Global Harmonization
Task Force GHTF

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Topics

- Who is MEDEC?
- Why GHTF?
- The Goal of Harmonization
- Manage the Future together
- The View of Industry
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