

GHTF Registration and Coffee

GHTF Steering Committee Meeting (Closed Session)

GHTF Study Group Meetings

Study Group 1

Study Group 2

Study Group 3

Study Group 4

Note: As a courtesy, delegates wishing to attend the Study Group meetings should contact the respective Study Group Chairs directly. The Chairs' contact details are available from the GHTF website - www.ghtf.org

Close of day

Steering Committee and Study Group Meetings may proceed beyond 17.00 at the Chairs' discretion

GHTF Registration and Coffee

GHTF Steering Committee Meeting (Closed Session)

GHTF Study Group Meetings

Study Group 1

Study Group 2

Study Group 3

Study Group 4

GHTF Registration

Close of day

Delegates assemble in hotel lobby for bus transfer to the CHIJMES Chapel

SUNDAY 12 MAY

07.00 - 09.00

Venus Ballroom Foyer
(3rd floor)

08.30 - 17.00

Jupiter 2

Venus Ballroom 1

Venus Ballroom 2

Jupiter Ballroom 1

Jupiter Ballroom 3

17.00

MONDAY 13 MAY

09.00 - 12.00

Venus Ballroom Foyer
(3rd floor)

08.30 - 17.00

Jupiter 2

Venus Ballroom 1

Venus Ballroom 2

Jupiter Ballroom 1

Jupiter Ballroom 3

14.00 - 16.00

Venus Ballroom Foyer
(3rd floor)

17.00

17.45

18.30

GHTF Conference Welcoming Reception

CHIJMES Chapel, 30 Victoria Street, Singapore

Guest Speaker: Terry Slater

National Manager, Therapeutic Goods Administration

Terry Slater is the National Manager of the Australian Therapeutic Goods Administration (TGA), with responsibility for the regulation of the medical devices, pharmaceutical and complementary medicines industries. Mr Slater has held this position since 1996. The TGA is also responsible for the regulation of blood and blood products, and the Office of the Gene Technology Regulator.

TUESDAY 14 MAY

08.30 - 11.45

Venus Ballroom 1
Venus Ballroom 2
Jupiter Ballroom 1
Jupiter Ballroom 3

10.45 - 11.45
Foyer (3rd floor)

Continuation of GHTF Study Group Meetings

Study Group 1

Study Group 2

Study Group 3

Study Group 4

Poster Presentations

Presenters

Poster 1

Shelley Tang - Head, Device Registration and Assessment Section, Therapeutic Goods Administration

Poster 2

Dr Jorge Garcia - Manager, Medical Device Laboratory Program, TGA Laboratories Branch

Poster 3

Klaus E Stinshoff - Division of Medical Devices, Swissmedic - Swiss Agency for Therapeutic Products *and*

Steven I Gutman - Director, Office of Device Evaluation, US Food and Drug Administration

Poster 4

Soichiro Isoke - Deputy Director, Evaluation and Licensing Division, Ministry for Health, Labor and Welfare, Japan

Lunch

11.45 - 13.00
Coffee House
(2nd floor)

New and Emerging Regulatory Systems

Asian Harmonization Working Party Information Session

Members of the Asian Harmonization Working Party (AHWP) will provide a presentation on recent activities and the session will demonstrate how the AHWP is meeting its objectives of -

- i) Forging a common direction for the harmonization of medical device regulation in Asia, encouraging increased understanding on the benefits of harmonization and facilitating a linkage with the GHTF; and
- ii) Discussing and initiating projects relating to GHTF harmonization among regulators and industry groups in Asia; and seeking to establish AHWP as a formal regional grouping under the GHTF.

Speakers:

Dr Clarence Tan Chief Executive Officer, Health Sciences Authority (HSA)
and Chair, AHWP

Wong Yew Sin Director, Centre for Medical Device Regulation, HSA

Heekyo Jeong Korea Food and Drug Administration

13.00 - 16.00
Venus Ballroom 2 & 3

Coffee

16.00 - 16.30

New and Emerging Regulatory Systems

Chinese Information Session

Senior officials from the Department of Medical Device Administration of the State Drug Administration (SDA) of China will provide a presentation of China's Medical Device Regulatory System, including an update on changes and new developments since September 2000.

Speakers:

The Hon Mr Hao Heping Director-General, Department of Medical Device Administration, State Drug Administration of China

Deng Gang Department of Medical Device Administration,
State Drug Administration of China

Jeffrey Gren Director, Office of Microelectronics, Medical Equipment &
Instrumentation, US Department of Commerce

Derek Rochford representing EUCOMED

16.30 - 19.00
Venus Ballroom 1

Close of day

19.00

WEDNESDAY 15 MAY

08.00
Venus Ballroom 1

09.30

10.00

Venus Ballroom 1

Venus Ballroom 2 & 3

New and Emerging Regulatory Systems

Latin American Information Session

This session will provide an update for GHTF Members on recent developments in medical device regulation within the Americas Region (Latin American and the Caribbean countries).

- Speakers:**
- Antonio Hernandez** - Regional Adviser, Health Services Engineering and Maintenance, Pan American Health Organisation
 - Dr Roland Rotter** - Acting Director, Medical Devices Bureau, Therapeutic Products Directorate, Health Canada
 - Christine Nelson** - Center for Devices & Radiological Health, US Food & Drug Administration
 - Dr Wayne Brod Beskow** - Agencia Nacional de Vigilancia Sanitaria - ANVISA, Brazil
 - Dulce Maria Martinez** - Centro de Control Estatal de Equipos Medicos, Cuba
 - Dr Nohra Rodriguez** - Vice Director, Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA, Columbia
 - Dr Juan Villacorta** - Director, Adjunto DOGEMID, Ministerio de Salud, Peru
 - Dr Eric Ulloa** - Director, Nacional Servicios de Salud, Ministerio de Salud, Panama

Officials from the Regulatory Authorities of Mexico and Chile - to be advised.

Coffee

Concurrent Workshop Sessions

Workshop 1: The Global Medical Devices Nomenclature (GMDN)

Leader: **Maurice Freeman**, Chair - GMDN Maintenance Agency Policy Group (MAPG)

Achieving consistency in nomenclature is fundamental to the overall goal of international harmonisation. The GHTF believes the Global Medical Devices Nomenclature (GMDN) will represent a major contribution to this among regulatory agencies, particularly in vigilance and the worldwide registration of products. This Workshop will provide an update on the GMDN and highlight the major outcomes arising from meetings of the newly established GMDN Maintenance Agency Policy Group.

Workshop 2: "Evaluation of Draft Guidelines for the Development of Medical Device Regulations"

Leader: **Michael Gropp**, Vice President - Global Regulatory and Public Policy, Guidant Corporation

Speakers: **Gerald Verollet**, Department of Blood Safety and Clinical Technology (BCT), World Health Organisation
Dr Michael Cheng, Temporary Adviser, World Health Organisation

The safety, performance and consistency in quality of medical devices have become an international public health issue. The Guide provides an overview of medical device safety, its basic issues and regulatory philosophy. The original World Health Organisation (WHO) Guidelines, which primarily focused on the USA and Canadian regulatory systems, have now been expanded. The WHO's goal is for the new guidelines to ultimately become relevant for global use by providing a general introduction to medical device regulations and an integrated reference to final GHTF Guidance Documents.

Workshop 3: The Regulation and Supply of Refurbished Medical Devices

Leader: **Robert Britain**, Vice President - Medical Products, NEMA

Speakers: **Dr Lillian Gill** - Acting Deputy Director for Science, Center for Devices and Radiological Health, US Food and Drug Administration

Kevin Murray - Vice-President - Regulatory Affairs, MEDEC, Canada

Masato Yoshida - Vice President, The Japan Federation of Medical Devices Associations (JFMDA)

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

Michael Flood - Medical Device Premarket Manager, Therapeutic Goods Administration

Dr Nohra Rodriguez - Vice Director, Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA, Colombia

Mark Salmon - Asia Manager for Rebuilt Equipment, GE Medical Systems, Singapore

Dr Peter Linders - International Standardisation & Regulatory Affairs, Philips Medical Systems, The Netherlands

The supply of refurbished medical devices is becoming big business. The innovation in some equipment is rapid and the business of refurbishment is now being seriously embraced by large global manufacturers.

As larger hospitals purchase the latest models, they trade-in their superseded equipment which is still in excellent condition. This equipment remains highly suitable for a wide range of applications and these larger hospitals are therefore also purchasing refurbished models. Refurbished devices are also being sold to rural hospitals and they also represent a sensible option for developing country markets.

There is global variation with respect to how different countries regulate refurbished medical devices imported into their economies. This Workshop will elaborate on the practice of refurbishment and seek to highlight the regulatory similarities and differences between a number of countries with both, developed and developing markets.

Lunch

Jupiter Ballroom 1

12.00
Coffee House
(2nd floor)

13.30
Venus Ballroom 2&3

GHTF Plenary

Opening Remarks

Rita Maclachlan, GHTF Chair & Director, Conformity Assessment Branch, Therapeutic Goods Administration, Australia

13.45

Welcoming Address

Dr Balaji Sadasivan - Minister of State (Health and Environment), Singapore

14.00

GHTF Annual Report

Rita Maclachlan, GHTF Chair

14.30

GHTF Strategic Plan: 2002-2007

Brian Vale, GHTF Vice Chair & Chief Executive Officer, Medical Industry Association of Australia

15.00

GHTF Study Group Chairs' Reports

The pillars of the global regulatory model are progressively being set in place via the GHTF Guidance Documents developed by the four GHTF Study Groups. The Chairs will report to the Conference, outlining the status of each Group's work, their current standing and future directions.

Maurice Freeman, Chair - Study Group 1 & Consultant to CEN on behalf of the European Commission

Kim Dix, Chair - Study Group 2 & Head, Medical Devices Compliance Unit, Health Products and Food Branch Inspectorate, Health Canada

Kimberly Trautman, Chair - Study Group 3 & Center for Devices and Radiological Health, US Food and Drug Administration

Dr Markus Zobrist, Medical Devices Division, Swissmedic - Swiss Agency for Therapeutic Products

16.20

GHTF Regional Updates - Asia and Latin America

Dr Clarence Tan, Chair - Asian Harmonization Working Party and Chief Executive Officer - Health Sciences Authority, Singapore

Antonio Hernandez, Regional Adviser, Health Services Engineering and Maintenance, Pan American Health Organisation

17.00

Close of day

17.45

Delegates assemble in hotel lobby for bus transfer to the Jurong Birdpark

GHTF Conference Dinner

Guest Speaker - Professor Tan Ser Kiat

Group Chief Executive Officer, Singapore Health Services Pte Ltd (SingHealth). Professor Tan Ser Kiat is also a senior and well-respected orthopaedic surgeon.

SingHealth is one of Singapore's public sector healthcare clusters which caters for the complete range of healthcare needs of patients at the primary, secondary, tertiary and quaternary levels through two acute general hospitals, 1 specialist women's and children's hospital, 4 national speciality centres for cancers, eye, heart and dental diseases, and 8 polyclinics. Clustering has provided SingHealth with the management infrastructure to pool the expertise of clinicians and administrators who work together as a committed and dedicated team under a strong and forward-looking leadership.

Lakeview Room - The Lodge on Flamingo Lake, Jurong Birdpark

Tucked away at the west-end of Singapore, the BirdPark is a tropical haven away from the hustle and bustle of the city. The large, open exhibits simulating natural habitats and featuring masses of birds are a hallmark of the Park. These create unique experiences, be it a leisurely stroll amidst nature or one-of-a-kind dining experiences with nature and wildlife.

Key Note Address

Catherine Livingstone, Chairman, CSIRO Board

CSIRO is Australia's Commonwealth Scientific and Industrial Research Organisation

Catherine Livingstone became a Member of the CSIRO Board in January 2001 and was appointed Chairman in November the same year.

In 1994 Ms Livingstone was appointed Chief Executive Officer of Cochlear Pty Ltd, then a division of Nucleus focused on commercialising the cochlear implant, known as the "bionic ear". In 1995 Cochlear was floated on the Australian Stock Exchange. Ms Livingstone remained as Chief Executive Officer of Cochlear until 2000.

CSIRO

CSIRO's origins date from the early years of World War I. In 1916, the Australian Government established the Advisory Council of Science and Industry as a step to create a 'National Laboratory' and so bring scientific research to a national standing in Australia. In 1926, legislation was passed that established the Council for Scientific and Industrial Research.

Today, CSIRO is one of the world's largest and most diverse scientific research institutions. Its work touches just about every aspect of Australian life: everything from the molecules of life to the molecules in space - finding ways to improve quality of life and economic performance.

19.30

THURSDAY 16 MAY

08.15

Venus Ballroom 2 & 3

09.00

Venus Ballroom 2 & 3

Plenary Session Two: New and Emerging Technologies

As medical technology evolves at an ever increasing rate, so it will be necessary to ensure that our regulatory systems are capable of meeting the challenges. This session will highlight the major issues involved with the regulation of new and emerging medical device technologies.

Moderator: **Dr David Jefferys**, Chief Executive, UK Medical Devices Agency

Speakers: **Dr David Feigal Jr**, Director, Center for Devices and Radiological Health, US Food and Drug Administration
Kenichi Matsumoto, The Japan Federation of Medical Devices Associations (JFMDA) and Chairman, Sakura Finetechnical Co Ltd, Japan
Rainer Voelksen, Head of Medical Devices Division, Swissmedic - Swiss Agency for Therapeutic Products

Panelists: **Catherine Livingstone**, Chairman of the Board, Commonwealth Scientific and Industrial Research Organisation (CSIRO), Australia
Joseph Putzeys, Advisor, DG Enterprise, European Commission
Rainer Voelksen, Head of Medical Devices Division, Swissmedic - Swiss Agency for Therapeutic Products
James Benson, Executive Vice President, Technology and Regulatory Affairs, AdvaMed
Werner Schöenbühler, Director, Group Office for Quality Management, Siemens AG, Germany

11.00

Coffee

11.30

Venus Ballroom 2 & 3

Plenary Session Three: The Global Regulatory Model

What is the vision for a globally harmonised medical device regulatory model? How do we get there? To date, how far have we got? Will the GHTF really serve to globally harmonise medical device regulations?

Moderator: **Dr Clarence Tan**, Chief Executive Officer, Health Sciences Authority, Singapore

11.40

Overview of the Global Regulatory Model for Medical Devices

Michael Gropp, Vice President - Global Regulatory and Public Policy, Guidant Corporation

The Scorecard

Members of the GHTF Steering Committee, representing regulatory authorities from the five

GHTF Founding Member countries will report to the Conference, outlining progress with the implementation of harmonised GHTF 'guidances' into national regulatory systems.

Rita Maclachlan, Director, Conformity Assessment Branch, Therapeutic Goods Administration, Australia

Joseph Putzeys, Advisor, DG Enterprise, European Commission

Dr David Feigal Jr, Director, Center for Devices and Radiological Health, US Food and Drug Administration

Dr Roland Rotter, Acting Director, Medical Devices Bureau, Therapeutic Products Directorate, Health Canada

Soichiro Isobe, Deputy Director, Evaluation and Licensing Division, Ministry for Health, Labor and Welfare, Japan

12.00

Lunch

Plenary Session Four: The Total Product Life Cycle: A Focus on Postmarket Surveillance and Vigilance

13.00
Coffee House
(2nd floor)

All products have life cycles with various points of control which are available to the regulator, both pre- and postmarket. The Session will focus on the parts of the product life cycle that occur after product Conformity Assessment.

- After design, clinical trial and regulatory approval, what then?
- What are the demands on manufacturers and their representatives?
- What assumptions do surveillance and vigilance systems make about manufacturers' technical files and quality management systems?
- Targeted postmarket surveillance for medical devices - what lessons can we learn from the pharmaceutical sector and other industries?

Moderator: Terry Slater, National Manager, Therapeutic Goods Administration, Australia

Speakers: **Dr David Feigal Jr,** Director, Center for Devices and Radiological Health, US Food and Drug Administration

Dr David Jefferys, Chief Executive, UK Medical Devices Agency

Roland Gerard, Director: Regulatory and Clinical Affairs, St Jude Medical Europe

14.30

Venus Ballroom 2 & 3

Rotation of the GHTF Chair to Japan

Rita Maclachlan, GHTF Chair

Souichi Ikegaya, Director - Evaluation and Licensing Division, Ministry for Health, Labor and Welfare - Japan

16.30

Close of Conference

17.00