IMDRF International Medical Device Regulators Forum

Japan Update
- Implementation of PMD Act -

March, 2015

厚生労働省
Ministry of Health, Labour and Welfare

pmda

Topics

- Implementation of PMD Act; Revision of Pharmaceutical Affairs Law (PAL)

- PMDA Medical Device Training Seminar

Implementation of PMD Act:

- The act came into force *on 25 November 2014*.

- Relevant guidelines for PMD Act have been issued in time. These can be found in the following site (in Japanese):

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000045726.html

Brief overview of PMD Act

- Salient points;
  1. Strengthen safety measures regarding drugs and medical devices
  2. Revise medical device regulations based on its characteristics
  3. Introduce cellular and tissue therapeutic product regulations based on its characteristics

- PAL has been renamed as “Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics” **= *“PMD Act”***.

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Some Class III Medical Devices undergo certification

GHTF Classification	
Class A	extremely low risk X-Ray film
Class B	low risk MRI, bronchial catheters
Class C	medium risk artificial bones, dialyzer
Class D	high risk pacemaker, artificial heart valves

Classification in Japan		
Category	Pre-market regulation	# of JMDN*
General MDs (Class I)	Self declaration	1,195
Controlled MDs (class II)	Third party Certification	1,801 (1,369 for 3rd Parties)
Specially Controlled MDs (class III & IV)	Minister's Approval (Review by PMDA)	757
		345

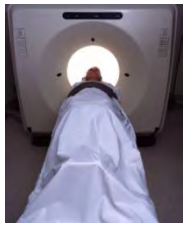
*JMDN: Japanese Medical Device Nomenclature As of April, 2014

Software as a Medical Device (SaMD) is newly regulated in PMD Act

Example of Medical Device with embedded program

Image Diagnostic Apparatus

It processes, stores and displays image data from CT, MRI etc.



Data from CT scanning

Processing by program

3D image of a skull

PAL

Software (program)

Hardware

Combination of hardware and software is regulated as a total system.

PMD Act

SaMD

Software (program)

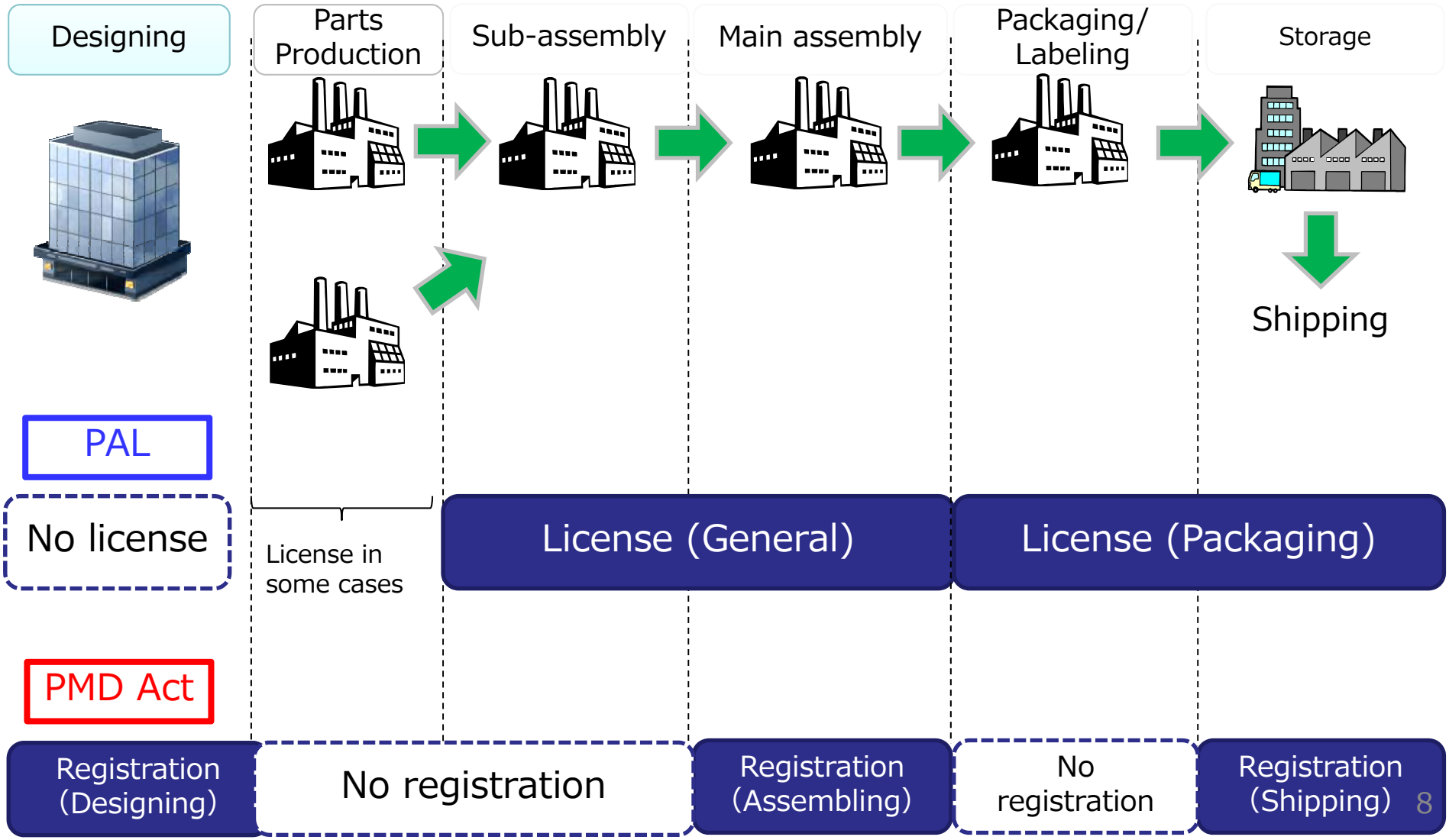
Software itself is independently regulated

Manufacturer is required to be registered, instead of to be licensed

	PAL	PMD Act
Licensing system	License (domestic) Accreditation (foreign)	Registration (both domestic and foreign)
Authority to provide license	Prefecture (domestic) MHLW (biological, foreign)	Prefecture (domestic) MHLW (foreign)
Category	General, Sterilization, Biological, Packaging etc.	No categorization
Requirements for licensing	No reasons for disqualification	No reasons for disqualification
	Facilities requirements (according to categories)	None (no practical/document inspection for facilities) ↓ Facilities are assessed in QMS inspection

- The Scope of manufacturers that should be registered is narrowed. However, a manufacturer in charge of designing is newly required to be registered.
- Required materials for registration is simplified.

Example of registration as a manufacturer



Introduction of more efficient QMS inspection system

1. QMS inspection is conducted on the Marketing Authorization Holder (including manufacturing sites), not site by site.

2. QMS inspection is conducted per product family, not on individual product.

3. Structure of QMS ordinance has been changed in alignment with ISO 13485:2003.

Topics

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- PMDA Medical Device Training Seminar

2nd PMDA Medical Device Training Seminar for regulators in other jurisdictions

- It was held on February 2 – 6, 2015 at PMDA (Tokyo, JAPAN).
- Topics such as pre-market review, QMS and PMS were provided.
- The following jurisdictions were participated:
  - ✓ Australia
  - ✓ Brazil
  - ✓ Singapore
  - ✓ Taiwan
  - ✓ Fellow of the Mansfield Foundation (USA)

Thank you

MHLW

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