Product Service

Choose certainty.
Add value.

Med-Info

International expert information
for the medical device industry

FAQs on Japanese regulations

Frequently asked questions about Japanese regulations

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 frequently asked questions and answers on the Amendments.

Transitional measures

Q1: We hold a valid Foreign Manufacturer Accreditation (FMA). Do we need to submit an application for listing our facility after the implementation date of the new regulation?

A1: No. If your FMA is valid, you do not need to list your facility. But before your FMA expires you need to submit an application to the PMDA (Pharmaceuticals and Medical Devices Agency) for listing. You can submit it via an MAH (Marketing Authorization Holder) as for FMA.

Q2: Are any actions necessary in connection with existing marketing certificate(s) and/or approval(s)?

A2: Yes. After listing all facilities, the MAH needs to convert marketing certificates or approvals into documents under the new regulations.

The information about manufacturing facilities must be updated. The due date of this conversion is one month after the most recent due date of a 5-year audit for the existing marketing certificate or approval held by the MAH. However, it is recommended that MAHs update all related marketing certificates and/or approvals after issuance of an applicable QMS Conformity Attestation ("Kijun Tekigo Sho" in Japanese).

Q3: As a foreign manufacturer, what should we do regarding the transitional measures?

A3: You should discuss with your MAH whether each facility needs to be listed. Please refer to Q&A No. 6 below.

Listing of facility

Q4: We hold a valid Foreign Manufacturer Accreditation (FMA) as a sterilization facility. We perform design and development at the same facility. Do we need to list the facility as a design facility?

A4: No. There are categories for FMAs (e.g. sterile, non-sterile, labeling), but there is no category for listing. A listed facility can perform all activities.

Q5: Currently, we do not hold a valid Foreign Manufacturer Accreditation (FMA). Where do we have to apply for listing?

A5: Foreign manufacturers apply for listing to the PMDA. You can submit your application via an MAH.

Q6: The Med-Info "Act on medical devices in Japan" states that the main design facility that has overall responsibility for design activities shall be listed. What does this mean?

A6: "Main design facility with overall responsibility for design activities" means a facility where the audit team can audit design activities. For example, procedures and records related to design and development, and personnel whom the auditors interview, are expected to be available at the facility. This approach also applies to a "main manufacturing facility".

Q7: As the outcome of discussion we and our MAH concluded that listing for several facilities is not necessary. Do we need to cancel the existing FMA of these facilities?

A7: No, this is not necessary. The existing FMA will expire at the end of its validity period.

J-QMS Ordinance

Q8: Our facility is certified according to EN ISO 13485. Do we need to prepare anything in addition in order to comply with the J-QMS Ordinance?

A8: Yes. Basically, chapter 2 of the J-QMS Ordinance is identical to EN ISO 13485. However, you also need to comply with the additional requirements in chapter 3. You must establish QMS change planning and identify the requirements that have to be met (QMS document changes, training, internal audits, management review, etc.) before you take the necessary actions.

Medical Device Single Audit Program (MDSAP) audit report

Q9: Our facility is certified according to MDSAP. Can we use the MDSAP audit report and MDSAP certificate to demonstrate conformity to J-QMS ordinance?

A9: PMDA and RCBs accept the MDSAP audit report and MDSAP certificate. If the MDSAP audit covered Japanese regulation, the audit report and certificate are evidence of conformity to J-QMS ordinance Chapter 2 and part of Chapter 3 (Article 65 to 68), which are applicable to manufacturing sites. If the MDSAP audit did not cover Japanese regulation, the audit report and certificate are evidence of conformity to J-QMS ordinance Chapter 2. Conformity to Chapter 3 needs to be verified by additional audit or document review.

5-year audit

Q10: If we do not undertake a 5-year audit within the time limit, what will happen?

A10: This is not changed by the amendment. If the MAH cannot show a suitable QMS Conformity Attestation (Kijun Tekigo Sho) within the time limit, a business improvement administration or a similar decision will be issued by the Ministry of Health, Labour and Welfare (MHLW) based on the Pharmaceuticals, Medical Devices Act (PMD Act). If you and/or the MAH fail to take adequate action in a timely manner after the decision, the marketing certificate or approval will be withdrawn.

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.

Georg Bauer
Phone: +49 89 5008-4143
Email: georg.bauer@tuev-sued.de

Julia Hoyer
Phone: +49 89 5008-4191
Email: julia.hoyer@tuev-sued.de

Eiko Tabuchi
Phone: +81 6 6396-0260
Email: eiko.tabuchi@tuv-sud.jp