



Regulatory Updates

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

Dec 5th, 2018

History of MO169

2004	MHLW Ministerial Ordinance No. 169 (2004), titled "Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents" was initially enacted in 2004. The purpose of the establishment was to make Medical Device QMS requirements be harmonized to ISO13485:2003. Although the requirements are substantially equivalent to ISO13485, it included many additional requirements characteristic to Japan.
2014	The initial version was revised to be more aligned to ISO13485:2003. The number of special requirements are reduced. The requirements from ISO13485 are placed in chapter 2 and the additional requirements are moved to chapter 3.
2017	A new chapter (chapter 5-2), which specifies the requirements for manufacturers of SUD, was added to the ordinance.
2016-2018	Since ISO13485:2016 was issued in 2016, discussion to revise the ordinance was started between the industry and the regulatory authority. They have agreed to revise it to be aligned to ISO13485:2016.

Updates of MO169

- Drafting of the new ordinance has almost completed. Waiting final review by Legal Bureau before public comment.
- The public comment will start in 2019.

Summary of the change

- **Possibility of Title Change ?**

The title and the number of ordinance is likely to be the same.

MO169 (2004) → MO169(2004) , revised by MOXXX(2019) ?
 └--> MOXXX(2019) ?

- **Contents**

Chapter 2 of the ordinance is going to be harmonized to ISO13485: 2016.

- **Additional requirements :**

The requirements which are characteristic to Japan will not be changed significantly. (Some requirements may be deleted. None of new additional requirement is planned to be introduced.)

Transition Period

2017			2018			2019			2020			2021			2022				
						2		?											
ISO13485:2016 (IAF)																			
MDSAP (HC)																			
									New Ordinance										

- ◆ The transition period is planned to be three years.
- ◆ Old and new ordinance would co-exist until middle of 2022.

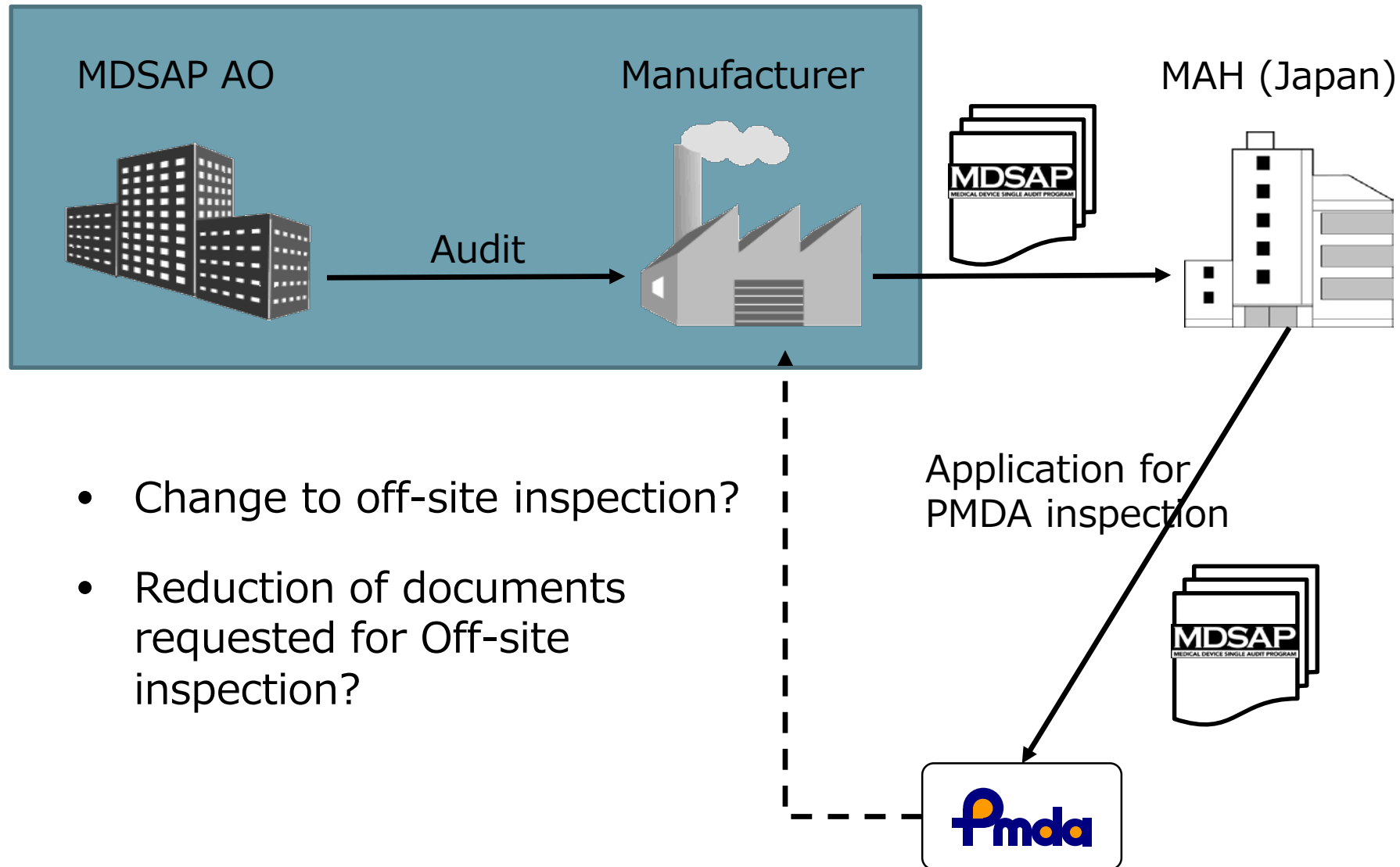
How PMDA uses MDSAP?



Basic Policy for PMDA MDSAP Audit report acceptance :

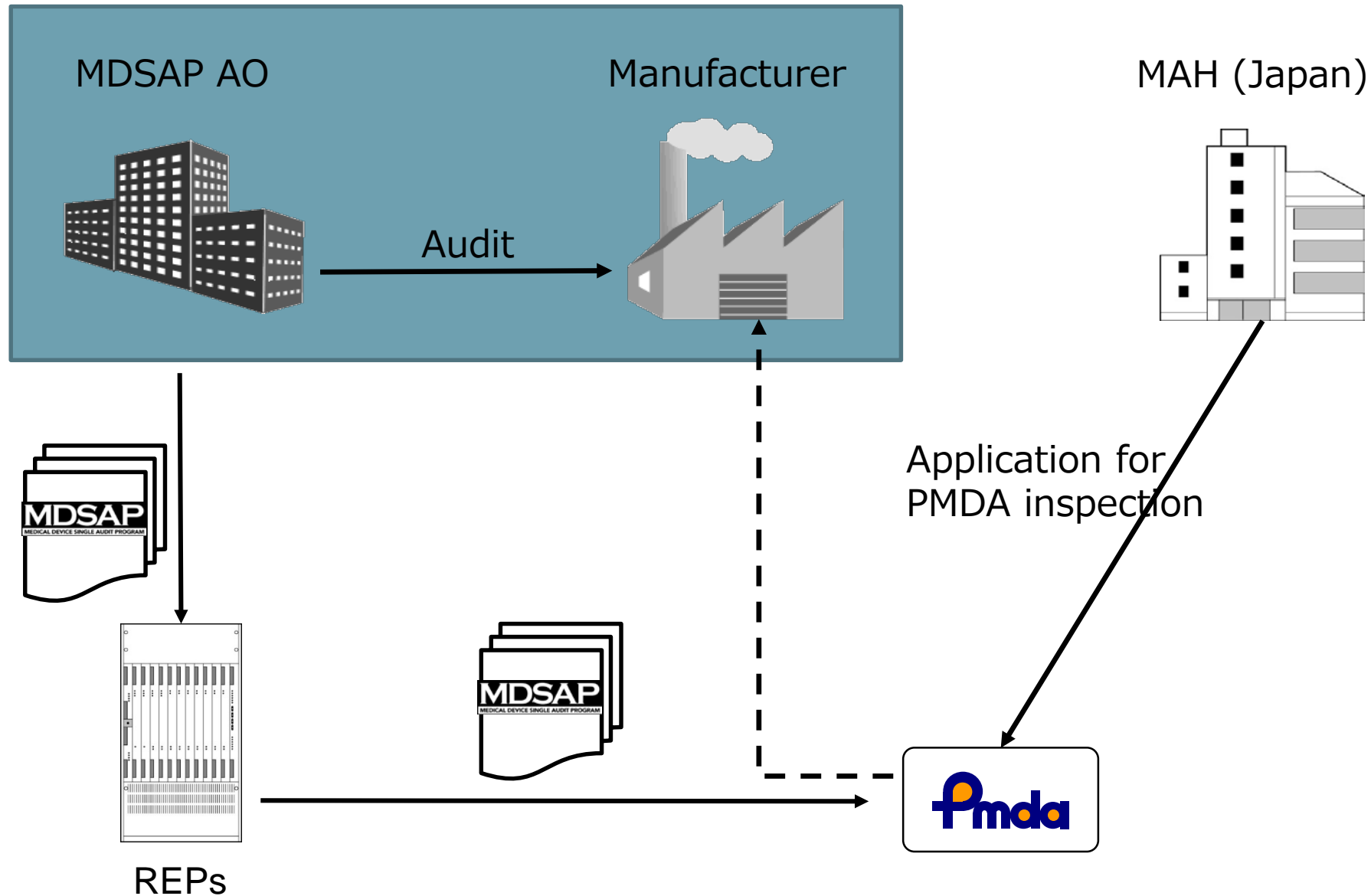
- PMDA accepts MDSAP audit reports, and reduce burden of manufacturers. PMDA may perform off-site inspection instead of on-site inspection or reduce documents for off-site inspection, when a MDSAP audit report is submitted.

The flow of PMDA QMS inspection and MDSAP (current)



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

The future goal of PMDA QMS inspection utilizing MDSAP



Thank you!

Contact information

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