Trial acceptance of MDSAP audit reports in Japan

Pharmaceuticals and Medical Devices Agency (PMDA),
Office of Standard and Compliance for Medical Devices

Japan's participation to MDSAP

International

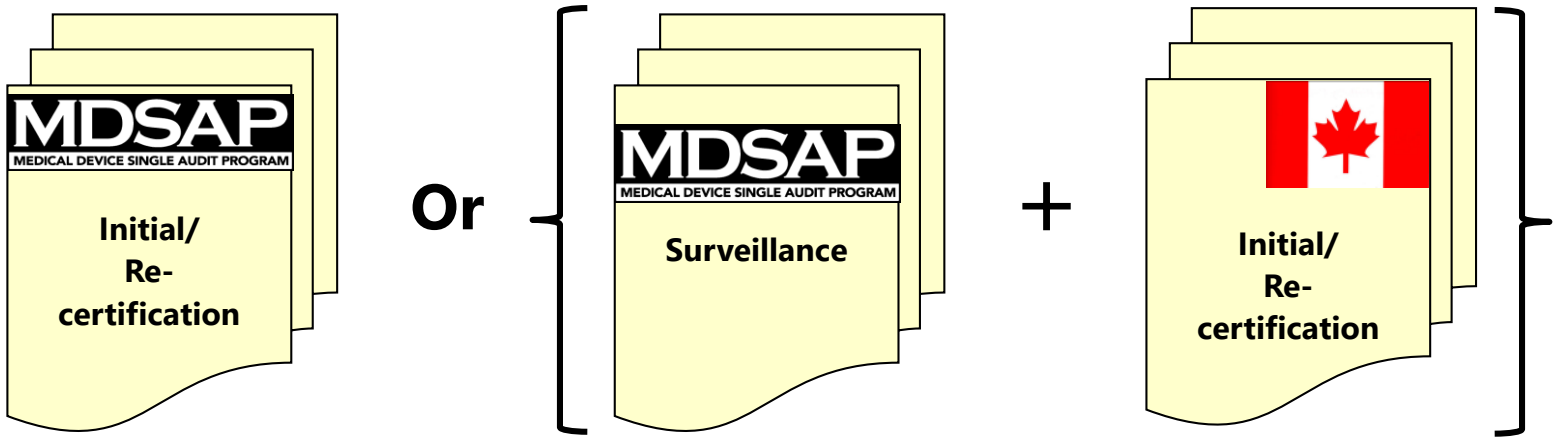
- Japan became official observers and active participants in the Pilot Program's Regulatory Authority Council (RAC) and Subject Matter Expert groups (SME) in the fall of 2013.
- Japan announced its participation to MDSAP Pilot in June 2015.
- PMDA has started to participate in assessments as assessors since the announcement.

Domestic

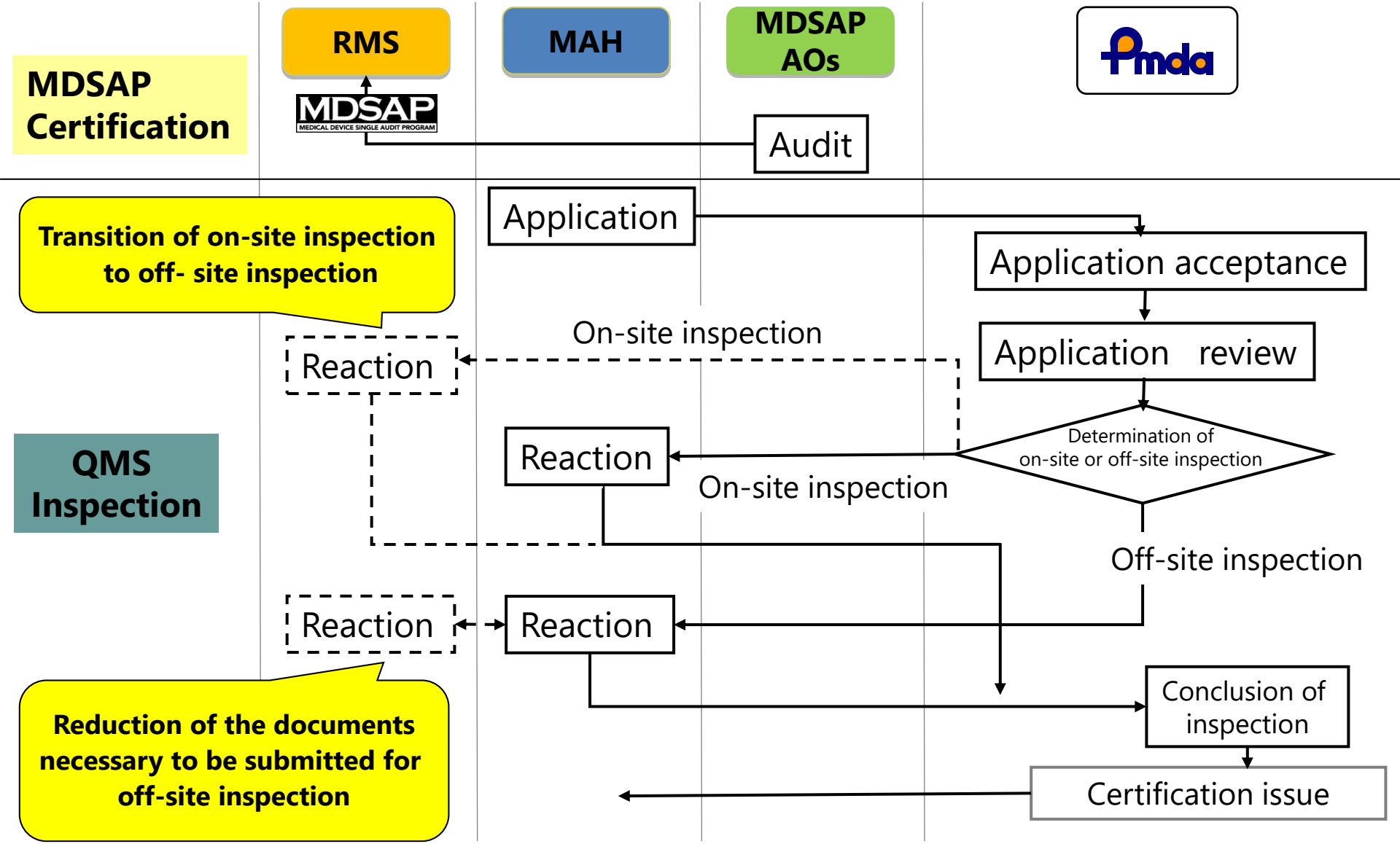
- Industry groups in Japan requested for and have been supported Japan's participation to MDSAP Pilot.
- After the announcement of participation to MDSAP Pilot, Japan has started discussion with stakeholders about how it should utilize the result of MDSAP audits
- After the evaluation of effectiveness of the MDSAP audit reports, Japan decided to accept MDSAP audit report as trial.
- MHLW and PMDA have issued guidances about the trial acceptance.

Acceptable MDSAP Audit Reports for Trial

- Acceptable MDSAP audit reports for the trial are the most recent initial or recertification audit reports.
- Meanwhile, the combination of a surveillance MDSAP audit report and the most recent initial or recertification CMDCAS audit report by the same MDSAP AO can also be submitted. In this case, PMDA will decide whether it can accept the reports on a case-by-case basis.



The flow of PMDA QMS Inspection and MDSAP



Criteria for Determining On-Site or Off-Site Inspection

In general, PMDA doesn't perform on-site inspection to a site a MDSAP audit report package is submitted to, except for the sites below:

a) A Registered Manufacturing Site (RMS) which manufactures medical devices made of human/animal tissues, and

b) A RMS which manufactures radioactive IVDs, and

c) A Marketing Authorization Holder.

Note: PMDA performs an on-site inspection, when it decides it's necessary taking into consideration of the status of compliance to the requirements and the control of the processes at the site.

Reduction of the Documents necessary for Off-Site Inspection

- The amount of documents for PMDA off-site inspection utilizing MDSAP audit reports etc. is limited compared to its routine off-site inspection.

- The documents to be submitted for the off-site inspection are:
  - Summary of the medical device file*
  - Any documentation which indicates the confirmation result of quality of the medical device to ensure safety of it, when the device is using biologically derived raw materials etc.

Summary of the medical device file*:
When MAH can demonstrate it is controlling the content of medical device file maintained in the site properly, PMDA doesn't require to submit the summary.

Documents of RMS which are to be attached to QMS application

No.	Documents	Normal Application	Application using MDSAP
1	ISO13485 Certification, registered certification body's Inspection report, etc	X	NA
2	Outline of the site	X	NA
3	A document requested by other notification separately to this matrix.	NA	X

See slide No.5 ("Acceptable MDSAP Audit Reports for Trial")

Documents of RMS required for off-site inspection

No.	Documents	Normal Application	Application using MDSAP
1	Arrangement of the facility	X	NA
2	Floor plan	X	NA
3	Organization chart	X	NA
4	Quality manual	X	NA
5	List of documents used in QMS	X	NA
6	Summary of medical device file	X	X*
7	State of implementation of validation	X	NA
8	Any documentation which indicates the confirmation result of quality of a medical device to ensure safety of it, when the device is using biologically derived raw materials etc.	X	X
9	Procedure etc. for communication with Marketing Authorization Holder in relation to adverse events	X	NA
10	Agreement with Registered Manufacturing Site	X	NA

X*: See slide No 9 for exceptional case

Note for the Documents required for Off-Site Inspection

Note: When any item to be audited by our normal off-site inspection is not covered in the MDSAP audit report, PMDA may require to submit additional documentation for the item.

For example, we require additional documents in case that Japanese characteristic requirements are not audited like below:

Case 1: Because the manufacturer was not manufacturing products that will be exported to Japan at the timing of the audit, the MDSAP audit report didn't cover requirements specific to Japan.

In case Japanese specific requirements are not audited, PMDA will require to submit additional document (in particular 5, 9, and 10 of slide No. 8).

Case 2: A Market Authorization Holder submitted a MDSAP audit report. The audit of the report was performed in January 2016.

Audits that were taken place before Feb. 2016 weren't performed according to revised Audit Model. So PMDA will require to submit additional document (in particular 5, 9, and 10 of slide No. 8) as well as Case 1.

Conclusion

- By following MHLW guidance's, PMDA reduces manufacturers' burden in its QMS inspection processes as a trial, when a MDSAP audit report is submitted. The trial period is planned to be until March 31, 2021.
- The content of the trial includes reduction of manufacturer’s QMS documentation required to be submitted to PMDA for its off-site inspection processes.
- MHLW/PMDA encourages manufacturers to participate in the trial and to provide feedback of this trial.

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