

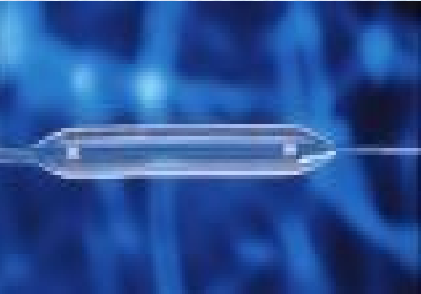
25 years
saving life....
improving the
quality of life



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Medical Technology

Technical Forum 28th April 2004 GHTF Presidency



GHTF in short!

- Created in 1992
- Founding members: Australia + Europe (EU + EFTA) + Japan + North America
- Regulators and Industry
- Purpose:
 - convergence in regulatory practice
 - Promotion of technological innovation
 - Facilitating international trade
- How? Guidance documents on regulatory practices



GHTF objectives

- Develop procedures and common understandings...to shape and maintain converging, balanced and predictable regulatory frameworks
- Facilitate communication between key actors
- Improved and faster access to medical technology products

GHTF European Chairmanship

3 Key Themes

- Design for patient safety
- Medical devices software
- New technologies

Further work on

- GHTF strategic direction/Ottawa rules
- Common data sets
- Cooperation with WHO and regional groupings (e.g. PAHO)
- Documents handling

Final approval at SC meeting of 6/04



GHTF organization

Chairman: Cees Brekelmans

Vice-Chair: Maurice Wagner

Secretariat:

- Suzanne Hoeke at Commission (political aspects)
- Ronda Balham at FDA (administrative aspects)
- No permanent secretariat

Steering Committee and four study groups



GHTF events 2004/06

- Handover meeting in 1/04: Japan takes over a lot from GHTF
- Standards meeting in Geneva
- Steering committee meetings (6/04, 5/05, end 05, 6/06, 11/06)
- Study groups meetings
- Regional meetings (?)
- Global Conference in June 2006
- Meeting with WHO

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Additional information on GHTF

www.gh tf.org

Don't forget either

www.eucomed.be

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Thank you

GRACIE MILLE