IMDRF/DITTA Joint Virtual Workshop
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Cybersecurity - Where are we today?

Best Practice Security Documentation

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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
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 (CE) Working Group
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
10. Medical Software & AI (MSW & AI) Working Group
Contribution to Medical Device Cybersecurity

1. Development of **best practice documents**

2. Supporting harmonization of significant **international standards**

3. Encouraging **information sharing** between manufacturers and healthcare providers via **security documents** such as the **MDS²** (Manufacturer Disclosure Statement for Medical Device Security) and **SBoM** (Software Bill of Materials)
Manufacturer Disclosure Statement for Medical Device Security (MDS²)

- MDS² v1.0 published in November 2004
- Last version of MDS² published October 2013
- Current official release published October 2019
  

Four new categories in current MDS² release

1. RMOT: Remote Service and Administration
2. SBoM: Software Bill of Materials
3. CONN: Connectivity Capabilities
4. MPII: Management of Personally Identifiable Information
Software Bill of Materials (SBoM)
- Actively maintained list of software components in a medical device
  - May also include vulnerabilities associated with those components
- Has been gaining global attention and being referenced in guidance docs
  - USFDA, Health Canada, Australian Therapeutic Goods Association (TGA), EU MDR, others...
- MDMs being requested to provide to customers and prospective customers
- US National Telecommunications and Information Administration (NTIA) developing a standardized SBoM format across all verticals, including healthcare
- USFDA is closely following NTIA activity as they prepare to release Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
Thank you!