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.

*PMDA* and *MHLW* work closely together to ensure the safety and efficacy of medical devices and pharmaceuticals in Japan.
Topics

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

2012 - 2013
Pre-Pilot

2014 - 2016
MDSAP Pilot

2012

Statement of Cooperation

Japan joins MDSAP as an official observer

2013

Japan joins MDSAP

2014

2015

2016

2017

2018

2019

End of the transition period from CMDCAS to MDSAP

2020
Topics

• Japan’s participation to MDSAP

• Acceptance of MDSAP audit outcomes

• Assessments to MDSAP AOs
Lifecycle of Medical device and Quality Management System inspection

Lifecycle of Medical device

- R&D
- Regulatory Review
- Application for approval
- Approval
- Application for partial change related to QMS
- Marketing

- Pre-approval Inspection
- Pre-approval inspection for partial change
- Post-approval Inspection

Every 5 years
Flow of PMDA QMS inspection

1. Application
2. Application Acceptance
3. On-Site or Off-Site Inspection
4. Conclusion of inspection
5. Certificate
6. Certification Issuance

- Manufacturing Site
- Marketing Authorization Holder (MAH)
MDSAP Audit report acceptance

- Switch to off-site inspection?
- Reduction of documents requested for off-site inspection?
• 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
- Acceptance of MDSAP audit outcomes
- Assessments to MDSAP AOs
Assessments to MDSAP Auditing Organizations

- ISO13485 certification scheme under IAF
- ISO17011, IAF MD8
- ISO17021-1, IAF MD9

Accreditation Body

Assess

Certification Body

Assess

Organization

MDSAP Certification Scheme

Regulatory Authorities

Assess

MDSAP Auditing Organization

Audit

Manufacturer

- IMDRF MDSAP/ N6 : Assessor training
- IMDRF MDSAP/ N11 : Assessment NC grading and criteria for recognition
- IMDRF MDSAP/ N3 : Recognition requirements
- IMDRF MDSAP/ N4 : Auditor competency requirements
- GHTF SG3 N19 : Audit NC grading
The assessment activities for MDSAP AO recognition (1/2)

**Year 0**
- Stage 1 assessment: Document review
- Stage 2 assessment: On site assessment to HQs/CLs
- 3 Witnessed audits
- Initial Recognition

**Year 1, 2 and 3**
- Surveillance Assessments: On site assessment to HQs/CLs
- Witnessed audit

**Year 4**
- Document review
- Re-recognition assessment: On site assessment to HQs/CLs
- Witnessed audit
- Re-recognition
• 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.
• 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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