



GHTEF 2006 Conference

Design for patient safety in a global regulatory model

Conference Programme Day 1 — Wednesday 28 June 2006
at MUK (Musik und Kongresshalle Lübeck), Willy-Brandt-Allee 10, 23554 Lübeck

Afternoon programme: 13:30 – 18:00

Workshops:

Topics:	<u>Chair / Contributor(s):</u>	Venue:
13:30 – 15:30		
∅ Intellectual property and internet promotion	<u>Alain Prat</u> / Michael Gropp / Steve Niedelman / Hiroshi Yamamoto / Tsukano Masaaki	MUK Room 1
∅ Auditing and risk management	<u>Horst Frankenberger</u> / Richard Moore / Xiaoli Ren / Erik Schwanbom / Jan Welch / Shigetaka Miura	MUK Room 2
∅ Emerging technology I – Plug & Play	<u>Julian Goldman</u> / Larry Kessler / Jörg-Uwe Meyer / Bertram König / Robert Britain	MUK Room 3
∅ Design for patient safety – Principles I	<u>Mike Wiklund</u> / David Jefferys / Ralf Dittmann / Matthew Weinger	MUK Room 4

Coffee Break 15:30 – 16:00

16.00 – 18.00		
∅ STED and the use of standards in conformity assessment	<u>Ginette Michaud</u> / Mike Flood / Hiroshi Ishikawa / Albert Li / Brian Vale / Peter Linders	MUK Room 1
∅ Post-production clinical follow up	<u>Philippe Auclair</u> / Graeme Harris / Roland Rotter / Karen Howes / François Simondet	MUK Room 2
∅ Emerging technology II – combination products	<u>Daniel Schultz</u> / Antonio Lacerda / Wolfgang Ecker / Dario Pirovano / Sabina Hoekstra-van den Bosch	MUK Room 3
∅ Design for patient safety – Principles II	<u>Matthew Weinger</u> / Mike Wiklund / David Jefferys / David Kelly / Carl F. Wallroth	MUK Room 4

Chair to coordinate workshop and hand-outs

Evening programme 18:30 – 22:30 **Venue:**

Reception 18:30 – 19:30	The Mayor of Lübeck	City Hall of Lübeck
Dinner 20:00 – 22:30	Conference participants and spouses	Schiffergesellschaft



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Conference Programme Day 2 — Thursday 29 June 2006

Morning programme **9:00 – 12:30** **Venue: MUK Foyer**

Opening addresses	Patrick Posso, EUROM President Stefan Dräger, Drägerwerk AG, Chairman of the Executive Board Peter-Harry Carstensen, Prime Minister of Schleswig-Holstein
Conference address Design For Patient Safety	Jeff Cooper

Coffee Break **10.30 – 11.00**

Keynote speeches	Gerhard Schröder (invited) Günter Verheugen (invited) Dagmar Roth-Behrendt, Vicepresident EP
Conference welcome and Global Regulatory Model	Georgette Lalis, GHTF Chair

Lunch **12:30 – 14:00** **Visit of poster exhibition (MUK 1st floor)**

Poster chair / Coordinators: Hans-Georg Will / Maurice Freeman, Ekkehard Stößlein

Afternoon programme **14:00 – 17:30** **Venue: MUK Foyer**

Panel: 'How the global regulatory model works '	Moderator: Maurice Wagner, GHTF Vice Chair, Asia Pacific: Rita MacLachlan, Hiroshi Yamamoto, Masato Yoshida, Barry Evers-Buckland North America: Roland Rotter, Daniel Schultz, Janet Trunzo Europe: Abraao Carvalho, Jos Kraus, Werner Schoenbuehler
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Coffee Break **15:30 – 16:00** **Visit of poster exhibition (MUK 1st floor)**

Panel: 'GHTF quo vadis'	Moderator: Naill Dixon N.N., MEP Roland Rotter Wolfgang Reim Georgette Lalis
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Evening programme **18:30 – 21:30** **Venue: Marien Church of Lübeck**

Gala banquet and concert: - Organ recital - Children's choir	Conference participants and spouses Prof Dr. Ernst-Erich Stender Lübecker Knabenkantorei
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Conference Programme Day 3 — Friday 30 June 2006

Morning programme **8:30 – 12:30** **Venue: MUK Foyer**

Study Group presentations	Moderator: GHTF Chair, Georgette Lalis
	SG1 Premarket: Ginette Michaud
	SG2 Vigilance: Jorge Garcia
	SG3 Quality: Alain Prat
	SG4 Auditing: Horst Frankenberger
	SG5 Clinical: Graeme Harris
	AHWP: Ir. Dr. M.S. Pillay Datuk (Chair)
	PAHO: Mirta Roses Periago (Chair)

Coffee Break **10.15 – 10.45** **Visit of poster exhibition (MUK 1st floor)**

New and emerging technologies I: – Balance safety /uncertainty – How safe is safe?	Moderator: Terry Slater Daniel Schultz Michael Gropp
New and emerging technologies II: – Science – Regulatory challenges	Moderator: Norbert Anselmann Julian Goldman Jean-Claude Ghislain

Lunch **12:30 – 14:00** **Visit of poster exhibition (MUK 1st floor)**

Poster chair / Coordinators: Hans-Georg Will / Maurice Freeman, Ekkehardt Stößlein
After the poster slot, attendants to vote for the poster award.

Afternoon programme **14:00 – 17:00** **Venue: MUK Foyer**

Poster award	Presenter: Hans-Georg Will
Design for patient safety: – Methodology – Post-market validation – Global Vigilance	Moderator: David Jefferys Mike Wiklund Matthew Weinger Rita MacLachlan

Coffee Break **15:45 – 16:15** **Visit of poster exhibition (MUK 1st floor)**

Closing session	Moderator: Larry Kessler Georgette Lalis, GHTF Chair Maurice Wagner, GHTF Vice Chair, Carl F. Wallroth, GHTF Conference Chair,
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Excursion: **17:30 – 22:30** **Venue: MUK River walk**

Boat trip: Lübeck - Travemünde - Lübeck	Conference participants and spouses
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NOTE: GHTF SG 1, 2, 3, 4, 5 and Steering Committee meetings as well as EUROM General Assembly to precede the Conference from June 25 to 28 followed by Steering Committee debriefing on July 1st at Dräger Medical, Moislinger Alle 53-55, 23542 Lübeck