

# Regulations and Standards

Collaboration between ISO, IEC, ITU-T and GHTF

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JFMDA

## JFMDA

- Stands for “the Japanese Federation of Medical Devices Associations”
- Un umbrella society of medical devices in Japan  
Members are 19 medical device industry associations
- Representing all medical device industries in Japan for international activities

# How to utilize standards?

- Regulated sector

Medical device sector is severely regulated. Regarding the law/act and regulations, deficiencies may cause recall, stop shipment, facility close etc. On the other hand, some standards are too ambitious for regulatory purposes.

- How to utilize standards for regulatory purposes?

- 1) To enforce a standard as a regulation e.g. ISO 13485:2003

- 2) To utilize a standard voluntarily for regulatory purpose e.g. Standards to demonstrate compliance with Essential Principles.

# How to enhance relation?

## How to enhance relation between ISO, IEC etc. and GHTF?

- Participation of regulators to WG of ISO, IEC, ITU-T  
Proposed by ISO/TC 210/WG 2 at ISO/TC 210 meeting
- Acceptance of comments on a draft of a standard from GHTF. Proposed for IEC 62304.
- Joint meeting between ISO, IEC, ITU-T and GHTF  
e.g. ISO 13485:2003
- Establishment of official relation e.g. MoU
- WSC workshop
- Clarification of purpose/intention of a document by NWIP

# ISO 13485:2003

- ISO 13485:2003 was developed by the joint meeting between ISO/TC 210 and GHTF SG 3 based on the MoU.
- ISO 13485:2003 was developed based on ISO 9001:2000. However, clauses on customer satisfaction and continual improvement were changed, because they are subjective and not suitable for regulation.
- ISO 13485:2003 is intended to use for regulatory purpose. It is stated in the title of the standard. GHTF recommends ISO 13485 as below. The statement has been posted on the GHTF website.

# GHTF Statement for ISO 13485:2003

GHTF considers ISO 13485:2003 “*Medical devices - Quality management systems - Requirements for regulatory purposes*” to be an adequate quality management system standard for medical device manufactures.

For the purpose of regulating medical devices, GHTF believes that:

- the generic ISO 9001:2000 is insufficient by itself and
- ISO 9001:2000 should not be required in addition to ISO 13485:2003.

Countries considering incorporation quality management system requirements directly into their regulation and not citing ISO 13485:2003 verbatim are encouraged to harmonize their regulation with ISO 13485:2003.

# Common data and standards (1)

- Common data

The GHTF Strategic Direction 2002 – 2007, Goal 3:

The GHTF will seek to evolve beyond convergence of regulatory requirements to embrace mutual acceptance of common data submissions, pre-market conformity assessment (including clinical evidence) processes, quality systems, quality systems auditing results, and a broad sharing of post-market experience. The objective will be to allow presentation of data that are acceptable in principle to relevant authorities as the basis for meeting regulatory requirements.

# Common data and standards (2)

- Fundamentals of common data

