IMDRF International Medical Device Regulators Forum

Conformity Assessment of Medical Devices

The Role of GHTF Guidance and International Standards

Wong Woei Jiuang
Health Sciences Authority, Singapore

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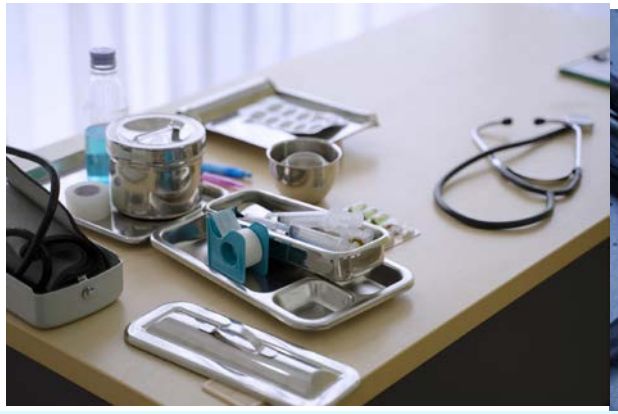
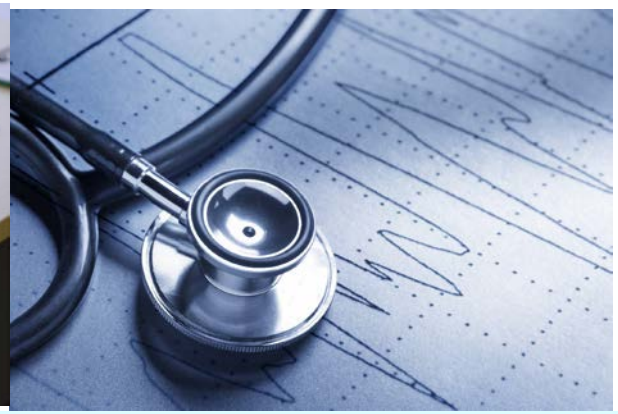
Setting the Stage

Medical devices touch lives every day

- From simple tools to advanced technologies
- Trust in safety and quality is non-negotiable





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Why Conformity Assessment Matters

Conformity Assessment = Confidence

- Protects patients & providers
- Builds regulatory trust
- Enables innovation & trade

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Historical Context

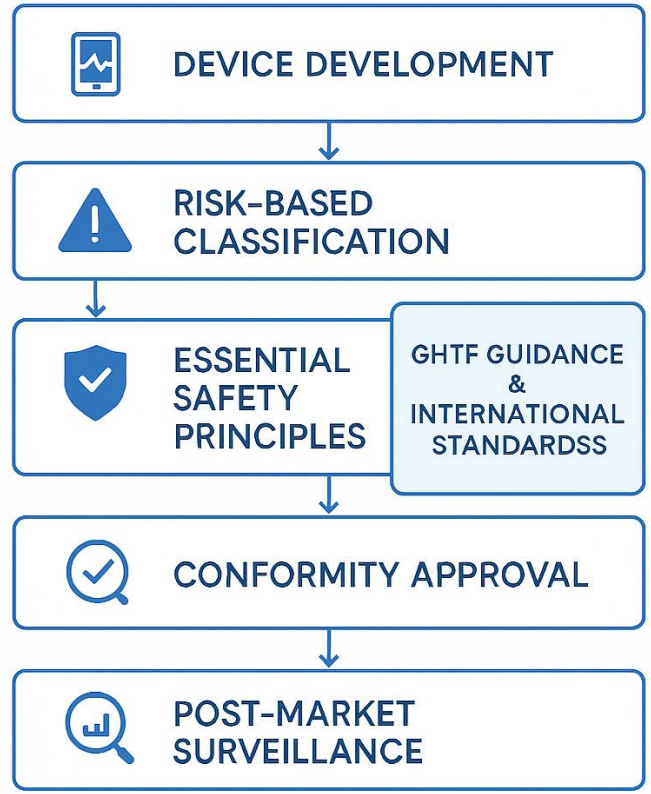
From Fragmentation to Harmonization

- Pre-1990s → fragmented oversight
- 1992 → Global Harmonization Task Force (GHTF)
- 2011 → International Medical Device Regulators Forum (IMDRF)

GHTF Contributions

Key Contributions

- Risk-based classification
- Essential safety & performance principles
- Quality management systems (ISO 13485)
- Post-market surveillance



Role of International Standards

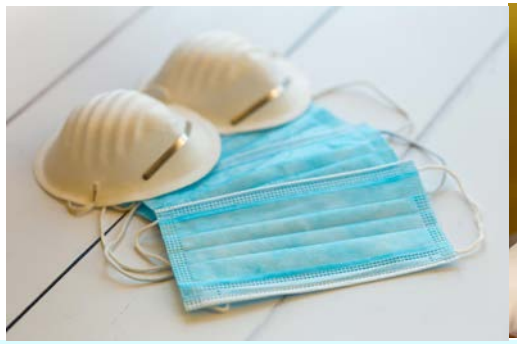
Standards = Common Language

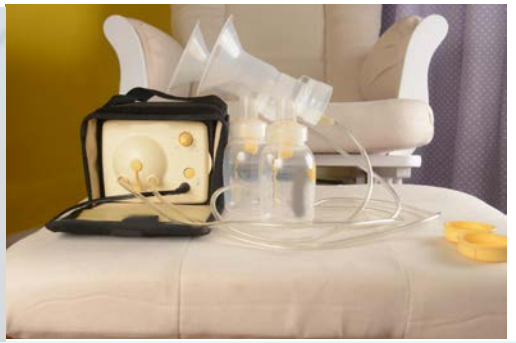
- ISO 13485 – Quality management
- ISO 14971 – Risk management
- IEC 60601 – Electrical safety

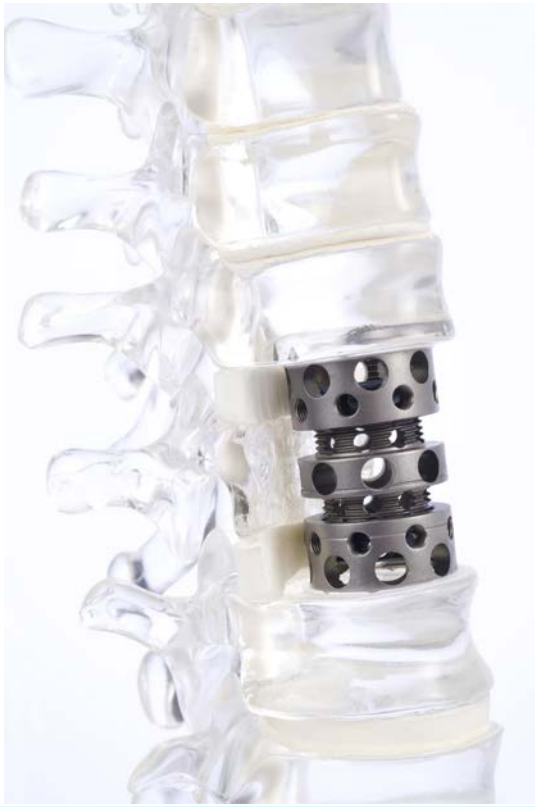
Case Studies

Lessons from Practice

- **Success:** COVID-19 ventilators, masks, diagnostics → fast approvals with standards
- **Caution:** Breast implants, orthopedic devices → fragmented oversight, patient harm



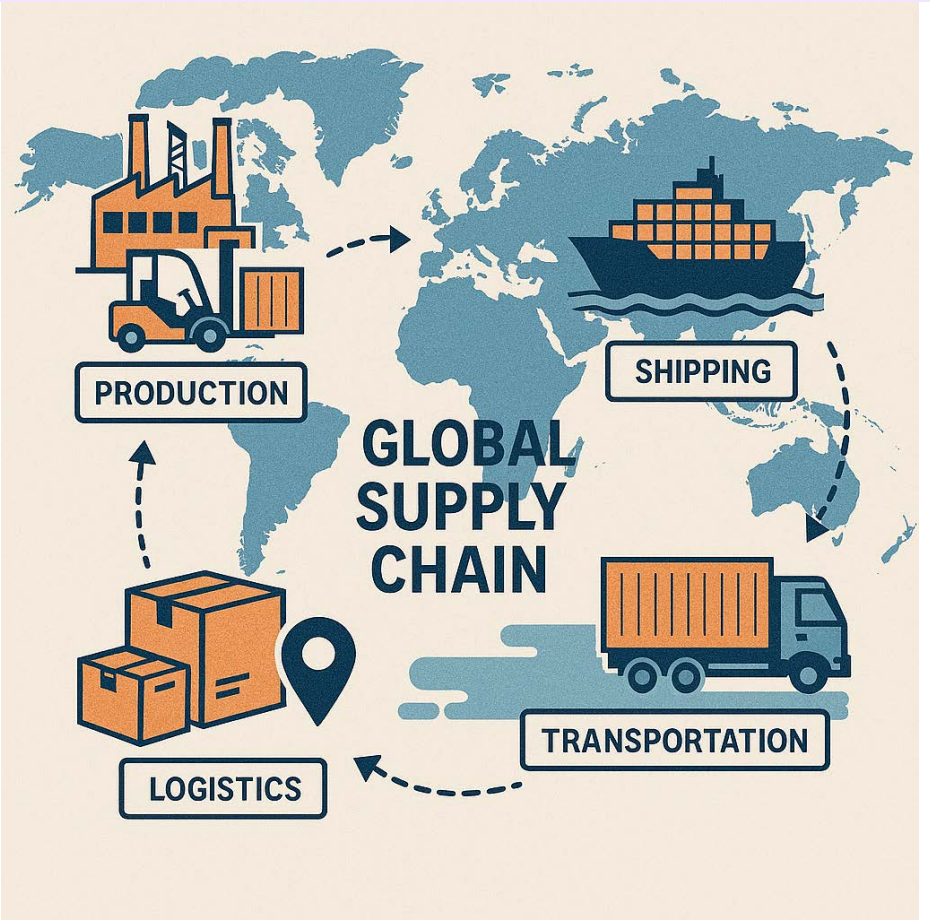




Current Challenges

Challenges Ahead

- Regulatory divergence remains
- Digital health & AI/ML validation
- Complex global supply chains
- Limited regulatory capacity in some regions



Opportunities Ahead

Opportunities for Progress

- Reliance & recognition frameworks
- Digital post-market surveillance
- Global capacity building
- Standards for emerging technologies

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Closing Message

"Conformity assessment is not about bureaucracy—it is about lives."

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