

Agenda

U.S.- German Standards Panel **“Innovation in the medical device sector”**

April 11th

18:00

Welcome dinner

Restaurant
Darlington House
1610 20th St NW
Washington, DC

Guest speaker:

Dr. Thomas Zielke, Representative of German Industry and Trade (RGIT) in Washington D.C.

April 12th

Venue

FHI 360 Conference Center
Academy Hall
1825 Connecticut Avenue NW
Washington, D. C.

Registrations opens at 8:00, Breakfast will be available

9:00

Welcome address

Joe Bhatia, President and CEO, American National Standards Institute (ANSI)

Welcome address

Rüdiger Marquardt, Member of the Executive Board, DIN

9:15

Keynote Speech

Recent developments in electronic medical records – Implications for standardization and public policy

Tim Büthe, Associate Professor of Political Science and Public Policy, Duke University

9:45

1. The Transatlantic Trade and Investment Partnership (TTIP)

Moderator: Sibylle Gabler, Senior Manager Government Relations, DIN

TBT Chapter and Annex on Medical devices

Isabel Pastor Arenillas, Trade Counselor, EU Delegation to the USA

U.S. perspective

Ashley Miller, Director, Industrial Goods Market Access (TTIP sectors), USTR

10:30

Coffee Break

10:45 2. Standards in the EU and US – A tool for meeting global requirements

Moderator: Gordon Gillerman, Director, Standards Coordination Office, NIST, US DoC

Harmonized Standards (EU)

Matthias Marzinko, Director International Standards Management, Drägerwerk AG & Co. KGaA

Recognized Standards (US)

Scott Colburn, Director, Standards, US FDA

Conformity Assessment – Keys to Multiple Market Access

Dr. Royth von Hahn, Global Director Functional Safety and Software, Medical and Health Services, TUV SUD Product Service Division

What Global Companies are Doing

Elisabeth George, Vice President of Global Government Affairs, Standards & Regulations, Philips Healthcare, USA

Brief Panel Discussion

12:05 Standards in Regulation - Use cases

Current issues - disposable medical products

Herrmann Riesenberger, Head of Working Group Standardization, BVMed, The German Medical Technology Association

Electromedical devices

Pamela Gwynn, Principal Engineer for Medical and Home Healthcare Equipment, Underwriters Laboratories (UL)

Standards and Medical Imaging

Diane Wurzburger, Executive, Regulatory Affairs, GE Healthcare/MITA

Brief Panel Discussion

12:50 Lunch

13:45 3. Interoperability in the medical device sector

Moderator: Hermann Behrens, Head of department Innovation, DIN

Internet of Medical Systems and IT Services

Prof. Dr. J.-Uwe Meyer, CEO, CTO, MT2IT GmbH & Co. KG

Implementing Information Exchange Standards in Healthcare Facilities

Dezso Csipo, President, Object Forge, Inc.

Interchange formats of medical documents – IT-specifications

Dr. Georg Heidenreich, Manager Healthcare IT Standards, Siemens Healthcare GmbH

Safety and Security Standards for Medical Application Platforms

John Hatcliff, University Distinguished Professor, Department of Computing and Information Science, Kansas State University

Medical Robots

Mike Yramategui, Fellow Regulatory Engineer, Intuitive Surgical, USA

15:25 Coffee Break

15:45 **4. Innovative future topics**

Moderator: Carol Herman, Senior Vice President, Standards & Policy Programs, AAMI

Safe and dynamic networking in operating room and hospital

Björn Andersen, Research Assistant, University of Lübeck Institute of Medical Informatics

Risk management of 3D printed medical devices

Roderick McMillan, Materials Development Manager, DePuy Synthes

Biocompatibility and evolution of risk management in safety evaluation of medical devices

Jon Cammack, Global Vice President of R&D/Clinical Quality, AstraZeneca

Innovation and Adaptation in the Development of Standards for Absorbable Implants

Byron Hayes, Biomaterials Research and Development, W.L. Gore & Associates, Inc.

Standardization in the field of regenerative medicine

Prof. Dr. Michael Doser, Deputy director, Head of development in Biomedical Engineering, Institute of Textile Technology and Process Engineering

17:05 **Panel Discussion on innovative future topics**

Participants:

- Prof. Dr. J.-Uwe Meyer, CEO, CTO, MT2IT GmbH & Co. KG
- Dr. Georg Heidenreich, Manager Healthcare IT Standards, Siemens Healthcare GmbH
- Jon Cammack, Global Vice President of R&D/Clinical Quality, AstraZeneca
- Byron Hayes, Biomaterials Research and Development, W.L. Gore & Associates, Inc

17:45 **Closing remarks**

Rüdiger Marquardt and Joe Bhatia

18:00 **Close of meeting**

April 12th

19:30

Reception and Dinner

Fairmont Hotel
2401 M St NW, Washington, DC 20037

Address: Peter Rondorf, Minister and Head of the Economic Department, German Embassy

Guest speaker

Elisabeth George Vice President Global Regulations & Standards Philips
Brian Markwalter, Sr. VP, Research & Standards, Consumer Technology Association

April 13th

8:30

Start from Hotel

10:00 –

Technical visit to National Institute of Standards and Technology (NIST)

12:30

Introduction to a number of NIST research activities that support innovations for medical devices

Gaithersburg, Maryland