



Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

GHTF Conference

LUBECK, June 2006

GHTF STUDY GROUP 3 **QUALITY SYSTEM**



- **Overview of the presentation**
 - **Study Group participation**
 - **Description of past and ongoing Activities**
 - **Feedback on preliminary works on guidance on suppliers and outsourced processes**



- **Purpose of the study group**

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.

And by consequence to provide guidance for these areas



- **Relationship with standardization process**

- SG3 is in charge of the arena of quality system requirements
- ISO/TC 210 is technical committee responsible for standardization in the field of quality management for medical device

Memorandum Of Understanding Between ISO/TC 210 And GHTF In The Field Of Quality Management

- *Promote communication*
- *Avoid duplication of work*



GHTF study group 3 on Quality system

- **Participants**

Mr. Alain Prat – Past Chairman

Mr Egan Cobbold – New Chairman

Mr. Gunter Frey – V/Chair, Sec.

Mr. Hideki Asai

Mr. Munehiro Nakamura

Mr. Werner Schöenbühler

Mrs. Kimberly Trautman

Dr. Victor Dorman-Smith

Mr. Yamamoto Junji

Dr. Ken Nicol

Mr. Keith M. Smith

Mr John Gams

Mr. Kenneth F. Kopesky

Links :

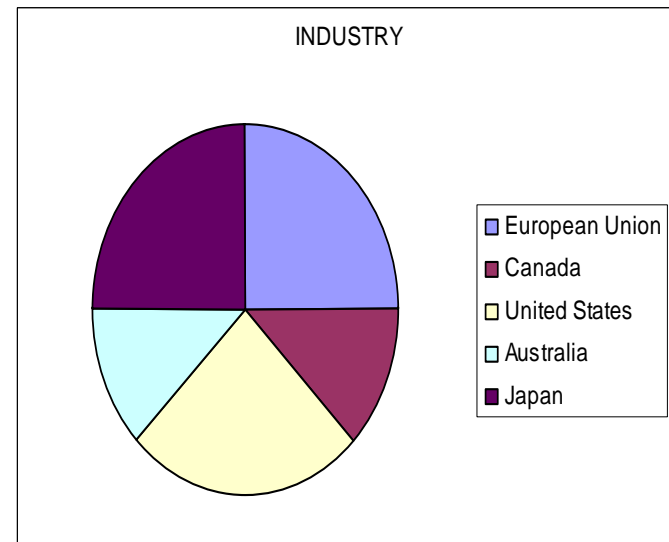
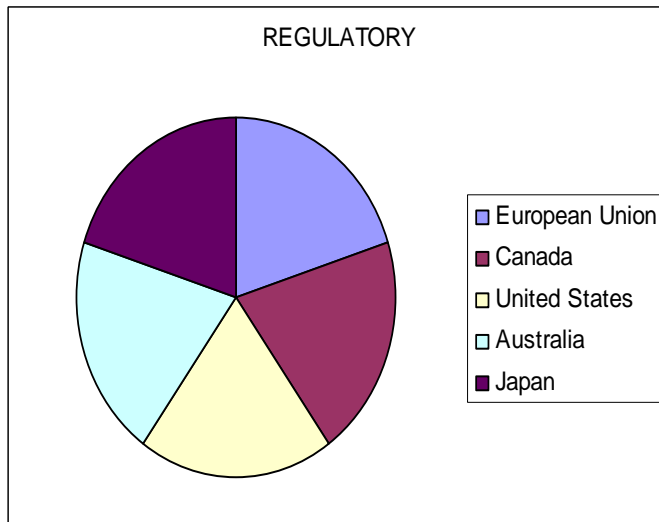
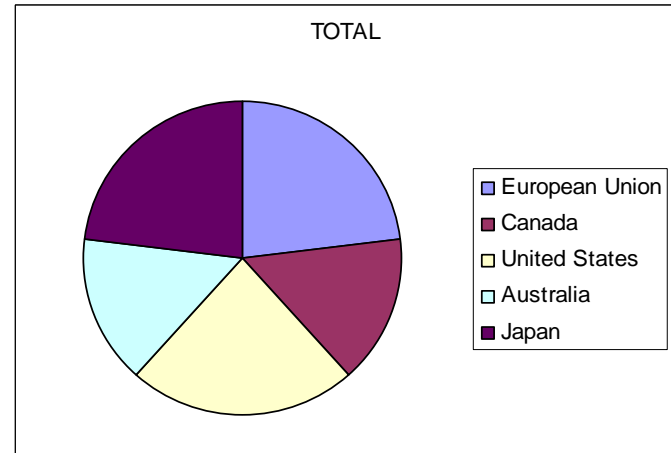
» *Mr Ed Kimmelman / TC 210*



GHTF study group 3 on Quality system

- **Participation**

- **Industry / Regulatory**
- **Five founding members**





- **Past works**

- **Guidance on Quality Systems for the Design & Manufacturing of Medical Devices Manufacturer**
- **Design Control Guidance for Medical Device Manufacturers**
 - **no longer the most current information available**
 - **SG3 provided a strong input by its participation in the drafting of ISO13485 (1996 & 2003) and TR14969**



- **Past works**

- **Quality Management Systems - Process Validation Guidance**
(SG3/N99-10 - Edition 2)
- **Implementation of Risk Management Principles and Activities Within a Quality Management System** (SG3/N15R8/2005)
 - Medical device manufacturers are generally required to have a quality management system as
 - As well as processes for addressing device related risks

Propose an integration of risk management principles and activities into quality management system



GHTF study group 3 on Quality system

- **Ongoing activities**

- **Develop the guidance on suppliers and outsourcing as approved by the steering committee**
 - **NWIP approved by SC 11- 2005 in London**
 - **Target date May 2007 - Proposed Document ready for SC**
- **Development of Technical cooperation on quality management aspects with other GHTF study groups on subject of common interest**
 - **SG4 on guidance on auditing strategy**
 - **SG1 on Definition of manufacturer**



- **Ongoing activities**

- **Training activities world wide (APEC Seminar Santiago in Chile)**
 - **limited capacity,**
 - **designate people not only members of SC or SG to speak in the name of GHTF**
 - **approved materials by SG**
- **Follows actively the ongoing revision of 9001**
 - **Provide comments**
 - **Anticipate the review/update of ISO13485:2003 and TR14969**



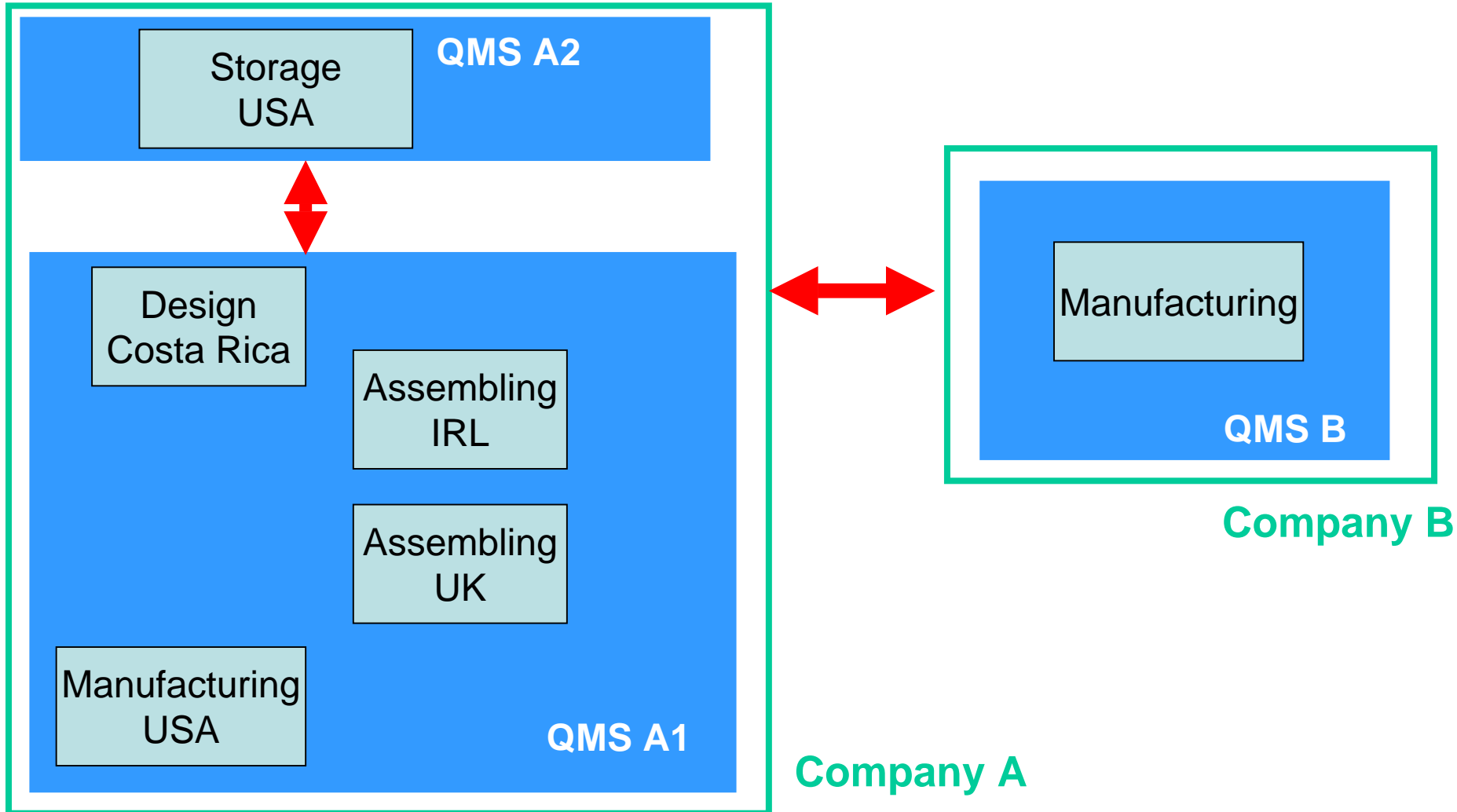
Feedback from preliminary works on outsourcing

- **Methodology used**

- **Review of literature : ISO guidance, regulators guidance, Articles**
- **Brainstorming, process mapping**
- **Definition of a product including hardware, services, software, processed products**
- **Definition of a supplier**
 - **Based on the scope of the QMS**



CONCEPT OF SUPPLIER / QMS Scope





Feedback from preliminary works on outsourcing

- Documented evidence of compliance to QMS requirements
 - Documentation, records

- Full Responsibility of the manufacturer
 - Globally differing definition of a manufacturer

- Risk based approach to determine the extend of controls

- Identified main scenarios:
 - Component & Sub-System,
 - Finished Device,
 - Packaging & Labeling,
 - Installation & Servicing, Contract Services, Etc...



GHTF study group 3 on Quality system

THANKS FOR YOUR ATTENTION