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The 5th India-Japan Medical Products Regulatory Symposium
Dec 22nd, 2021

International Standardization of Medical Device (IMDRF, MDSAP)

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Agenda

1. International Medical Device Regulator Forum (IMDRF)
2. Medical Device Single Audit Program (MDSAP)

International Medical Devices Regulatory Forum (IMDRF)

Management Level

Management Committee; MC

MC Members

EU, U.S., Canada, Australia, Japan, Brazil, China, Russia, Singapore, Korea

Official Observers

WHO, UK, Argentina

Operational Level

Regional harmonization initiatives

APEC LSIF RHSC

AHWP

PAHO

Stakeholders

industry, academia, healthcare professionals, patients, consumers, etc.

Working Groups

Artificial Intelligence Medical Devices

Develop an aligned approach to the management of artificial intelligence based medical devices.

Medical Device Cybersecurity Guide

Manage cybersecurity risks in medical devices through a life-cycle approach. Striking the right balance between pre-market and post-market requirements.

Personalized Medical Devices (PMD)

Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.

Adverse Event Terminology

Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.

Good Regulatory Review Practices

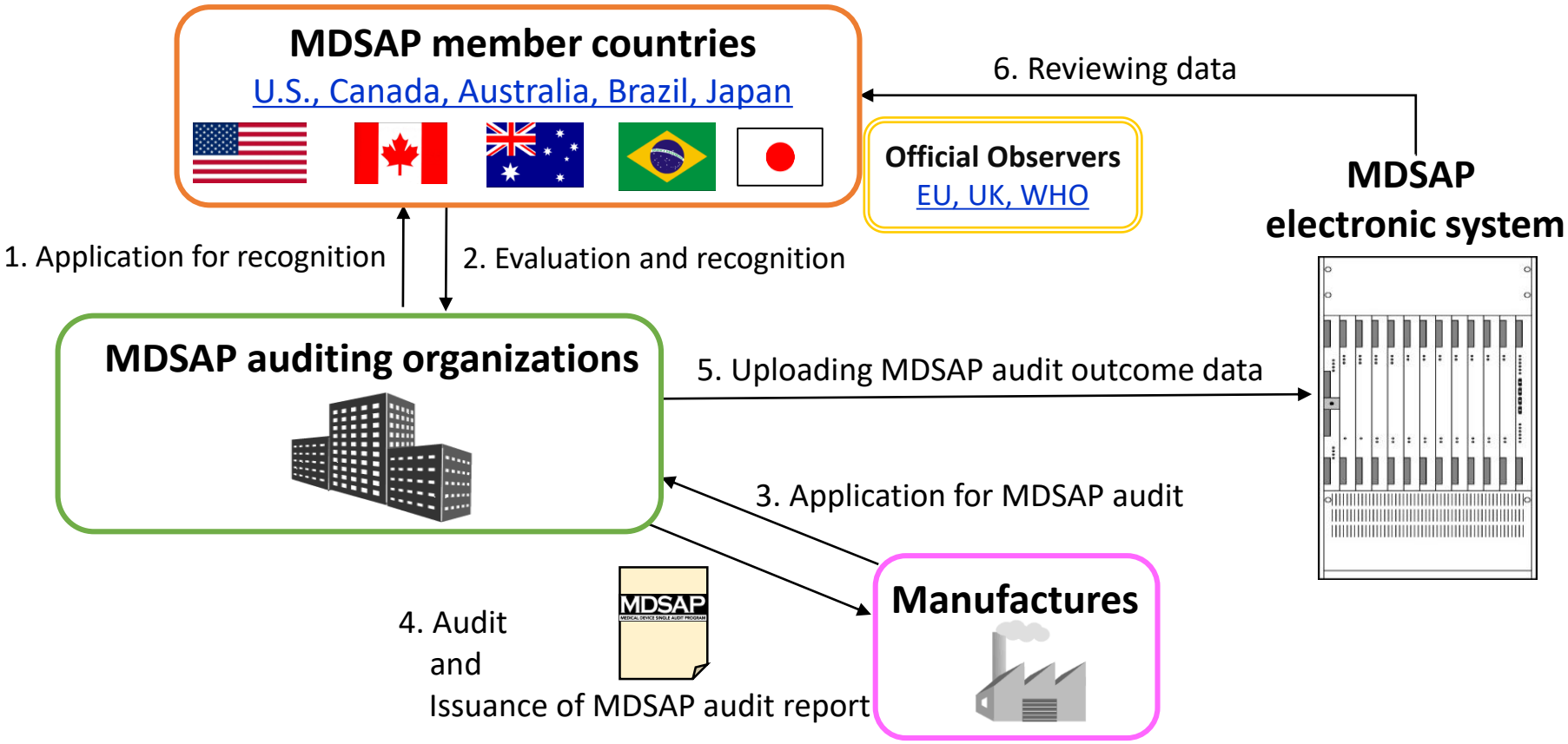
Develop good review practices for pre-market reviews and evaluations.

Regulated Product Submission

Harmonize the format and content of regulatory submissions.

IMDRF website URL: https://www.imdrf.org/

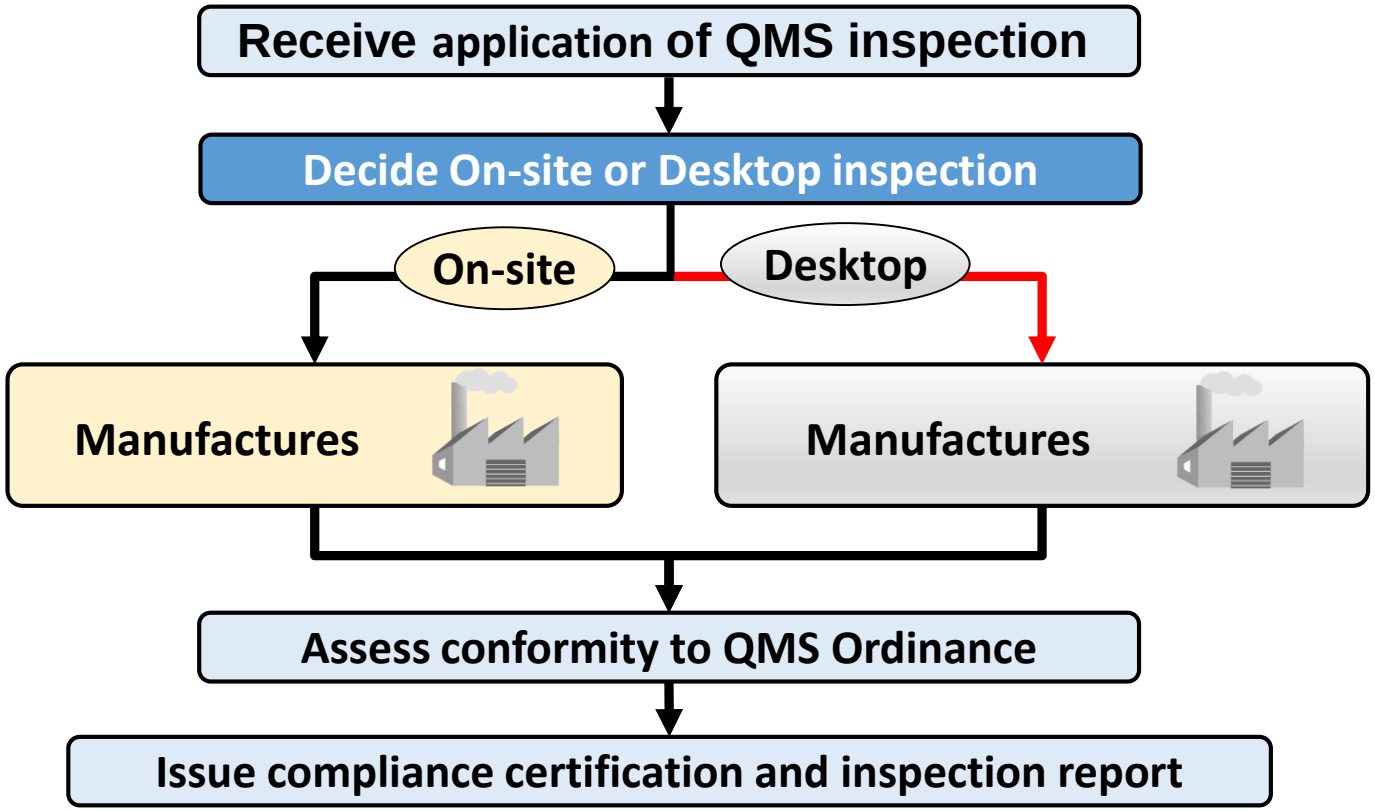
Medical Device Single Audit Program (MDSAP)



Japan's participation to MDSAP

- Japan has participated in MDSAP since June 2015.
- Japan has accepted MDSAP audit reports as pilot project since June 2016.
- Japan will practically accept MDSAP audit reports from April 2022.

Use of MDSAP Audit Reports in QMS Inspection in Japan



Streamline inspections

- Basically desktop inspections if the MDSAP audit report and conditions of subjected facilities are acceptable
- Reducing the volume of documents to submit for desktop inspections

Thank you for your attention !

MHLW Website
https://www.mhlw.go.jp/english/