

# Links Between Regulators and Standards Developers

Standards - fit for the purpose ?

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# The Role of Standards in Medical Device Regulations

- ▶ The benefits
  - ▶▶ - industry
  - ▶▶ - public health
  
- ▶ Expectations

# The Role of Standards

- ▶ GHTF model
  - ▶▶ Standards provide a tool to demonstrate compliance with the Essential Principles

Standards bodies should:

- ▶ ensure Standards reflect current broadly applicable technologies
- ▶ ensure the suitability of Standards
- ▶ ensure a coherent Standards programme, linked to the GHTF Essential Principles

# The Standards Programme

Should address

- ▶▶ basic
- ▶▶ group
- ▶▶ product

Safety Standards

Regulatory authorities should provide a  
“mechanism for recognising  
international Standards”

# The Current Issues

- ▶ Timely introduction for Standards
- ▶ Efficiency of the process
- ▶ resources/affordability
- ▶ prescriptive vs general approach
- ▶ co-ordination /prioritisation of programmes

# Issues continued

- ▶ Duplication of effort
- ▶ Time to develop a Standard
- ▶ Drawbacks from the consensus approach
- ▶ Transparency of process
- ▶ Involvement of the Regulators
- ▶ Involvement of the industry
- ▶ Involvement of healthcare professions

# Drivers for Change

- ▶ Globalisation
  - ▶▶ industry
  - ▶▶ regulation
- ▶ Common global safety agenda
- ▶ rapid development of new technologies
- ▶ transparency
- ▶ dialogue/partnership during development
- ▶ patient empowerment
- ▶ designing for patient safety

# Complementary Instruments

- ▶ Guidelines
- ▶ Common Technical specification
- ▶ points to consider documents
- ▶ emerging issues documents

# The Challenge

To develop an effective and efficient process which meets the needs of a innovate rapidly challenging sector which enhances public health and helps industry