



Global Medical
Technology Alliance
Innovating for a Healthier World

U.S. Medical Device Cybersecurity Efforts and Initiatives

DITTA Cybersecurity Workshop

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Who Are We?

- 25 member associations
- Origins date to 1990s as informal network
- Formally established in 2010 with Secretariat and website in Geneva; legally constituted in Switzerland as an “association” in 2013; WHO recognized NGO in 2015
- Membership open to medical technology associations (not companies):
 - Willing to accept GMTA governance rules
 - With functioning code of ethical business practices



GMATA Cybersecurity Principles

- Objective
 - Provide principles for use by the medical technology industry to establish effective cybersecurity for its medical devices
 - Demonstrate the device industry's commitment to patients and health care practitioners to provide secure medical devices
- Application
 - Applies to connected devices only (for example, devices that connect via internet, hospital networks, or directly to another medical device)



GMTA Cybersecurity Principles

1. Cybersecurity risk management program to include premarket and postmarket considerations
2. System level security: Device cybersecurity is a shared responsibility
3. Establish coordinated disclosure policies
4. Cooperative effort among regulators, manufacturers and security experts to develop standards and regulations



Cybersecurity risk management program to include premarket and postmarket considerations

- US FDA Guidance Documents
 - Premarket and Postmarket guidances
 - Clarifies application of quality system regulation
- Congressional Legislation
 - Prescriptive vs. general
 - Government contracts vs. commercial purchasing



System level security: Device cybersecurity is a shared responsibility

- Vulnerability sharing through established bodies
- Software bill of materials
- Coordinated efforts
 - Sector coordinating council
 - Federal government leadership



Establish coordinated disclosure policies

- Allow researchers to submit findings
- Implement response mechanisms
- Case study: Muddy Waters and St. Jude Medical



Cooperative effort among regulators, manufacturers and security experts to develop standards and regulations

- Standards development processes
 - MITA MDS2
 - AAMI TIRs
- Workshops and conferences
- FDA guidance process