MEDICAL TECHNOLOGY REGULATION

Understanding Where We Have Been and Where We Are Going with Harmonization

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Health Technology and Cosmetics
• 20 years of GHTF (1992-2012)
• Inception of IMDRF (2011-2012): The Vision
• Two years of IMDRF operation (2013-2014)
• Considerations on:
  - expansion
  - deployment
  - transparency
  - regulatory transposition
- Conceived in 1992, rotation of Chairmanship every 3 years

- Purpose: international harmonization in MD regulations for safety, effectiveness, performance adequacy/quality of MDs

- Publication of harmonised guidance docs on regulatory practices.

- Guidance docs for adoption by Regulatory Authorities.

- GHTF cooperates with Asian Harmonisation Working Party AHWP
Adoption of GHTF guidelines – comparison between jurisdictions

- Not adopted
- Pending adoption
- Adopted in part
- Adopted in full
ACHIEVEMENTS OF GHTF

- A Global Regulatory Model
- 38 Guidance documents
- A world-wide reference
- Aspirational vs Implementable
- An effective forum for collaboration

But...

Image of old economies, not global enough!

Risk of confusion of roles (Industry ↔ Regulators)
Rationale

After 20 years of GHTF – Time for change!

Expansion from the 5 original members

Separating Industry from Regulators

Outsourcing deployment to other fora (AHWP, APEC, WHO...)

Health and Consumers
An aspiration to convergence

IMDRF

Deployment fora

OBS.
International Medical Device Regulators' Forum

Australia, Therapeutic Goods Administration
Brazil, National Health Surveillance Agency (ANVISA)
Canada, Health Canada
China, China Food and Drug Administration
Europe, European Commission DG Health and Consumers
Japan, Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency
Russia, Russian Ministry of Health
United States of America, US Food and Drug Administration

+ Observers (WHO), Affiliates (AHWP, APEC)
2012 Australia
- 1st meeting in Singapore 28 Feb- 1 March
- 2nd meeting in Sydney: 25-27 September

2013 Europe
- 3rd meeting in Nice/Sophia Antipolis 19-21 March
- 4th meeting in Brussels 12-14 November

2014 USA
- 5th meeting in San Francisco 25-27 March
- 6th meeting in Washington DC 16-18 September

2015 Japan
- 7th meeting in Tokyo 24-26 March
- 8th meeting in Kyoto 15-17 September
IMDRF Structure

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM

MANAGEMENT COMMITTEE
Regulators (rotating chair)
AUS, BZ, CAN, EU, JAP, US (CN, IND, RU tbc)
Official Observers by Invitation

MANAGEMENT LEVEL:
Decision Making, strategic direction, workplan monitoring

SECRETARIAT
Administrative Tasks
Edition, maintenance of website
‘BRANDING’: Benefit of ‘Global’ image,
Promotion of Global Regulatory Model

OPERATIONAL LEVEL:
Technical document development (Regulators, industry, other stakeholders)
- Review of the NCAR system
- Unique Device Identification
- Medical Device Single Audit Program
- Lists of Recognized Standards
- Regulated Product Submission
- Software as a Medical Device
UDI Work Group

US-FDA
ADVAMED
HEALTH CANADA
EU COMED/EDMA
AHWP

CHINA CFDA
EU DG SANCO
JAPAN PMDA
DITTA
JFMDA/JIRA
ANVISA

...With some invited observers.
IMDRF UDI Guidance

The IMDRF UDI Guidance was adopted as a final document (IMDRF/WG/N7:2013) by the Management Committee on 15 November 2013.

Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

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Gradual Convergence → Regulatory Harmonization

• Harmonization means...
  Regulatory requirements are consistent between jurisdictions

• Harmonization does not mean...
  a single regulatory system across jurisdictions

• Convergence is the path...
IMDRF VISION

- Conceived as a forum to discuss future directions in medical device regulatory harmonization.

- The Forum builds on the work of GHTF with the aim of accelerating international medical device regulatory harmonization and convergence.

- Oversight by a Management Committee comprised of a voluntary group of medical device regulators from around the world and the World Health Organization.
Do you recognize this gentleman?

Clues:
- XV Century
- Great Scientist
- Revolutionary view

Mikolaj Kopernik
(1473-1543)
The World does not rotate around our planet!
THE SHARED VISION

Jurisdiction

Nat'l 'Regulation'

International Trade

Global 'Guidance'

Two sides of the same medal

→ INTERNATIONAL REGULATORY CONVERGENCE!
A Chinese Saying...

Mō zhe shītōu guò hé.

摸着石头过河。

Crossing the river by feeling each stone.
Thank You for your attention!

Visit: WWW.IMDRF.ORG


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