



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**

