DITTA Update
Asian Harmonization Working Party

14 November 2019, Oman

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DITTA
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: 9 WORKING GROUPS

1. Regulated Product Submission (RPS) Working Group
2. Medical Device Single Audit Program (MDSAP) Working Group
3. Unique Device Identification (UDI) Working Group
4. Standardisation (STA) Working Group
5. Clinical Evaluation
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
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DITTA session at AHWP meeting 2019
UNIQUE DEVICE IDENTIFICATION (UDI)

• Support consistent implementation of IMDRF guidance documents globally

• Principles: flexibility, availability of guidance and mapping documents

• Emphasize commonality for key aspects of a UDI system
NOMENCLATURES

- DITTA considers proliferation of nomenclature systems undesirable as it will add burden on industry to use multiple systems.

- DITTA recommends a coordinated approach to ensure maximum benefit with minimal impact on stakeholders.
IMDRF/DITTA workshop on standardization (March, Russia)

Key recommendations
• Advance harmonized use of standards in regulatory frameworks
• Build productive relationships between regulators and standards development organizations
• Long term goal: consistency in conformity assessment approaches
GOOD REFURBISHMENT PRACTICE

- Successful workshop on import of refurbished medical devices to Vietnam (April, Hanoi)

- Promotion of IEC PAS 63077: 2016 “Good refurbishment practices for medical imaging equipment”
MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

• Continuing strong industry support for MDSAP program

• Desire to have additional jurisdictions accept MDSAP reports in place of their need for audits - opportunity of newly established category of “affiliate member”
IMDRF/DITTA Workshop (September, Russia): discussion on the opportunities and challenges of Artificial Intelligence in healthcare

Attendance: over 100 participants

Key Take-Aways:

• High level of interest and engagement from all stakeholders
• Necessity for harmonized healthcare-specific AI terminology
• Consider enriching existing IMDRF guidance to foster more convergence
• Issue of access to high-quality data

Find all presentations here.
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