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Global Harmonization Task Force

How to minimize risks without constraining innovation and
harming free trade

The role of international standards

And their application at regional and national levels

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GHTF

- Informal platform of authorities and industry
- Europe, US-Canada, Japan-Australia
- 80% of world market



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GHTF core activities

- Coherent implementation of common elements in regulatory systems
- Regulatory guidance
- Common data sets
- Identification of new regulatory challenges
- Exchange of information



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GHTF is not a standards or a standardizing body

- No legal status
- No formal commitment to implement
- Concentrate on regulatory requirements
- Develop a regulatory model
- Not involved in development of technical solutions to meet regulatory requirements



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Main areas of GHTF activities under European Chair:

- Current work-program on regulatory guidance
- Common data sets, in particular clinical data
- Medical Software, design for patient safety, emerging technologies
- Relations with international organizations



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Essential Principles

- Design and manufacture
- Intended conditions and purpose
- Clinical condition or safety and health
- Risk benefit analysis
- High level of protection of health and safety
- Achieve performance intended



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Essential Principles on solutions adopted:

- Conform to safety principles
- Generally acknowledged state of the art
- Identify hazards and risks
- Inherently safe design and construction
- Adequate protection measures on remaining risks
- Inform users of residual risks



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Role of international standards in GHTF model

- A building block for harmonized regulatory processes to assure safety, quality and performance of medical devices
- a privileged tool to demonstrate compliance with Essential Principles



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Role of international standards

Requests to authorities

- Encourage and support development
- Encourage the use of international standards
- Develop mechanisms for recognition of international standards



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Role of standards

Requests to standards bodies

- Consider the suitability of standards
- Current broadly applicable technology
- Current state of the art



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Role of standards : what GHTF partners consider important to highlight

- Compliance to be demonstrated with Essential Principles
- Use remains responsibility of manufacturer
- Alternatives to international standards
- Recognition and legal effect remain national competence



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GHTF partners consider that progress is possible at the level of transparency

- A coherent, user-friendly standards program
- A clear identification of Essential Principles addressed
- GHTF making available a list of standards recognized by founding members



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GHTF partners consider that progress is possible at the level of cooperation

- Special arrangements, if needed, such as MoU ISO TC 210 and GHTF
- Consider relations with WHO and other bodies that might work in the area of medical device
- Identify new priorities and potential for international standards



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GHTF partners are interested in outcome of this workshop and its follow-up and invite ISO-IEC-ITU to report accordingly.