance,
EU Working Group (Hørsholm, DK)

16:00 **Telemedicine in Denmark – A Walkthrough of the Reference Architecture**
Thor Schliemann,
NSI (National Board of e-Health, Copenhagen, DK)

16:30 **New Legislative Requirements for Software**
Mathias Klümper,
Lützeler Klümper (Lawyers, Hamburg)

17:00 *Refreshments & free networking*