Value of International Standards in Japan

Pharmaceuticals and Medical Devices Agency (PMDA)
Regulatory Authorities in JAPAN

**MHLW**
Pharmaceutical Safety and Environmental Health Bureau, MHLW

- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

**PMDA**
Pharmaceuticals and Medical Devices Agency

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.

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September 18, 2017 DITTA Workshop
# Overview of Medical Device Regulation

<table>
<thead>
<tr>
<th>Classification</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
<th>Class IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk</td>
<td>Low risk</td>
<td></td>
<td></td>
<td>High risk</td>
</tr>
<tr>
<td>Category</td>
<td>General MDs</td>
<td>Controlled MDs</td>
<td>Specially controlled MDs</td>
<td></td>
</tr>
<tr>
<td>Premarket regulation</td>
<td>Self-declaration</td>
<td>Third party certification</td>
<td>MHLW approval (PMDA review)</td>
<td></td>
</tr>
</tbody>
</table>

**Example**

- Post market safety (vigilance/surveillance)

PMDA and MHLW
# How International Standards are utilized

## Standards and guidelines for review

<table>
<thead>
<tr>
<th>Type</th>
<th>Premarket Regulation</th>
<th>Reviewed by</th>
<th>Required Conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification Standards (CS)</td>
<td>Third party certification</td>
<td>Registered Certification Bodies*</td>
<td>Exactly</td>
</tr>
<tr>
<td>Approval Standards (AS)</td>
<td>MHLW approval</td>
<td>PMDA</td>
<td>Exactly</td>
</tr>
<tr>
<td>Review Guidelines (RG)</td>
<td>MHLW approval</td>
<td>PMDA</td>
<td>Reference base</td>
</tr>
</tbody>
</table>

*Based on ISO/IEC/17021,17065*
### How International Standards are Utilized

#### Number of Technical Standards & Guidelines As of May, 2017

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-market regulation</th>
<th>Technical Standards &amp; GL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>Self declaration</td>
<td>NA</td>
</tr>
<tr>
<td>Class II</td>
<td>Third Party Certification</td>
<td>CS : 935</td>
</tr>
<tr>
<td>Class III</td>
<td>President’s Approval (Review by PMDA)</td>
<td>CS : 11</td>
</tr>
<tr>
<td>Class IV</td>
<td>AS : 14 (include class IV)</td>
<td>AS : 30 (class III)  RG : 8 (Class III)</td>
</tr>
</tbody>
</table>

As of May, 2017

Number of Technical Standards & Guidelines September 18, 2017 DITTA Workshop

5
Certification Standards

◆ Certification Standards for Third party Certification

The “Certification Standards” are issued by MHLW.

In Certification Standards, requirements for applicable products are specified with certain ministerial ordinances as well as Japanese Industrial Standards (JIS).

Manufacturers must show the exact conformity of the medical device to the Certification Standard applied to its product nomenclature (JMDN).

Registered certification bodies utilize Certification Standards in their review to confirm the conformity.
Japanese Industrial Standard (JIS)

JIS: Japanese Technical Standard based on International Standard

JIS are standards written in Japanese, developed as a translation of International Standard or other recognized standard, whichever is used internationally.

Most of them are based on ISO/IEC but in the case there is no such standard by ISO/IEC, then alternatively using Guidance Documents issued by National Competent Authorities (NCAs) or Industry Standards such as NEMA* Standard, etc.

* National Electrical Manufacturers Association (USA)
# How International Standards are Utilized

## Example for Essential Principles Checklist of CS

**Ministerial Notification No. 112, Appendix Table, No.3-53**

**Essential Principles Checklist (Camera, fundus)**

<table>
<thead>
<tr>
<th>Essential Principles</th>
<th>Applied / Not applied</th>
<th>Identity of Specific Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 1   General Requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Article1</td>
<td>Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
</tr>
<tr>
<td>Article2</td>
<td>Applied</td>
<td>JIS T 14971:</td>
</tr>
<tr>
<td>Article3</td>
<td>Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004</td>
</tr>
<tr>
<td>Article4</td>
<td>Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
</tr>
<tr>
<td>Article5</td>
<td>Applied</td>
<td>MHLW Ministerial Ordinance No. 169 dated December 17, 2004; JIS T 14971:</td>
</tr>
<tr>
<td>Article6</td>
<td>Applied</td>
<td>JIS T 14971:</td>
</tr>
</tbody>
</table>

**Identity of Specific Documents**

- MHLW Ministerial Ordinance No. 169 is based on ISO 13485:2003
- JIS T 14971 is based on ISO 14971:2007 (IDT)

**Identity of Specific Documents**

- JIS T 7320:2015 “Fundus cameras”
- 4.2 Optical performance

- ISO 10940:2009
- “Ophthalmic instruments – Fundus Camera”
- 4.2 Optical properties

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PMDA interacts with JFMDA and initiates discussions with industry, MHLW and experts within PMDA regarding the contents of the standards and develop draft proposal.

PMDA receives the preliminary draft of certification standards, approval standards, and review guideline from JFMDA.

PMDA serves the Committee as the secretariat to be discussed JFMDA proposed draft. Committee members are delegated from academia, users (physicians), industry and regulators.

PMDA submits the final draft to MHLW. After public consultations, MHLW will finalize and publish the standards/guidelines.

*1 The Japan Federation of Medical Devices Associations
Summary

Utilization of international Standards in regulation may make win-win-win situations among Industries-regulators-patients.

• Reduce duplication
• Enhance Transparency
• Save preparing time/cost
• Reduce review time
• Ensure Safety and Effectiveness
• Timely introduction of the innovative or high-risk devices