

Regulatory Cooperation on Medical Devices

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Environment Surrounding Medical Device Regulations

1. Medical devices have been rapidly globalized on manufacturing, clinical development and post-marketing.
2. Each regulatory authority has undertaken different regulations, definitions and categorizations, requirements of quality, non-clinical and clinical, resulting in overlap and deviation.
3. Each regulatory authority needs resource and capability to keep up with rapid technical innovation and divergent regulations or standards.



Regulatory authorities around the world should promote [regulatory harmonization activities](#) in bilateral or multilateral collaboration to create common International standards.

WHO (World Health Organization)

SIXTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA67.20

Agenda item 15.6

24 May 2014

Regulatory system strengthening for medical products

1. WHO promotes “[Regulatory cooperation](#)” to strengthen capacity of National Regulatory Authorities (NRAs).
2. WHO promotes “[Reliance](#)” concept, where a regulatory authority utilizes other authorities’ decisions, to streamline decision making processes.
3. WHO publishes “Global Benchmarking Tool ([GBT](#))”, “WHO Listed Authorities ([WLA](#))”, “Collaborative Registration Procedures ([CRP](#))” and “Support for Harmonization Networks ([SHN](#))”, to promote capacity building of authorities.

Regulatory Authorities of Medical Devices in JAPAN

MHLW

Pharmaceutical Safety and
Environmental Health Bureau

(厚生労働省医薬・生活衛生局)



- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities



PMDA

Pharmaceuticals and Medical Devices
Agency that is independent from the
government (医薬品医療機器総合機構)



- Scientific Review for Medical Device
- GCP/GMP/QMS Inspection
- Gathering and Analyzing of Safety information
- Consultation on Clinical Trials etc.



Approval/Certification system of Medical Devices in Japan

1. Application to PMDA or RCB (Registered certification body)



2. Review and Inspection

[Requirements]

QMS-Compliance, Quality, Efficacy, Safety of products



3. Registration of Manufacturers

[Requirements]

QMS-Compliance, Governance



4. License of Marketing Authorization Holder (MAH)

[Requirements]

QMS/GMP/GVP (Good Vigilance Practice)-Compliance, Governance

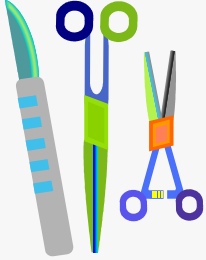





5. Approval/Certification of marketing



6. Product Release (Post-marketing surveillance)

Regulation of Medical Devices in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Pre-market Regulation	Self-Declaration	Registered Certification Body	PMDA Review MHLW Approval	
Example				
Post-Market Safety	PMDA/MHLW			

- Japan applies definition and risk-based classification aligned with GHTF/IMDRF guidelines.
- Nomenclature “JMDN” is a group of General names of Medical devices created based on Global Medical Device Nomenclature (GMDN).
- There is no international harmonization of the General names of medical devices. Slide 6

International Medical Device Regulators Forum (IMDRF)

GHTF: 1992-, IMDRF: 2011-

IMDRF Management Committee



Australia, Brazil, Canada, China, EU, Japan, Russia, Singapore, South Korea, the United States

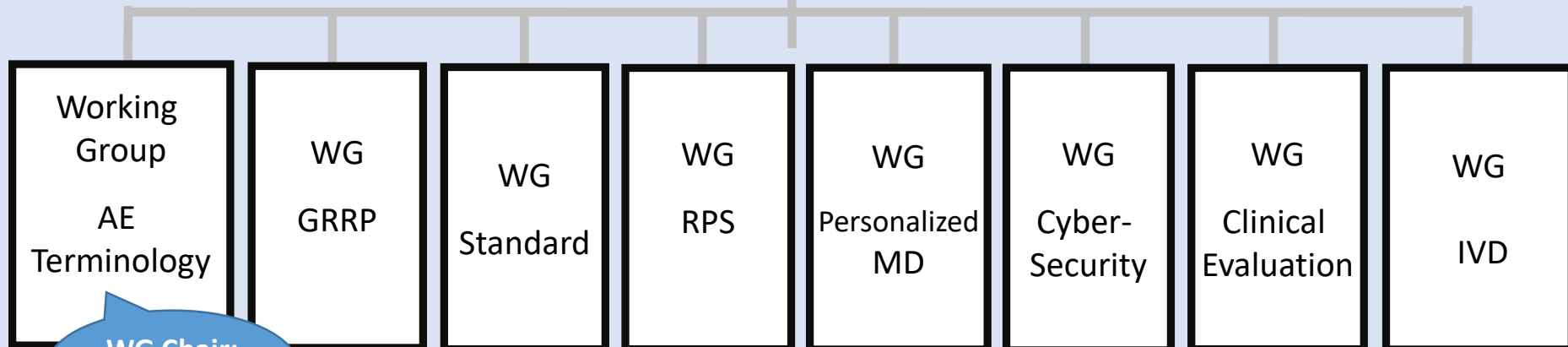
Official Observer
WHO

Regional Harmonization Initiatives

APEC / LSIF / RHSC / AHWP / PAHO

Stakeholders

Industries / Academia



WG Chair:
Japan

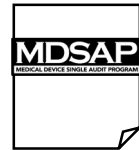
Before using Medical Device Single Audit Program (MDSAP)



- MDSAP is used for conformity assessment process of QMS-compliance (ISO 13485).
- Before MDSAP started, five regulatory authorities conducted duplicated QMS Audits to one manufacturing site exporting products to the five countries.

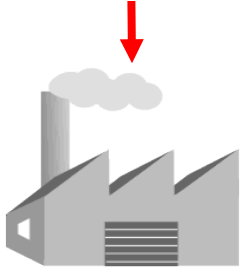
Application using Medical Device Single Audit Program (MDSAP)

MDSAP Auditing Organization



[2. Upload MDSAP Audit Reports]

[1. Audit]



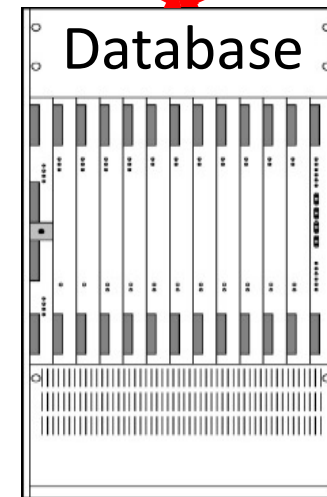
We are accepted by a single MDSAP audit !

Exporting Manufacturer (in MDSAP members)

MDSAP member countries



[3. Data Review]



[Merits of Exporting Manufacturers using MDSAP]

- PMDA has accepted many applications using MDSAP Audit Reports and issued its certificates. (This acceptance has been conducted on a trial basis.)
- MDSAP Audit Reports can reduce manufacturer's burden in inspection process.
- Improve predictability of method and response of inspection.

Before using Medical Device Single Audit Program (MDSAP)

We have to coordinate with many overseas facilities.



Importing Manufacturer

[1. Application for inspection]



[2/5. Enquiry/Reply about Foreign Manufacturing site]



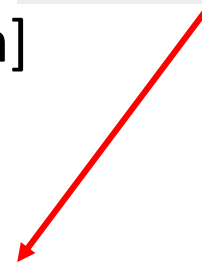
[3. Enquiry/ Reply]



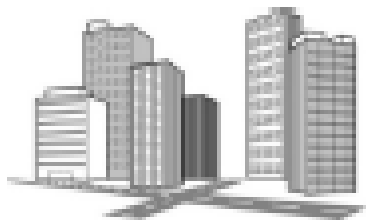
[6. Coordinating On-site inspection]



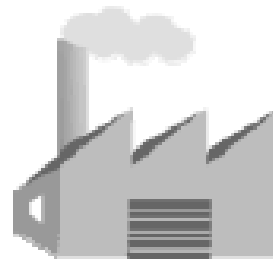
[7. On-site inspection]



[4. Enquiry/ Reply]

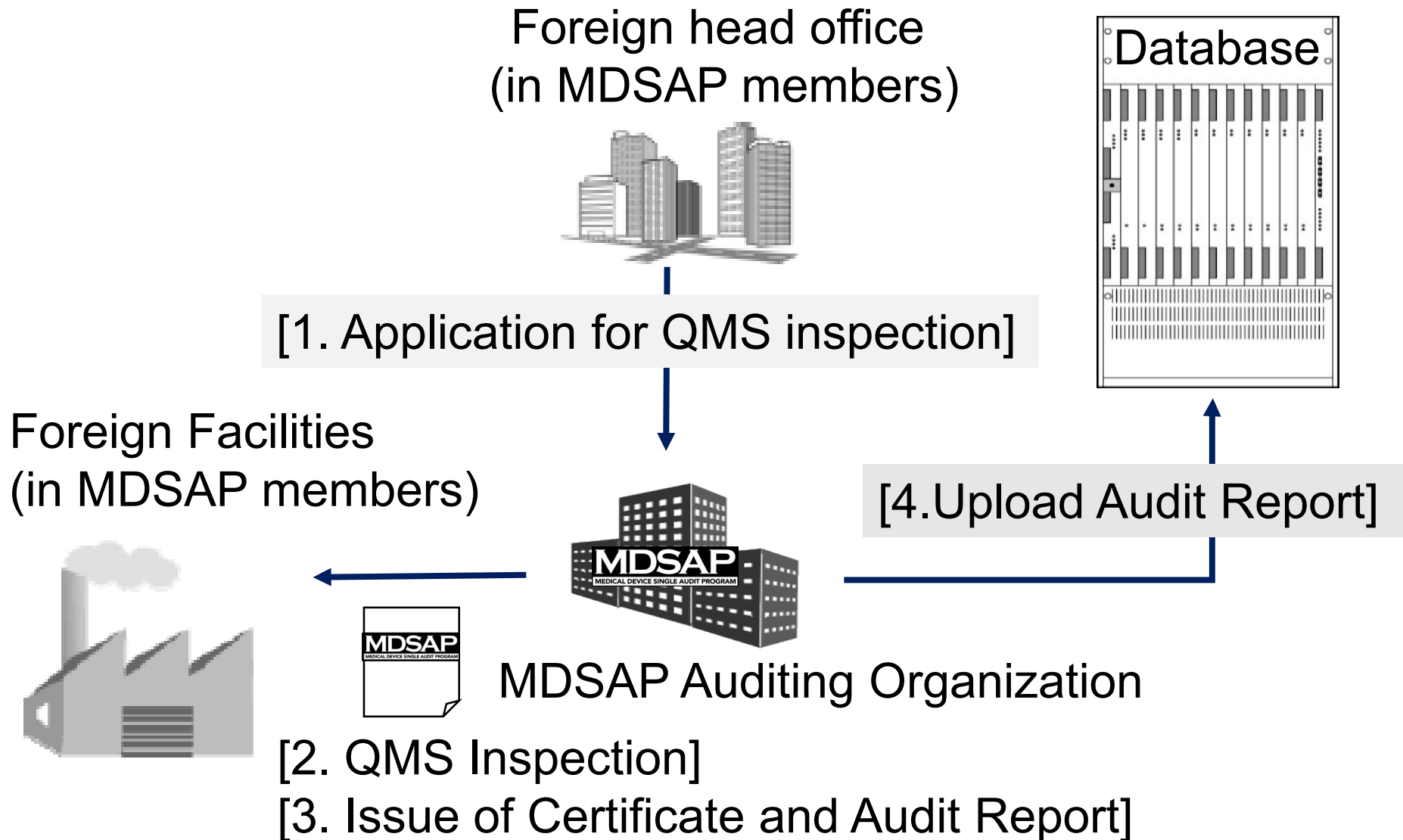


Foreign head office



Foreign Manufacturing sites

MDSAP Merits for Importing Manufacturer (1)

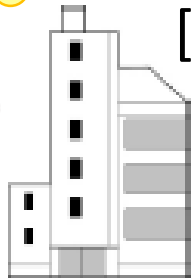


MDSAP Merits for Importing Manufacturer (2)

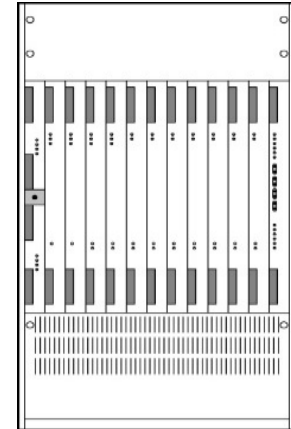
MDSAP reduces our burden of coordinating with overseas facilities !

MDSAP database

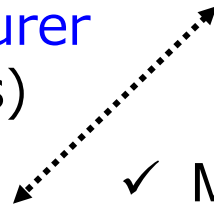
[5. Application for inspection] [6. Data query]



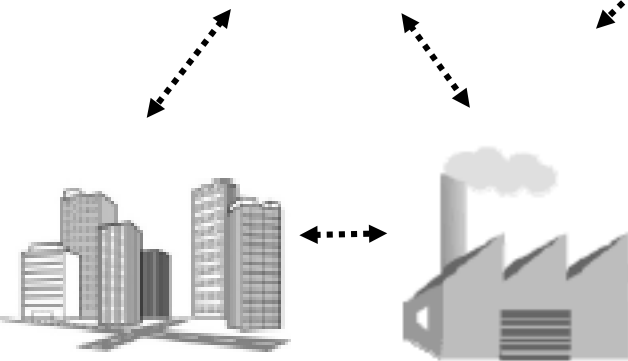
Importing Manufacturer
(in MDSAP members)



[7. Confirmation of MDSAP Audit data]



- ✓ MDSAP **reduces documents/attachments** to be submitted for written investigation.
- ✓ MDSAP **reduces coordination** between Importing Manufacturer and Foreign facilities.
- ✓ MDSAP **reduces costs for on-site inspection.**
- ✓ MDSAP members can use MDSAP database. (Manufacturers of non-MDSAP members have to provide copy of all survey reports.)



Foreign Facilities
(in MDSAP members)

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

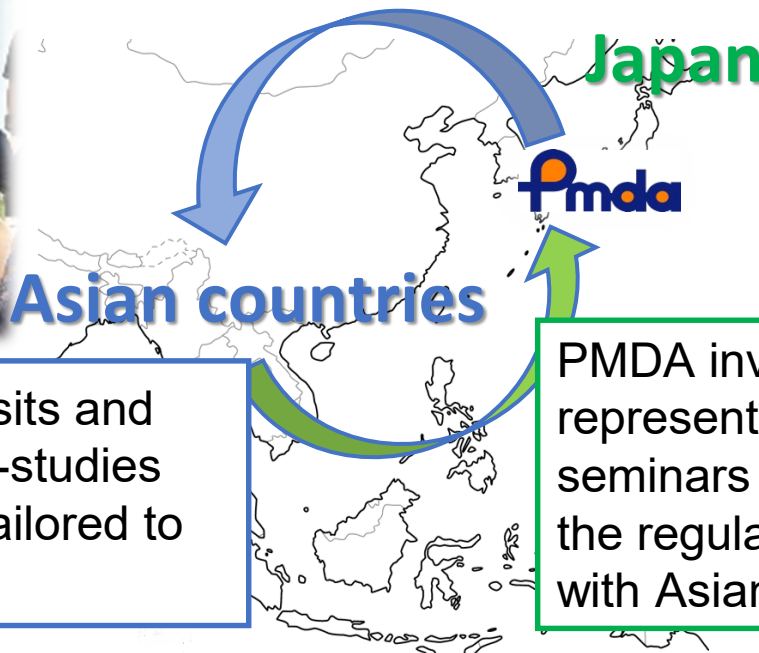
PMDA-Asia Training Center, established in April 2016, was approved as a Center of Excellence to promote capacity building and human resource development through training seminars for Asian regulators.

Action Policy of PMDA- PMDA-Asia Training Center

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian Region.



PMDA organizes site visits and conducts lectures, case-studies and practical trainings tailored to local needs.



PMDA invites Asian regulatory representatives and offers training seminars to share experiences in the regulation of Medical Devices with Asian countries.

Summary

1. Regulatory cooperation is recognized as an important measure to strengthen authorities and is recommended by WHO.
2. Common standard settings in GHTF/IMDRF and ISO/IEC and common conformity assessment in MDSAP are taking place.
3. Japan is providing capacity building seminars for other regulatory authorities through PMDA-Asia Training Center.



Guiding questions

1. What collaborative approaches in Medical Device sector have most effectively advanced regulatory compatibility?
 - **The collaborative development of International Standards in International Conference (GHTF, IMDRF) and International Standards Bodies (ISO, IEC) is an effective collaborative approach in Medical Device sector.**
 - **WHO recommends to promote “Regulatory cooperation” as an important measure to strengthen capacity of national regulatory authorities around the world.**
2. What have been the most significant benefits of cooperation in medical devices for both for the regulators and the industry being regulated?
 - **Regulators can establish effective regulations considering inputs and concerns from Industries, reducing burden of manufacturers and regulatory authorities.**
3. What are the advantages of early cooperation in a new technology area?
 - **Regulators can obtain information on how they should assess effectiveness and safety based on harmonized International Standards in advance.**
 - **Early cooperation will provide opportunities for a new technology to access market and contribute to early treatments of many patients around the world.**
4. How can Members participate in and/or benefit from ongoing cooperation activities?
 - **Regulators participating in ongoing cooperation activities to create International Standards can improve level of their regulations, streamline works of conformity assessment procedures and accept results of conformity assessment.**