



Global Harmonization Working Party

Towards Medical Device Harmonization



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

DITTA Update

GHWP Annual Meeting

30th November 2023

Sunny Woo
KMDIA



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DITTA'S GLOBAL PRESENCE



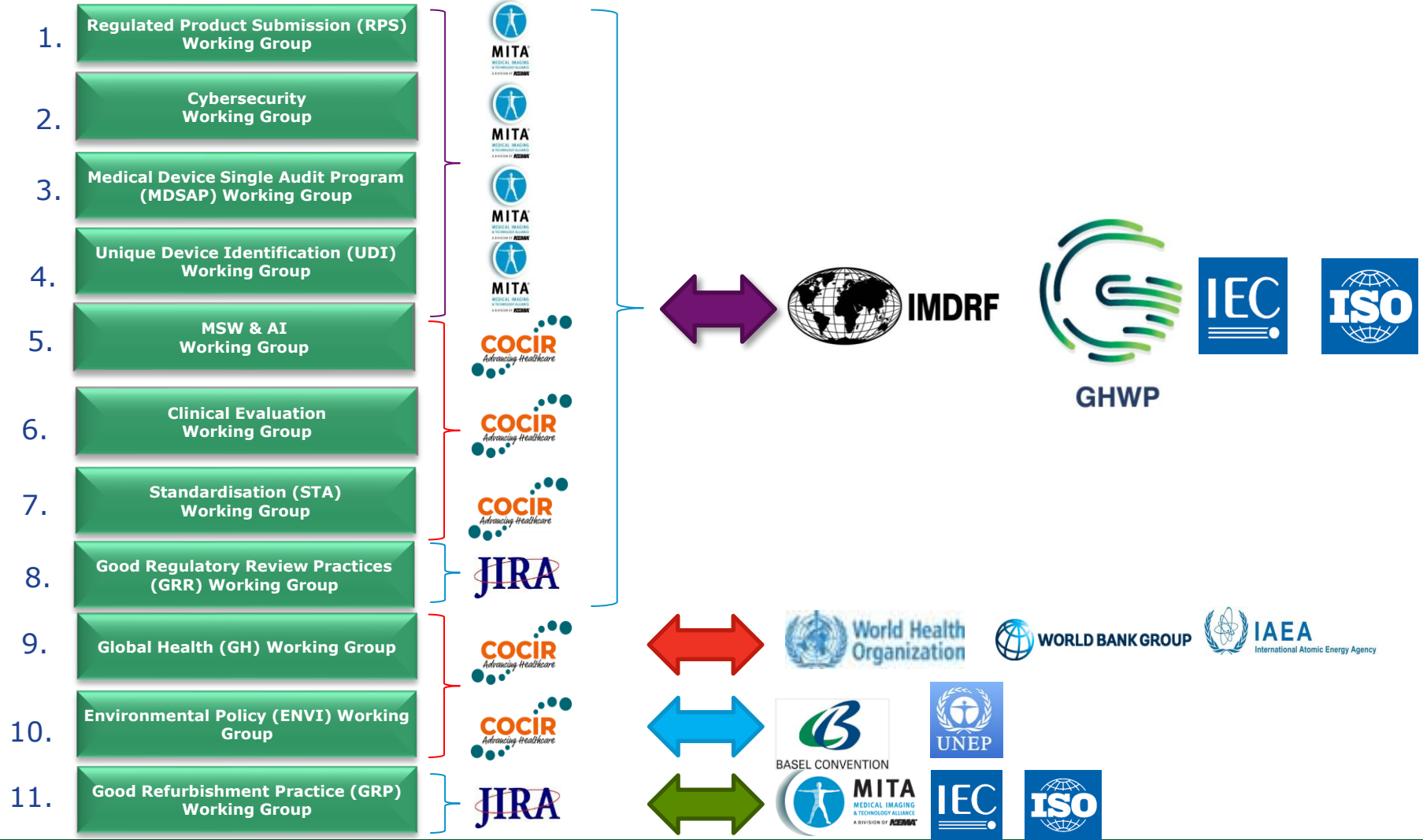
- 2018: DITTA as a recognized non state actor in official relations with WHO
- 2016: DITTA MoU with the World Bank
- 2015: DITTA was granted a NGO status with WHO
- 2014: DITTA has official liaison with AHWP (now GHWP)





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DITTA: 11 WORKING GROUPS





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DITTA PRIORITIES

- Global harmonization of medical device regulations
- Convergence of regulatory frameworks
- Regulatory reliance
- Support training and capacity building





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DITTA PRIORITIES, CONT.

Global Health

Support easier access and increased use of medical technology in Lower- and Middle-Income Countries through official relations with the World Health Organization and by improving procurement practices through partnership with the World Bank.

Digital Health/Cybersecurity

Contribute to the convergence of globally harmonized regulatory approaches and monitors progress in various jurisdictions. Share industry best practices and guidelines that manufacturers can implement to improve their cybersecurity capabilities.

Regulations & Standards

Advocate an industry-friendly regulatory environment accelerating access to market. Support the convergence of regulatory frameworks and promote the use of international standards.

Environment

Promote alignment on environmental legislation , monitor developments globally and promote the adoption of Good Refurbishment Practice.





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DITTA VIEWS

- **DITTA supports...**
 - **GHWP efforts towards regulatory harmonization and reliance**
 - **GHWP efforts on education and capacity building**
 - **A collaborative working relationship with IMDRF, ISO, other standards organizations, and ensuring complementary documents**
 - **E.g. IMDRF workshop with DITTA and GMTA**





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DITTA VIEWS-GWHP DOCUMENTS

- **Appreciate openness of Working Groups to DITTA experts for collaboration**
- **DITTA provides feedback on the documents as available**





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DITTA EXPERTS IN GHWP

- **DITTA experts participate in several GHWP working groups, sometimes as advisers or experts from GHWP member economies**
 - **E.g., WG-5 Clinical Evidence for Performance and Safety**
- **DITTA experts have participated in GHWP workshops**

And ...

- **DITTA looks forward to collaborating with GHWP in more competence areas!**





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THANK YOU!

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