Value of International Standards in Japan

Pharmaceuticals and Medical Devices Agency (PMDA)

Regulatory Authorities in JAPAN

MHLW

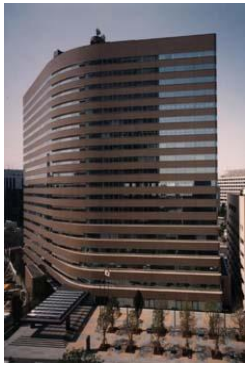
Pharmaceutical Safety and Environmental Health Bureau, MHLW

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

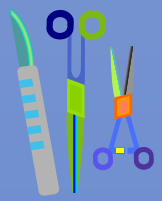
PMDA

Pharmaceuticals and Medical Devices Agency

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



Overview of Medical Device Regulation

Classification	Class Ⅰ	Class Ⅱ	Class Ⅲ	Class Ⅳ
Risk	Low risk →			High risk
Category	General MDs	Controlled MDs	Specially controlled MDs	
premarket regulation	Self-declaration	Third party certification →	MHLW approval (PMDA review)	
Example		 	 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

How International Standards are utilized

Standards and guidelines for review

Type	Premarket Regulation	Reviewed by	Required Conformity
Certification Standards (CS)	Third party certification	Registered Certification Bodies*	Exactly
Approval Standards (AS)	MHLW approval	PMDA	Exactly
Review Guidelines (RG)	MHLW approval	PMDA	Reference base

***Based on ISO/IEC/17021,17065**

How International Standards are Utilized

Number of Technical Standards & Guidelines As of May, 2017

Category		
Classification	**Pre-market regulation**	**Technical Standards & GL**
Class I	**Self declaration**	**NA**
Class II	**Third Party Certification**	**CS：935**
Class III	**Minister's Approval (Review by PMDA)**	**CS:11**
		AS：30（class Ⅲ） RG：8（Class Ⅲ）
Class IV		**AS:14 （include class Ⅳ）**

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

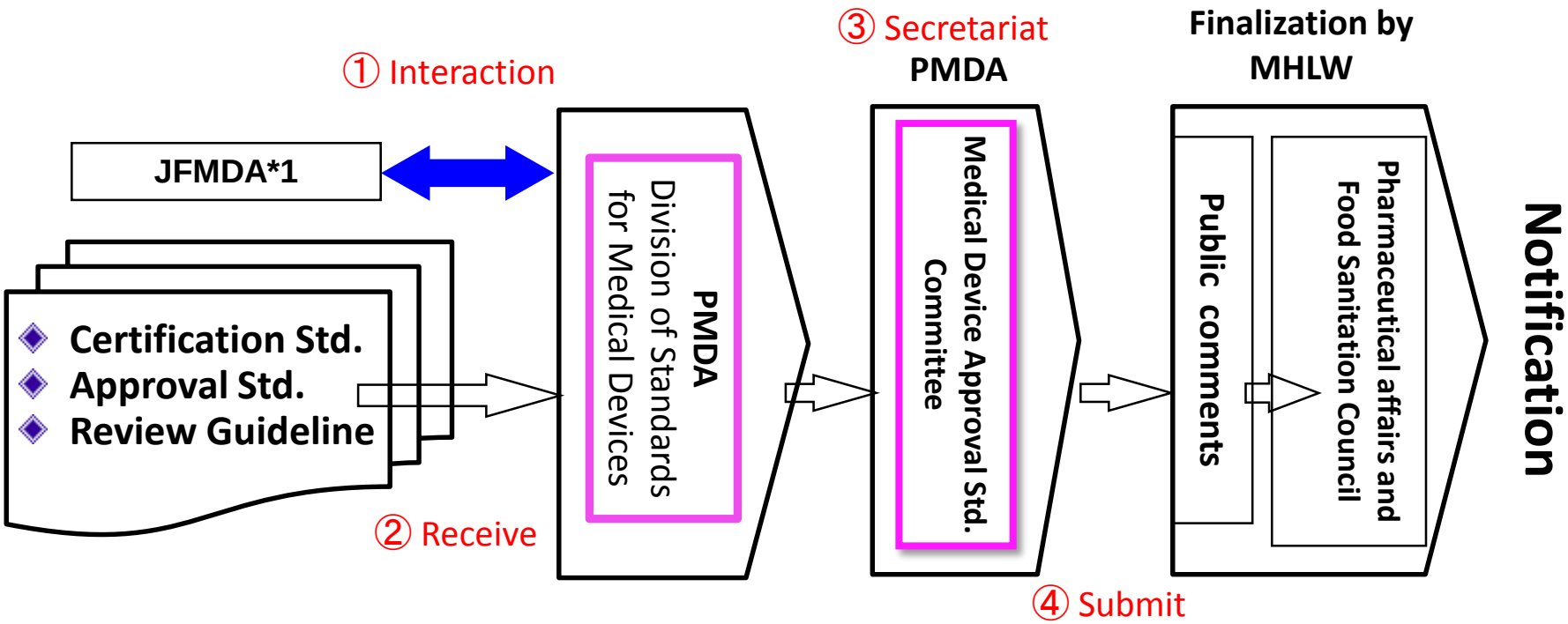
Ministerial Notification No. 112, Appendix Table, No.3-53
Essential Principles Checklist (Camera, fundus)

Essential Principles			*Applied / Not applied*	*Identity of Specific Documents*
Chapter 1 General Requirements				
Article1			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIST 14971:
Article2			Applied	JIS T 14971:
Article3			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004
Article4			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIST 14971:
Article5			Applied	MHLW Ministerial Ordinance No. 169 dated December 17, 2004;JIST 14971:
Article6			**Applied**	**JIS T 14971:** **JIS T 7320:2015 "Fundus cameras"** **4.2 Optical performance**

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 T7320:2015 (IDT) "Fundus Cameras" 4.2 Optical performance = ISO10940:2009 "Ophthalmic instruments – Fundus Camera" 4.2 Optical properties

Process and Development for Certification Standards



① PMDA interacts with JFMDA and initiates discussions with industry, MHLW and experts within PMDA regarding the contents of the standards and develop draft proposal.

② PMDA receives the preliminary draft of certification standards, approval standards, and review guideline from JFMDA.

③ PMDA serves the Committee as the secretariat to be discussed JFMDA proposed draft. Committee members are delegated from academia, users (physicians), industry and regulators.

④ 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*