DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

13 September 2022

Masaaki Ohtsuka, DITTA Chair

Secretary General, JIRA

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协会 China Association for Medical Devices Industry · ABiMED · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

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DITTA GLOBAL PRESENCE

2018: DITTA as a recognized non state actor in official relations with WHO
2016: DITTA MoU with the World Bank
2015: DITTA was granted a NGO status with WHO
2014: DITTA has official liaison with AHWP

DITTA: 11 WORKING GROUPS

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1. Regulated Product Submission (RPS) Working Group — MITA
2. Cybersecurity Working Group — MITA
3. Medical Device Single Audit Program (MDSAP) Working Group — MITA
4. Unique Device Identification (UDI) Working Group — MITA
5. MSW & AI Working Group — COCIR
6. Clinical Evaluation Working Group — COCIR
7. Standardisation (STA) Working Group — COCIR
8. Good Regulatory Review Practices (GRRP) Working Group — JIRA

New Working Group

9. Global Health (GH) Working Group — COCIR
10. Environmental Policy (ENVI) Working Group — COCIR
11. Good Refurbishment Practice (GRP) Working Group — JIRA

IMDRF, GHWP, IEC, ISO

World Health Organization, World Bank Group, IAEA

Basel Convention, UNEP, MITA, IEC, ISO

COCIR, JIRA, Medtech Canada, MITA, THAIMED, IMEDA, 中国医疗器械行业协会, ABIMED, Kmdica, KMDIA Korea Medical Devices Industry Association, TECHNATION CA

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1. DITTA FEEDBACK ON IMDRF WORK ITEMS

1. **Good Regulatory Review Practices (GRRP)**
2. **Regulated Product Submission (RPS)**
3. **Medical Device Cybersecurity Guide (CYBER)**
4. **Artificial Intelligence Medical Devices (AIMD)**
5. **Software as a Medical Device (SaMD)**
6. **Standards** - **Improving the quality of international medical device standards for regulatory use**
7. **Unique Device Identification Application Guide (UDI)**
8. **Medical device single audit program (MDSAP)**

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KEY POINTS

1. Good Regulatory Review Practices (GRRP)

- DITTA welcomes the opportunity of public consultation on the draft N71 “Marketing Review Report Work Instruction” and supports the development of key elements for the CAB review system
- DITTA suggests IMDRF move toward the implementation of the CAB review system

2. Regulated Product Submission (RPS)

- DITTA supports ongoing work on the Table of Contents as an essential building block for the CAB review system and appreciates the opportunity for further engagement

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KEY POINTS

3. Medical Device Cybersecurity Guide (CYBER)

- DITTA remains actively engaged with IMDRF in their goal to publish Legacy and SBOM documents
- DITTA is committed to working with the IMDRF in ensuring that medical devices are deployed securely on networks and operate in a safe, effective way

4. Artificial Intelligence Medical Devices (AIMD)

- DITTA welcomes the publication of IMDRF/AIMD WG /N67:2022 “Machine Learning-enabled Medical Devices: Key Terms and Definitions ”

- DITTA supports development of dedicated IMDRF guidance on change management related to AI-enabled medical devices

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KEY POINTS

5. Software as a Medical Devices (SaMD)

- DITTA welcomes the start of revising the existing SaMD documents.

6. Standards -Improving the quality of international medical device standards for regulatory use

- DITTA emphasizes that international standards are vital for global convergence
- DITTA welcomes “Standards Liaison Program Framework” (IMDRF/Standards WG/N72)
- DITTA urges IMDRF to operationalize its liaisons to ISO and IEC to ensure regulators’ input into development of standards for regulatory use

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KEY POINTS

7. Unique Device Identification Application Guide (UDI)

- DITTA supports global harmonization of UDI requirements
- DITTA recommends updating documents,
  "IMDRF/UDI WG/N53 "Use of UDI Data Elements across different IMDRF Jurisdictions"
  "IMDRF/UDI WG/N48 "Application Guide"

8. Medical device single audit program (MDSAP)

- DITTA continues to support the MDSAP program and encourages continuous improvement of the program based on experience and input from manufacturers, AOs, and regulators
- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits
- DITTA encourages the MDSAP Consortium membership to add Affiliate Members

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IMDRF / DITTA JOINT VIRTUAL WORKSHOP ON STANDARD FOR HEALTH SOFTWARE

Objectives:

- Better understand what are the needs & challenges from regulator perspective and industry perspective
- Exchange views on how better health software standards for regulatory use can be developed

Attendance:

- NNN registered participants, MMM attendees
  (regulators, auditing organisations, healthcare providers, scientific societies and industries)

Speakers: 3 from jurisdictions, 3 from industries

- IMDRF Jurisdictions: Madoka Murakami (Japan MHLW) , Johan Ordish (UK MHRA), Brendan O'Leary (US. FDA)
- Industries: Varun Verma, Martin Mayer (DITTA), Pat Baird (GMTA)
- Academia : Hwiyoung Kim(Yonsei University)
- SDOs: Brodie Pedersen(IEC SC62B), Peter Linders (ISO TC210)

Panelists:

- IMDRF Jurisdictions: U.S. FDA
- IMDRF Regional Harmonization Initiatives: GHWP
- Healthcare Professional & Provider: from Australia
- Test Laboratory: BSI
- Industries: DITTA, GMTA

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THANK YOU!

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