Japan Pharmaceutical & Medical Devices Act (JPMD Act)

BSI 2015 Medical Device Roadshow
Agenda

• Brief overview of Pharmaceutical and Medical Device Act
• Manufacturing site licensing scheme changes
• Classifications and routes to market
• Revised QMS requirements review
1. Brief Overview of JPMD Act
Title of Law

- Former law: PAL - Pharmaceutical Affairs Law

- November 25, 2014

  PMD Act: Pharmaceutical and Medical Device Act

- Official title of law:
  “Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics”
Revised Points of PMDAct (focus on Medical Devices)

• Manufacturing License simplified to “registration” from “accreditation”

• Marketing Authorisation Holder (MAH – the Legal manufacturer in Japan) will be responsible for QMS and Good Vigilance Practice (GVP)

• Medical devices and pharmaceuticals sections in separate chapters

• All Class II devices’ design control activities will be covered in the quality management system audit (Article 30-36, 7.3)
Revised Points of PMDA\textbf{c}t (continued)

• Some Class III devices with defined certification criteria are moved to certification scheme of 3rd party certification bodies
  • Examples: contact lenses, dental implants, infusion pumps, injection sets for insulin, heparin coated blood filters for artificial heart-lung machines

• Standalone software for diagnosis etc., becomes a medical device

• Draft package insert required in new application. Class IV devices will require submission to MHLW in advance
Gain market access in Japan with PMD Act and PMDA approval

Pharmaceutical and Medical Device Act (PMD Act) regulation

The distribution of medical devices in Japan is regulated in accordance with the Pharmaceutical and Medical Device Act (PMD Act) regulation by the Ministry of Health, Labour and Welfare (MHLW).

The former regulation, Japanese Pharmaceutical Affairs Law (JPAL) was replaced by PMD Act on November 25, 2014. The revision includes third party certification systems for Class III medical devices and expansion of the

Japan resources

Learn more about Japan's regulations.

› A guide to JPAL (170KB)
› Revised QMS Ordinance
› JPAL regulatory process
› Japan Standards Association (JSA)

View all resources
December 17, 2004

Revision by MHLW Ministerial Ordinance No. 87 Dated July 30, 2014

Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and *In Vitro* Diagnostic Reagents

CONTENTS

Chapter 1   General Provisions (Article 1 to Article 3)
Chapter 2   Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices, etc.
Definitions

Registration (toroku)
Licence (kyoka)
Accreditation (nintei)

Approval (shonin)
Certification (ninsho)

PMDA
MHLW
RCB

MO No. 169 (GMP/QMS)
MO No. 135 (GVP)
MO No. 136 (GQP)

Manufacturer MAH

Important to understand the definitions
2. Manufacturing License Scheme: from “Approval”/ “Accreditation” to “Registration”
Relationship between MAH and Manufacturing sites

**MAH (Applicant)**

- **Marketing Authorization (Approval/ Certification)**
  - Quality Assurance Manager

**Manufacturing sites**

- **Activities are**
  - Design
  - Manufacturing
  - Assembly
  - Sterilization
  - Final Shipping (Japan)

- **Subject to Registration**
- **Subject to implementation on the applicable articles of MO No.169**

**QMS - GVP Ordinance**

*Supervise for Compliance of QMS Ordinance (MO No.169)*
Manufacturing Sites Registration

Manufacturing site registration scheme simplified from accreditation.

The most of manufacturers already have FMA (Accreditation Certificate of Foreign Medical Device Manufacturer).

The current FMA will be still alive until the expiry date.

Attachments on application are simplified

Who takes care of it? MAH and/or DMAH.

(all documents shall be written in Japanese)
## Registration Applicable Scope of Manufacturer

### <Medical Devices>

<table>
<thead>
<tr>
<th>Manufacturing Process</th>
<th>MD Class II ~ IV</th>
<th>MD Class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>○</td>
<td>×</td>
</tr>
<tr>
<td>Main Manufacturing Process (Main Assembly etc.)</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Sterilization</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Storage for Final Shipment in Japan</td>
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<td>○</td>
</tr>
</tbody>
</table>

New
Design

- New registration scope requirement by PMDAct

- General rule:

  1 site should be registered as design site (organization) (multiple sites are also OK)

  The organization which is in charge of whole design, not a part of design only, such as circuit board or other components
Main Assembly etc.

• The manufacturing site which is in charge of final assembly should be registered.

• Not all the manufacturing sites are required to be registered. (The sites for sub assembling are not required to be registered)
Sterilization

Existing sterilization manufacturer is applicable
No particular difference between former and revised law

Storage for Final Shipment in Japan

Only the manufacturing site which is in charge of judgment of shipment to market is applicable

Sites which do only packing and/or labelling are NOT applicable
Sites outside Japan which do only packing etc., are NOT applicable
In case different manufacturing sites are involved in manufacturing processes:

- R&D
- Parts Manufacturing
- Manufacturing (Sub assembly)
- Main Assembly
- Final Packing Labelling
- Storage (Final Shipment)

Accreditation required

- Manufacturer (Category: General)

Registration is NOT required

- Manufacturer (Category: Packing)

Registration is NOT required

- Registration Manufacturer (Design)
- Registration Manufacturer (Assembly etc.)
- Registration Manufacturer (Shipment)

Former PAL

NOT required

PMD Act

Registration is NOT required

Accreditation required
Registration Applicable Scope of Manufacturer (example 2)

Registration as Manufacturer (Category: General)

Former PAL: NOT required

PMDAct: NOT required

Registration Manufacturer (Design): Registration is NOT required
# Registration Applicable Scope of Manufacturing License

<IVD>

<table>
<thead>
<tr>
<th>Manufacturing Process</th>
<th>IVD other than Radioactive</th>
<th>Radioactive IVD</th>
<th>IVD Class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Filling Process of reagent relating to Reaction System to Final Product</td>
<td>○</td>
<td>○ (All Manufacturing Processes after Filling Process)</td>
<td>○</td>
</tr>
<tr>
<td>Storage for Final Shipment in Japan</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
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</table>
3. Classifications & Routes to Market
# Regulatory Categories of Medical Devices

<table>
<thead>
<tr>
<th>Class</th>
<th>Regulatory Category in Japan</th>
<th>Product Approval or Certification</th>
<th>QMS Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV</td>
<td>Specially Controlled Medical Devices</td>
<td>Approval (Shonin)</td>
<td>PMDA</td>
</tr>
<tr>
<td>III</td>
<td>Specially Controlled Medical Devices</td>
<td>Approval (Shonin)</td>
<td>PMDA</td>
</tr>
<tr>
<td></td>
<td>Specially Controlled Medical Devices with Certification Standards</td>
<td>Certification (Ninsho)</td>
<td>Registered Certification Body</td>
</tr>
<tr>
<td>II</td>
<td>Controlled Medical Devices</td>
<td>Approval (Shonin)</td>
<td>PMDA</td>
</tr>
<tr>
<td></td>
<td>Controlled Medical Devices with Certification Standards</td>
<td>Certification (Ninsho)</td>
<td>Registered Certification Body</td>
</tr>
<tr>
<td>I</td>
<td>General Medical Devices</td>
<td>Notification (Todokede)</td>
<td>Exempt</td>
</tr>
</tbody>
</table>
Route to Japanese market

1) Select MAH
2) Classify devices (with MAH)
3) Obtain Registration
4) Choose Certification Body (if controlled with standards)
5) Prepare STED
6) Write MO#169 into QMS and implement
7) Obtain MO#169 assessment
8) Certification/Approval depending on class
9) Conduct PMS activities
Pharmaceuticals and Medical Devices Agency/
Ministry of Health, Labor and Welfare

Japanese Pharmaceutical and Medical Devices Act
Market Authorisation Holder

BSI is a Registered Certification Body (RCB)

Class I
General

Class II, III
Specified Controlled

Class III, IV
Highly Controlled

Pre-market submission

Quality system
ISO 13485 + MO #169

Quality system
ISO 13485 + MO #169

Pre-market approval
STED + JIS

Pre-market approval
STED + JIS

Self Declaration
(Todokede)

Certificates
RCB – Ninsho

Certificates
MHLW – Shonin
4. Revised QMS Compliance Review
QMS System Realignment
(international harmonization and MAH standardization)

Device Approval/Certification Requirement (per manufacturing site)

Former PAL
- QMS Ordinance (ISO13485+Japanese Local Regulation)
  - Manufacturing Accreditation Requirement
  - Manufacturing Facility Regulation

Revised QMS MO No. 169
- Chapter 2 ISO13485
  - Chapter 3 Additional Requirement
  - Chapter 6 Manufacturer QMS

Product Approval / Certification Requirements

System Consolidation = MAH is responsible for all related QMS including manufacturing sites
Chapter 1  General Provisions (Article 1 to Article 3)  
*Compliance Requirement of MAH

Chapter 2  Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices  =ISO 13485:2003

- Section 1  General Provisions (Article 4) *
- Section 2  Quality Management System  (Article 5 to Article 9)
- Section 3  Management Responsibilities (Article 10 to Article 20)
- Section 4  Resource Management (Article 21 to Article 25)
- Section 5  Product Realization (Article 26 to Article 53)
- Section 6  Measurement, Analysis and Improvement (Article 54 to Article 64)

Chapter 3  Additional Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices  (Article 65 to Article 72-3) *Differences between ISO13485 and QMS
Revised QMS Ordinance Structure

• Chapter 4  Manufacturing Control and Quality Control of Biological Medical Devices  (Article 73 to Article 79)

• Chapter 5  Manufacturing Control and Quality Control of Radioactive *In Vitro* Diagnostics  (Article 80 and Article 81)

• Chapter 6  Application *mutatis mutandis*, etc. to Manufacturers, etc. of Medical Devices, etc.  
  (Article 82 to Article 84)  *Exporting MDs and QMS of OEMs*
# QMS Subsystem and relationship of the organization

<table>
<thead>
<tr>
<th></th>
<th>MAH</th>
<th>Design</th>
<th>Main Assembly</th>
<th>Sterilization</th>
<th>Final Shipment</th>
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<tbody>
<tr>
<td>Name of the organization</td>
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<tr>
<td>Quality System Manual</td>
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<td>(including MO No.169)</td>
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<td>★ Common or Individual ★</td>
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<tr>
<td>Management</td>
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<tr>
<td>Design</td>
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<tr>
<td>Product Documentation</td>
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<tr>
<td>Manufacturing, Assembly</td>
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<tr>
<td>CAPA</td>
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<tr>
<td>Purchasing Control</td>
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<td>Document and record</td>
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<td>Customer</td>
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Article 65  Quality Management System of Registered Manufacturing Site

In case that the business facility to which the processes specified under Article 5, Paragraph 4 are outsourced or the business facility of the supplier of the purchased products is the registered manufacturing site pursuant to the provisions of Article 23-2-3, Paragraph 1 or Article 23-2-4, Paragraph 1 of the PMD Act (hereinafter referred to as the "registered manufacturing site"), the marketing approval holder, etc. shall perform necessary verification about that the manufacturer or the foreign manufacturer of medical devices, etc. specified in the same paragraph (hereinafter referred to as the "manufacturer, etc. related to the registered manufacturing site") related to the registered manufacturing site performs the manufacturing control and quality control based on the appropriate quality management system.
Article 66 Additional Requirements Regarding Quality Management System

The marketing approval holder, etc. shall establish, document, implement the quality management system pursuant to the provisions of Chapter 3 to Chapter 5 inclusive (limited to the provisions that shall apply pursuant to the provisions of Article 3, hereinafter the same in this article) as well as the provisions of Chapter 2 and also shall maintain its effectiveness.

2. The marketing approval holder, etc. shall manage processes pursuant to the provisions of Chapter 3 to Chapter 5 inclusive, as well as the provisions of Chapter 2.

3. The marketing approval holder, etc. shall describe the procedures and records specified in Chapter 3 to Chapter 5 inclusive, as well as the matters specified in Article 6, Paragraph 1, in the documents related to the quality management system specified under the same paragraph.
Article 67  Retention Period of Quality Management System Documents

The period during which the marketing approval holder, etc. retain the quality management system documents or their copies pursuant to the provisions of Article 8, Paragraph 4 shall be the following periods (5 years for the documents for training) from the date of abolition of the quality management system documents.

Proviso: This provision shall not apply to the quality management documents used for the manufacturing or testing of the products when they are maintained to be available for the period specified in the next article.
Article 67  Retention Period of Quality Management System Documents

(1) **15 years** for the products with the specially designated maintenance control required medical devices [one year plus the shelf life for the products of which the shelf life or the expiry date (hereinafter simply referred to as the "shelf life") plus one year exceeds 15 years]

(2) 5 years for the products with the medical devices, etc. other than the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).
Article 68  Retention Period of Records

The marketing approval holder, etc. shall retain the records specified under Article 9, Paragraph 1 or in this chapter for the following periods (5 years for the records of the training) from the preparation date.

(1) 15 years for the products with the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 15 years)

(2) 5 years for the products with the medical devices, etc. other than the specially designated maintenance control required medical devices (one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).
Article 69  Reporting Adverse Events, etc.

The marketing approval holder, etc. shall make all the facilities and relevant registered manufacturing sites establish and document the procedure to notify the marketing approval holder, etc. of the matters specified in the items of Article 228-20, Paragraph 2 of the Enforcement Regulations concerning the products when the facilities and relevant registered manufacturing sites recognize the matters concerned.
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