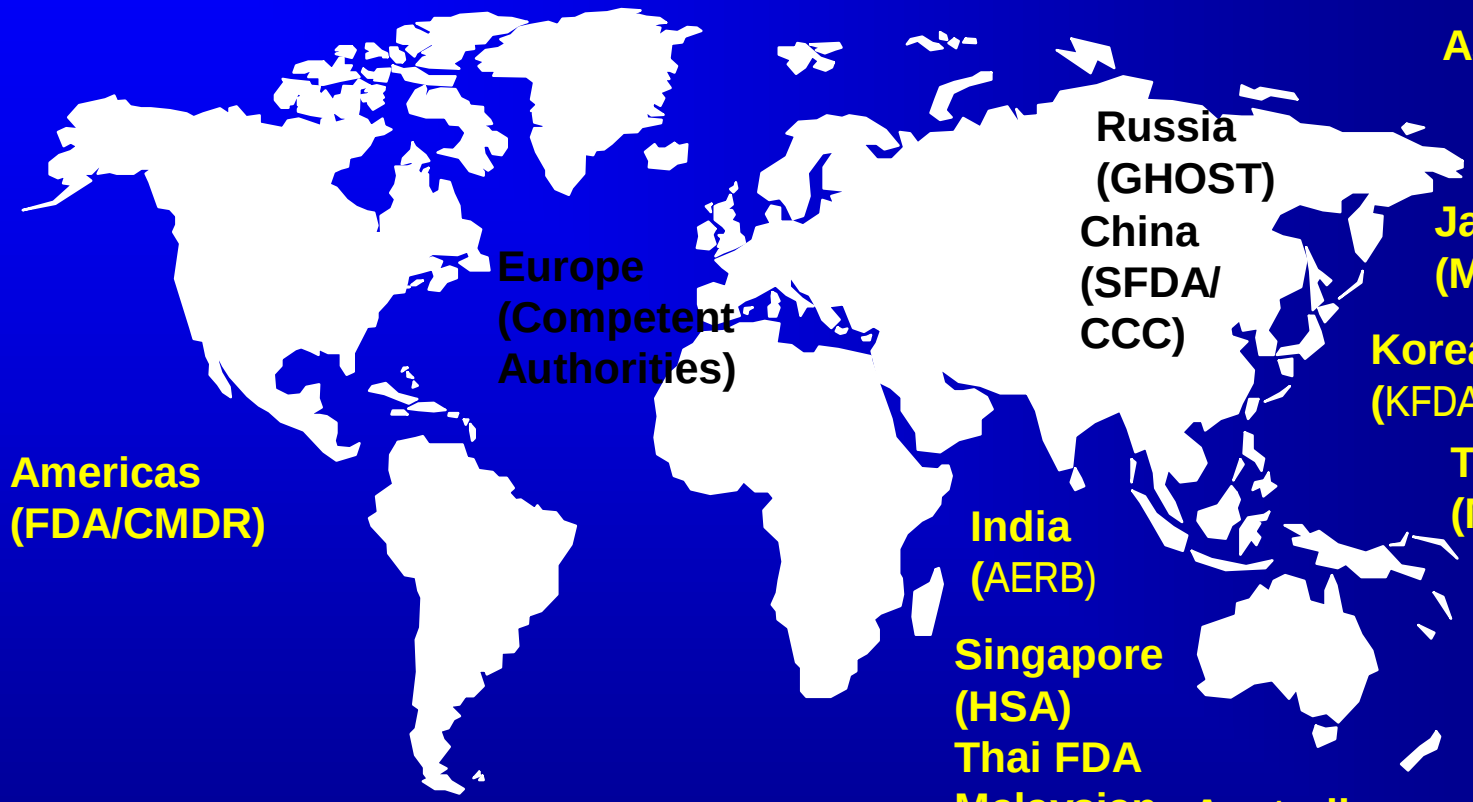
An Introduction to GHTF SG3

Gunter Frey
Member, SG3

NEMA®
Setting Standards for Excellence

GHTF

Regulatory Authorities - A Global View



Asia

Russia (GHOST)

China (SFDA/ CCC)

Japan (MHLW)

Korea (KFDA)

Taiwan (MOH)

Europe (Competent Authorities)

Americas (FDA/CMDR)

India (AERB)

Singapore (HSA)
Thai FDA
Malaysian Govt

Australia (TGA)

New Zeeland (Medsafe)

(Trans Tasman Agency)

Timeline for Major Standards/Regulations

ISO9001:1994

Retired

ISO13485:199
6

ISO9001:2000

To be retired 07/2006

ISO13485:2003

EN46001:1996

Retired 03/2004

21CFR Part 820:
1978 GMP (Preamble still in effect today!)
1997 QSR (Replaced GMP except preamble!)

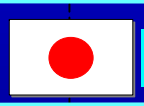
EN/ISO13485:2000

To be retired 07/2006

1978 Federal Food, Drug, and Cosmetic Act (and amendments)

EN/ISO13485:2003

1990 Safe Medical Devices Act (amends Food, Drug, and Cosmetic Act)



1999 Japan GMPi

1999 KFDA GMPi

2000 SDA Requirements for Quality Assurance

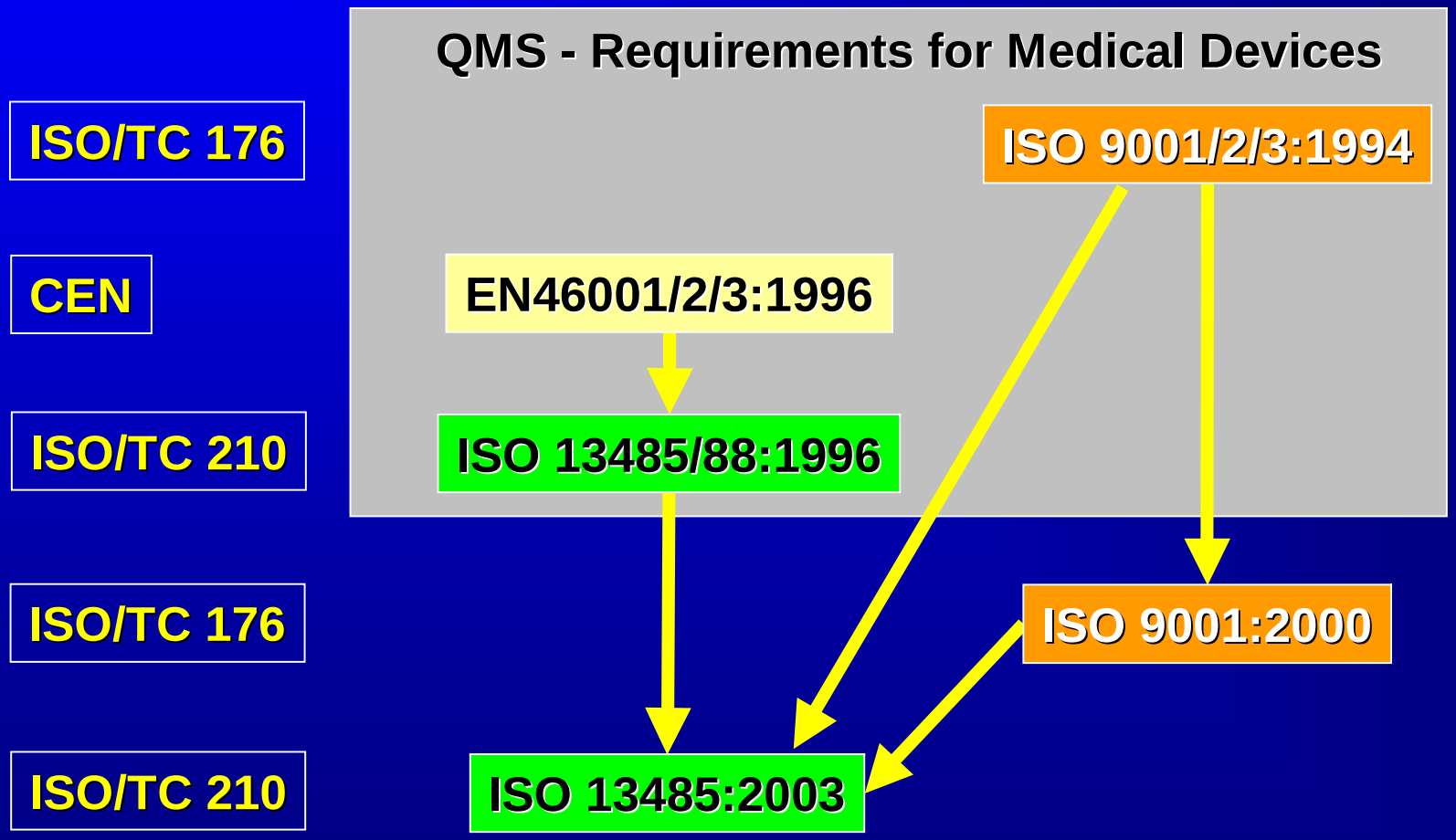
1998 CMDR

1993 MDD

1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005

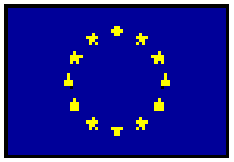
Blue boxes depict regulations

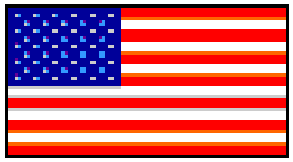
ISO 13485 - History



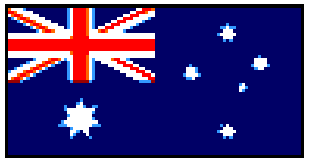
Global Harmonization Task Force

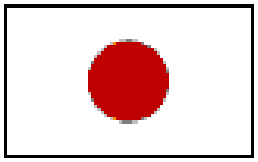
- GHTF was conceived in 1992 in an effort **to respond to the growing need for international harmonization in the regulation of medical devices**. It is a voluntary group of **representatives** from national medical device **regulatory authorities** and the **regulated industry**.
- The founding members of the GHTF are:


European Union


United States


Canada


Australia


Japan

Purpose

- encourage convergence in regulatory practices to ensure safety, effectiveness & performance, quality of medical devices
- promoting technological innovation
- facilitating international trade

How?

- Development, publication & dissemination of harmonized guidance documents on basic regulatory practices.
- Documents developed by five (5) different GHTF Study Groups,
- Can be adopted/implemented by national regulatory authorities.

GHTF – A Forum for Information Exchange

- The GHTF also serves as an information exchange forum
- countries developing medical device regulatory systems can benefit from the experience of those with existing systems and/or pattern their practices upon those of GHTF founding members.

Study Group 3: Members

- **Membership is made up of National Competent Authorities and regulated Industry/Others**
  - 12 members from Australia, Ireland, Germany, Canada, Japan, France, & United States
  - Technical Experts (industry and regulatory authorities) are frequently invited

Study Group 3: Purpose

- **responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization.**

Study Group 3: How?

- **Development, publication and dissemination of harmonized guidance documents on basic regulatory practices.**
- **Documents can be adopted or implemented by national regulatory authorities.**

SG3 Guidance Documents

- **GHTF.SG3.N99-8: Guidance On Quality Systems For The Design And Manufacture Of Medical Devices**
- **GHTF.SG3.N99-9: Design Control Guidance for Medical Device Manufacturers – *to be revised***
- **GHTF.SG3.N99-10: Process Validation Guidance**

SG3 Guidance Documents

- **GHTF.SG3.N15R6: Risk Management as an Integral Part of the Quality Management System – *this document was posted January 22, 2004 for public comment (comment period is now closed; document revised and submitted to GHTF Steering Committee)***

ISO13485:2003 and ISO/TR14969

Under the MOU between GHTF and ISO TC210, SG3 had a central role in TC210's efforts of developing

- **ISO13485:2003,** ***Medical devices - Quality management systems - Requirements for regulatory purposes***
- **ISO/TR 14969,** ***Medical devices - Quality management systems - Guidance on the application of ISO13485:2003***

SG3 Next Meetings/Work Plan

- **Boston, USA** **Q2/2005**
  - Review comments and revise SG#3 guidance, "Risk Management as an Integral Part of the Quality Management System"
- **Location to be determined** **2006**
  - Joint Drafting Team - joint work item with SG#4, to draft guidance on auditing risk management aspects within Quality Management System audits.
- **Location to be determined** **TBD**
  - Reviewing and updating GHTF SG#3 "Design Control Guidance for Medical Device Manufacturers"

Note: Above work plan published as of April 11, 2005.

It is subject to change under direction of the Steering Committee.

For further information, please visit www.ghtf.org

Thank you on behalf of the GHTF and Study Group 3 for your time and attention.

Questions?