MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

How the Regulatory Authorities use MDSAP (PMDA/ Japan)

Office of Manufacturing/ Quality and Compliance,
Division of Registered Certification Body Assessment,
Pharmaceuticals and Medical Devices Agency (PMDA)

May 9th, 2018

- Japan has announced its participation to MDSAP in June 2015.

- After the participation, MHLW/PMDA discussed with stakeholders and issued notifications for the acceptance of MDSAP Audit Reports in June 2016.

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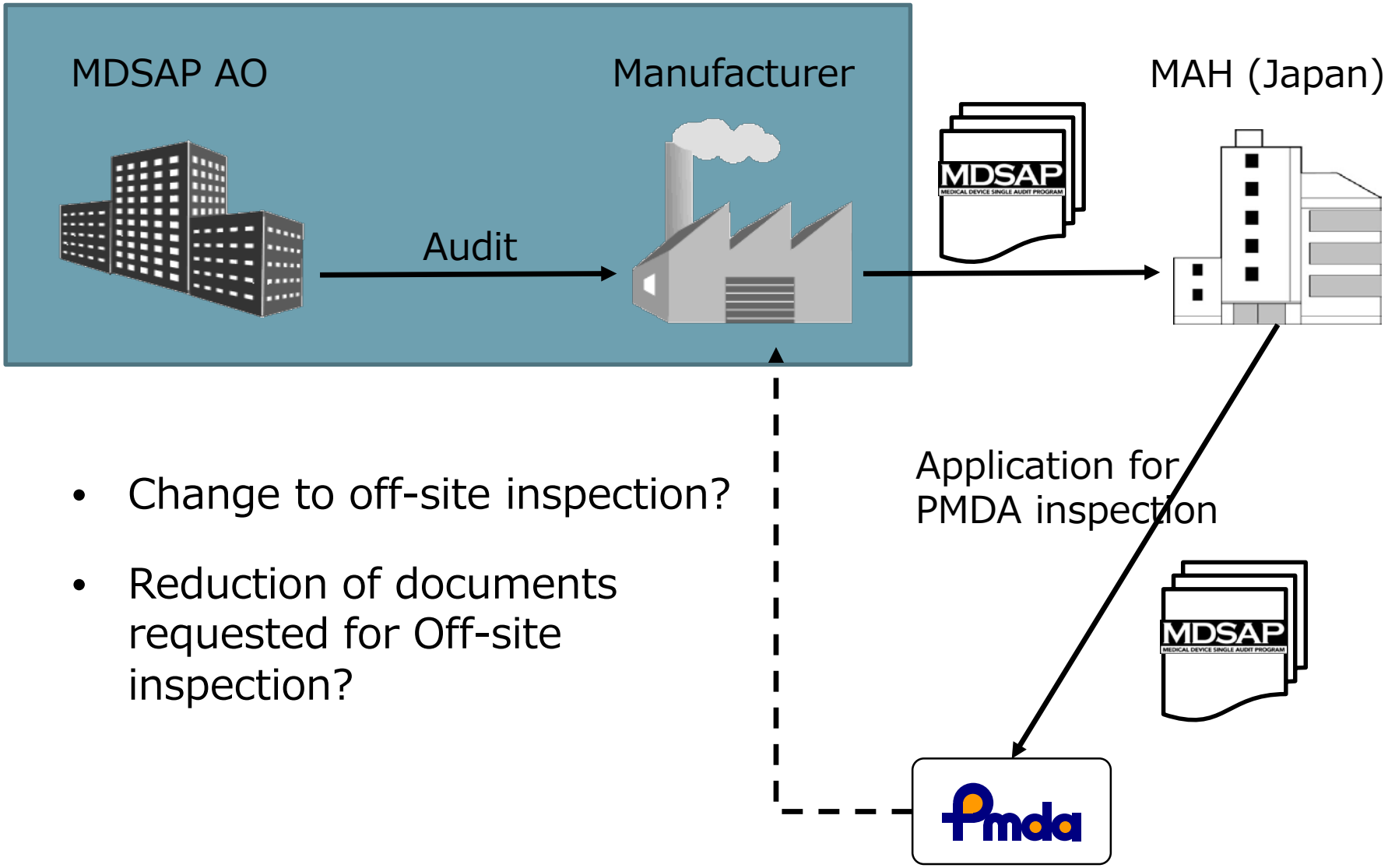
Overview of PMDA MDSAP Audit Report Acceptance

Basic Policy for PMDA MDSAP Audit report acceptance :

- PMDA accepts MDSAP audit reports, and reduce burden of manufacturers. PMDA may perform off-site inspection instead of on-site inspection or reduce documents for off-site inspection, when a MDSAP audit report is submitted. The acceptance is performed as a trial.

- The trial period is planned to be until the end of March 2019. PMDA will not charge any extra fee for the acceptance during the trial period.

The flow of PMDA QMS inspection and MDSAP



- Change to off-site inspection?
- Reduction of documents requested for Off-site inspection?

Conclusion

- PMDA has accepted many applications using MDSAP audit reports and issued its certificates. This acceptance has been conducted on a trial basis.

- Japanese regulatory authorities will re-start discussion with stakeholders about our future directions based on the data collected during the trial period.

- PMDA encourages foreign manufacturers to use MDSAP audit reports for the QMS inspection application. Communication between MAHs and manufacturers is necessary, when manufacturers want to use the reports.

Thank you!

Contact information
Mail: mdsap@pmda.go.jp

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