MDSAP Regulatory Authorities use of MDSAP and program experiences

Division of Registered Certification Body Assessment,
Office of Standards and Compliance for Medical Devices,
Pharmaceuticals and Medical Devices Agency (PMDA)

Dec 5th, 2019

Regulatory Authorities in JAPAN

MHLW

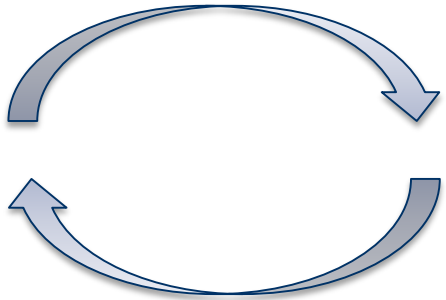
Pharmaceutical Safety and Environmental Health Bureau, MHLW

- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

PMDA

Pharmaceuticals and Medical Devices Agency

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.



Topics

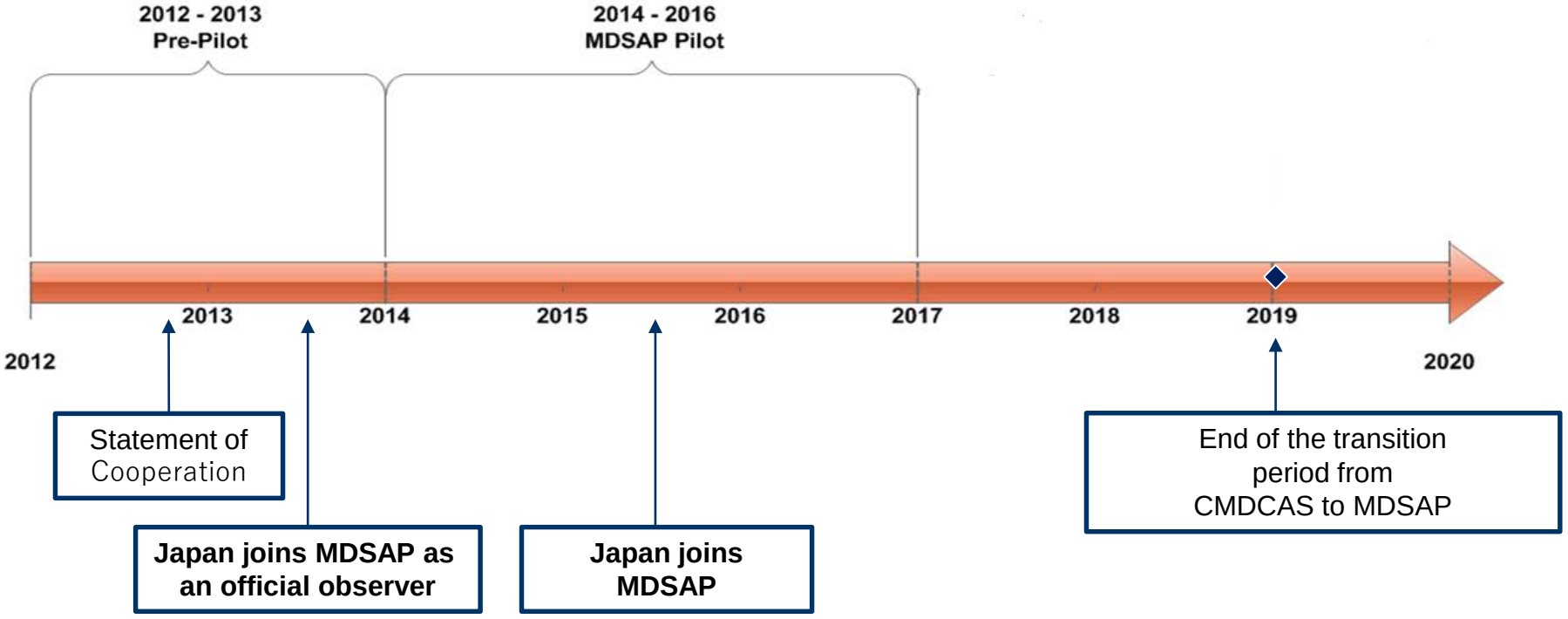
- Japan’s participation to MDSAP
- Acceptance of MDSAP audit outcomes
- Assessments to MDSAP AOs

History of Medical Device Regulatory Harmonization

1992: Global Harmonization Task Force (GHTF) launched
1993: GHTF Study Groups (SGs)
SG1 Premarket Evaluation
SG2 Post-market Surveillance/Vigilance
SG3 Quality Systems
SG4 Auditing
2004: GHTF SG5 Clinical Evaluation

2011: International Medical Device Regulators Forum (IMDRF) launched
2012: Termination of GHTF

Japan's participation to MDSAP



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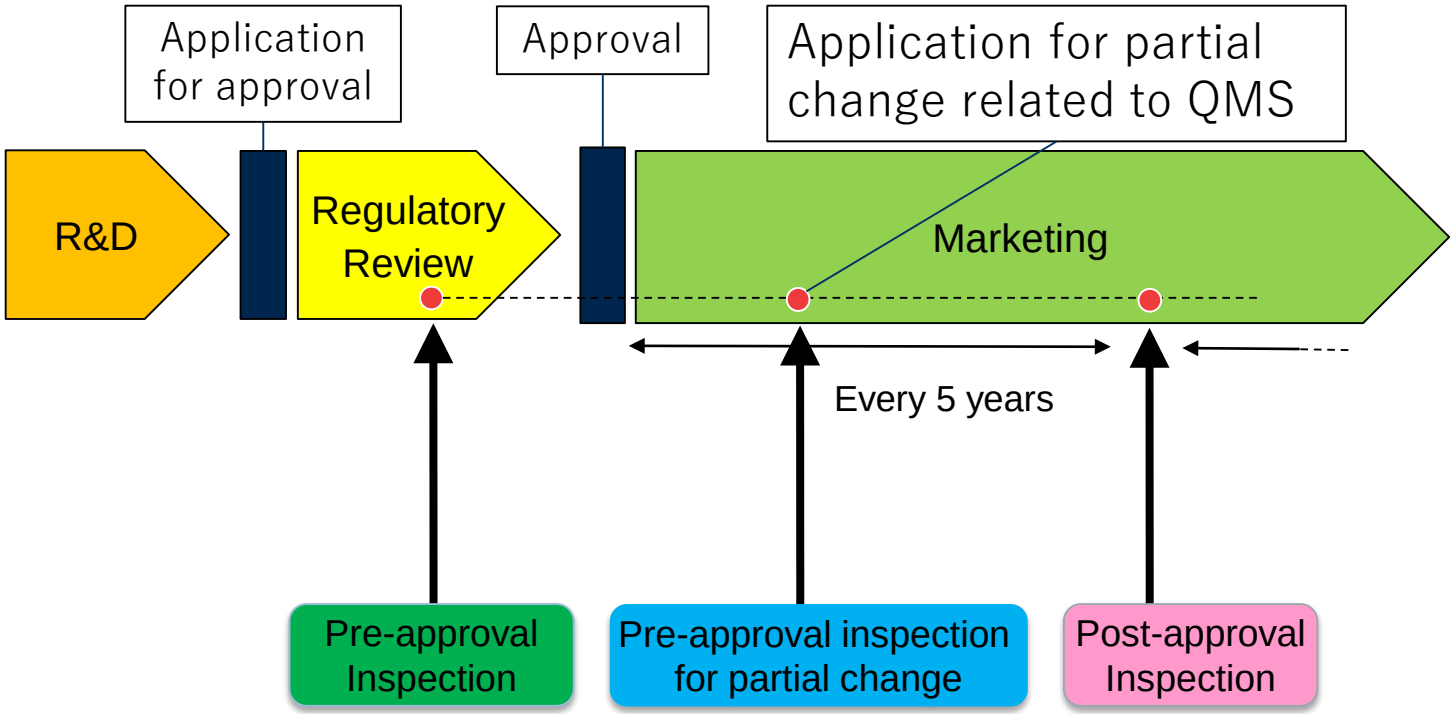
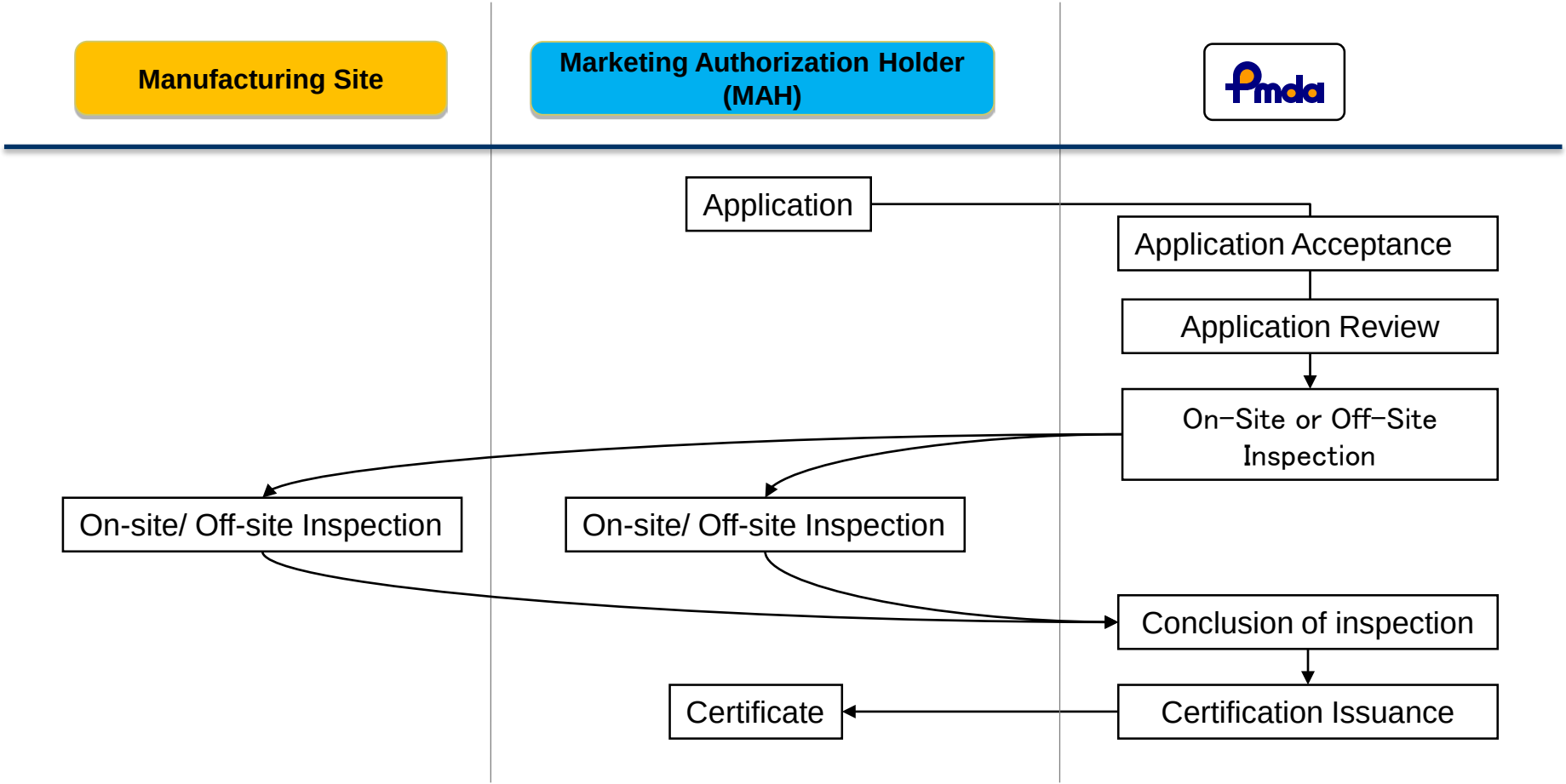
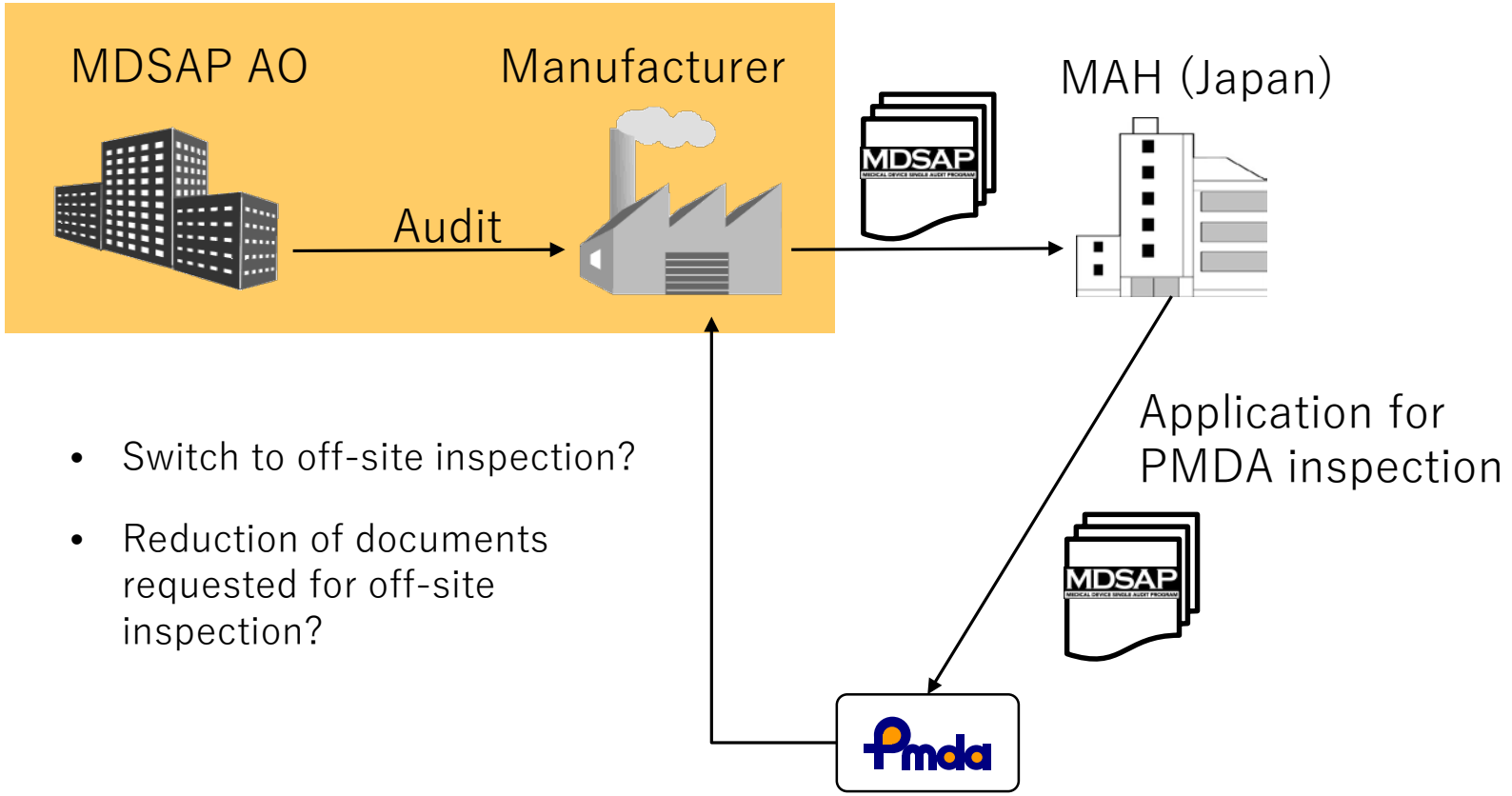
Lifecycle of Medical device



Flow of PMDA QMS inspection



MDSAP Audit report acceptance



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

Result of MDSAP audit report acceptance

- PMDA started to accept MDSAP audit reports in June 2016.

- PMDA has accepted more than 352 QMS inspection applications which utilize MDSAP audit reports (as of September 2019). In most cases, the acceptances resulted in switch to Off-site inspections from On-site inspections and/or abbreviated Off-site inspections.

Topics

- Japan's participation to MDSAP
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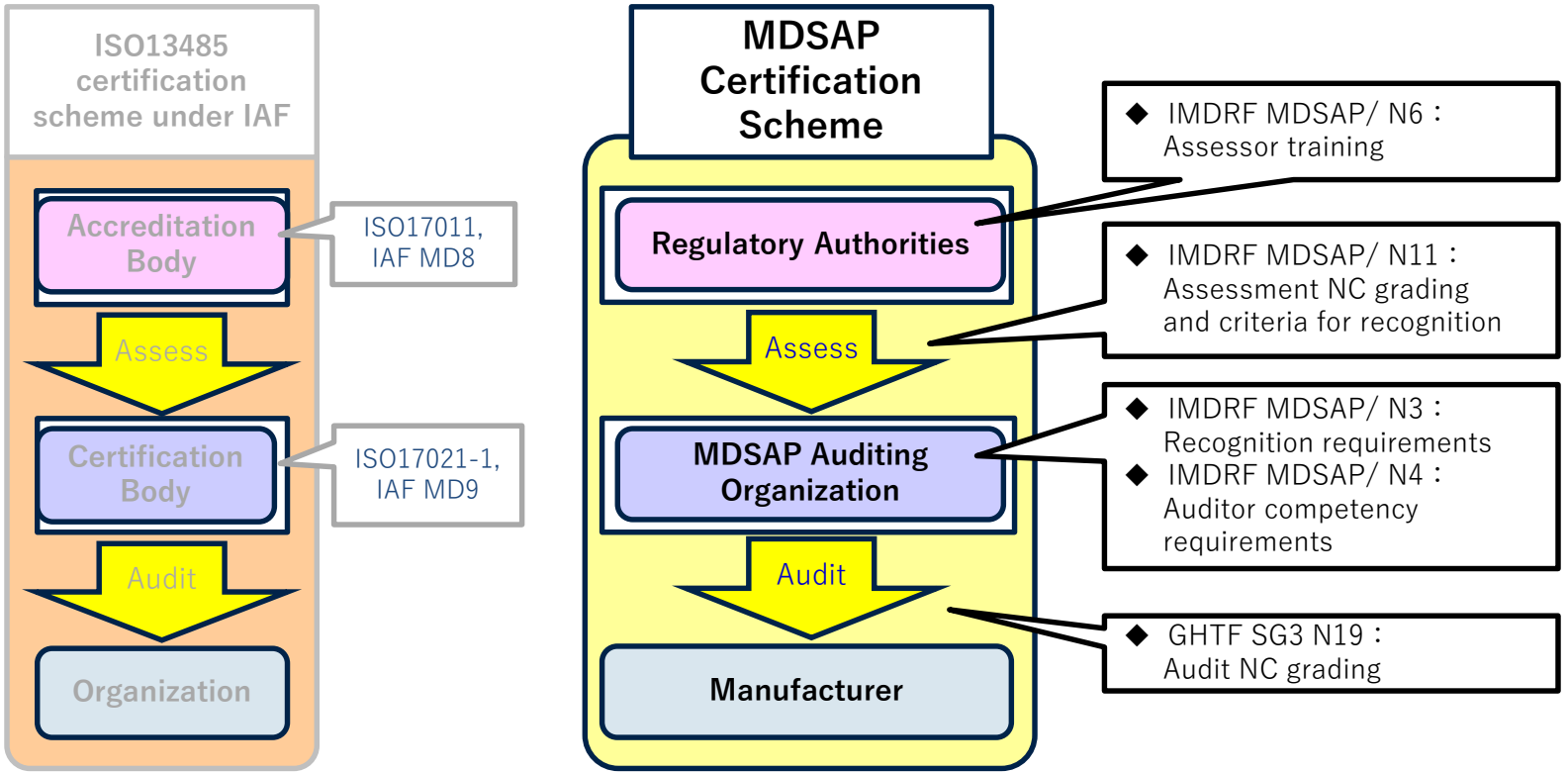
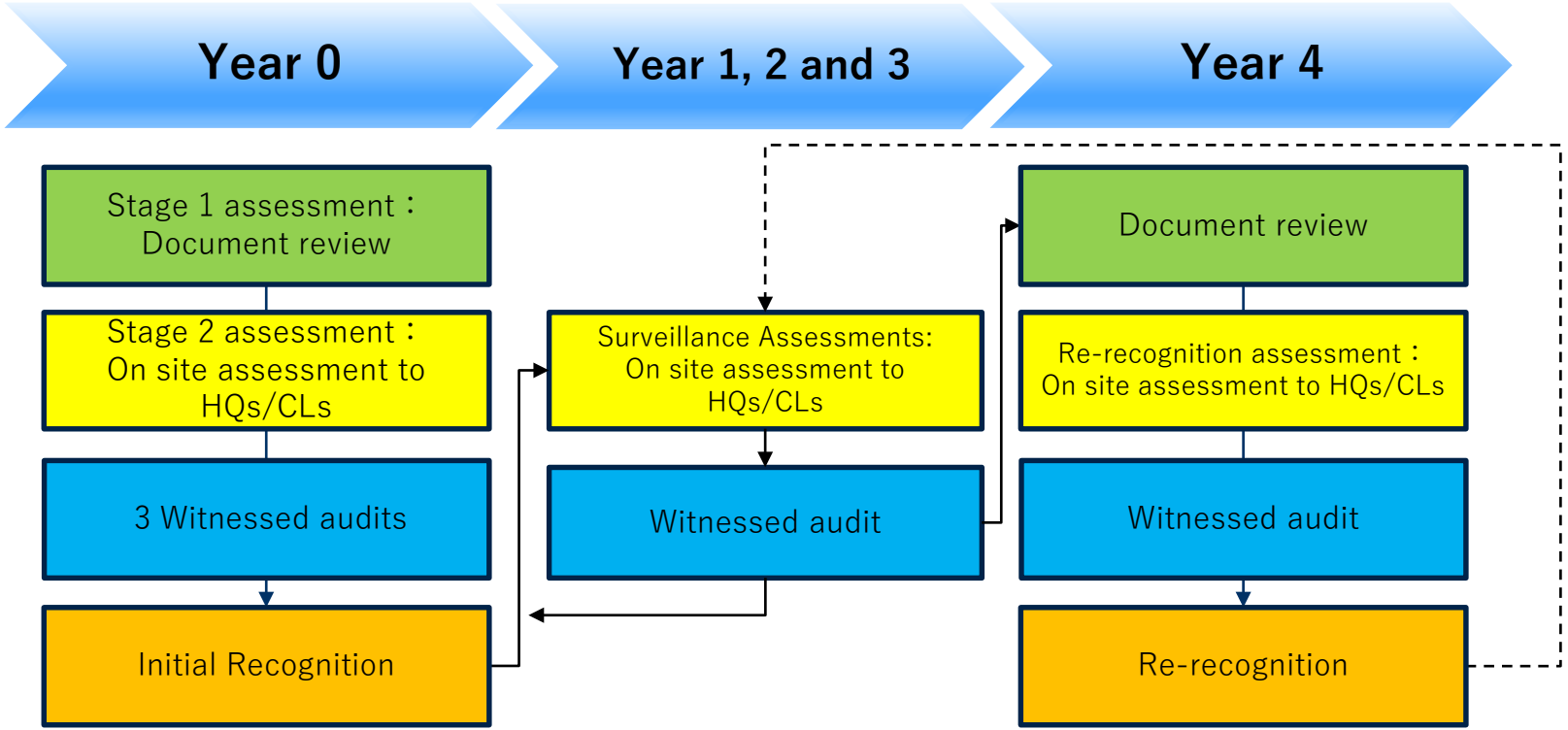
- Assessments to MDSAP AOs

Assessments to MDSAP Auditing Organizations



The assessment activities for MDSAP AO recognition (1/2)



The assessment activities for MDSAP AO recognition (2/2)

- In principle, each assessment activity is performed by 2 assessors from different jurisdictions.

- Recognition decision is made by the committee consisting of the representatives from all of MDSAP participating countries.

Conclusion

- Japan has actively committed to MDSAP since its early stage.
- Gained knowledge and experiences related to QMS and AO assessments through the work with international partners.
- PMDA has been accepting MDSAP audit reports in order to confirm compliance to the requirements.

Thank you!

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM