MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Regulatory Updates

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

May 9th, 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 and draft making is being conducted. Public Comment will be implemented soon.

Summary of the change

Possibility of Title Change :

Because wording of the ordinance is planned to be changed significantly, the revised one may be issued as a new ordinance. The number of ordinance may also be changed.

MO169 (2004)→ MO169(2004) , revised by MOXXX(2018) ?

└──→ MOXXX(2018) ?

Or

Contents :

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

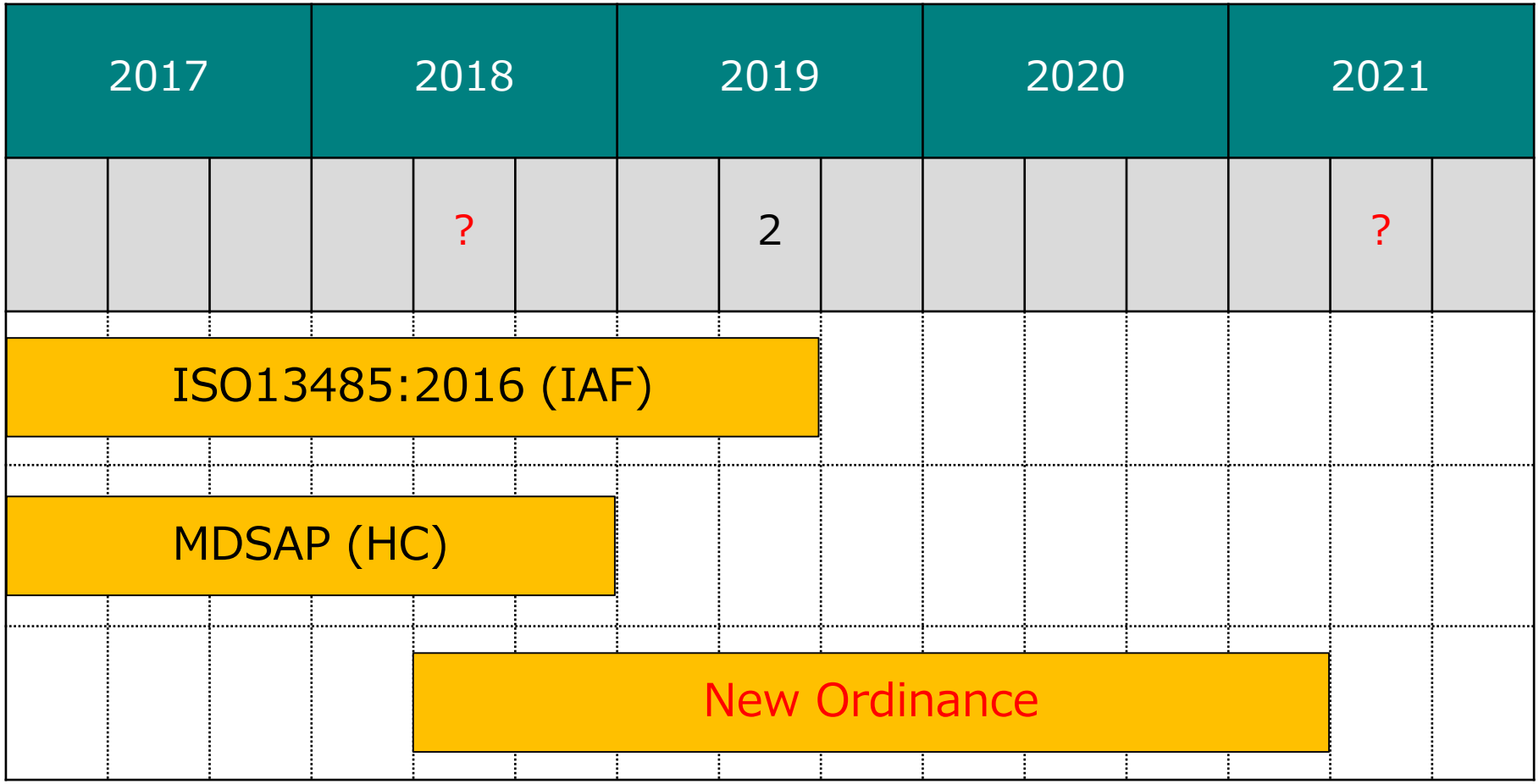
Additional requirements :

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.)

Image of the change

Current Ordinance	New Ordinance
Chapter 1: Purpose, Definition of Terms, and Scope of Application	Chapter 1: Purpose, Definition of Terms, and Scope of Application
Chapter 2: Basic Requirements aligned to ISO13485:2003.	**Chapter 2: Basic Requirements aligned to ISO13485:2016.**
Chapter 3: Additional Requirements	Chapter 3: Additional Requirements
Chapter 4, 5, and 5-2: Product Specific Requirements (Biological Products, Radioactive IVDs, SUD)	Chapter 4, 5, 6: Product Specific Requirements (Biological Products, Radioactive IVDs, SUD)
Chapter 6: Others	Chapter 7: Others

Transition Period



- The transition period is planned to be three years.
- Old and new ordinance will co-exist until middle of 2021.

Revision of Audit Model and Companion Doc

During the transition period, manufacturers can select either New or Old ordinance as Japanese QMS requirements.

Example (companion document):

Audit Tasks and Links to Other Processes:

1. Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced. Verify that a quality manual has been documented.

Clause and Regulation: [ISO 13485:2016: 4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 5.4.2; TG(MD)R Sch3 P1 1.4(4); RDC ANVISA 16/2013: 2.1, 5.6; MHLW MO169: 5, 7, 14/ MHLW MOXXX: 5, 7, 14; 21 CFR 820.20]

Thank you!

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