# GHTF Study Group 4
# Regulatory Auditing

# Overview of SG 4 Activities

Jan Welch
Chairman, Study Group 4

AHWP Meeting
Hong Kong
November 7, 2009

# Role of GHTF Study Group 4

- Has been charged with the task of examining quality management system auditing practices and developing guidance documents providing harmonized principles for the medical device auditing process

# Study Group 4

- Provide guidance for parties responsible for establishing, planning, carrying out and documenting audits of quality management systems to address regulatory requirements for manufacturers of medical devices
- Outline competence criteria for the auditing team
- Eliminate duplication of effort and inconsistencies in auditing practices

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# Study Group 4

- Began work on the series of documents in 1994-1996
- At that time the ISO 10011 series of standards for auditing quality systems was available (1990-1991)
- Also available was ISO 14011:1996 for environmental auditing

# Study Group 4 Membership

- Unites States
  - 2 regulatory
  - 1 industry
- Canada
  - 1 regulatory
  - 1 industry
- Australia
  - 1 regulatory
- European Union
  - 2 regulatory
  - 3 industry
  - 2 Notified Body
- Japan
  - 2 regulatory
  - 1 industry
- Taiwan
  - 1 regulatory (AHWP liaison)

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# SG 4 Guidance Documents

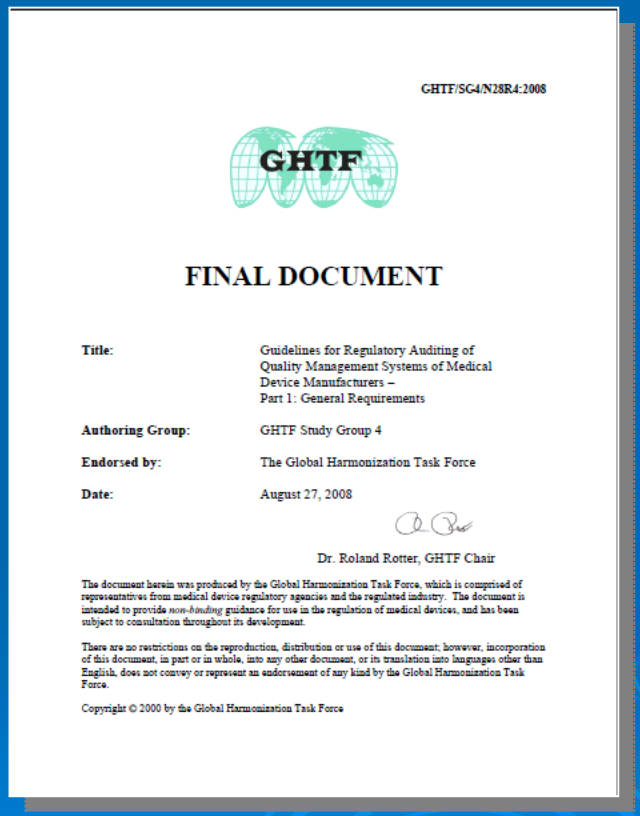
- Umbrella group of documents
- Guidelines for Regulatory Auditing Quality Management Systems of Medical Device Manufacturers
- Currently three parts; two more in draft

# SG 4 Guidance Documents

- **SG4 N28 Part 1: General Requirements**
- **SG4 N30 Part 2: Regulatory Auditing Strategy**
- **SG 4 N33 Part 3: Regulatory Audit Reports**

# GHTF/SG4/N28R4: 2008
# Part 1 General Requirements

- Endorsed by GHTF in 1999
- Revised in 2008
  - Revised structure
  - Reference to pertinent sections of relevant standards such as ISO 19011: 2002, ISO 17000:2004, and ISO 17021: 2006
  - Elimination of duplicate information
  - Updated with current terminology and practice



GHTF/SG4/N28R4:2008

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**FINAL DOCUMENT**

| | |
|---|---|
| **Title:** | Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements |
| **Authoring Group:** | GHTF Study Group 4 |
| **Endorsed by:** | The Global Harmonization Task Force |
| **Date:** | August 27, 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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# SG4/N28R4: 2008
# Part 1 General Requirements

- Provide guidance to regulators and auditing organizations conducting audits of quality management systems (QMS) of medical device manufacturers based on the process approach to QMS requirements (e.g., ISO 13485 and 21 CFR 820)
- Provide the opportunity for developing mechanisms that would lead to global harmonization by incorporating QMS requirements into applicable regulations

# SG4/N28R4: 2008
# Part 1 General Requirements

- Provide guidance for auditing organizations responsible for establishing, planning, carrying out, and documenting audits of medical device manufacturers' QMS
- Provide guidance on related requirements on the follow-up of corrections, corrective, preventive, or improvement actions
- Describe the competence criteria of the audit team

# GHTF-SG4-(00)3
# Part 1 General Requirements Supplement 2
# Training Requirements for Auditors

- Prepare an individual to be an auditor
- Qualify auditors to conduct regulatory audits of medical device manufacturers' quality systems
- Maintain auditors' qualifications
  - Training program
  - On-the-job training
  - Continuous professional development
  - Advanced training elements of auditors
  - Auditor qualification

GHTF-SG4-(00)3

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FINAL DOCUMENT

**Title:** Training Requirements for Auditors

**Authoring Group:** SG4

**Endorsed by:** The Global Harmonization Task Force

**Date:** February 24, 2000

Beth Pieterson, GHTF Chair

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# GHTF/SG4/N30R20:2006
# Part 2: Regulatory Auditing Strategy

- This guideline is intended to be used by regulators and auditing organizations conducting QMS audits of medical device manufacturers based on the process approach to QMS requirements (e.g., ISO 13485:2003 and 21 CFR Part 820).
- This guideline applies to initial and surveillance audit
- To promote consistency in conducting audits – a necessity for harmonization and mutual recognition of audit results

GHTF/SG4/N30R20:2006

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**FINAL DOCUMENT**

**Title:** Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy

**Authoring Group:** Study Group 4

**Endorsed by:** The Global Harmonization Task Force

**Date:** 28 June 2006

Georgette Lalis, GHTF Chair

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# GHTF/SG4/N30R20:2006
# Part 2: Regulatory Auditing Strategy

- The audit should be process-oriented and should preferably follow the workflow processes of the medical device manufacturer
- The audit should be risk-based with a focus on key processes of QMS necessary to manufacture the medical devices covered by the audit
- The auditor should concentrate on factors that are most likely to affect safety of the medical devices while at the same time ensuring adequate coverage of all classes of medical devices within the scope of the audit

# GHTF/SG4/N30R20:2006
# Part 2: Regulatory Auditing Strategy

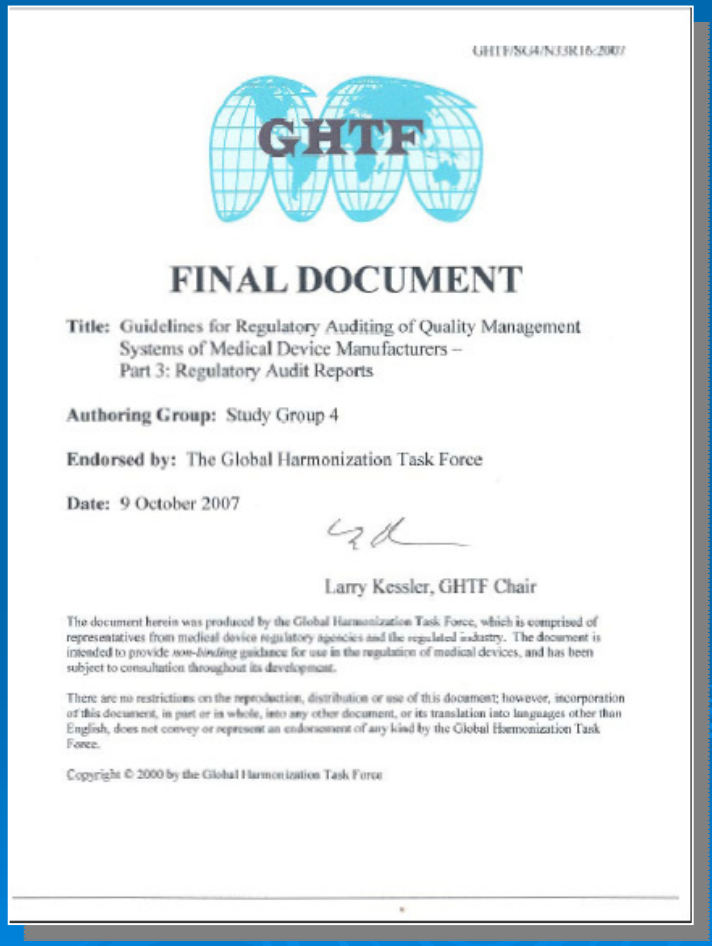
- New proposed Appendix 5 to this strategy to address auditing of software
- Proposed document is currently posted on the GHTF web site for Study Group 4
- Comment period is now open and closes on

  November 16, 2009

  http://www.ghtf.org/sg4/sg4-proposed.html

# SG4/N33 R16
# Part 3: Regulatory Audit Report

- This document is intended to be used by regulators and auditing organizations as a guide for writing a report of a regulatory medical device QMS audit
- This guideline describes a report which can be exchanged with other regulatory or auditing organizations with which the auditing organization has a formal relationship concerning confidentiality
- The purposes of this document are to harmonize the content of audit reports and to provide guidance on best practices for reporting audit results



GHTF/SG4/N33R16:2007

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**FINAL DOCUMENT**

**Title:** Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

**Authoring Group:** Study Group 4

**Endorsed by:** The Global Harmonization Task Force

**Date:** 9 October 2007

Larry Kessler, GHTF Chair

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# SG4/N33 R16
# Part 3: Regulatory Audit Report

- Harmonize the content of audit reports
- Provide guidance on best practices for reporting audit results
- Provide a structure for audit reports that may be used in multiple jurisdictions
- Promote consistency and uniformity and will assist the auditor in preparing a report for use by multiple regulators and/or auditing organizations

# SG4 N83 PD
# Part 4: Multiple Site Auditing

- Supplements audit strategy guidance in Part 2 document

- Provides guidance on developing, executing, and completing an audit program for the auditing of a manufacturer with multiple sites operating with one Quality Management System

# SG4 N83 PD
# Part 4: Multiple Site Auditing

- Proposed document is currently posted on the GHTF web site for Study Group 4
- Four month comment period now open – September 16, 2009 – January 16, 2010
- Target for final document – 2Q 2010

# SG4 N84 PD
# Part 5: Auditing of Manufacturer Control of Products from Suppliers

- Supplements the auditing strategy guidance in Part 2 document
- Provides guidance on the auditing of a manufacturer's control over supplied products and services
- Provides guidance on when and how to conduct an audit at the manufacturer's suppliers

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# SG4 N84 PD
# Part 5: Auditing of Manufacturer Control of Products from Suppliers

- Proposed draft has been sent to GHTF Steering Committee for approval
- Target for posting to GHTF web site for comment – December 2009
- Four month comment period
- Target for posting final document – 3Q 2010

# Value of GHTF SG 4 guidance

- Used as a reference in several harmonization efforts
  - FDA-Health Canada Pilot Multipurpose Audit Program
  - Advamed Common Template Working Group
  - Health Canada Registrar guidance documents
- Used in training initiatives for emerging regulatory models

# Value of GHTF SG 4 guidance

- Being incorporated into the medical device regulatory regimes of countries and areas implementing new legislation
- Incorporated into a new proposed global certification program by the International Accreditation Forum (IAF)
  - ISO 13485 Medical Device Conformity Assessment System (MDCAS)

# Questions??

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