



IMDRF

International Medical
Device Regulators Forum

5 Years of IMDRF

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Presentation Objectives

- Examine factors that led to the creation of the International Medical Devices Regulators Forum (IMDRF)
- Highlight key attributes of the Forum
- Summarize progress to date



GHTF

- Global Harmonization Task Force (GHTF): created in 1992 as voluntary harmonization initiative comprised of regulators and industry from Europe, US, Japan, Canada and Australia
- Purpose: encourage convergence in regulatory requirements, practices and systems to promote:
 - safety, effectiveness/performance and quality of medical devices
 - technological innovation, and
 - international trade
- Mechanism: harmonized guidance documents on basic regulatory practices by 5 study groups



STUDY GROUPS

- Study Groups covering product lifecycle backbone of GHTF:
 - Study Group 1 - Premarket Evaluation
 - Study Group 2 - Post-Market Surveillance/Vigilance
 - Study Group 3 - Quality Systems
 - Study Group 4 - Auditing
 - Study Group 5 - Clinical Safety/Performance
- Ad Hoc WGs also assigned specific tasks



Steering Committee

- SGs pre-date SC, independently initiating work plans and guidance documents
- Steering Committee inaugurated in 2001 to provide management oversight and strategic direction; GHTF procedures subsequently established
- SC composed of representatives from regulators and trade associations of five founding members
- Rotating regulatory chair/industry vice-chair and secretariat across 3 geographical regions⁵



Accomplishments

- Over 50 guidances and documents that define the most important elements of a harmonized regulatory system
- GHTF Regulatory Model which integrates all guidance documents over medical device lifecycle
- Reference and forum for exchange with countries with developing medical device regulatory systems, notably those part of Asian Harmonization Working Party (AHWP)



Time for Change

- With existing GHTF work coming to an end, regulatory members felt a new operating model was necessary to achieve original GHTF objectives and meet the increasing challenges of globalization and emerging technologies
- Belief informed by SC review of achievements and challenges in May 2010 and resulting 'scorecard'



Considerations

- Increasing need for environment conducive to promoting inter- agency exchange of best practices and confidential information, moving cooperation beyond development of work products
- Recognition that regulators have ultimate responsible for protection of public health, and in so doing interacting with many stakeholders



Considerations

- Changing global face of product development, manufacture and marketing and rise of emerging economies
- Lessons learned: including importance of selecting limited number of well-defined work items of high value and limited duration which may then be implemented by regulators



Launch of IMDRF

- IMDRF launched at planning meeting in Ottawa in October 2011 where draft ToR developed
- Singapore meeting (March 2012) marked official inauguration with third meeting in Sydney
- Invitation to regulators from BRIC countries to form management committee reflects need to broaden regulatory participation
- Brazil, China and Russia are official members
- WHO and APEC are Official Observers and confirmation of AHWP and PAHO as Affiliate Organizations also signals importance of close cooperation in achieving common goals



Meetings To-Date

- Chair and secretariat rotate on annual basis, beginning with Australia (2012), EU (2013), US (2014), Japan (2015), Brazil (2016)
- Australia hosts new IMDRF website, which also serves as official repository for GHTF documents
- Two 3 day meetings per year, each of which features a public session that serves to update and hear from stakeholders



Important Facts

- While management committee (MC) composed of regulators, the Forum - and notably working groups - may and do include industry and other stakeholders
- Industry now also afforded time on MC agenda
- Two types of IMDRF work products: governance and technical
- Decisions by consensus and not voting
- In exceptional cases, an MC member organization may opt-out of a technical activity



Important Facts

- New Work Items (NWIs) endorsed by MC define technical work of IMDRF and remit of Working Groups (WGs)
- WGs will be disbanded once assigned work completed
- WGs will generally include stakeholders with significant involvement and expertise in topic
- WGs responsible for matters relating to regulatory practices or exchange of confidential information will be comprised of regulators



Important Messages

- IMDRF efforts build upon solid foundation provided by GHTF work products
- MC committed to rapid progress and concrete deliverables – reflected by addition of new stage in draft operating procedures:
Implementation
- Transparency and engagement key to building trust
- Goal of regulators and industry aligned: true regulatory convergence and harmonization

->IMDRF is the vehicle



New Work Items

5 NWIs were selected to launch the IMDRF work plan:

- Review of National Competent Authority Reporting (NCAR) system: EU lead
- Implementation roadmap for Unique Device Identifier (UDI) system: EU
- Medical Device Single Audit Program (MDSAP): US
- Recognized International Standards: EU
- Regulated Product Submission (RPS): Canada



NCAR Review

- NCAR established under GHTF to facilitate regulatory exchange of relevant post market safety information on medical devices
- Aim: trigger rapid adoption of field safety corrective actions in concerned geographies
- IMDRF project: review current system and advise on opportunities for improvement and possible expansion



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IMDRF NCAR N14 Document

- The NCAR Exchange Program will be used to exchange information relating to significant concerns or potential trends that individual authorities have observed in their jurisdictions, but have not yet resulted in recalls or Field Safety Corrective Actions (FSCAs).



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IMDRF NCAR Exchange Program

- Pilot Phase October 2015-March 2016
- Full Implementation April 2016



Unique Device Identifier

- Purpose: define roadmap to implementing a globally harmonized approach to uniform device identification system
- Builds upon and replaces GHTF document adopted Sept. 2011
- Serves as framework for regulators intending to develop their own UDI systems



IMDRF UDI N7 Document

- Elements of guidance include:
 - UDI
 - UDI Carrier
 - UDI Database
 - Rules for specific device types including UDI assignment and placement
- Implementation of a UDI System has started in one IMDRF member



Single Audit Program

- Purpose: develop standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems
- Represents critical step in establishing a Medical Device Single Audit Program (MDSAP)



IMDRF MDSAP Documents

Documents for the Regulatory Authority assessments of AOs are based on:

- IMDRF/MDSAP WG /N5 FINAL:2013 – “Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations”
- IMDRF/MDSAP WG /N6 FINAL:2013 – “Regulatory Authority Assessor Competence and Training Requirements”
- IMDRF/MDSAP WG/N8 FINAL:2015 – “Regulatory Authority Assessment Method Guidance”
- IMDRF/MDSAP WG/N11 FINAL:2014 – “MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization



IMDRF MDSAP Documents

Recognition, monitoring and re-recognition of Auditing Organizations documents:

- IMDRF/MDSAP WG/N3FINAL:2013 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
- IMDRF/MDSAP WG/N4FINAL:2013 – “Competence and Training Requirements for Auditing Organizations”
- IMDRF/MDSAP WG/N24 – “MDSAP Audit Report Guidance”



MDSAP Pilot

International consortium of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in an Audit and Assessment Pilot Program (Australia, Brazil, Canada, Japan and United States)

The MDSAP Pilot documents are based on the foundation established by the International Medical Device Regulatory Forum (IMDRF) MDSAP documents



Recognized Standards

- Objective: create list of International Standards used for medical device regulatory purposes that are recognized by IMDRF Management Committee members
- Report Published in 2014
- Listing of Recognized Standards in each IMDRF member posted on the website in 2014.



Regulated Products Submission

- Composed of two complementary components:
 - Beta testing of RPS Standard to confirm fit for purpose for medical devices
 - Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD)
- Project takes account of existing work:
 - Beta testing: HL7 RPS WG and ICH
 - ToC: GHTF STED documents
- Seen as important step towards goal of common premarket requirements for device applications



Regulated Products Submission

- Beta Testing concluded that HL7 Standard can accommodate medical devices
- HL7 RPS ballot passed in 2014; now a normative standard
- Table of Contents for IVD and nIVD published in 2014
- IMDRF currently running a Table of Content Pilot until Fall 2016 with a possibility of extension



Additional New Work Items

- Software as a Medical (US lead)
- Patient Registries (US lead)
- Adverse Event Terminology (Japan lead)
- Good Regulatory Review Practices-
Competence and Training Requirements
for Pre-market Reviewers (US lead)
- Standards- improving the quality of
international medical device standards for
regulatory use (EU lead)



IN SUMMARY

- IMDRF efforts build upon solid foundation provided by GHTF work products
- Good progress being made that will have a direct influence on advancing regulatory convergence
- 3 Work Items have finished
- 7 Work Items are at various stages of progress.



Thank you

Questions!