Acceptance of MDSAP audit reports in Japan

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

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Japan's participation to MDSAP

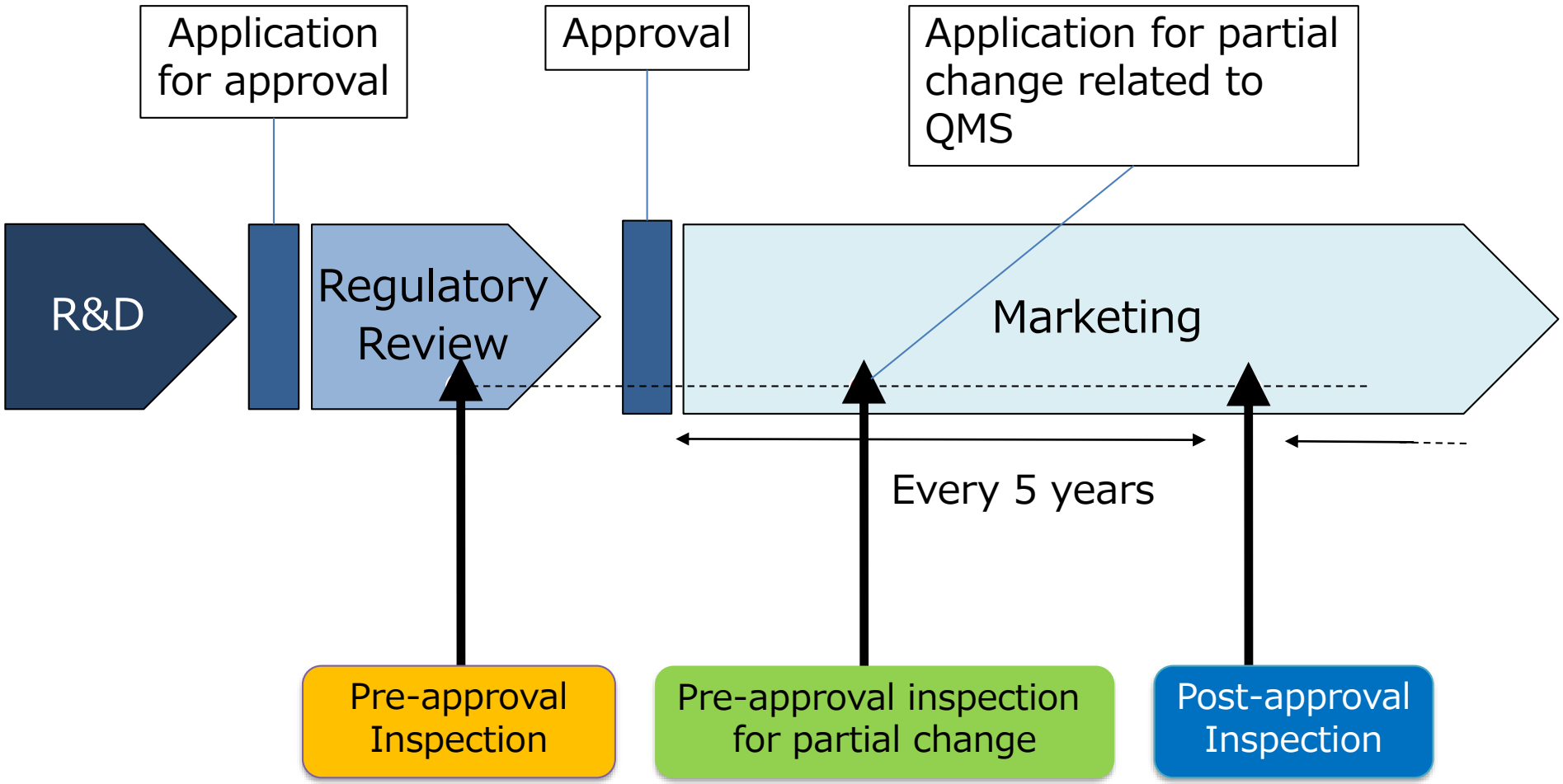
International

- 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.

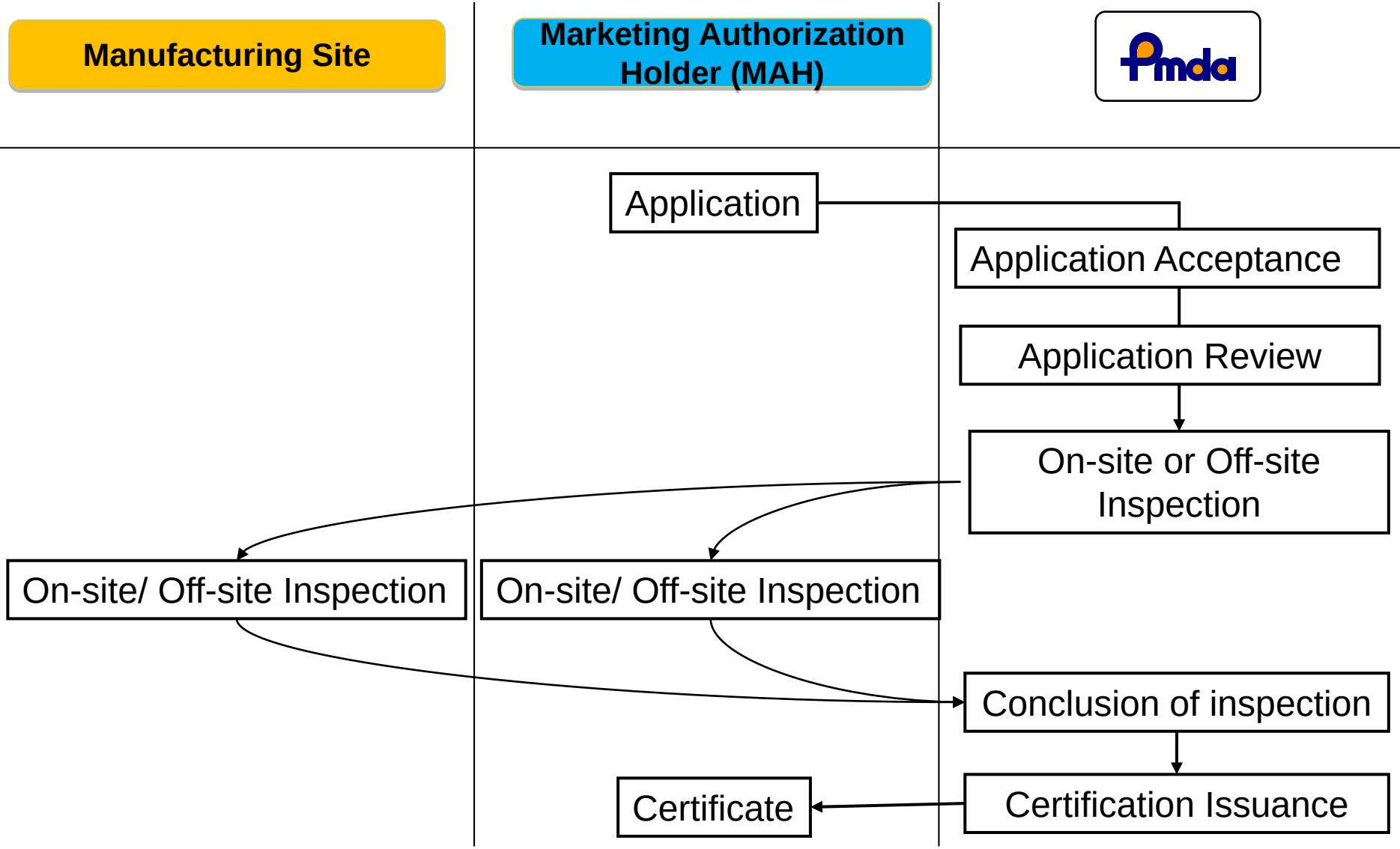
Domestic

- 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 reports.
- MHLW and PMDA have issued guidance about the acceptance.

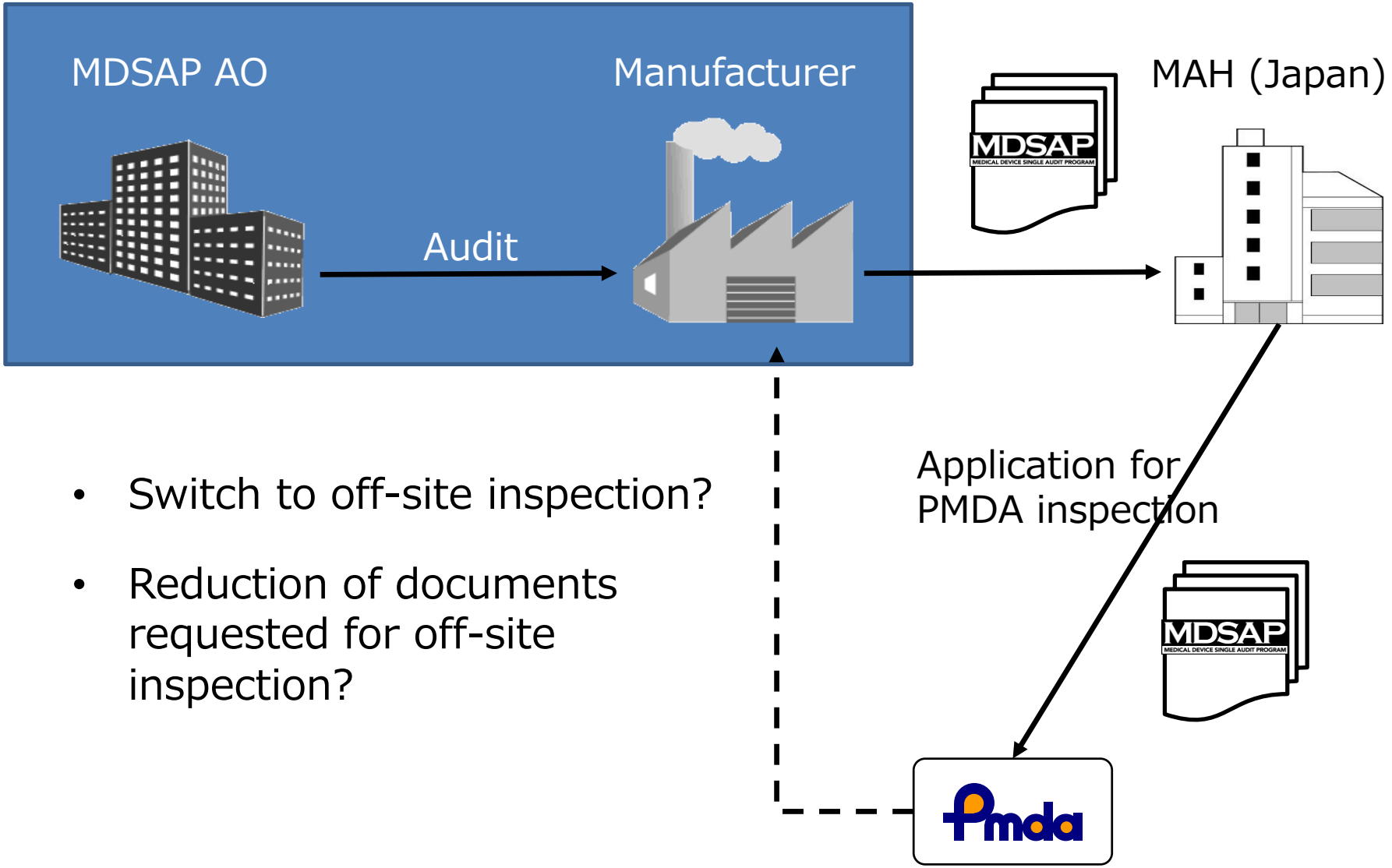
The timing of QMS inspection by PMDA



The flow of QMS inspection by PMDA



MDSAP audit report acceptance



- Switch to off-site inspection?
- Reduction of documents requested for off-site inspection?

Conclusion

- By following MHLW guidance's, PMDA reduces manufacturers' burden in its QMS inspection processes, when a MDSAP audit report is submitted.
- Submission of MDSAP audit report may lead to:

1) Reduction of manufacturer’s QMS documentation required to be submitted to PMDA for its off-site inspection and/ or

2) Switching to off-site inspection from on-site inspection.

- MHLW/PMDA encourages manufacturers to participate in this activity and provide feedbacks.

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Ministry of Health, Labour and Welfare