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QMS requirements in Japan

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Practice-oriented summary of the most important aspects and requirements of Japanese regulations on medical devices.

Amendments to the Japanese Pharmaceutical Affairs Law (PAL) were adopted in November 2013. The amendments were launched as of November 25, 2014. Please refer to Med-Info "Act on medical devices in Japan" for an overview of the changes. This Med-Info provides you with an explanation on changes to the J-QMS Ordinance and the handling of audit results.

J-QMS Ordinance

The MHLW (Ministry of Health, Labour and Welfare) Ordinance No. 169 from 2004, known as the "J-QMS Ordinance", was amended by the MHLW Ordinance No. 87, issued on July 30, 2014. ARCB¹ prepared a summarized version of the revised J-QMS Ordinance in English. It is available on the TÜV SÜD Japan webpage.
<http://www.tuv-sud.jp/jp-en>

1. Configuration and applicability

As shown in the figure below, the revised J-QMS Ordinance consists of six chapters. Chapters 2 and 3 apply to the quality management systems of all organizations.

Chapter 4 applies in addition to chapters 2 and 3 to the quality management systems of organizations which handle products of animal origin (see definition on the right).

If a medical device is composed of one of the following tissues, it is recognized as product of animal origin in Japan:

- Bovine pericardial membrane
- Equine pericardial membrane
- Pig heart valves

If a medical device contains living mouse cells, it is also recognized as an animal-origin product in Japan.

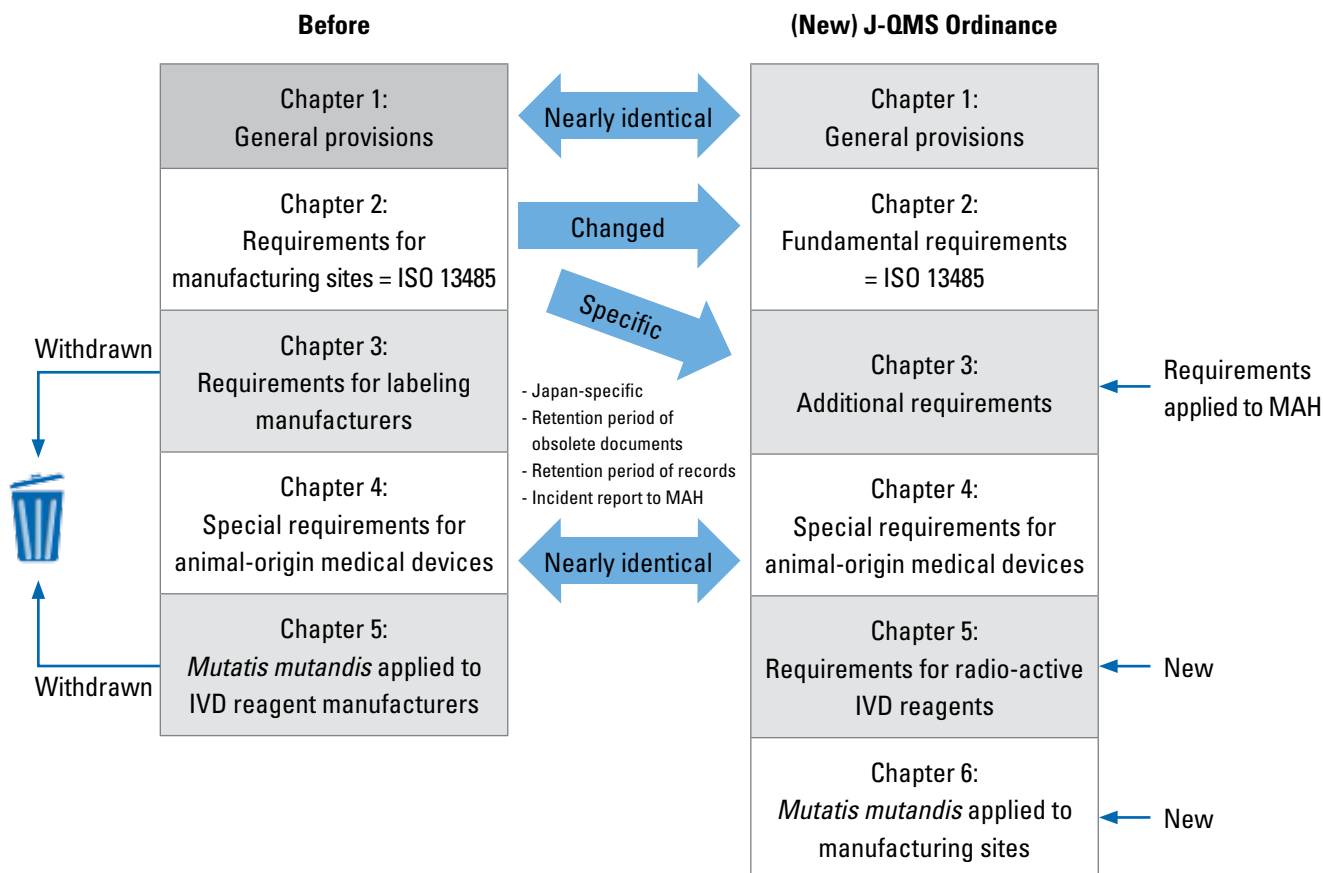
If a medical device other than a medical device for the collection of blood contains one of the following materials, the device is also recognized as an animal-origin product in Japan:

- Urokinase
- Sheep antibody
- Human serum albumin
- Heparin calcium
- Heparin sodium
- Mouse antibodies
- Enamel matrix derivative extracted from the tooth germ of young pigs

Chapter 5 applies in addition to chapters 2 and 3 to the quality management systems of organizations which handle radio-active IVD reagents.

Chapter 6 applies *mutatis mutandis* to manufacturing sites.

¹ ARCB: Association of Registered Certification Bodies under PMD Act.



2. Exclusion and non-applicable requirements

In the past, design and development control applied to only certain types of medical devices. For example, it applied to only 3% of class II medical devices and did not apply to IVD reagents. Now, it applies to medical devices and IVD reagents which need market certificates or approvals.

Please refer to Med-Info “FAQs on Japanese Regulations” for information on transitional measures under this change. Marketing Authorization Holders (MAH) which market only class I medical devices or IVD reagents exempt from marketing approval can exclude requirements for design and development from their quality management system (Articles 30 to 36 of J-QMS Ordinance (= clause 7.3 of ISO 13485:2003)). The majority of other MAHs cannot exclude these requirements. If any requirements in “product realization” (Articles 26 to 53 of J-QMS Ordinance (= clause 7 of ISO 13485:2003)) are not applicable to the MAH’s quality management system due to the nature of the medical device(s), the MAH can treat such requirements as “not applicable”.

If any requirements in chapters 2 to 5 are not applicable to the quality management system of a listed manufacturing facility (including design facility) due to processes implemented in the facility, such requirements may be treated as “not applicable”.

3. Designated MAH (D-MAH)

If a foreign manufacturer wants to hold a marketing certificate or approval, it can designate an MAH to act as a domestic representative in Japan. In such cases, all requirements applicable to the MAH under the J-QMS Ordinance are likewise applicable to the foreign manufacturer. Requirements applicable to a D-MAH are limited due to its responsibilities under the J-QMS Ordinance. Merit of the D-MAH scheme is the ease of changing a D-MAH.

A change of D-MAH does not affect any marketing certificates/approvals which the foreign manufacturer holds. Under the usual MAH scheme, a new marketing application is required if a foreign manufacturer wants to replace the MAH by a different one and a new certificate/approval number is assigned.

QMS audits

In this Med-Info, the term QMS audit stands for audits that include the requirements of the revised J-QMS-Ordinance.

1. Who performs QMS audits?

The table below shows the organizations which perform QMS audits.

Class of product	Organization which performs QMS audits
Class I	No QMS audit required
Class II	RCB (Registered Certification Body) or PMDA (Pharmaceuticals and Medical Devices Agency)
Class III	
Class IV	PMDA

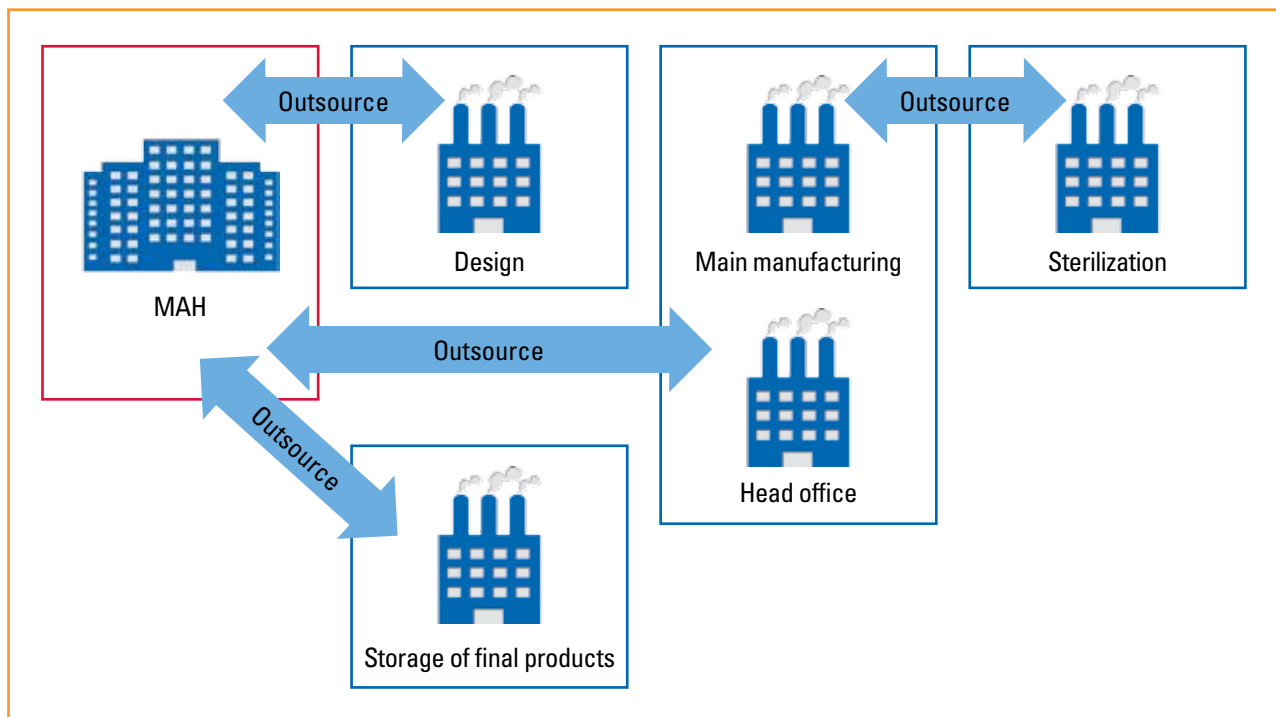
Either an RCB or PMDA performs QMS audits for class II and III devices. The results of an audit by an RCB or PMDA must be accepted by other RCBs or PMDA.

2. When is a QMS audit required?

Before marketing certificates or approvals are issued, the RCB or PMDA which received the application performs a QMS audit. After marketing certificates or approvals are issued, QMS audit is required every fifth year. This audit is known as a 5-year audit. Otherwise, the marketing certificate or approval will be withdrawn. The MAH shall apply for a 5-year audit in a timely manner to the RCB or PMDA which certified or approved the product. Multiple 5-year audits can be applied for at once. In this case, the MAH should apply for the audit to the RCB or PMDA that first certified or approved it.

3. Which organizations are the subject of QMS audits?

An RCB or PMDA performs QMS audits at the MAH's premises and all listed manufacturing facilities, regardless of whether all sites are covered by one quality management system. Non-listed facilities may be audited if the RCB or PMDA needs to audit the facility – for example, if the head office is not a listed facility, but records of management review and CAPA (Corrective action and preventive action) are maintained at the head office only. In such cases, the RCB or PMDA conducts the audit at the head office. The figure below shows the subject of the QMS audit.



- Scope of QMS audits
- MAH's quality management system
- Quality management system of each facility

4. How are QMS audits performed?

Chapter 2 of the J-QMS Ordinance is identical to ISO 13485:2003. Therefore, if your quality management system is certified according to ISO 13485:2003, fulfillment of chapter 2 can be verified by an ISO 13485 certificate and/or audit report. If your quality management system is not certified according to ISO 13485:2003, an on-site QMS audit will be necessary. Conformity to chapter 3 can be verified either on-site or off-site (document review). Fulfillment of chapter 4 or chapter 5 is basically verified on-site.

5. What are the outcomes of a QMS audit?

Similar to the usual ISO audits, an audit report with a list of findings is one of the outcomes of an on-site QMS audit. After the RCB or PMDA has audited all quality management systems in the scope, it issues a QMS Conformity Attestation (Kijun Tekigo Sho in Japanese) to the applicant (i.e. the MAH or foreign manufacturer holding the certificate/approval).

QMS Conformity Attestation (Kijun Tekigo Sho)

1. How does the MAH use the QMS Conformity Attestation?

After receiving the QMS Conformity Attestation, the MAH can skip QMS audits provided that all the following conditions are met:

- The applicant is identical to the holder of the QMS Conformity Attestation.
- The product in question falls into the product category entered in the QMS Conformity Attestation.
- The listed facilities involving the product in question are identical to the facilities entered in the QMS Conformity Attestation.
- The QMS Conformity Attestation has not expired.

“MAH can skip QMS audits” means that the MAH does not need to apply for QMS auditing when applying for marketing certificate or approval, or that the MAH does not need to apply for a 5-year audit.

2. How long is the validity of the QMS Conformity Attestation?

It is valid for five years after issuance.

3. What does “product category” mean?

For all class II and class III medical devices, product categories are defined based on NBOG BPG 2009-3. For various class IV medical devices, product categories are defined. Each JMDN (Japanese Medical Device Nomenclature) is categorized in one (or more in rare cases) product category.

TÜV SÜD as your partner for J-QMS

TÜV SÜD Japan is one of the biggest RCBs and has been certifying Class II medical devices and IVD reagents since 2005, as well as Class III me-too medical devices under revised regulation. The global TÜV SÜD group provides J-QMS audits. J-QMS audits can be performed in combination with usual audits based on ISO 13485, MDD, and/or CMDCAS.

Furthermore, TÜV SÜD

- offers reliable and flexible assistance and acts promptly;
- has long-standing experience with the Japanese Quality System requirements > PMD Act and J-QMS Ordinance;
- has detailed knowledge of all criteria that must be fulfilled to succeed MAH or foreign manufacturer J-QMS audits.

Your contact partner at TÜV SÜD Product Service can provide further information.

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