IMDRF/DITTA Joint Virtual Workshop
Monday 21 Sept. 2020
Cybersecurity - Where are we today?

Regulatory Update in Japan
Introduction of IMDRF Guidance

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Recent Trends in Cybersecurity Assurance of Medical Devices in Japan

The following risks are assumed in the event of a cyberattack on a medical device:

- **Suspension of diagnosis or incorrect diagnosis** (e.g., Testing or Diagnostic system)
- ** Interruption of treatment** (e.g., Therapeutic device),
- **Excessive or inadequate irradiation** (e.g., Radiation therapy system).

MAHs for medical devices:

*Requested evaluate the cybersecurity risks properly*

By notification; “Guidance on Ensuring Cyber Security of Medical Devices”, July 24, 2018
Notification regarding IMDRF Guidance

To Japanese Stakeholders

Informed “IMDRF Guidance” released
(May 13, 2020; Administrative notification)

Contribute to improve the safety of medical device cybersecurity.
(e.g.; SBoM, CVD, etc. are important for cybersecurity)

This notification enhances medical device cybersecurity in Japan
(For Japanese manufacturers/other stakeholders)
Future Works in Japan

How to introduce the IMDRF Guidance to Japan?

IMDRF Guidance

2020.03

Japanese Guidance for Cybersecurity of medical device

“Guidance on Ensuring Cyber Security of Medical Devices”, PFSB/ELD/OMDE/C0428 No.1 and PFSB/SD 0428 No.1, April 28, 2015

“Guidance on Ensuring Cyber Security of Medical Devices”, PSEHB/MDED0724No.1 and PSEHB/PSD 0724 No.1, July 24, 2018

Main Tasks (Methodology for implementation)

*Discussion with stakeholders such as...
  MAHs, medical staff (Dr, Ns, etc.), IPA, PMDA, etc.,
*Assignment of roles such as...
  Reporting for Adverse events, Cybersecurity incidents, etc.,

Next guidance?

Continue discussing how to introduce the IMDRF guidance to JP regulation.
Thank you!