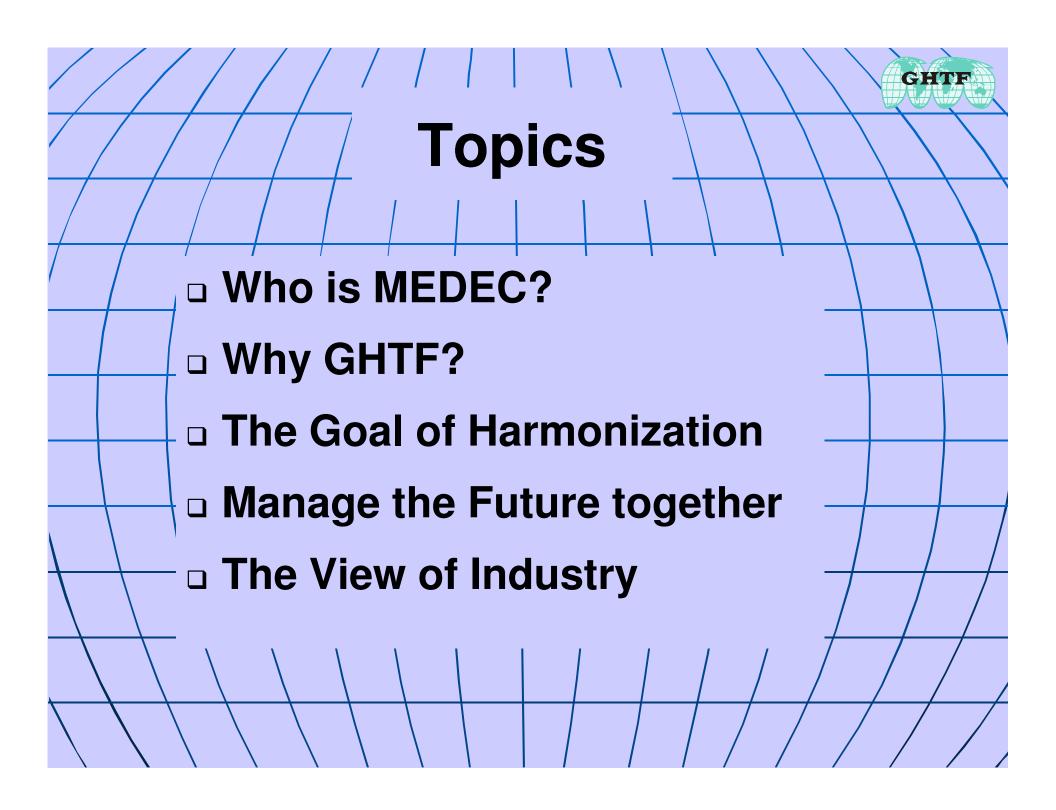


Global Harmonization Task Force GHTF

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Who is MEDEC?

- National association created by and for the Canadian Medical Device Industry
- Source for Advocacy, Information and Education on the Medical Device Industry for members, the greater healthcare community, industry partners and the general public
- Vision: Advancing health outcomes for Canadians by accelerating access to medical technologies



Why GHTF?

- 1992 The 5 founding members seek convergence of regulatory practices to ensure the enhancement of medical devices safety
- Fostering medical technological innovation and facilitating global trade
- Collaboration of regulators and industry



The Goal of Harmonization

Avoid additional requirements

- Prevent regulatory redundancy
 - No gain in safety
 - Delays access to technology
- Encourage recognition by emerging markets



Manage the Future together

 Global Measure for Safety and Effectiveness

- Learn New Lessons together
- Expand on successful principles that accept different means for same goals

 Stick to the GHTF principles and encourage mutual recognition



The View of Industry

- Aim for Global Regulatory Model iron out divergent requirements
- One Assessment, one Inspection same Product Information on Label
- Unique Device Identifier welcome –
 Comprehensive Information in identical Format on Global Product

