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

DITTA UPDATE

AHWP Annual Meeting
25 October 2018, KL, Malaysia

Naoki Morooka

Steering Committee Member, DITTA

COCIR JIRA MEDEC MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

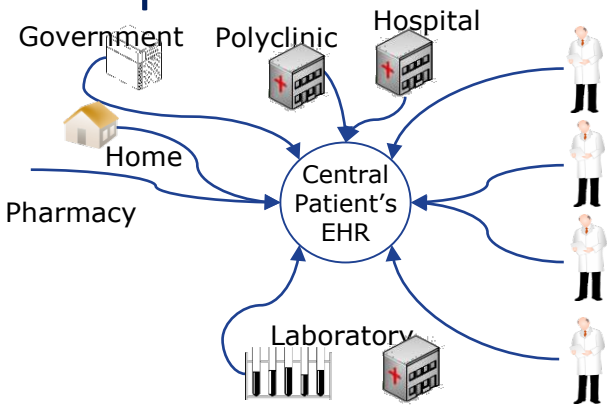
DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA is a non-profit trade association,
created in 2000 and incorporated in 2012 represents
more than 600 companies around the globe

DITTA covers the following industry sectors:

1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. and Radiopharmaceuticals

Our Industry leads in state-of-art
advanced technology and provides
integrated solutions
covering the complete care cycle



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DITTA GLOBAL PRESENCE

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DITTA GOVERNANCE

Board of Directors

MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA · JIRA · COCIR

DITTA Chair:
Patrick Hope, MITA Executive Director
DITTA Vice-Chairs:
Nicole Denjoy, COCIR Secretary General
Kiyoshi Inaba, JIRA Business Execution Director

Members:
- Founding Organisations
- Executive Mgmt of each organisation
- Chairs of their International Groups

Steering Committee

Chair: DITTA Chair
Members:
- Heads of each organisation
- Leadership of their International Groups
- Leadership of DITTA WGs

TCONs: one per month

Working Groups

One Chair, Two Vice-Chair per Working Group
Members:
- Mixture of trade associations and company experts
- Coordination: MITA, JIRA, COCIR

TCONs: as needed

DITTA: 10 WORKING GROUPS

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

1. Regulated Product Submission (RPS) Working Group — MITA
2. Medical Software (MSW) Working Group — COCIR
3. Unique Device Identification (UDI) Working Group — MITA
4. Standardisation (STA) Working Group — COCIR ⟷ IMDRF, AHWP, IEC, ISO
5. Clinical Evaluation — COCIR
6. Cybersecurity Working Group — MITA
7. Medical Device Single Audit Program (MDSAP) Working Group — MITA ⟷ MDSAP RAC
8. Global Health (GH) Working Group — COCIR ⟷ IAEA International Atomic Energy Agency, WORLD BANK GROUP, World Health Organization
9. Environmental Policy (ENVI) Working Group — COCIR ⟷ BASEL CONVENTION, UNEP
10. Good *Refurbishment Practice (GRP) Working* Group — JIRA ⟷ MITA Medical Imaging & Technology Alliance, IEC, ISO

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PRESENTATION OUTLINE

Key Topics for AHWP from DITTA

1. Standards/IMDRF Standards WG
2. Cybersecurity- IMDRF NWIP
3. Good Refurbishment Practice

- Additional Information.

  APEC LSIF RHSC – Medical Device Priority Work Area

GOAL:

Global Harmonization & Regulatory Convergence

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STANDARDS

Our Goal:

- International consensus standards are key to safe medical devices
- They are the most effective means of demonstrating conformance to legal requirements and a powerful tool for regulatory convergence

Outcome by IMDRF Standard WG ←NWIP initiated by DITTA 3years ago.

- N47 “Optimizing Standards for Regulatory Use”
- MoU with SDOs(ISO/TC210,IEC/TC 62), and liaison for TC from IMDRF.
- Preparation for survey of the recognized standards.

DITTA is recommending and suggesting;

1. *IMDRF to establish the procedure for supporting the liaison member from IMDRF to TC in SDOs*
2. *DITTA expect good influence for developing IEC60601-1 4th edition by IMDRF liaison to IEC/TC62.*

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CYBERSECURITY

Our Goal:

- Enable patient safety and privacy through a regulatory and standards environment that emphasizes protection of the patient and the safeguarding of all associated sensitive information

DITTA Actions:

DITTA held the workshop and submitted the NWIP to IMDRF.

→***It was endorsed in IMDRF Beijing meeting.***

- This work item should deal with the following concept:
  1. Cybersecurity is a shared responsibility among all stakeholders
  2. Promote broad information sharing policies
  3. Define the terms and clarify the understanding on medical device cybersecurity

DITTA engages in the development of another Cybersecurity document:

- DITTA is developing another Cybersecurity document for medical device manufacturers followed by the previous cybersecurity white paper.

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GRP GOOD REFURBISHMENT PRACTICE FOR MEDICAL IMAGING EQUIPMENT

Our Goal:

・Open new markets for safe and effective refurbished medical imaging devices

Refurbishment Process:

・Essential to ensure safety and effectiveness of refurbished medical imaging devices

・DITTA developed requirements of the Refurbishment Process for medical imaging devices to ensure Safety and Effectiveness

History:

・COCIR standard on GRP(2007)

→ NEMA/MITA 01 standard (2015)

→ IEC PAS 63077 (2016)

In 2018:

・NWIP of IEC 63077 was proposed and was approved in February 2018

・IEC SC62B WG53 was established and the standard development started in March 2018

・Proceeding to CDV was approved at the SC62B meeting in London, April 2018

・CDV will be circulated for voting by the end of 2018

NWIP: New work item proposal; CDV: committee draft for voting

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ADDITIONAL INFORMATION
APEC LSIF RHSC MEDICAL DEVICES PWA

JIRA is one of major Industry Association in Japan, and is a Founding Organization of DITTA.

JIRA is promoting MD-PWA as co-coalition leader in APEC LISF RHSC.

Goal of PWA (Priority Work Area) for MD in APEC

- Develop training and education related to topics across the product life cycle of the device (i.e., pre-market, post-market, etc.) and gain greater understanding of international best practices, achieve harmonized approaches, and facilitate regulatory convergence for medical devices in APEC economies

Roadmap of PWA for MD

- Establish the Center of Excellence(CoE) of regulatory sciences for medical devices.
- Development the training curriculum for international harmonization
- Training for regulators by the recognized CoE.

JIRA suggest;

- JIRA suggest to avoid the duplication with APEC and AHWP.

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THANK YOU!

www.globalditta.org

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