Medical Device Regulations and Utilization of International Standards in Japan

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Div. of Standard for Medical Devices
Office of Standards and Guidelines Development
Pharmaceuticals and Medical Devices Agency
Agenda

• Overview of Risk-based Medical Device Regulations in Japan
• Process of Developing Standards in Japan
• Utilization of Standards
Agenda

• Overview of Risk-based Medical Device Regulations in Japan
  • Process of Developing Standards in Japan
  • Utilization of Standards
### GHTF Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Risk Level</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>extremely low risk</td>
<td>X-Ray film</td>
</tr>
<tr>
<td>B</td>
<td>low risk</td>
<td>MRI, digestive catheters</td>
</tr>
<tr>
<td>C</td>
<td>medium risk</td>
<td>artificial bones, dialyzer</td>
</tr>
<tr>
<td>D</td>
<td>high risk</td>
<td>pacemaker, artificial heart valves</td>
</tr>
</tbody>
</table>

### Medical Device Category in Japan

<table>
<thead>
<tr>
<th>Class</th>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>General MDs</td>
<td>X-Ray film</td>
</tr>
<tr>
<td>II</td>
<td>Controlled MDs</td>
<td>MRI, digestive catheters</td>
</tr>
<tr>
<td>III</td>
<td>Specially Controlled MDs</td>
<td>artificial bones, dialyzer</td>
</tr>
<tr>
<td>IV</td>
<td>Specially Controlled MDs</td>
<td>pacemaker, artificial heart valves</td>
</tr>
</tbody>
</table>

Risk based classification
N77 Principles of Medical Devices Classification
GHTF (Global Harmonization Task Force) Guidance and Japanese Regulation (Relationship)

GHTF
- SG1 Definition
  Risk base classification (N77)
  Essential Principle (EP) (N68)
  STED (N11)
- SG2 AE Reporting
  Field Safety Notice
- SG3 Auditing
- SG4 QMS
- SG5 Clinical Investigation

Japan (PMD-Act)
- Definition
  Risk base classification
  Essential Principle
  STED
- GVP Ordinance
  AE Reporting
  Field Safety Notice
- Auditing
- QMS Ordinance
- Notifications on Clinical Investigation
JMDN
Japanese Medical Device Nomenclature

• Based on GMDN 2003
  (GMDN: Global Medical Device Nomenclature)
• Implemented in 2005
• Not updated simultaneously with current GMDN
• MHLW creates new JMDN referring to current GMDN, when a medical device which doesn’t meet any of existing JMDN is approved
# Medical Device Classification in Japan

## Medical Device Classification in Japan

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-market regulation</th>
<th># of JMDN*</th>
</tr>
</thead>
<tbody>
<tr>
<td>General MDs (Class I)</td>
<td>Self Declaration</td>
<td>1,195</td>
</tr>
<tr>
<td>Controlled MDs (class II)</td>
<td>Third party Certification</td>
<td>1,972</td>
</tr>
<tr>
<td>Specially Controlled MDs (class III &amp; IV)</td>
<td>Minister’s Approval (Review by PMDA)</td>
<td>771</td>
</tr>
</tbody>
</table>

*JMDN: Japanese Medical Device Nomenclature

**As of January, 2016**
Resource Allocation depending on potential risk

Class I MD
Self Declaration (submit Marketing Notification to PMDA)

Class II & Class III MD with Certification Standard
Certification by Registered Certification Body (RCB)

Class III/IV
Approval by MHLW (reviewed by PMDA)

MHLW/PMDA can Focus on the thorough review of higher-risk/innovative Medical Devices
Certification
RCBs review Class II & Class III MD with Certification Standard

RCB:
• Gives certification for marketing to the applicant
• Not “Accredited Body for ISO certificate”
• Registered by MHLW
• Assessed by PMDA
• Conducts review with Certification Standards (CS)

Products out of scope of CS or not comply with CS should go to Minister’s Approval process
Certification Standards (CS)

- Associated with JMDN
- Essential Principle Check List with relevant standards is attached to each Certification Standard

Structure

1. Scope
   Applicable JMDN to the CS is listed

2. Technical Standard
   Japanese Industrial Standard (JIS) (in most case) which the product must comply with

3. Indication for Use
   Based on the definition of applicable JMDN
Japanese Industrial Standard (JIS)

JIS:

**Japanese Technical Standard based on International Standards** or other recognized standards which is **used internationally**.

If there is no such international standards to refer, then alternatively using **Guidance Documents** which National Competent Authorities (NCA) issues or **Industry Standard such as NEMA* Standard etc.**

* National Electrical Manufacturers Association (USA)
# Example of Certification Standard

## Essential Principles Checklist

**Ministerial Notification No. 112, Appendix Table, No.3-1**
**Essential Principles Checklist (The standard for X-ray system, diagnostic, general-purpose, mobile, analogue etc)**

<table>
<thead>
<tr>
<th>Essential Principles of Safety and Performance of Medical devices</th>
<th>Applicable</th>
<th>Method of Conformity</th>
<th>Identity of Specific Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. General requirements</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Design) Clause 1 Medical devices should be designed and manufactured</td>
<td>Applicable</td>
<td>Show the conformity with recognized standard included requirements</td>
<td><strong>Ordinance</strong> on Standards for Manufacturing Control and Quality Control of Medical Devices and <em>In Vitro</em> Diagnostic Reagents (MHLW Ministerial Ordinance No. 169 in 2004) <strong>JIS T 14971</strong>:「Medical devices -- Application of risk management to medical devices」</td>
</tr>
<tr>
<td>(Risk management) Clause 2 The solutions adopted by the manufacturer</td>
<td>Applicable</td>
<td>Show risk management is conducted according to recognized standard</td>
<td><strong>JIS T 14971</strong>:「Medical devices -- Application of risk management to medical devices」</td>
</tr>
<tr>
<td>(Effective for medical devices) Clause 6 All known and foreseeable risks, and</td>
<td>Applicable</td>
<td>verify the effective to conduct risk analysis. Show the conformity with recognized Standard to verify the effective</td>
<td><strong>JIS T 14971</strong>:「Medical devices -- Application of risk management to medical devices」 <strong>JIS Z 4751-2-54:2012</strong>:「Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 203.6.3.2.101, 203.6.3.2.102, 203.6.4.3.104.3, 203.6.4.3.104.4〜5and/or6 203.6.4.7.」</td>
</tr>
</tbody>
</table>
### Example of Certification Standard

#### Essential Principles Checklist

<table>
<thead>
<tr>
<th>Essential Principles of Safety and Performance of Medical devices</th>
<th>Applicable</th>
<th>Method of Conformity</th>
<th>Identity of Specific Documents</th>
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<tbody>
<tr>
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<td></td>
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<tr>
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<td>Applicable</td>
<td>Show the conformity with recognized standard included requirements</td>
<td>Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and <em>In Vitro</em> Diagnostic Reagents (MHLW Ministerial Ordinance No. 169 in 2004)</td>
</tr>
<tr>
<td>(Risk management)</td>
<td>Applicable</td>
<td>Show risk management is conducted according to recognized standard</td>
<td>JIS T 14971:「Medical devices -- Application of risk management to medical devices」</td>
</tr>
<tr>
<td>Clause 6 All known and foreseeable risks, and</td>
<td></td>
<td>Conduct risk analysis. Show the conformity with recognized Standard to verify the effective</td>
<td>JIS Z 4751-2-54:2012:「Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 203.6.3.2.101, 203.6.3.2.102, 203.6.4.3.104.3, 203.6.4.3.104.4a〜5and/or6 203.6.4.7.」</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)
# Example of Certification Standard

## Essential Principles Checklist

<table>
<thead>
<tr>
<th>Essential Principles of Safety and Performance of Medical devices</th>
<th>Applicable</th>
<th>Method of Conformity</th>
<th>Identity of Specific Documents</th>
</tr>
</thead>
</table>

### 1. General requirements

**(Design)**

- **Clause 1**
  - Medical devices should be designed and manufactured.

- **Method of Conformity**
  - Show the conformity with recognized standard included requirements.

- **Identity of Specific Documents**
  - Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169 in 2004)
  - JIS T 14971: 「Medical devices -- Application of risk management to medical devices」

**(Risk management)**

- **Clause 2**
  - All known and foreseeable risks, and

- **Method of Conformity**
  - Show risk management is conducted according to recognized standard.

- **Identity of Specific Documents**
  - JIS T 14971: 「Medical devices -- Application of risk management to medical devices」

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**Identity of Specific Documents**

JIS Z 4751-2-54:2012 is based on IEC 60601-2-54:2009 (MOD)

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**Clause b**

- All known and foreseeable risks, and

- **Method of Conformity**
  - Conduct risk analysis.
  - Show the conformity with recognized standard to verify the effective management to medical devices.

- **Identity of Specific Documents**
  - JIS Z 4751-2-54:2012: 「Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 203.6.3.2.101, 203.6.3.2.102, 203.6.4.3.104.3, 203.6.4.3.104.4～5and/or6 203.6.4.7.」
Approval
PMDA reviews Class III/IV MDs

Applicant
Consultation \(\uparrow\downarrow\) Application

PMDA
Conformity Audits (GLP/GCP/QMS)
Scientific Review
Approval Standards (AS)
Review Guideline (RS)
Inquiry \(\uparrow\downarrow\) Answer
External Experts

Review report

PAFSC: Pharmaceutical Affairs and Food Sanitation Council

MHLW
Advisory body
PAFSC
Consultation \(\uparrow\downarrow\) Advice
Minister

Approval
### JMDN and CS/AS and RG

As of 2016 Mar

<table>
<thead>
<tr>
<th>Category</th>
<th>JMDN</th>
<th>Number of TS or Review Guideline (RG)</th>
<th>JMDN Covered %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>1195</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Category II</td>
<td>1972</td>
<td>936 CS (1519 JMDN)</td>
<td>77</td>
</tr>
<tr>
<td>Category III</td>
<td>771</td>
<td>10 CS (39 JMDN) 8 RG (32 JMDN)</td>
<td>14</td>
</tr>
<tr>
<td>Category IV</td>
<td>350</td>
<td>43 AS (89 JMDN)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4288</td>
<td>996 (1679 JMDN)</td>
<td></td>
</tr>
</tbody>
</table>

CS: Certification Standard  
AS: Approval Standard  
RG: Review Guidance
Agenda

• Overview of Risk-based Medical Device Regulations in Japan
• Process of Developing Standards in Japan
• Utilization of Standards
Standards and Guidance setting in PMDA

**Office of Standards and Guidelines Development**

**Division of Pharmacopoeia and Standards for Drugs**
- Secretariat of Japanese Pharmacopoeia Expert committees
- Registration of Master Files for Drug Substances

**Division of Standards for Medical Devices**
- Secretariat of Committees for Certification and Approval Standards
- Cooperation to setting of JIS, ISO and IEC standards
- Openness these standards to the public in a timely manner.
JIS standards are submitted to MHLW via JSA. After JISC and offering comments, etc., JIS standards are reported to MHLW Meeting and then announced in public.

Making Process of AS/CS/RG

Responsibility:
Office of Standards
PMDA
Involvement in JIS, ISO and IEC Standards Development

1) JIS Standards
PMDA participates in **Medical Devices Technical Committee** as a delegate.

2) ISO IEC standards
PMDA participates in **Domestic Committee** and also attends these international meetings.

### JIS Standards
- **PMDA participates in Medical Devices Technical Committee as a delegate.**

### ISO IEC standards
- **PMDA participates in** Domestic Committee **and also attends these international meetings.**

---

**JISC:** Council in METI. Member of ISO/IEC (Representative of Japan)
- Conducted by a general meeting: 22 representative members from Academic conference, Industrial Association, Media and Consumer etc. (As of April 1, 2012)

**Standard Board**
- 26 technical committees by sectors (16 members from university, industrial association, Consumer)
- 15 members from university, academic conference, and industrial association (METI) (MHLW also participate because JIS is used in the PMD Act.)

**ISO/IEC**
- Each TC secretariat

**ISO/IEC**
- JFMDA, Academic conference
- (JFMDA, Academic conference)

<table>
<thead>
<tr>
<th>Domestic Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secretariat</td>
</tr>
<tr>
<td>ISO/TC</td>
</tr>
<tr>
<td>JFMDA</td>
</tr>
<tr>
<td>TC210</td>
</tr>
<tr>
<td>MT Japan</td>
</tr>
<tr>
<td>TC76, TC83, TC150</td>
</tr>
<tr>
<td>JEITA</td>
</tr>
<tr>
<td>IEC/TC62</td>
</tr>
<tr>
<td>Others</td>
</tr>
<tr>
<td>TC/00</td>
</tr>
</tbody>
</table>
**PMDA’s Involvement in ISO/IEC TC**

PMDA is involved to/participate **Standard Technical Committee**

<table>
<thead>
<tr>
<th>ISO/TC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>210</td>
<td>Quality management and corresponding general aspects for medical devices</td>
</tr>
<tr>
<td>194</td>
<td>Biological and clinical evaluation of medical devices</td>
</tr>
<tr>
<td>TC 62</td>
<td>Electrical equipment in medical practice</td>
</tr>
<tr>
<td>215</td>
<td>Health informatics</td>
</tr>
<tr>
<td>106</td>
<td>Dentistry</td>
</tr>
<tr>
<td>229</td>
<td>Nanotechnologies</td>
</tr>
<tr>
<td>276</td>
<td>Biotechnology</td>
</tr>
<tr>
<td>172</td>
<td>Optics and photonics</td>
</tr>
<tr>
<td>121</td>
<td>Anaesthetic and respiratory equipment</td>
</tr>
<tr>
<td>150</td>
<td>Implants for surgery</td>
</tr>
</tbody>
</table>
Agenda

• Overview of Risk-based Medical Device Regulations in Japan
• Process of Developing Standards in Japan
• Utilization of Standards
What is “Standard”?

GHTF/SG1/N44: 2008

Standard: Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

NOTE: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits. (ISO/IEC Guide2:2004, definition 3.2)
Demonstrating Conformity Assessment

Essential Principles
Demonstrating Conformity Assessment

Any ways are acceptable if the set of tests satisfies the EP
2.2 Purpose
To:

• encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the Essential Principles of Safety and Performance of Medical Devices (hereafter referred to as ‘Essential Principles’);

• encourage manufacturers to conform with appropriate international standards;

• persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the GHTF harmonized Essential Principles;

• support the concept that in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.
Utilization of International Standards

Utilization of international Standards under the same concept and in the same assessment,
Can make win-win situation for both Industries and regulators

- Reduce duplication
- Enhance Transparency
- Save preparing time/cost
- Reduce review time
- Enhance Safety and Efficacy
DHANYAVAD!!

URL http://www.pmda.go.jp
http://www.std.pmda.go.jp/stdDB/index_e.html
Medical Devices
Regulations
and
Capacity Building

Dr. S. Eswarara Reddy
Joint Drugs Controller (India), CDSCO (HQ)
18th May, 2016
Outline:

- Introduction
- Definitions
- Notified Devices
- Related Rules/Schedules
- Concerns with present regulations
- Proposed Regulations
- Conclusion
Introduction

Medical Devices:

- Market Size: Rs 40,000 Cr ($ 6.5 US Billion)
- Around 350 Licenses
- Only Notified devices are regulated
- Regulated as Drugs
- Mostly Imports
- Dynamic in nature
- 100% FDI
- Medical Technology to Rural and Semi-rural population
Introduction contd...

Medical Technologies/Devices:
1. Medical Equipments/Instruments
   Eg. CT Scan, MRI, X-Ray machines etc
2. Medical Implants
   Eg. Cardiac Stents, IOL, Orthopedic Implants
3. Medical Disposables
   Eg. Syringes, Needles, Catheters
4. Medical Furniture
   Eg. Hospital Beds, Wheel Chair etc.
Medical Device Industry

Strength:
- Potentially huge market with growing urban middle class population
- Growing private hospitals aiming to attract Health Tourism
- Success of pharma and other paramedical areas
- Increasing healthcare expenditure

Opportunities:
- Overseas companies investing in India to set up R&D units
- Increasing Joint ventures & Overseas aid assisted projects
- Development of medical devices parks
  - Common Testing Facilities
  - Infrastructure
  - Developing at strategic locations
Drugs and Cosmetics Act and Rules
Definition

• Medical Devices and Diagnostics are considered as “Drugs”

• Section 3 (b) (iv)
  “Such devices intended for Internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board”
## History of MD Regulations:

<table>
<thead>
<tr>
<th>Definition</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initially 3 devices are notified as Drugs</td>
<td>March, 1989</td>
</tr>
<tr>
<td>Schedule M-III</td>
<td>Feb, 1994</td>
</tr>
<tr>
<td>The Second notification (IVD)</td>
<td>August, 2002</td>
</tr>
<tr>
<td>The Third notification</td>
<td>October, 2005</td>
</tr>
<tr>
<td>The fourth notification</td>
<td>January, 2016</td>
</tr>
</tbody>
</table>
The Govt of India has notified...

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of the device</th>
<th>SLA/CLAA</th>
<th>Date of notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Disposable Hypodermic Syringes</td>
<td>SLA</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>2</td>
<td>Disposable Hypodermic Needles</td>
<td>SLA</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>3</td>
<td>Disposable Perfusion Sets</td>
<td>SLA</td>
<td>17-03-1989</td>
</tr>
<tr>
<td>4</td>
<td>In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera</td>
<td>SLA</td>
<td>27-08-2002</td>
</tr>
<tr>
<td>5</td>
<td>Cardiac Stents</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>6</td>
<td>Drug Eluting Stents</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>7</td>
<td>Catheters</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>8</td>
<td>Intra Ocular Lenses</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>9</td>
<td>I.V. Cannulae</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>10</td>
<td>Bone Cements</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>11</td>
<td>Heart Valves</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>12</td>
<td>Scalp Vein Set</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>13</td>
<td>Orthopedic Implants</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>14</td>
<td>Internal Prosthetic Replacements</td>
<td>CLAA</td>
<td>06-10-2005</td>
</tr>
<tr>
<td>15</td>
<td>Ablation Devices</td>
<td>*CLAA</td>
<td>25-01-2016</td>
</tr>
</tbody>
</table>
In-Vitro Diagnostic Kits/reagents

• Notified Kits
  • Eg. HIV, HbsAg, HCV
  • Requires manufacturing License
  • For Import – Both Registration Certificate and import license.

• Non-Notified Kits
  • Eg. Testing kits for Malaria, TB, Cancer, etc.
  • Requires Manufacturing License
  • For Import- Only Import License
MD that are not notified, but regulated as Drug

- Condoms
- Intra Uterine Devices - Cupper T
- Vaginal Tubal Rings
- Blood bags
- Sutures and Ligatures
- Blood Grouping Sera
- Surgical Dressing
- Umbilical Tapes
Specific Rules and Schedules to MD & IVD

- Rule 109-A  Labeling of Medical Devices
- Rule 125-A  Standards for Medical Devices
- **Schedule M III**  GMP Requirements
- Schedule R  Standard for Mechanical Contraceptives
- Schedule R₁  Standards for Medical Devices
- Schedule DII Annexure B - IVD
Inadequacies of regulatory systems

- Devices regulated as “drugs”
- Many provisions of D&C Act and Rules not appropriate for devices
- Regulations not harmonized with international practices
- Absence of risk based classification
- Lack of standards for QMS, Clinical Investigation, performance evaluation
Initiatives taken

- Developed MD specific guidelines for import and manufacturing.
- Constituted Subject Expert Committees
- Imparted training to Drugs Inspectors of CDSCO and State Inspectors on MD
- FAQ are posted on CDSCO website
- New set of Rules are being finalized for medical devices under D&C Act.
- Introduced Materiovigilance program
- Regular interaction with Industry/ Associations
Proposed Regulatory framework for medical devices
Medical Device Bill, 2016 is being drafted

- Medical Devices (Regulation) Bill
- New Definitions for - Medical Device, Manufacture, Clinical Investigation, Substantial Equivalence, Predicate device
- Clinical Investigation Requirements
- Designated MD Testing Centers
- “Medical Device Officer” in place of “DI”
- Medical Devices Technical Advisory Board.
- Classification of Medical Devices based on risk
- Standards for Medical Devices
- Role of Notified Bodies and Penal Provisions
MEDICAL DEVICES

- Instruments
- Apparatus
- Implants
- Machines
- Appliances
- Software
- Materials
- Related articles

which doesn’t achieve its primary intended action in or on the human / animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices

{ disease / injury }
(ii) an accessory to such an instrument, apparatus, appliance, material or other article;
(iii) a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination intended to be used for examination and providing information for medical or diagnostic purposes by means of \textit{in vitro} examination of specimens derived from the human body or animals.
Salient features of proposed Regulation for India under Rules

1. Separate set of Rules for medical devices for Import, Manufacture, Clinical Investigation and Sale
2. Risk Based classification
3. Notification of additional medical devices
4. Authorities to regulate medical devices
5. Standards for medical devices
6. No renewal of licence
7. Essential Principles of Safety and Performance of Medical Devices
8. Registration & Regulation of Notified Bodies
9. Use of IT enabled services
## Classification in other countries

<table>
<thead>
<tr>
<th>Risk Criteria</th>
<th>India (Proposed)</th>
<th>USFDA</th>
<th>EU</th>
<th>Japan</th>
<th>Singapore</th>
<th>IMDRF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Class A</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Low-Moderate</td>
<td>Class B</td>
<td>II</td>
<td>IIa</td>
<td>II</td>
<td>B</td>
<td>B</td>
</tr>
<tr>
<td>Moderate-High</td>
<td>Class C</td>
<td>III</td>
<td>IIb</td>
<td>III</td>
<td>C</td>
<td>C</td>
</tr>
<tr>
<td>High</td>
<td>Class D</td>
<td>III</td>
<td>IV</td>
<td>D</td>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>
## Global Risk Criteria for Classification

<table>
<thead>
<tr>
<th>Category</th>
<th>Risk Involved</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class A</td>
<td>Low</td>
<td>Malfunctioning of which may cause negligible risk to the patient/user.</td>
</tr>
<tr>
<td>Class B</td>
<td>Low-Moderate</td>
<td>Malfunctioning of which may cause temporary injury to patients/user.</td>
</tr>
<tr>
<td>Class C</td>
<td>Moderate-High</td>
<td>Malfunctioning of which may cause permanent injury to patients/user.</td>
</tr>
<tr>
<td>Class D</td>
<td>High</td>
<td>Malfunctioning of which may cause permanent injury amounting to grievous hurt or death to patient/user.</td>
</tr>
</tbody>
</table>

Malfunctioning may lead to wrong diagnosis, injury/disability/death, under performance, which depends on the severity of harm caused by device.
## Proposed Classification

<table>
<thead>
<tr>
<th>Risk Criteria</th>
<th>India (Proposed)</th>
<th>IMDRF</th>
<th>Regulatory Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Class A</td>
<td>Class A</td>
<td>Notified Body*</td>
</tr>
<tr>
<td>Low-Moderate</td>
<td>Class B</td>
<td>Class B</td>
<td>Notified Body*</td>
</tr>
<tr>
<td>Moderate-High</td>
<td>Class C</td>
<td>Class C</td>
<td>CDSCO</td>
</tr>
<tr>
<td>High</td>
<td>Class D</td>
<td>Class D</td>
<td>CDSCO</td>
</tr>
</tbody>
</table>

* Electronic online system – Random Selection
Regulatory scrutiny increases with Risk

- Lower
  - Class A
    - QMS Compliance
    - Registration
    - Post Market

- Medium
  - Class B
    - Premarket Data

- Highest
  - Class C & D
    - Clinical Data
    - Premarket data
    - QMS Compliance Licence
    - Post Market
Low Risk sterile & non sterile
Controls for Class A devices

- Online application to CDSCO for registration of site and product
- Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.
- Compliance with QMS (Schedule M-III) to be verified by Notified Body within 30 days
- Non conformance- rectification by manufacturer
- Re-assessment by Notified Body
- Automatic registration of Manufacturing site/product by CDSCO where recommended by Notified body.
- Electronic generation of Registration Certificate
- Post market surveillance.
- Existing manufacturer to be registered within one year from date of enactment of these rules.
- Clinical Trial/investigation, Animal testing, and Biocompatibility data not required.
Low-Moderate Risk
Controls for Class B devices

- Online application to CDSCO for registration of site and product
- Automatic transmission to a randomly selected Notified Body in case of domestic manufacturer and in case of imports CDSCO to take a call about in-house or external assessment.
- Class B devices to comply with:
  - QMS
  - Data requirements at the time of electronic submission of application
  - Performance standards for functional conformance
  - Biocompatibility
  - Animal study (if any)
  - Device Master File including essential requirements
  - Labelling requirements
  - Post Marketing Surveillance
- No Clinical Trial/investigation data required
Medium Risk

Moderate High Risk

External Cardiac Pacemaker Dual Chamber (DDD)
High Risk

CLASS-D

Pacemaker leads
Right atrium
Right ventricle
Controls for Class C & D devices

- Online application to CDSCO for registration of site and product
- Class C & D devices to comply with:
  - QMS
  - Functional conformance
  - Biocompatibility
  - Animal study (if any)
  - Device Master File including essential requirements
  - Labelling requirements
  - Clinical investigation data
  - Post Marketing Surveillance
  - Sample of the device
  - Device having predicate device exempted from clinical investigation data.
## Requirements for approval of product

<table>
<thead>
<tr>
<th>Regulatory Compliance</th>
<th>Class A</th>
<th>Class B</th>
<th>Class C</th>
<th>Class D</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Electrical Safety/EMI/EMC testing data</td>
<td>*✓</td>
<td>*✓</td>
<td>*✓</td>
<td>*✓</td>
</tr>
<tr>
<td>Risk Analysis Report</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Device Master File</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biocompatibility data</td>
<td>**✓</td>
<td>**✓</td>
<td>**✓</td>
<td></td>
</tr>
<tr>
<td>Animal Testing</td>
<td>**✓</td>
<td>**✓</td>
<td></td>
<td>**✓</td>
</tr>
<tr>
<td>Clinical Data</td>
<td>***✓</td>
<td>***✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Only for Electrical supply based devices
**Only for invasive or implantable devices
***Only for Investigational devices
## Regulatory Authorities

<table>
<thead>
<tr>
<th>Scope of Regulation</th>
<th>Reviewer / Auditors</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Investigation and approval of investigational medical devices</td>
<td>Medical Device Officer (MDO)/ Drugs Inspector (DIs)/ External subject experts</td>
<td>CDSCO</td>
</tr>
<tr>
<td>Import</td>
<td>All Class</td>
<td>CDSCO issue licence/certificate</td>
</tr>
<tr>
<td>Class A&amp;B</td>
<td>MDO/ DI</td>
<td>CDSCO</td>
</tr>
<tr>
<td>Class C&amp;D</td>
<td>Notified Body</td>
<td>CDSCO</td>
</tr>
<tr>
<td>Sales</td>
<td>MDO/ DI (State officers)</td>
<td>State Licensing Authority</td>
</tr>
</tbody>
</table>
Notification of additional devices

- Devices to be notified along with its respective risk class by Central Government
- A committee of experts to be constituted to lay down criteria for classification and identification of devices to be notified
- International classification to be taken as the broad basis for classification
- CDSCO to place recommendations before DTAB with experts in relevant fields
- Phased notification of devices based on preparedness of regulatory structures
- Transition time to be provided
Removal of provisions for renewal of RC, Import, sale and manufacturing licence

- A registration certificate or import license shall remain valid, till it is suspended or cancelled from its date of issue
- Provided the applicant pays a certificate/licence retention fee on annual basis in the month of December.
- Provision for payment with late fee up to a maximum period of two months. After 2 months license will be deemed to have been cancelled.
- Manufacturer shall be audited on annual basis.
- Submission to CLA on changes in respect of site or significant changes in product, reportable complaints, recall etc.
Standards for medical devices

- QMS/ISO 13485
- Standards to be adopted for demonstrating compliance in respect of:
- Manufacturer to comply with:
- BIS standards, if available, or
- ISO/IEC standards, or
- Manufacturer’s validated methods
Essential Principles of Safety and Performance

- General Requirements (Risk assessment, qualification of personnel etc.)
- Design and Manufacturing Requirements (material selection, verification and validation etc.)
- Requirements for medical devices connected to or equipped with an energy source
- Requirements for devices with a diagnostic or measuring function
- Protection against radiation
- Protection against mechanical risks
- Protection against risks posed to the patient by devices for self-testing or self-administration
- Clinical Evaluation
Human Resources

• A separate vertical with dedicated staff for medical devices
• Medical Device officers (MDO) in place of Drugs Inspectors
• Qualification of MDO
   Biomedical Engineers
   Electrical & Electronic Engineers
   Plastics Engineers
   Mechanical Engineers
   Pharmacy
• External Subject Experts
• Contractual technical staff
• Training
• Accredited Notified Bodies (Class A & Class B)
• State Drugs Regulators (for sales)
Scope of Notified Bodies

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- Conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license/registration
- CDSCO to audit notified bodies and test audit 5% of the licenses/registrations issued on the recommendation of each Notified Body
Registration & Regulation of Notified Bodies

- Only NABCB accredited Notified bodies to be registered with CDSCO
- Weightage to be given to accreditation by International bodies, but accreditation by NABCB will be mandatory
- ISO standards to be laid down in schedules to apply for accreditation/recognition
- System of Audit/inspection/unannounced Audits of Notified Bodies by CDSCO
- Schedule of fee to be charged by notified bodies to be prepared with provision for automatic upward revision based on WPI
- Refundable security deposit and revenue sharing model
- Duties, functions and obligations of notified bodies including penal provisions to be specified
IT Enabled Services

- Online submission, review and approval of applications
- E-learning programme
- Separate Online interface for Notified Bodies under CDSCO portal.
- Access to applicant, CDSCO and Notified Body through a single web based user interface
- Development of a centralized live database of registered establishments and devices
- Provisions of e-archival web based system for internal and public data
Capacity Building

- Manpower
  - Medical Device Officers
  - Technical Experts
- New Medical Devices Testing Centres
- Use of IT enable services
- Materiovigillance program
- New regulations
- Standard setting organisations
- Registration of Notified bodies
Thank you