

## **DRAFT Agenda**

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

---

**April 11<sup>th</sup>**

**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 12<sup>th</sup>**

**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**

**Opening**

**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**

Geraldine Emberger, Trade Counselor for Regulatory Issues, EU Delegation to the USA

**U.S. perspective**  
Lead Negotiator, USTR

10:30 Coffee Break

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

Moderator: Gordon Gillerman, Director, 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, TÜV Süd

**What Global Companies are Doing**

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

**12:05 Standards in Regulation - Use cases**

**Current issues - disposable medical products**

Herrmann Riesenberger, Head of R&D, B. Braun Melsungen AG

**Electromedical devices**

Pam Gwynn, Principal Engineer for Medical and Home Healthcare Equipment

**Imaging**

GE or Siemens, USA

**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, Germany

**Implementing Information Exchange Standards in Healthcare Facilities**

Dezso Csipo, Object Forge, Inc.

**Interchange formats of medical documents – IT-specifications**

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

**Interoperability of devices in hospitals**

Dr. John Hatcliff, Kansas State University (inv.)

### **Medical Robots**

Mike Yramategui, Intuitive Surgical, USA

15:25

Coffee Break

15:45

#### **4. Innovative future topics**

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

##### **Secure 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 and ASTM chair of F04.12 on Metallurgical Materials

##### **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**

17:45

##### **Closing remarks**

Rüdiger Marquardt, Member of the Executive Board, DIN

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

18:00

##### **Close of meeting**

---

**April 12<sup>th</sup>**

19:30

##### **Reception and Dinner (possibly at German Embassy)**

Guest speaker:

tbd

---

**April 13<sup>th</sup>**

10:00 –  
12:00

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