Japan Update
- Implementation of PMD Act -

March, 2015
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/000045726.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”.
Some Class III Medical Devices undergo certification

<table>
<thead>
<tr>
<th>GHTF Classification</th>
<th>Classification in Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>Category</td>
</tr>
<tr>
<td>extremely low risk</td>
<td>General MDs (Class I)</td>
</tr>
<tr>
<td>X-Ray film</td>
<td>Controlled MDs (class II)</td>
</tr>
<tr>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>low risk</td>
<td>Specially Controlled MDs (class III &amp; IV)</td>
</tr>
<tr>
<td>MRI, bronchial catheters</td>
<td></td>
</tr>
<tr>
<td>Class C</td>
<td></td>
</tr>
<tr>
<td>medium risk</td>
<td></td>
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<tr>
<td>artificial bones, dialyzer</td>
<td></td>
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<tr>
<td>Class D</td>
<td></td>
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<tr>
<td>high risk</td>
<td></td>
</tr>
<tr>
<td>pacemaker, artificial heart valves</td>
<td></td>
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</tbody>
</table>
It processes, stores and displays image data from CT, MRI etc. Data from CT scanning 3D image of a skull

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

Example of Medical Device with embedded program

Image Diagnostic Apparatus

Software (program) + Hardware

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

PMD Act

SaMD

Software itself is independently regulated
Manufacturer is required to be registered, instead of to be licensed

<table>
<thead>
<tr>
<th>Licensing system</th>
<th>PAL</th>
<th>PMD Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>License (domestic)</td>
<td>License (domestic)</td>
<td>Registration</td>
</tr>
<tr>
<td>Accreditation (foreign)</td>
<td>Accreditation (foreign)</td>
<td>(both domestic and foreign)</td>
</tr>
<tr>
<td>Authority to provide license</td>
<td>Prefecture (domestic)</td>
<td>Prefecture (domestic)</td>
</tr>
<tr>
<td>MHLW (biological, foreign)</td>
<td>MHLW (foreign)</td>
<td></td>
</tr>
<tr>
<td>Category</td>
<td>General, Sterilization, Biological, Packaging etc.</td>
<td>No categorization</td>
</tr>
<tr>
<td>Requirements for licensing</td>
<td>No reasons for disqualification</td>
<td>No reasons for disqualification</td>
</tr>
<tr>
<td>Facilities requirements (according to categories)</td>
<td>None</td>
<td>Facilities are assessed in QMS inspection</td>
</tr>
</tbody>
</table>

- 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

Designing

Parts Production

Sub-assembly

Main assembly

Packaging/Labeling

Storage

PAL

No license

License in some cases

License (General)

License (Packaging)

No registration

Registration (Assembling)

No registration

Registration (Shipping)
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

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

• 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