

The 10th Global Harmonization Task Force (GHTF) Conference

Design for Patient Safety in a Global Regulatory Model



Working Towards Harmonization in Medical Device Regulation

June 28 – 30, 2006

Musik- und Kongresshalle Luebeck,
Luebeck, Germany

Organizer: GHTF – European Commission, Brussels, Belgium

Hosted by: EUROM – European Industry Federation for Precision
Mechanical and Optical Industries, Lausanne, Switzerland

Sponsored by: EUROM VI – Medical Technology, Berlin, Germany

COCIR – The European Coordination Committee of
the Radiological and Electro medical and Healthcare IT Industry, Brussels,
Belgium

EDMA – European Diagnostic Manufacturers Association, Brussels, Belgium

EUCOMED – European Medical Technology Industry Association , Brussels,
Belgium

EUROMCONTACT – The European Federation of National Associations and
International Companies for Contact Lens Manufacturers, Wemmel, Belgium

FIDE – European Dental Industry, Cologne, Germany

GHTF – Conference Flyer – February, 2006

GHTF and its Goal

The **GHTF** is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: **Europe, Asia-Pacific (Australia, Japan)** and **North America (Canada, USA)**, each of which actively regulates medical devices using its own unique regulatory framework.

The goal of the GHTF is to provide a forum for representatives of member regulatory authorities and industry representatives to work together to encourage convergence in regulatory practices related to ensuring safety, effectiveness, performance and quality of medical devices in ways that protect public health, promote technological innovation and facilitate international trade. This is accomplished via the publication and dissemination of **harmonized guidance documents on basic regulatory practices**. These documents are developed by five different GHTF Study Groups. The documents – approved by the GHTF-Steering Committee – can then be adopted / implemented by member regulatory authorities.

Overview of the GHTF Conference Programme

The **European Commission** is currently holding the rotating Chair of GHTF for Europe and is hosting the 10th GHTF Conference, which will be held in Lübeck, Germany, from Wednesday 28th to Friday 30th June, 2006. The European Chairmanship stands under the overriding theme of “Patient Safety” and accordingly design for patient safety is the subject of the Conference. This Conference will be the flagship event of the European Chairmanship of GHTF.

The GHTF conference serves as an information exchange forum through which conference participants from the medical device industries meet the representatives of the medical device regulatory authorities. Developing an exciting and interactive programme the following topics are offered – detailed on the GHTF-website: www.GHTF.org :

Conference Welcome and the Global Regulatory Model

Georgette Lalis, European Commission, Brussels, Belgium – GHTF Chair

Introduction to Design for Patient Safety

Jeff Cooper, Harvard Medical School, Boston, USA

Conference Lectures

Design for Patient Safety: David Jefferys, Eisai Ltd, London, UK

- **Methodology**
Mike Wiklund, Wiklund Research & Design, Concord, USA
- **Post-market Validation**
Matthew Weinger, Vanderbilt University School of Medicine, Nashville, USA
- **Global Vigilance**
Rainer Voelksen, Therapeutic Goods Administration, Symonston, Australia

Workshops I

- 1. Intellectual Property and Internet Promotion**
Alain Prat^{*)}, AFSSAPS, St. Denis, France
- 2. Auditing and Risk Management**
Horst Frankenberger^{*)}, Forum für Medizintechnik e.V., EUROM VI, Luebeck, Germany
- 3. Emerging Technology I – Clinical Expert and Control Systems, Plug & Play**
Julian Goldman, Massachusetts General Hospital, Boston, USA
- 4. Design for Patient Safety – Principles I**
Mike Wiklund, Wiklund Research & Design, Concord, USA^{*}

Workshops II

- 5. STED and the Use of Standards in Conformity Assessment**
Ginette Michaud^{*)}, Center for Devices and Radiological Health, FDA, USA
- 6. Post-production Clinical Follow up**
Philippe Auclair^{*)}, EUCOMED, Guidant Europe Diegem, Belgium
- 7. Emerging Technology II – Combination Products**
Daniel Schultz, Director Center for Devices and Radiological Health, FDA, USA
- 8. Design for Patient Safety – Principles II**
Matthew Weinger, Department of Biomedical Informatics, Nashville, USA

Panels

1. How the Global Regulatory Model works

Moderator: Maurice Wagner, GHTF-Vice-Chair, EUCOMED, Brussels, Belgium

Asia Pacific

Rita Mac Lachlan^{*)}, Director Office of Devices, Blood and Tissues Therapeutic Goods Administration, Symonston, Australia
Brian Vale^{*)}, Medical Industry Association of Australia, St. Leonards, Australia
Hiroshi Yamamoto^{*)}, Director, Office of Medical Devices Evaluation Ministry of Health, Labour and Welfare, Tokyo, Japan
Masaaki Naito^{*)}, Japanese Federation of Medical Device Associations, Tokyo, Japan

North America

Roland Rotter^{*)}, Director, Medical Devices Bureau Health Canada, Ottawa, Canada
Daniel Schultz, Director Center for Devices and Radiological Health, FDA, USA
Janet Trunzo^{*)}, Advanced Medical Technology Association ADVAMED, Washington DC, USA –

Europe

Abraao Carvalho, European Commission, Brussels, Belgium
Jos Kraus^{*)}, Health Care Inspectorate, The Hague, Netherlands
Werner Schoenbuehler^{*)}, Siemens AG / COCIR, Erlangen, Germany

2. GHTF quo vadis

Moderator: Alf Dolan, University of Toronto, Toronto, Canada

Georgette Lalis, European Commission, Brussels, Belgium – GHTF Chair
[N. N., Member of the European Parliament, Strasbourg, France / Brussels, Belgium](#)
Roland Rotter^{*)}, Director, Medical Devices Bureau Health Canada, Ottawa, Canada
Wolfgang Reim, Draeger Medical, EUROM VI, Luebeck, Germany
Mukundan Pillay, Asian Harmonization Working Party (AHWP), Ministry of Health of Malaysia, Putrajaya, Malaysia
Alwin Götz, University Hospital Eppendorf, Hamburg, Germany

^{*)} Member of GHTF Steering Committee and/or GHTF Study Group
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3. New and Emerging Technologies I

Moderator: David Graham, Therapeutic Goods Administration, Symonston, Australia

- **Balance Safety / Uncertainty**
Daniel Schultz, Director Center for Devices and Radiological Health, FDA, USA
- **How safe is safe?**
Michael Gropp^{*)}, Advanced Medical Technology Association
ADVAMED, Guidant Europe, Diegem, Belgium

4. New and emerging technologies II

Moderator: Norbert Anselmann, European Commission, Brussels, Belgium

- **Science**
Julian Goldman, Massachusetts General Hospital, Boston, USA
- **Regulatory Challenges**
Jean-Claude Ghislain^{*)}, AFSSAPS, Saint Denis, France

Presentations

Moderator: Georgette Lalis, European Commission, Brussels – GHTF Chair

SG1: Premarket Approval

Ginette Michaud^{*)}, Center for Devices and Radiological Health, FDA, USA

SG2: Vigilance

Jorge Garcia, Therapeutic Goods Administration, Symonston, Australia

SG3: Quality Systems

Alain Prat^{*)}, AFSSAPS, St. Denis, France

SG4: Regulatory Auditing

Horst Frankenberger^{*)}, Forum für Medizintechnik e.V., EUROM VI, Luebeck, Germany

SG5. Clinical Evidence

Graeme Harris^{*)}, Therapeutic Goods Administration, Symonston, Australia

Call for Poster

Poster chair coordinators:

Ekkehard Stösslein^{*)}, Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany

Maurice Freeman, European Commission / CEN, Brussels, Belgium

Who should attend?

Senior Management, Quality and Risk Management experts, Regulatory Affairs Professionals, Notified Bodies, Design and Development Staff in the Medical Devices sector

Regulatory authorities, Regulators and Auditors for Medical Devices

Students and Professors in Medical Technology and Regulatory Affairs

Date and Venue

Wednesday, June 28, 2006	13:30 – 22:30 Conference followed by City Hall Reception and Conference Dinner
Thursday, June 29, 2006	08:30 – 21:30 Conference followed by Gala Banquet and Concert
Friday, June 30, 2006	08:30 – 22:30 Conference followed by Boat trip

Luebeck, Germany – Musik und Kongresshalle
Willy Brandt Allee 10
23562 Luebeck

Conference language is English

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Registration / Fees

- € 300 for industry / non-government representatives.
- € 200 for current and past GHTF-members, government representatives, notified bodies, students and faculty members.
- € 100 for accompanying persons (only attending the evening programmes and excursion)

The registration fee of € 300 or € 200 includes

- Unlimited access to all conference sessions and poster presentations;
- Delegate's kit including conference satchel, programme and conference papers;
- Evening programme on 28 June, 29 June and excursion on 30 June; and
- Lunch and morning/afternoon coffee where indicated on the programme.

For details on methods of payments, see separate Registration Form on GHTF-website

"Early bird discount" – see GHTF-website: www.GHTF.org

A 25 % reduction of the fee is granted for registration with payments made before **February 15, 2006**.

Information about Luebeck

Luebeck – the former capital and Queen City of the Hanseatic League – was founded in 1143 as the first German city on the Baltic Sea and prospered until the 16th century as the major trading centre for Northern Europe. Luebeck also rose to head of the Hanseatic League as the leader of the economic power in mediaeval times. It has remained a centre for maritime commerce to this day, particularly with the Nordic countries. Today Luebeck is also an important centre for medical technology.

Despite the damage it suffered during the Second World War, the basic structure of the old city, consisting mainly of 15th- and 16th-century patrician residences, public monuments (the famous Holstentor brick gate), churches and salt storehouses, remains unaltered. In 1987 parts of Luebeck's Old Town were declared a World Heritage Site by UNESCO. For further information: www.luebeck-tourism.de

The temperature in Luebeck during the period of the meeting usually ranges between 20°C and 30 ° C.

There are direct flights with Ryan Air to Luebeck from **London (Stansted), Milano (Bergamo), Stockholm (Skavsta), Glasgow/Prestwick, Pisa, Dublin (starting 25. APRIL 2006)**

Other national and international airlines arrive at the Hamburg airport in a distance of about 65 km from Luebeck.

Conference Programme 28 June 2006

Topics	
Workshops I	13:30 – 15:30
Coffee Break	15:30 – 16:00
Workshops II	16:00 – 18:00
Conference Programme is followed by	
Reception Mayor of Luebeck	18:30 – 19:30
Dinner	20:00 – 22:00

Conference Programme 29 June 2006

Topics	
Opening, Introduction to Design of Patient Safety	09:00 – 10:30
Coffee Break	10:30 – 11:00
Visit of Poster Exhibition	
Keynote Speeches, Conference Welcome and Global Regulatory Model	11:00 – 12:30
Lunch	12:30 – 14:00
Visit of Poster Exhibition	
Panel: How the Global Regulatory works	14:00 – 15:30
Coffee Break	15:30 – 16:00
Visit of Poster Exhibition	
Panel: GHTF quo vadis	16:00 – 17:30
Conference Programme is followed by	
Gala Banquet and Concert	18:30 – 21:30

Conference Programme 30 June 2006

Topics	
GHTF-Study Group Presentations Presentations AHWP and PAHO	09:00 – 10:15
Coffee Break	10:15 – 10:45
Visit of Poster Exhibition	
New and Emerging technologies I	10:45 – 12:30
New and Emerging Technologies II	
Lunch	12:30 – 14:00
Visit of Poster Exhibition	
Poster Award	14:00 – 14:15
Design for Patient Safety	14:15 – 15:45
Coffee Break	15:45 – 16:15
Closing Session	16:15 – 17:00
Conference Programme is followed by	
Boat Trip	17:30 – 22:30