14th AHWP Meeting

Hong Kong

November 4 – 7th

Study Group 3 - Quality Systems: Status Report

Gunter Frey
Vice Chair SG3

overview of report

our role …

membership…

what we've accomplished since last conference…

what we plan to do in the near future…

our role ...

"SG3 is responsible for the task of examining existing quality system requirements in countries having developed device regulatory systems and identifying areas suitable for harmonization."

www.ghtf.org/sg3/sg3.htm

membership...

Australia

Mr Ken Nicol	MIAA/St. Jude
Mr Keith Smith	TGA/OMQ

Canada

Mr Egan Cobbold	HC/MDB (Chair of SG3)
Mrs Laila Gurney	MEDEC/GE Healthcare

membership...

European Union

Mr Carlos Arglebe	COCIR/Siemens(Secretary)
Mr Emmett Devereux	EUCOMED/Cook Medical
Mr Dirk Wetzels	EU/BfArM

Japan

Mr Hideki Asai	JFMDA/Hitachi
Mr Munehiro Nakamura	JFMDA/Kaneka
Mr Nagai Hirotada	MHLW
Ms Tokiko Hasimoto	MHLW
Mr Tsutomu Makino	PMDA

membership...

United States of America

Ms Kimberly Trautman	US FDA
Mr Gunter Frey	NEMA/Philips (V-Chair)
Mr Scott Sardeson	AdvaMed/3M

Asia Harmonization Working Party (WG3)
(Regional Members from AHWP)

Mr Ali Al Dalaan	Saudi FDA
Mr Ron Goon	Singapore/J&J

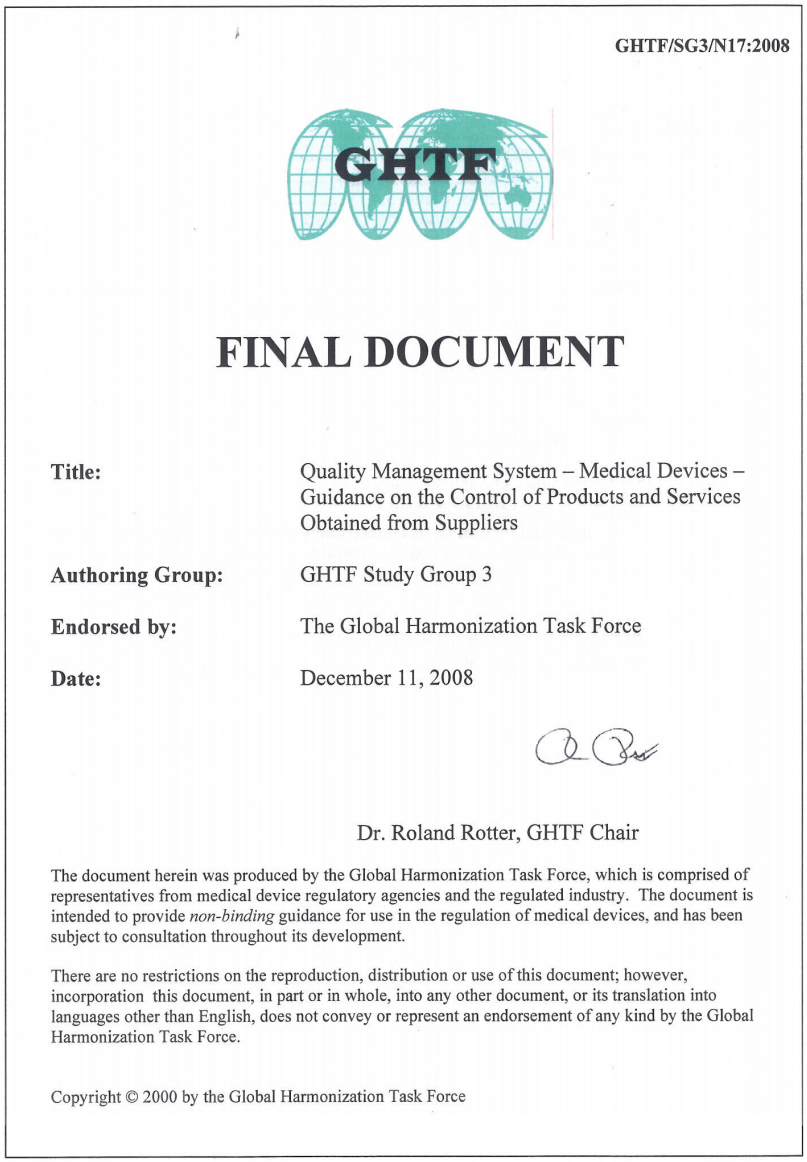
membership…

Regulatory reps.	8
Industry reps.	9
Observers	1 – 2 (upon request)
Technical experts	1 – 2 (when invited)

what we've accomplished since last conference...

For the past 2 years the members of SG3 have completed the drafting and editing of document N17.

Final Document version published on GHTF website February 5, 2009.



GHTF/SG3/N17:2008

GHTF

FINAL DOCUMENT

Title:	Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
Authoring Group:	GHTF Study Group 3
Endorsed by:	The Global Harmonization Task Force
Date:	December 11, 2008

Dr. Roland Rotter, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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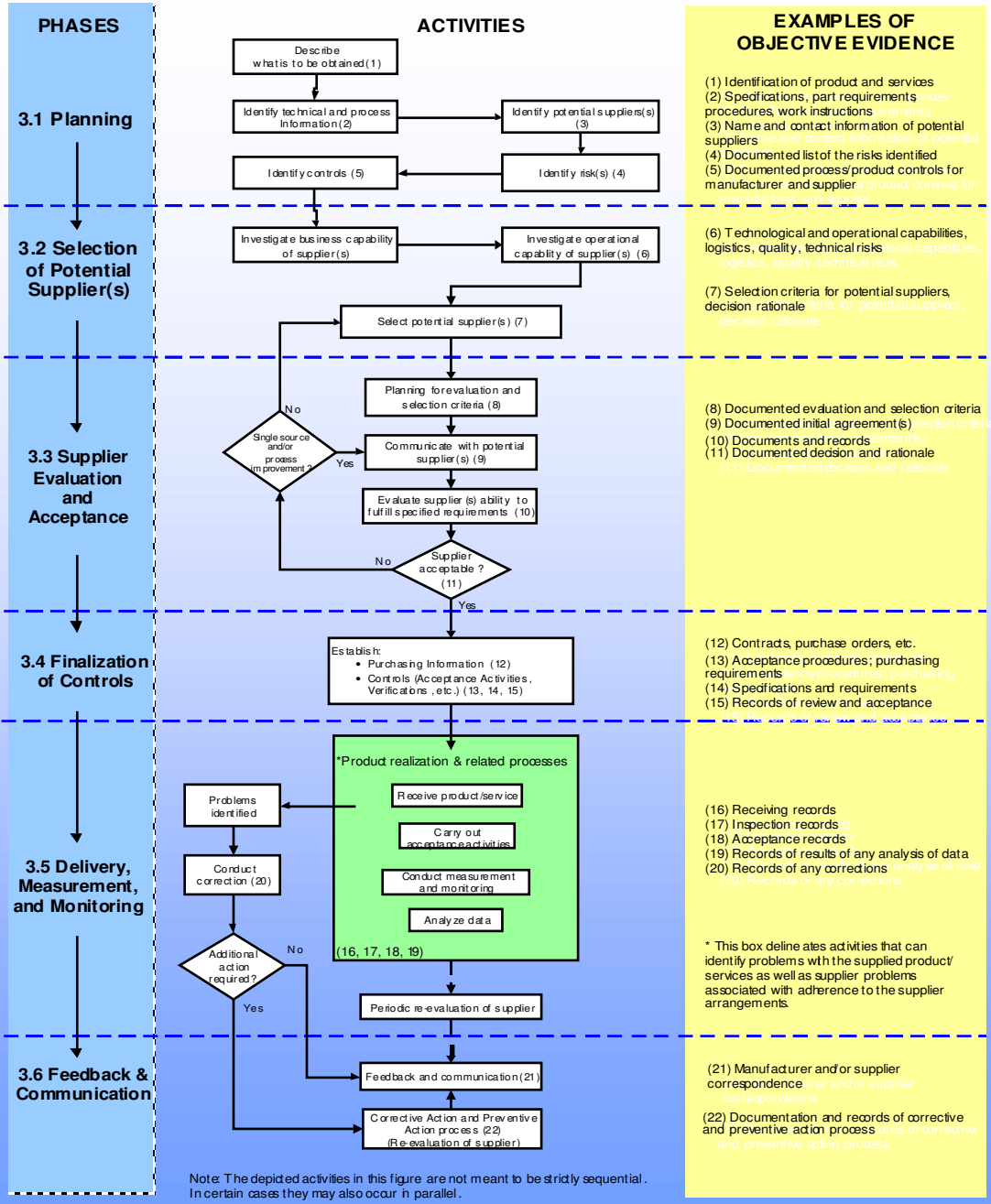
what we've accomplished since last conference…

The purpose of N17 is to provide good guidance and examples on the type and extent of control a device manufacturer could impose on its suppliers of a part or service.

Guidance provided in the context of an effective ISO 13485:2003 quality management system



what we've accomplished since last GHTF conference…

Study Group 3 is about to publish a proposed draft of N18 (Guidance on Corrective Action and Preventive Action and related QMS processes) – will be posted soon for 6 month comment period

SG3 is now focusing on N19 (Significance of nonconformities**). Proposed draft is expected for Q4 2010

(** Working title)

what we've accomplished since last GHTF conference...

Study Group 3 has also been actively involved via joint meetings, teleconferences, and e-mails with other study groups, ad hoc groups, and ISO committees in the development of medical device related guidance documents and standards.

Examples of collaboration

- ►Steering Committee's ad hoc groups on software, combination products and global regulatory model
- ►Study Group 1's work on definition of a manufacturer and device registration
- ►Study Group 4's work on auditing
- ►ISO TC 210 / WG1's work on revision of ISO 13485:2003

what we've accomplished since last GHTF conference...

On the organizational side, SG3 has strengthened the GHTF's ties with the Asian Harmonization Working Party (AHWP) by formally welcoming the full-time membership of the Chair and Vice-Chair of the AHWP Work Group 3 – Quality Management System.

Similarly, the Vice-Chair of SG3 has joined AHWP WG3 as a Liaison member.

Examples of collaboration

►Working Draft copies of SG3 guidance documents will be shared with AHWP WG3 for their comment.

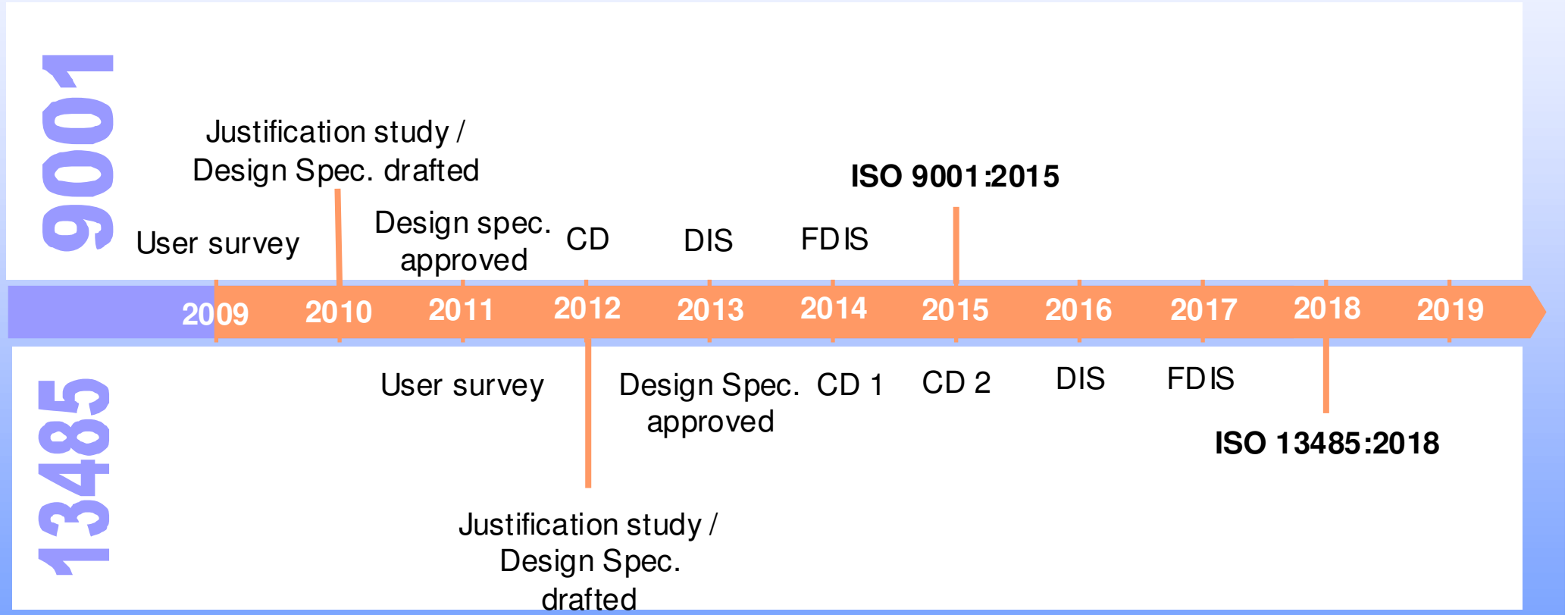
►The Chair of AHWP WG3 will update SG3 from time to time on the work of WP3

►When possible, members of SG3 will attend AHWP WG3 meetings

what we plan to do in the near future…

- Complete the drafting of N19
- Participate in joint GHTF SG3 – ISO TC 210/WG1 meetings dedicated to the revision of ISO 9001:2008 (expected to take place in the next 4 to 5 years). The purpose of this work will be to understand and contribute to any future changes to ISO 9001 because it is the foundation of ISO 13485.
- Review and update as necessary existing SG3 Final Documents on GHTF website.
- Respond where possible to Industry and Regulatory needs for guidance on specific medical device QMS topics

ISO standards expected timeline



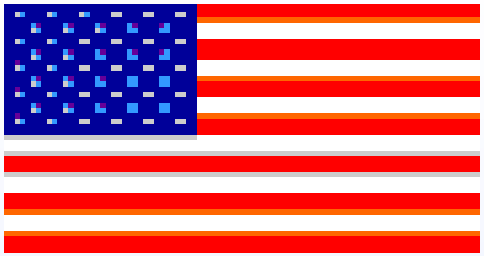
ISO standards
expected timeline

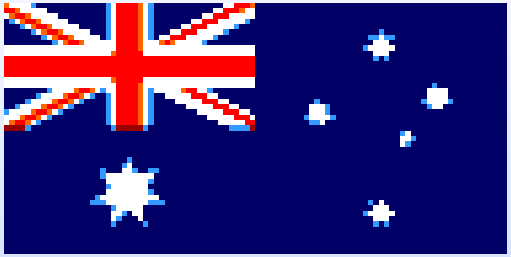
Maintaining and enhancing harmonization of QMS by leveraging the SG3 achievements through influencing the incorporation of aspects of SG3 guidance documents into standards.

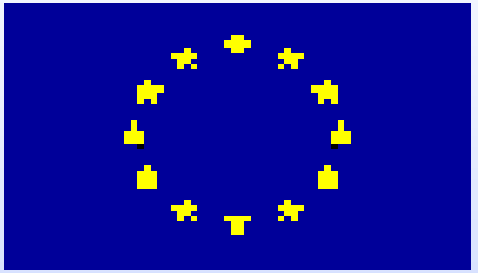
- **The ISO Technical Management Board requires all sector QMS standards to be based on ISO 9001**
- **ISO 9001:2008 was limited to editorial revisions, major revisions are scheduled for 2015**
- **The work on ISO 9001 will have a major impact on ISO 13485**
- **A GHTF liaison with TC 176 is necessary to have both industry and regulators to be part of the standards development process and needs to occur no later than end of 2009**

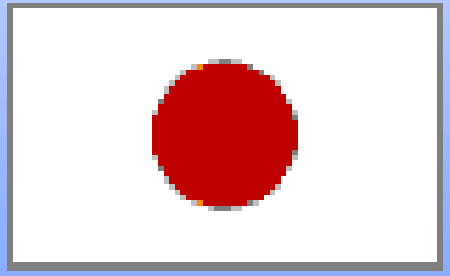
Meeting Planner

SG3 is currently planning for the following meetings:









Thank You …