Asia-Pacific
Economic Cooperation

Report on APEC-Funded Seminars on Harmonization of Medical Device Regulations

Kuala Lumpur, Malaysia March 5 – 7, 2008 and Toronto, Canada May 14 – 16, 2009

Life Sciences Innovation Forum
APEC Committee on Trade and Investment

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CTI 22/2008T

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Part 1: Kuala Lumpur, Malaysia, March 5 – 7, 2008

A. *Summary:* The first segment of the Fourth APEC Seminar on Harmonization on Medical Device Regulations, which took place from May March 5 – 7, 2008, in Kuala Lumpur, Malaysia, was an overwhelming success. This was the first of two seminars funded by APEC project number CTI 22/2008; the second seminar took place in Toronto, Canada in 2009 (*see* Part 2, below).

B. *Attendance:* A total of 261 regulators and industry representatives attended the training seminar. Ten APEC economies with developing regulatory systems were represented as well as two non-APEC economies with developing regulatory systems (India and Saudi Arabia). In addition, all five GHTF founding member economies were represented. Economies represented included:

i) APEC economies with developing regulatory systems:

1. Brunei (regulators)
2. China (regulators and industry representatives)
3. Chinese Taipei (industry representatives)
4. Hong Kong, China (industry representatives)
5. Korea (regulators and industry representatives)
6. Malaysia (regulators and industry representatives)
7. Philippines (regulators and industry representatives)
9. Singapore (regulators industry representatives)
10. Thailand (regulators and industry representative)

ii) GHTF founding members represented at event:

1. Australia (regulator and industry representatives)
2. Canada (regulator and industry representative)
3. European Union (regulators and industry representatives)
4. Japan (industry representatives)
5. United States (regulators and industry representatives)

Total attendance at the seminar of 261 regulators and industry representatives broken down as follows:

Regulators or government officials from APEC economies with developing regulatory systems: 58

Industry representatives from APEC economies with developing regulatory systems: 181

Regulators from non-APEC economies with developing regulatory systems: 3

Others (trainers, government and industry representatives from GHTF founding member economies, notified bodies, press, etc.): 19

Total: 261

C. *Trainers and presenters:* Sixteen trainers and presenters were selected to conduct the training program. All trainers were members of the various GHTF Study Groups. A list of trainers and presentations is attached.

D. *APEC Funding:* APEC authorized an expenditure of $13,716 to fund round-trip airfare to Kuala Lumpur and $9,240 for *per diem* for regulators from selected APEC economies. APEC provided $5,100 for honoraria for expert trainers, to be split among the five industry expert trainers.

	Funds Authorized	*Funds Spent*
APEC regulators' airfare:	$13,716	
APEC regulators' *per diem*	$9,240	
Trainers' honorarium	$5,100	
Trainers' *per diem*:	$2,400	
Hosting, conference space and logistical costs:	$5,000	
Publications and copying costs:	$5,000[1]	
Consultant (including researcher) fees	$5,000	
Consultant's secretary	$1,000	
Equipment / Materials	$1,000[2]	
Photocopying	$500	
Communications	$500	
Total	$48,006	$

Regulators from APEC economies, trainers, Datuk Dr. M. S. Pillay representing the Malaysian Ministry of Health, and Jeffery Gren as Project Overseer, were not charged a fee to attend the seminar. All other attendees were charged US$300.00 to attend to offset seminar costs.

The APEC proposal included cost sharing. Although APEC did not require recordkeeping for cost sharing, below is an estimate:

Jeffrey Gren's advance trip:	$2,385
Jeffrey Gren's travel to Malaysia for the seminar itself:	$2,835
Consultant (including researcher) fees:	$1,731
Eleven government trainers travel costs:	$27,953[3]
Twenty-five attendees travel costs not funded by APEC	$46,132[4]

[1] Includes $4,000 for video recording and production of video CDs. The U.S. Government and industry will share costs for video CDs.
[2] Includes audiovisual equipment for presentations.
[3] Includes $4,260 for expenses for three government trainers from the United States, and two from all other GHTF founding member economies (Canada, Australia, Japan, and the European Union), and $23,693 for airfare.

Industry registration fees: $XXX

In addition to the above travel costs, government and industry trainers provided significant time, (preparation, travel and time at the seminar itself) which represent significant value if computed based upon average salary levels. Moreover, the U.S. Department of Commerce provided the funding ($2,499) for a hospitality reception on the evening of March 5.

E. *Program:* Attached is a program agenda and announcement. Below is a summary of the regulatory training program.

1) *Asian Harmonization Working Party (AHWP) organizational meeting.* Before the training started on March 5, the AHWP held a meeting.

2) *Opening Plenary*. Jeffrey Gren of U.S. Department of Commerce made opening comments and outlined how the three-day seminar would be organized.

Datuk Dr. M. S. Pillay, Deputy Director General of Health of the Malaysian Ministry of Health, welcomed the seminar attendees to Kuala Lumpur and expressed the importance of global and Asian medical device harmonization.

Dr. Larry Kessler, GHTF Steering Committee Chair, and Janet Trunzo, GHTF Steering Committee Vice Chair, gave an overview of the GHTF, the role of GHTF study groups, and future GHTF activities.

Jorge Garcia of Australia's Therapeutic Goods Administration gave an overview of Study Group 2 and of the National Competent Authority Report (NCAR).

The last portion of the plenary consisted of a panel discussion titled: *The Role of and Responsibility in the Supply Chain for Medical Devices: Safety, Performance, and Conformity Assessment Throughout the Total Product Life Cycle.* Dr. Kessler served as moderator, and John Brennan of the European Commission, Shelley Tang of Australia's Therapeutic Goods Administration, Dr. Roland Rotter of Health Canada, Pang Kim Sun of Zuellig Pharma Malaysia, Gunter Frey of GE Healthcare, and Datuk Dr. Pillay served as panelists.

3) On Thursday, March 6, John Brennan of the European Commission and Michael Gropp of Medtronic opened with Study Group 1 (Convergence of Regulatory Systems) training, followed by a panel discussion to include John Brennan and Michael Gropp, as well as Shelley Tang, Petra Kaars-Wiele of Abbott Laboratories, and Alfred Kwek of Singapore's Health Sciences Authority, representing the Asian Harmonization Working Party. Study Group 1 training continued with a special emphasis on *in vitro* diagnostic (IVD) classification and conformity guidelines, led by Shelly Tang and Petra Kaars-Wiele.

The last session of the day was on Study Grop 5 (Clinical Safety and Performance), led by Johan Brinch of Cochlear Ltd., Australia, representing the Medical Industry Association of Australia, and Greg LeBlanc, of Cook (Canada).

[4] Includes $16,500 for expenses and $29,632 for airfare for twenty five attendees not paid by APEC.

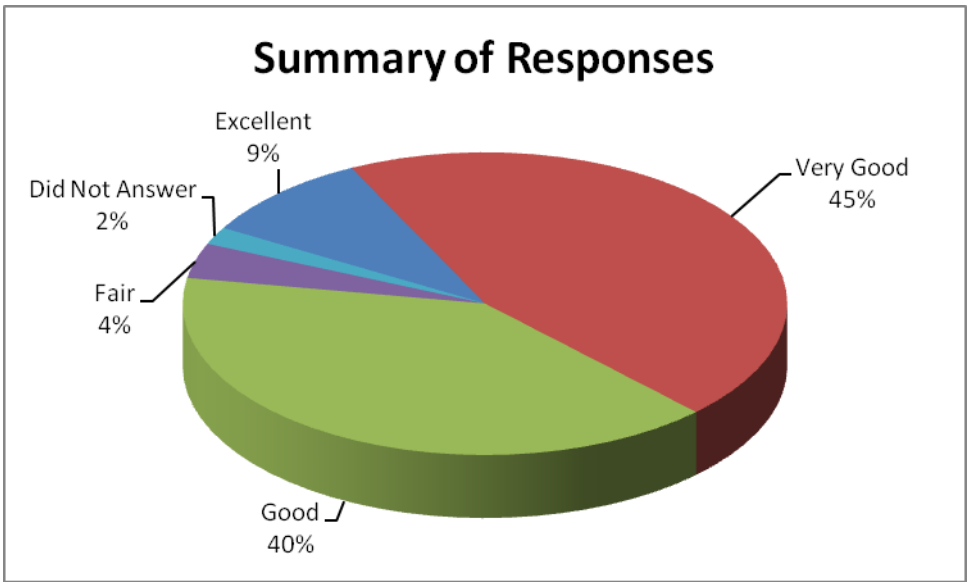
That evening, attendees participated in a hospitality dinner event hosted by the Malaysian Ministry of Health.

On Friday, March 7, Dr. Roland Rotter, Hideki Asai of Hitachi Ltd., and Gunter Frey led Study Group 3 (Quality Systems) training for most of the day.

Tim Missios of Boston Scientific gave a summary of Study Group completed the day with a summary of Study Group 4 (Auditing).

4) *Seminar Close and Closing Comments.* The seminar was viewed as very successful due to expert coverage and representation from a large number of economies. There was strong support for the following seminar of this APEC-funded project to be held in Toronto, Canada in May, 2009.

F. *Evaluation.* The feedback from the March 5 – 7 APEC Seminar on Harmonization of Medical Device Regulations was extremely positive, the majority of attendees submitted evaluation forms. A copy of the evaluation form is attached, and responses regarding the overall quality of the seminar are broken down as follows:[5]



Excellent	15
Very Good	72
Good	64
Fair	6
Poor	0
Did Not Answer	3

[5] Based on 160 submitted answers to this question.

G. *Next Steps:* Each attendee at the training seminar received a binder with most presentations included. All presentations, with the exception of "Challenges to Regulators from Advanced Medical Technologies," have been posted on the Asian Harmonization Working Party (AHWP) website at http://asiahwp.org/?page=article&id=263.

U.S. DOC, the Pan American Health Organization, Health Canada, and the GHTF Steering Planning Committee later focused on planning the 2009 Latin America regulatory seminar.

H. *Conclusion:* The APEC Asia regulatory training program was viewed as an overwhelming success. A significant number of regulators and industry representatives from APEC economies with developing regulatory systems attended and were very satisfied with the program based on evaluation forms. The trainers also did an excellent job and the slides developed of the seminar will serve as a future reference for regulators. The slides have been made available to regulators from APEC economies that did not attend the seminar.

The key to continued success is the involvement of APEC regulators and industry representatives in the Asian Harmonization Working Party and the Global Harmonization Task Force.

U.S. DOC, AHWP, and GHTF wish to thank APEC for providing this funding, which will have a positive impact on the global harmonization of medical device regulations, auditing procedures, and safety vigilance.

List of Speakers and Presentations in Kuala Lumpur, Malaysia, March 5 – 7, 2008:

Asai, Hideki: Regulatory Compliance Officer, Life Science Business Group Hitachi High-Technologies Corporation (Study Group 3). *"GHTF SG3 Training Overview"* with Gunter Frey; *"ISO13485:2003 -- An Overview"* with Gunter Frey; *"GHTF.SG3.N15-R8: Implementation of Risk Management Principles and Activities Within a Quality Management System"* with Gunter Frey; *"Regulatory Links & Sources of Standards"* with Hideki Asai.

Brennan, John: European Commission, DG Enterprise (Study Group 1). *"Principles of Medical Device Classification;" "Role of Standards in the Assessment of Medical Devices;" "Labeling for Medical Devices."*

Brinch, Johan: Vice President, Regulatory Affairs, Cochlear, Ltd. Australia, representing Medical Industry Association of Australia (Study Group 5). *"Overview of Global Harmonization Task Force Study Group 5"*[6]with Greg LeBlanc.

Frey, Gunter: GE Healthcare, Representing National Electrical Manufacturers Association (Study Group 3). *"GHTF SG3 Training Overview"* with Hideki Asai; *"GHTF Study Group 3: Role, Members, Documents;" "Quality Management Systems: History and Evolution;" "ISO13485:2003 -- An Overview"* with Hideki Asai; *"GHTF.SG3.N15-R8: Implementation of Risk Management Principles and Activities Within a Quality Management System"* with Hideki Asai; *"Process Validation Guidance;" "Regulatory Links & Sources of Standards"* with Hideki Asai.

Garcia, Jorge: Manager, Medical Device Regulatory Programs, Australia Therapeutic Goods Administration (Study Group 2). *"Overview of GHTF SG2 and NCAR."*

Gren, Jeffrey L.: Director, Office of Health and Consumer Goods, U.S. Department of Commerce, and APEC Project Overseer.

Gropp, Michael: Vice President, Global Regulatory Strategy, Medtronic, Inc. (Study Group 1). *"Definition of the Term: Medical Device." "Definition of the Terms: 'Manufacturer,' 'Authorised Representative,' 'Distributor,' and 'Importer.'" "Essential Principles of Safety and Performance of Medical Devices." "Study Group 1, Accomplishments and Future Direction."*[7]

Kaars-Wiele, Petra: Abbott Laboratories, Germany, Representing EDMA. (Study Group 1) *"IVD Medical Devices – the GHTF Guidance Documents"*

Kessler, Larry, Ph.D.: GHTF Steering Committee Chair, and Director, Office of Science and Engineering Laboratories, CDRH, U.S. Food and Drug Administration *"The Global Harmonization Task Force"* with Janet Trunzo.

Kwek, Alfred: Asian Harmonization Working Party (Study Group 1) *SG1 – Practical Implementation of Harmonised Guidelines."*

[6] Slide development with the assistance of Herb Lerner.
[7] Authored by Ginette Michaud, Chair, Study Group 1.

LeBlanc, Greg: Cook Canada, Inc. (Study Group 5). *"Overview of Global Harmonization Task Force Study Group 5"* with Johan Brinch.

Missios, Tim: Boston Scientific. (Study Group 4). *"Regulatory Auditing Strategy."*

Michaud, Ginette, M.D: Center for Devices and Radiological Health, Food and Drug Administration (Study Group 1). *"Study Group 1 Accomplishments & Future Direction."*

Pillay, Datuk Dr. "*The Roles and Responsibilities in the Supply Chain For Medical Devices: Safety, Performance and Conformity Assessment Throughout the Total Product Life Cycle."*

Rotter, Roland, Ph.D.: Health Canada.

Sun, Pang Kim: National Logistics Manager, Zuellig Pharma Malaysia. *"A Zuellig Pharma Presentation."*

Tang, Shelley: Therapeutic Goods Administration, Australia. (Study Group 1) *"Medical Devices – Integrity in the Supply Chain." "IVD Medical Devices – the GHTF Guidance Documents."*

Trunzo, Janet: Executive Vice President, Technology and Regulatory Affiars, AdvaMed, Vice Chair, GHTF (Study Group 1) *"Global Harmonization Task Force"* with Larry Kessler.

Report on APEC-Funded Seminar on Harmonization of Medical Device Regulations (CTI 22/2008T)

Part 2: Toronto, Canada, May 14 -- 16 2009

A. *Summary:* The second segment of the "Fourth APEC Seminar on Harmonization on Medical Device Regulations," which took place from May 14 – 16, 2009 in Toronto, Canada, was a significant success. This was the second of two seminars funded by APEC project number CTI 22/2008; the first seminar took place in Kuala Lumpur, Malaysia in March, 2008.

B. *Attendance:* A total of 64 regulators and industry representatives attended the training seminar.

i) APEC economies with developing regulatory systems:

1. Chile	(regulators)	(2)
2. Chinese Taipei	(regulators and industry representatives)	(5)
4. Korea	(regulators and industry representatives)	(4)
4. Mexico	(regulators and industry representatives)	(4)
5. Peru	(regulators)	(3)

ii) GHTF founding members represented at event:

1. Australia	(industry representative)	(1)
2. Canada	(regulator and industry representative)	(17)
2. European Union	(regulators and industry representatives)	(4)
3. Japan	(industry representative)	(1)
4. United States	(regulators and industry representatives)	(13)

iii) Authorized non-APEC economies

1. Argentina	(industry representative)	(1)
2. Brazil	(regulator and industry representatives)	(3)
3. India	(industry representatives)	(2)
4. Panama	(regulators)	(2)
5. Switzerland	(industry representative)	(1)
6. Uruguay	(industry representative)	(1)

Total attendance at the seminar of 64 regulators and industry representatives broken down as follows:

Regulators or government officials from APEC economies with developing regulatory systems: 11

Industry representatives from APEC economies with developing regulatory systems: 7

Regulators from non-APEC economies with developing regulatory systems: 6

Others (trainers, government and industry representatives from GHTF founding member economies, notified bodies, press, etc.): 40

Total: 64

C. *Trainers and presenters:* All trainers and presenters selected to conduct the training program were members of the various GHTF Study Groups. A list of trainers and titles of their presentations is attached. All presentations can be found at www.ghtf.org/meetings/conferences/5thapec/index.html .

D. *APEC Funding:* APEC authorized an expenditure of $6,927 to fund round-trip airfare to Toronto and $16,392 for *per diem* for regulators from selected APEC economies.

	Funds Authorized	*Funds Spent*
APEC regulators' airfare:	$6,927	
APEC regulators' *per diem*	$16,392	
Speakers' honorarium	$7,500	
Translator fees	$12,000	
Hosting, conference space and logistical costs:	$7,500	
Publication costs:	$5,000	
Consultant (including researcher) fees	$5,000	
Consultant's secretary	$1,000	
Equipment / Materials	$1,000	
Photocopying	$500	
Communications	$250	
Total	$ 63,069	$

Regulators from APEC economies, trainers, and Jeffrey Gren, as Project Overseer, were not charged a fee to attend the seminar. All other attendees were charged US$200.00 to attend to offset seminar costs.

The APEC proposal included cost sharing. Although APEC did not require recordkeeping for cost sharing, below is an estimate:

Jeffrey Gren's travel to Toronto:	$2,791
Eleven government trainers travel costs:	$30,701
Twenty-five attendees travel costs not funded by APEC	$69,775
Industry registration fees:	$6,554

In addition to the above travel costs, government and industry trainers provided significant time, (preparation, travel and time at the seminar itself) which represent considerable value if computed based upon average salary levels. Moreover, the U.S. Department of Commerce provided $1,095 in funding for a hospitality reception on the evening of Friday, May 15.

E. *Program:* Attached is a program agenda and announcement. Below is a summary of the regulatory training program.

1) *Latin American Harmonization Working Party (LAHWP) organizational meeting.* Part of the APEC-funded regulator training program included an LAHWP meeting.

2) *Opening Plenary*. Jeffrey Gren of U.S. Department of Commerce made opening comments and outlined how the three-day seminar would be organized.

Antonio Hernandez of the Pan American Health Organization (PAHO) welcomed the seminar attendees to Toronto and expressed the importance of global and Latin American medical device harmonization.

Dr. Roland Rotter, GHTF Steering Committee Chair, gave an overview of the GHTF, the role of GHTF study groups, and future GHTF activities.

The last portion of the plenary consisted of a panel discussion titled: *The Role of and Responsibility in the Supply Chain for Medical Devices: Safety, Performance, and Conformity Assessment Throughout the Total Product Life Cycle.* Jeffrey Gren served as moderator, and Meghal Khakahar of Baylis Medical, Canada; Petra Kaars-Wiele of Abbott Labs and the European Diagnostics Manufacturing Association (EDMA); Miang Chadaporn Tanakasemsub of Bausch and Lomb; and Jos Kraus of the Netherlands Healthcare Inspectorate served as panelists.

3) On Friday, May 15, Maria Carballo of Health Canada; Michael Morton of Medtronic and AdvaMed; Brenda Murphy of SciCan and MEDEC; and Petra Kaars-Wiele opened with Study Group 1 (Convergence of Regulatory Systems) training. Study Group 1 training included a special emphasis on *in vitro* diagnostic (IVD) classification and conformity guidelines.

The event continued on Friday, May 15 with a session on Study Group 2 (Post Market Surveillance/Vigilance) led by Ekkhard Soesslein of BFARM, Germany and Greg LeBlanc of Cook, Canada.

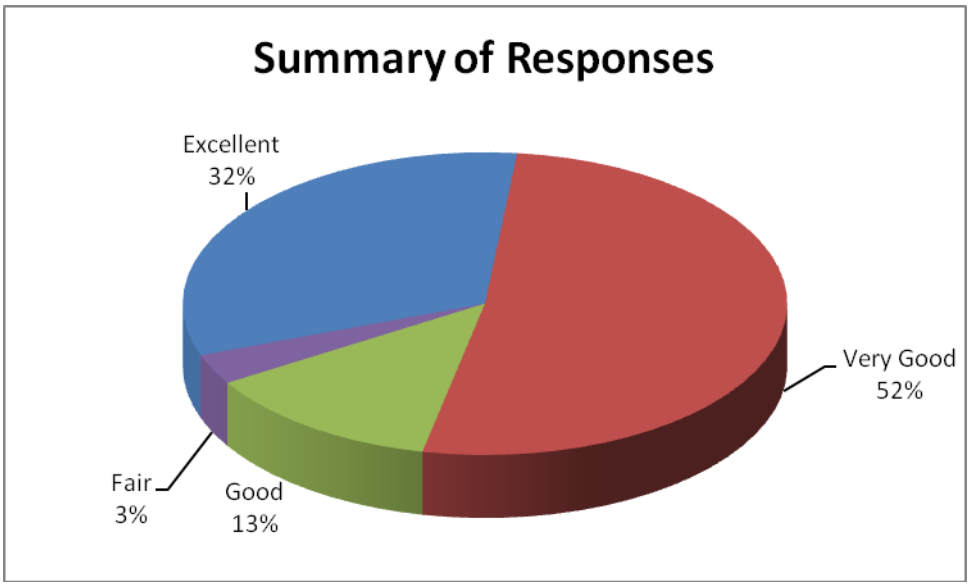
That evening, attendees participated in a hospitality dinner event hosted by the USDOC.

On Saturday, May 16, the training continued with a morning session on Study Group 3 (Quality Systems). Trainers included Egan Cobbold of Health Canada, and Gunter Frey of Philips Healthcare and MITA.

The training concluded with an afternoon session on Study Group 4 (Auditing), conducted by Amand Tsai of Health Canada and Albert Li of the Industrial Technology Research Institute of Chinese Taipei.

4) *Seminar Close and Closing Comments.* The seminar was viewed as very successful due to expert coverage and representation from a large number of economies. Jeffrey Gren made closing remarks.

F. *Evaluation.* The feedback from the May 14 – 16 APEC Seminar on Harmonization of Medical Device Regulations was extremely positive, and 34 attendees submitted evaluation forms. A copy of the evaluation form is attached, and responses regarding the overall quality of the seminar are broken down as follows:



Excellent	10
Very Good	16
Good	7
Fair	1
Poor	0

G. *Next Steps:* Each attendee at the training seminar received a binder with most presentations included.

H. *Conclusion:* The APEC Latin America regulatory training program was viewed as a success. Attendance was adversely impacted by the H1N1 influenza threat, because several delegations canceled or curtailed their participation, including China, Japan, Brazil, Korea, and Chinese Taipei. The regulators and industry representatives who attended from APEC economies with developing regulatory systems were very satisfied with the program based on evaluation forms. The trainers also did an excellent job and the slides developed for the seminar will serve as a future reference for regulators.

The key to continued success is the involvement of APEC regulators and industry representatives in the Latin American Harmonization Working Party and the Global Harmonization Task Force (GHTF).

U.S. DOC, AHWP, and GHTF wish to thank APEC for providing this funding, which will have a positive impact on the global harmonization of medical device regulations, auditing procedures, and safety vigilance.

List of Speakers and Presentations:

- **Thursday**
  - Dr. R.G. Rotter - *The Global Harmonization Task Force: Overview and Status*
  - Dr. Meghal Khakhar - *Role of Distributor in Global Harmonization and Integrity of Medical Device Supply Chain*
  - Jos Kraus - *Legislation, Regulators and the Safety of the Distribution Chain*
  - Miang Tanakasemsub - *The role of regulators, industry, and distributors in global medical device regulatory harmonization and the integrity of the medical device supply chain*
  - Greg LeBlanc - *Global Harmonization Task Force Study Group 5*

- **Friday**
  - Michael C. Morton - *Principles of Medical Device Classification*
  - Maria Carballo - *Classification of In vitro Diagnostic Devices (IVDs)*
  - QUIZ – Classification of IVDs
  - Brenda Murphy - *Introduction to Summary Technical Documentation (STED)*
  - Maria Carballo - *STED Implementation, The Canadian Experience*
  - Dr. Petra Kaars-Wiele - *Proposed Document - Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer*
  - Brenda Murphy - *Proposed Document - Registration of Manufacturers and other Parties and Listing of Medical Devices*
  - Dr. Ekkehard Stösslein & Dr. Philippe Auclair - *GHTF SG2 Guidance: Reporting of Medical Device Adverse Events*
  - Ekkehard Stösslein & Jorge Garcia & Mark Segstro & Deborah Yoder - *GHTF SG2: National Competent Authority Report Program*

- **Saturday**
  - Egan Cobbold & Gunter Frey
    - *GHTF SG3 Training (Quality Systems)*
    - *SG3/N15R8/2005 Implementation of Risk Management Principles and Activities Within a Quality Management System*
    - *Process Validation Guidance GHTF/SG3/N99-10:2004*
    - *SG3/N17R9/2009 Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers - A Status Update and Introduction*
  - Armand Tsai & Albert T.W. Li - *Introduction to Global Harmonization Task Force Study Group 4 Regulatory Auditing*