Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

MHLW Regulatory Update

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MHLW Ministry of Health, Labour and Welfare of Japan

28th GHWP Annual Meeting and 28th GHWP TC Meeting, 9th - 12th Dec 2024
Kuala Lumpur, Malaysia

Agenda

- Establishment of PMDA’s International Hubs
- Software as a Medical Device
- Cybersecurity

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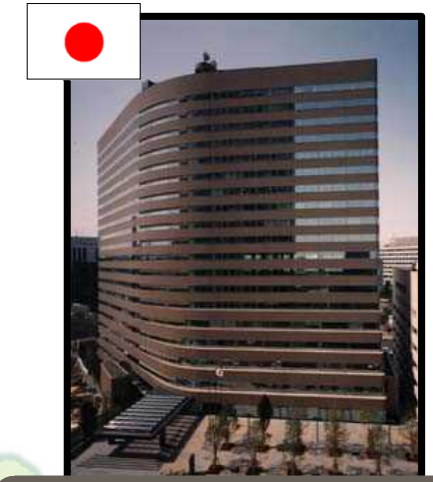
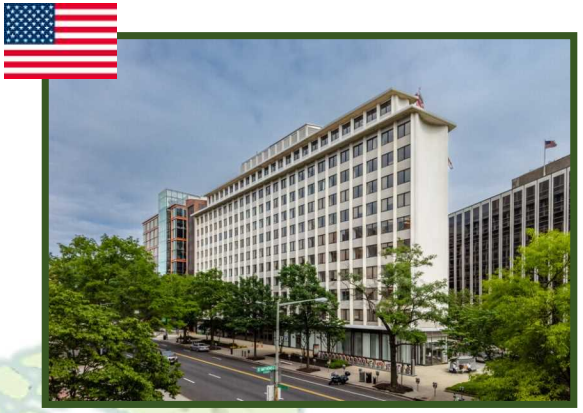
PMDA's International Hubs

Asia Office, Bangkok



PMDA Central Office, Tokyo



Washington D.C Office

Establishment of PMDA's international hubs to enhance international contribution/capability for regulatory proposal

PMDA's 5th mid-term plan

Initiatives to strengthen cooperation
with Asian countries / with the United States & EU

- **To support innovative medicines & medical devices access in Japan and Asian countries,**
  - Strengthening cooperation with ASEAN countries
  - Supporting promotion of regulatory harmonisation with Asian countries
  - Developing an environment for smooth clinical development

→ Establishment of Asia Office in Bangkok, Thailand

- **Close collaboration between Japan, US and European regulatory authorities is essential in supporting;**
  - Development/distribution of innovative medicines and medical devices
  - Regulatory review
  - Post-marketing measures

→ Establishment of Washington D.C. Office, USA

PMDA dispatches a staff to EMA as a liaison officers (since 2009~).

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Software as a Medical Device

DASH for SaMD 2（2023/9/6）

- Organize and publicize the two-step approval scheme for SaMD
- ***Develop guidelines for approval review and marketing procedures for SaMD for the general public***
- Promotion of overseas acceptance of our review results (such as English translation of review reports)
- Subsidies for development funds for SaMD developers
- Support for SaMD developers to actively business overseas

DASH for SaMD（2020/11/24）

- Setup an office to review SaMD in MHLW and PMDA
- Establishment of SaMD centralized consultation service
- Next-generation medical device evaluation index, development guidance, audit points, and certification criteria formulation
- Trial implementation of priority review, etc. for innovative SaMD
- Promote the use of IDATEN (Improvement Design within Approval for Timely Evaluation and Notice) and streamline procedures, etc.

<Expand and continue>

- Upgrade from office to Department for reviewing SaMD in PMDA
- Establishment of SaMD-specific consultation service
- (Continue)
- (Continue)
- (Continue)

Review point for;

- Software for Peritoneal Dialysis Treatment
- Supporting Software for Dental Implant Treatment
- Software for Ophthalmic Surgery Treatment Planning
- Supporting Software for Detecting Lesion with Endoscopic Imaging
- Computer-Aided Diagnosis Program to Support Interpretation of Medical Images

DASH for SaMD: DX(Digital Transformation) Action Strategies in Healthcare for SaMD(Software as a Medical Device)

English version available

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Cybersecurity

*Guidelines for the Security Management of Medical Information Systems Version 6.0 (May 2023)
** Standards for medical devices established by the Minister of Health, Labor and Welfare pursuant to the provisions of Article 41, Paragraph 3 of the Act on Ensuring the Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, etc.
（Ministerial Notification No. 122 of 2005, Partial amendment of Ministerial Notification No. 403 of 2014, Partial amendment of Ministerial Notification No. 67 of 2020）

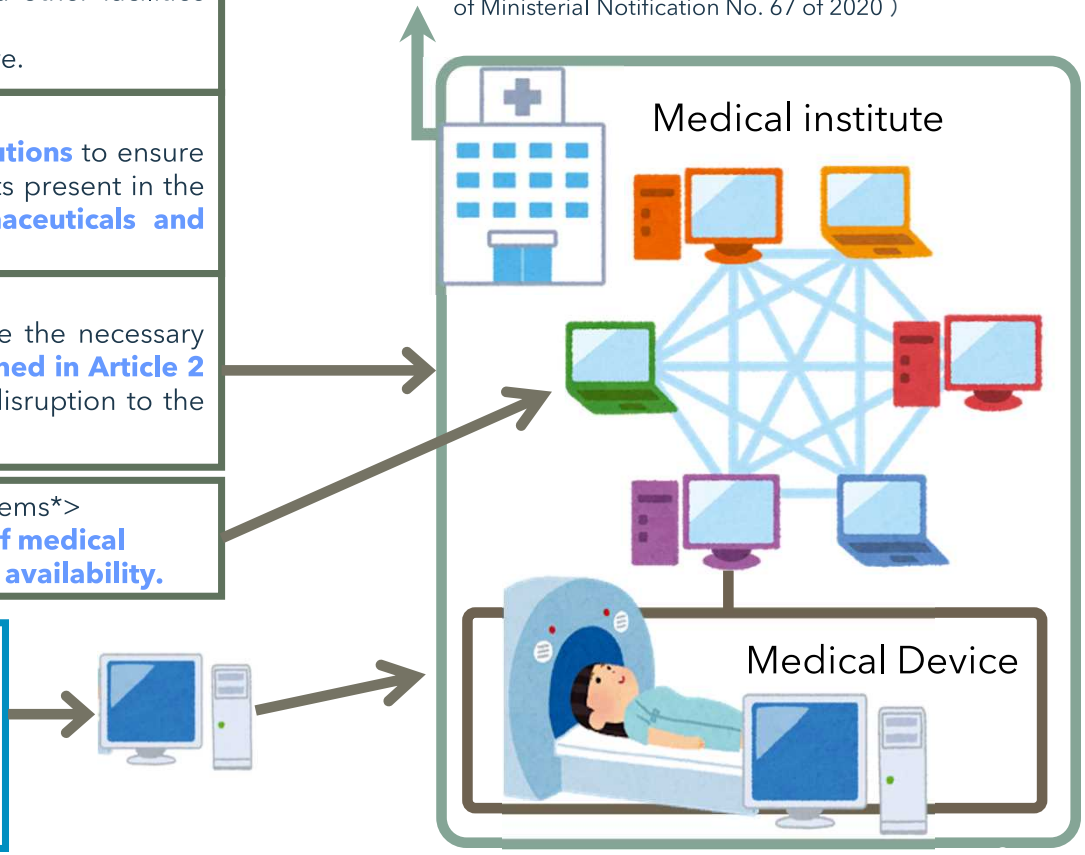
<Article 1-11, p.,1, Enforcement Regulations of the Medical Care Act>
Pursuant to Article 6-12 of the Law, administrators of hospitals and other facilities must **ensure the following systems for safety management**:
- Establish guidelines for safety management related to medical care.

<Article 14, p.,1, Enforcement Regulations of the Medical Care Act>
The administrator of a hospital or clinic must **take necessary precautions** to ensure that the drugs, medical devices, and regenerative medicine products present in the hospital or clinic do **not violate the provisions of the Pharmaceuticals and Medical Devices Act.**

<Article 14, p.,2, Enforcement Regulations of the Medical Care Act>
The administrator of a hospital, clinic, or midwifery clinic must take the necessary measures to **ensure cybersecurity (meaning cybersecurity as defined in Article 2 of the Basic Act on Cybersecurity)** so as to avoid any significant disruption to the provision of medical care.

<Guidelines for the security management of medical information systems*>
Medical institutions will take the initiative **in managing the security of medical information systems to ensure their confidentiality, integrity, and availability.**

< Essential Principles**, Article12-3 >
Medical device manufacturers to play a key role in **maintaining the functionality of medical devices and patient safety against cyber risks.**
Provide necessary information to medical institutions and cooperate with them.



Cybersecurity

2005 **2014** **2020** **2023** **2024**

Ensuring cybersecurity in medical devices (PFSB/ELD Notification No. 0428-1, April 28, 2015)

Guidance on ensuring the cybersecurity of medical devices (PFSB/ELD Notification No. 0724-1, July 24, 2018)

Cyber attacks by ransomware targeting medical institutions (alert) (Administrative communication, June 28, 2021)

Cybersecurity related notifications

Essential Principles were introduced for the first time in the medical device regulations in Japan with the amendment of Pharmaceutical Affairs Law.

Guidance on Medical Device Cybersecurity Principles and Practices by the IMDRF (Dissemination Request) (PFSB/ELD Notification No.0513-1, May 13, 2020)

Guidelines for ensuring and enforcing cybersecurity for medical devices (PFSB/ELD Notification No.1224-1, Dec. 24, 2021)

Vulnerability management to ensure cybersecurity of medical devices (PFSB/ELD Notification No.0328-1, Mar. 28, 2024)

SaMD became subject to medical device regulations and EPs were revised accordingly

EPs were revised based on the published IMDRF documents such as cybersecurity guidance.

Application of Article 12-3 of EP for medical devices (PSEHB MDED Notification No.0331-8, Mar. 31, 2023)

Essential Principles* ***Amd*** ***amd***

Nov. 2014 ***Mar.2023*** ***Apr. 2024***

Transition period

English information available

Thank you for your attention