

**2nd APEC Seminar on the
Harmonization of Medical Device Regulations**

**Friday, 17 - Saturday, 18 May 2002
Novotel Apollo Hotel
Singapore**

DAY 1: Friday, 17 May 2002

7.30am

Registration

9.00am

I. Welcome/Opening Address

Dr Clarence Tan - Chief Executive Officer, Health Sciences Authority, Singapore

9.20am

II. Global Harmonization Task Force

“Historical Overview, Goals, Objectives, Infrastructure, 5-year Strategic Plan”

Ms Rita Maclachlan - GHTF Chair; and Director, Conformity Assessment
Branch, Therapeutic Goods Administration, Australia

10.05am

III. The Global Medical Device Market and Regulatory Harmonization

A keynote on the world market economics for medical devices, the diversity of national regulatory approaches and consequences, the potential for harmonized approaches and the potential for use of internationally accredited conformity assessment bodies. The address will make comment on the status and potential usefulness of existing and future mutual recognition agreements.

Mr Michael Gropp

10.50am

Coffee Break

11.10am

IV. Quality Systems

Topics to be addressed:

- “Quality Systems, the foundation for regulatory programs” - Tony Gould
- “ISO 9001:2001 versus ISO 13485:200x / EN 46001:1996 versus type testing” - Dr Victor Dorman-Smith
- “FDA’s QSIT concept and audit approaches by EU, Japan, Canada and Australia” - Markus Zobrist, Christine Nelson, Bob Turocy

12.30 - 2.00pm

Lunch

2.00pm

Presentations on pertinent QS and audit documents from GHTF Study Groups 3 and 4:

- “Regulatory auditing” - Andrew Muir
- “Process validation” - Dr Victor Dorman-Smith
- “Design control” - Egan Cobbold

followed by a panel discussion (Markus Zobrist, Victor Dorman-Smith, Egan Cobbold, Shigetaka Miura, Christine Nelson, Andrew Muir, Bob Turocy, Tony Gould

3.10pm

V. Post Market Surveillance

Presenter : Kim Dix

Topics:

1. Overview: How it all goes together: the Précis - N12
 - a. The basis of reporting: mandatory reporting by manufacturers
 - b. Staying with existing laws
 - c. The current regulatory reporting systems: N6
 - d. Where we are headed in the future
 - e. Links with Quality Systems

3.40pm

Coffee Break

4.00pm

Presenter: Larry Kroger

Topics:

2. The beginning: What is an adverse event and what is a reportable event: N21 along with examples
3. When exemptions need to be reported: Trends: N36 (with examples)
4. Concept of well understood events and summary reporting: N30 (examples)
5. What information needs to be reported
 - a. Minimum data set: N7
 - b. Universal data set: N32
 - c. GMDN: a brief summary

Presenter : Jorge Garcia

Topics:

6. To Whom to Report ? a vision of the future: N40

7 .The NCA Vigilance System

- a. Overview: What we are trying to accomplish
- b. What are the criteria for a vigilance report: N20
- c. How to handle vigilance reports: N8
- d. What gets reported and how: N9
- e. How to participate in the NCAR system: N38
- f. A few examples of where things did not fare so well
- g. Some examples of where things went well

5.30pm End Day 1

DAY 2: Saturday, 18 May 2002

9.00am

VI. Harmonized Approaches to Medical Device Registration, Classification and Approval

Topics to be addressed:

- Different levels of control for different classes of devices
- Labelling language/use of symbols
- Local language labelling
- Role of International Standards

"Regulatory Perspective" - Mr Maurice Freeman

"Industry Perspective" - Mr Fred Halverson

10.20am

Panel Members GHTF Study Group 1

Fred Halverson, Mike Flood, Johann Rader, Maurice Freeman, Johan Brinch, Klaus Stinshoff, Michael Gropp, Barry Simpson, Masato Yoshida

10.50am

Coffee Break

11.10am

VII. Present and Proposed Implementation of GHTF Recommendations by Founding Members

How will or could the GHTF Founding Members' regulatory activities be different five years from now?

“Panel” -

Canada - Egan Cobbold

EU - Klaus Stinshoff

Japan - Daisuke Koga

USA - Christine Nelson

Australia - Mike Flood

12.30 - 2.00pm

Lunch

2.00pm

VIII. Present and Proposed Implementation of GHTF Recommendations by APEC National Authorities

Moderator - Mr Michael Gropp

Chair and Vice Chair, Asian Harmonization Working Party - tba

Singapore - Mr Wong Yew Sin - Health Sciences Authority

Chinese Taipei - Dr Huang Hsiau Wen

(1) Regulators could give their views on:

(a) local public health priorities

(b) how medical technology can help address those priorities, and

(c) their priorities for regulation (i.e., what causes the most concern today?)

(c) how their regulatory systems will protect public health, facilitate patient and clinician access to technology, and facilitate trade.

(2) Regulators could share their views on how harmonisation can help/hinder local manufacturers in exporting.

(3) What is required to implement or further develop their regulatory systems?

(4) An industry member of the AHWP Technical Committee could offer comments on the issues which cause the most practical difficulties today. This could stimulate a discussion on practical measures and/or how GHTF guidance might help.

3.00pm

IX. Round Table Discussion

Question and Answer Period for all seminar attendees and speakers

Moderator: Mr Jeffrey Gren, Director - Office of Microelectronics, Medical Equipment & Instrumentation, US Department of Commerce

4.00pm

Coffee Break

4.30pm

X. Seminar Close

Dr Clarence Tan - Chief Executive Officer, Health Sciences Authority, Singapore

Mr Robert Britain - Member, GHTF Steering Committee; and Vice President - Medical Products, NEMA

5.00pm

End Day 2