



# MEDTEC Europe

CONFERENCE

22–24 March 2011  
Messe Stuttgart, Germany

*Streamed into focused sessions, the conference ensures all attendees receive information they can immediately apply to their job responsibilities from regulation to design and manufacture.*

Over three days the multi-track conference will feature the very latest on:

- *The 510(k) Premarket Notification Process and EU Medical Device Law*
- *A Review of Recent Trends in FDA Inspections and Warning Letters*
- *The Latest Reaction to REACH, ROHS and Upcoming Worldwide Legislation on Substance Reporting and Environmental Regulations*
- *Regulation in Emerging Markets with a Focus on the Middle East and Africa*
- *Selecting and Using Materials for Innovative Medical Devices*
- *Product Development and the FDA Approval Process*
- *Plus in-depth tracks on Risk Management and how to build an Effective Design and Process Validation Programme*



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## Day One: Tuesday 22nd March 2011

### 08.45 Registration

#### Session 100—The 510(k) Premarket Notification Process and EU Medical Device Law: Current Status and Anticipated Changes

In both the US and EU, significant changes to the regulatory processes for bringing medical devices to market are being considered. This track will provide an in-depth analysis of both the “510(k)” premarket notification process and the CE marking process from a variety of perspectives, focusing on reforms likely to occur in the coming year in the US and EU. The overlap as well as the differences between the 510(k) and CE marking pathways will be highlighted. In addition, special topics will include common pitfalls in the preparation of 510(k)s and in responding to FDA questions during the 510(k) review, and regulation of in vitro diagnostics. Speakers will include FDA insiders, regulatory lawyers from the US and EU, consultants, and experienced representatives from small and large medical device manufacturers

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- 9.20 Chair’s Opening**  
Steven Datlof, M.D., J.D., Partner, Hogan Lovells US LLP and Elisabethann Wright, Partner, Hogan Lovells International LLP
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- 9.30 Anticipated Changes to the 510(k) Process—Overview**  
Steven Datlof, M.D., J.D., Partner, Hogan Lovells US LLP
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- 10.30 Anticipated Changes to EU Law Governing Medical Devices**  
Elisabethann Wright, Partner, Hogan Lovells International LLP
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- 11.15 Break**
- 
- 11.30 View of FDA 510(k) Reform and Experience with the 510(k) Process**  
Miriam C. Provost, Ph.D., Senior Consultant, Medical Devices, Biologics Consulting Group
- 
- 12.15 Lunch**
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- 13.45 Increasing International Challenges in Regulatory and Compliance for In Vitro Diagnostic Products**  
Dr. Petra Kaars-Wiele, Director International Regulatory Affairs / Affiliate Compliance, Abbott GmbH & Co KG
- 
- 14.30 510(k) and CE Marking: Industry Perspective**  
Vicky Taylor, Regulatory Affairs Manager Tissue Regenix Group Plc
- 
- 15.00 Break**
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- 15.15 Increasing International Challenges in Regulatory and Compliance for In-Vitro Diagnostic Products**  
Dr. Petra Kaars-Wiele, Director International Regulatory Affairs / Affiliate Compliance, Abbott GmbH & Co KG
- 
- 15.15 Similarities and Differences Between the Regulatory Procedures Governing Medical Devices in the US and EU**  
Dr. Stefan Menzl, Director Regulatory Affairs, Compliance, EMEA, Abbott Medical Optics
- 
- 16.00 Debate**
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- 16.30 Q&A**
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- 16.45 Chair’s Closing**
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- 17.00 End of Day One**

#### Session 101—Selecting and Using Materials for Innovative Medical Devices

This track will examine next generation medical devices; covering aspects of planning, development and manufacture. Speakers will include experienced representatives from large medical device manufacturers, medical surgeons and research academia.

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- 9.20 Chair’s Opening**  
Cláudia Vaz, Business Development Manager, DSM
- 
- 9.30 New Hydrophilic, Non-Fouling and Anti-Microbial Coatings for Medical Devices**  
Onko Jan Gelling, RT&D Manager, Biomaterials, DSM Biomedical
- 
- 10.15 Next Generation Medical Devices: Aspects of planning, development and manufacturing of next generation medical devices**  
Jörg Vienken, VP BioSciences, Fresenius Medical Care Deutschland GmbH
- 
- 11.00 Break**
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- 11.15 Biodegradable Magnesium Implants—Challenges and Advantages**  
Dr Frank Witte, Laboratory for Biomechanics and Biomaterials, Orthopaedic Clinic, Hannover Medical School
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- 12.00 Lunch**
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- 13.30 Challenges and Experiences in Using New Materials—Panel Discussion**  
Jörg Vienken, VP BioSciences, Fresenius Medical Care Deutschland GmbH, Dr. Cláudia Vaz, Business Development Manager, DSM, Dr Frank Witte, Laboratory for Biomechanics and Biomaterials, Orthopaedic Clinic, Hannover Medical School, Prof., Dr. Bert Müller, Thomas Straumann, Professor für Materialwissenschaft in der Medizin Biomaterials Science Center (BMC), Universität Basel, Dr. Ing. Cyril Voisard, Group Manager Materials & Surfaces, Synthes Innovation, Dr. Michael Doser, Industrial Liaison, Institute for Textile and Process Engineering, Department of Biomedical Engineering, European Society of Biomaterials
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- 14.15 Development and Assessment of Functionalized Medical Devices**  
Dr. Michael Doser, Industrial Liaison, Institute for Textiles and Process Engineering, Department of Biomedical Engineering, European Society of Biomaterials
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- 15.00 Break**
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- 15.15 Imaging the Nanostructure of Human Tissues to Realise Nature-Analogue Implants**  
Prof. Dr. Bert Müller, Thomas Straumann, Professor für Materialwissenschaft in der Medizin Biomaterials Science Center (BMC), Universität Basel
- 
- 16.00 Selected Materials for Osteosynthesis**  
Dr. Ing. Cyril Voisard, Group Manager Materials & Surfaces, Synthes Innovation
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- 16.45 Chair’s Closing**
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- 17.00 End of Day One**

## Day Two: Wednesday 23rd March 2011

### 08.45 Registration

#### Session 200—Regulation

This track will begin by giving you a step by step guide on how you can monitor FDA enforcement activity to avoid common problems; how manufacturers should be aware of these common FDA observations and what compliance strategies should be deployed. Finally, learn how to prepare warning letter responses which will meet FDA expectations.

With the new ROHS being agreed in the European parliament, examples of how the environmental product laws will impact manufacturers and the new ROHS and its consequences will be addressed.

For many companies who are already selling in US and EU markets, the emerging markets of the Middle East and North Africa, Latin America, Russia, India, Korea, Japan and China are the next step. This track will give you an overview of the regulatory requirements in these emerging markets.

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- 9.20 Chair’s Opening**  
Kevin Morningstar, Senior Consultant, Morningstar Consulting Group LLC
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- 9.30 Recent Trends in FDA Inspections and Warning Letters—A Review**  
Kevin Morningstar, Senior Consultant, Morningstar Consulting Group LLC
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- 10.15 FDA Requirements for CAPA and Nonconforming Product - Compliance Strategies**  
Stefan Klein, Director of Quality and Compliance, Sensortechnics GmbH

#### Session 201—Building an Effective Design and Process Validation Program

This course provides design, manufacturing, process development and regulatory/quality systems professionals with the knowledge and fundamentals needed to comply with design and process validation requirements while offering information on how to implement an effective validation program.

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- 9.20 Chair’s Opening**  
Thomas T. Dzierozynski, Senior Partner, Avarent
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- 9.30 Define the Fundamental Requirements for Design and Process Validation**  
Thomas T. Dzierozynski, Senior Partner, Avarent
- 
- 10.15 Risk Management – Why Integration, Simplicity and Efficiency is the Way Forward**  
Gary Fahey, Risk Manager EMEA, Teleflex Medical
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- 11.00 Break**
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- 11.15 Learn Best Practices of Protocol and Report Writing**  
Thomas T. Dzierozynski, Senior Partner, Avarent
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- 12.00 Lunch**

## Day Two: Wednesday 23rd March 2011 (continued)

### Session 200—Regulation

11.00	Break
11.15	<b>What To Do After Receiving an FDA Warning Letter</b> Kevin Morningstar, Senior Consultant, Morningstar Consulting Group LLC
12.00	Lunch
13.30	<b>How Philips Healthcare is Dealing with REACH and the Implementation of BOMcheck in Their Supply Chain</b> Poppe Onrust, Project Manager Sustainability, Product Substance Management, Philips Healthcare
14.15	<b>ROHS and REACH - From a Manufacturer's Perspective Consequences and Implementation</b> Laila Strange Lundtoft, Chemical Engineer BSc., Corporate Regulatory Affairs Manager, Ambu A/S, Denmark
15.00	Break
15.15	<b>The Regulatory Environment in MENA (Middle East and North Africa): New Challenges for Regulatory Professionals</b> Momchil Blagoev, Regional Manager Regulatory Affairs, Edwards Lifesciences
16.15	<b>Emerging Markets for Medical Devices; Overview of the Regulatory Requirements in Brazil, Russia, India, Korea, Japan and China</b> Jens Grothues, General Manager Germany, Emergo Group
16.55	Chair's Closing
17.00	End of Day Two

13.30	<b>Applying Statistical Methods to Validation</b> Thomas T. Dzierozynski, Senior Partner, Avarent
14.15	<b>Sustaining the Validated Stated to Reduce Business and Compliance Risk</b> Thomas T. Dzierozynski, Senior Partner, Avarent
15.00	Break
15.15	<b>Discussion: Lessons Learned From Case Study of Current Validation Programs and Gaps</b> Thomas T. Dzierozynski, Senior Partner, Avarent
16.00	Q&A
16.30	Chair's Closing
16.35	End of Day Two

## Day Three: Thursday 24th March 2011

### 08.45 Registration

#### Session 300—Risk Management for Medical Devices

This track will cover risk management concepts and terminology and provide an understanding of regulatory requirements. Packed full of tips for integrating risk management into the design and development lifecycle and how to combine traditional FMEA with an HACCP approach, evaluation of biocompatibility and how human factors engineering relates to risk management.

9.20	<b>Chair's Opening</b> Dr. Ir. Gert Bos, Head of Regulatory and Clinical Affairs Healthcare, BSI Healthcare
9.30	<b>A Practical Approach to Risk Management EN ISO 14971:2009</b> Dr. Dieter R. Dannhorn, CEO and President, MDT Medical Device Testing GmbH
10.10	<b>Risk Analysis by Combining Traditional FMEA with an HACCP Approach</b> Michael Schaefer, Manager QA/RA R&D Dialyzers, Gambro Dialysatoren GmbH
10.50	Break
11.05	<b>Evaluation of Biocompatibility within a Risk Management System. Provisions of the New EN ISO 10993-1:2009 Standard</b> Dr. Dieter R. Dannhorn, CEO and President, MDT Medical Device Testing GmbH
11.45	<b>The New GCP standard ISO 14155:2010 for Clinical Investigations of Medical Devices</b> Dr. Ir. Gert Bos, Head of Regulatory and Clinical Affairs Healthcare, BSI Healthcare
12.25	Lunch
14.00	<b>Risk Management as Part of the 3rd Edition of the Basic Safety Standard, IEC 60601-1. The Practical Approach for the Safety of MR Scanners at Philips Healthcare</b> Hans Engels, MR Safety Consultant, MRcomp, Retired MR safety Director, Philips Healthcare
14.40	<b>Continuous Cycle of Improvement of Medical Devices (CCI)</b> Robert E. Geertsma, M.Sc., Centre for Biological Medicines and Medical Technology, RIVM - National Institute for Public Health and the Environment
15.20	Break
15.35	<b>Life Cycle Aspect in Risk Management</b> Sten Elkjær Andersen, Corporate QA Engineering Manager, Ambu A/S, Denmark
16.15	Chair's Closing
16.20	End of Day Three

#### Session 301—Product Development and FDA Approval Process for Medical Devices

Understanding total product life cycle. What are the challenges associated with managing R&D, regulatory and marketing teams during the product development and regulatory approval process for the US and global markets. This track will guide you through the process including IP considerations during product development, do's and don'ts during the pre-clinical evaluation process and regulatory and clinical considerations.

9.20	<b>Chair's Opening</b> Semih Oktay, PhD, President, CardioMed Device Consultants
9.30	<b>Product Development Process</b> Thomas Bauer, Senior Research Manager, Medtronic Invatec CardioVascular
10.50	Break
11.05	<b>Intellectual Property Considerations During Product Development</b> Peter K. Hess, IP Specialist, Partner, Bardehle Pagenberg
11.45	<b>Q&amp;A</b> Semih Oktay, PhD, President, CardioMed Device Consultants
12.25	Lunch
14.00	<b>FDA Approval Process for Medical Devices.</b> Semih Oktay, PhD, President, CardioMed Device Consultants
14.40	<b>Regulatory and Clinical Considerations: Industry Perspective</b> Rikke Arendt Christiansen, Senior Consultant, Clinical, RA/QA, Qmed Consulting, Denmark
15.20	Break
15.35	Q&A
16.15	Chair's Closing
16.30	End of Day Three

## Booking Information

### MEDTEC EUROPE CONFERENCE 2011

Conference registration includes coffee breaks, electronic access to session materials for the day(s) you are registered, entrance into the exhibition halls, and lunch for the day(s) you are registered.

Please call +49 (0) 6922 223115 for details of exhibitor, group, student, academic and government discounts.

We are happy to welcome a substitute delegate, provided a written request is received by 25 February 2011. After 25 February 2011, a 50 € transfer fee will apply. For cancellations, we offer a refund, less a service charge (100 €), providing the cancellation is received in writing before 25 February 2011. We regret no refunds can be made after 25 February 2011.

### SPONSORSHIP OPPORTUNITIES

Sponsoring the MEDTEC Europe Conference is an excellent way to promote your organisation. Your company's name can be prominently displayed in the conference or exhibition halls, conference proceedings, press releases, the website, the catalogue and other publications.

For further details, please contact:  
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Tel: +49 2211 6847665  
E-mail: [gregor.bischkopf@ubm.com](mailto:gregor.bischkopf@ubm.com)

### HOTEL AND TRANSPORTATION

For information about hotels and transportation, please visit our website: [www.medteceurope.com](http://www.medteceurope.com)

### ENQUIRIES

If you have any questions about the conference or how to register, please do not hesitate to contact the MEDTEC Europe Helpdesk, who will be pleased to assist you:

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Email: [medteceurope@ubm.com](mailto:medteceurope@ubm.com)

### CONFERENCE PROCEEDINGS

If you are not able to attend the conference, but would be interested in receiving the conference proceedings, they will be available after the conference. The fee is 295 €.

### CONFERENCE LANGUAGE

The official conference language is English.

### PROGRAMME ALTERATIONS

It may be necessary, for reasons beyond the control of the organisers, to alter the content and timing of the conference presentations.

### DATA PROTECTION

The information you provide will be held on a database for our own use. It will not be released to third parties unconnected with the conference without your express permission.

### THE ORGANISERS

The MEDTEC Europe Conference is organised by UBM Canon. UBM Canon, the leading B-to-B media company dedicated exclusively to the global \$3 trillion advanced manufacturing sector, helps support the flow of information, commerce and innovation in such sophisticated segments as medical devices and pharmaceutical development. UBM Canon also addresses cutting-edge developments in broader areas of advanced engineering design and manufacturing, and manufacturing processes and packaging.

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UBM Canon also publishes a multitude of industry magazines, including European Medical Device Technology, China Medical Device Manufacturer, Japan Medical Design and Manufacturing Technology, Medical Device and Diagnostic Industry and Medical Product Manufacturing News.

With this unique media portfolio, UBM Canon is able to connect over 3,500 medical-device industry suppliers with more than 100,000 design and manufacturing professionals every year.

For more information, please visit:  
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