MEDICAL DEVICES
REGULATORY FRAME WROK

CURRENT REGULATORY STATUS

- “Medical Devices” regulated as “Drugs” under sub clause (iv) of section 3(b) of D&C Act, 1940
- 15 categories of Medical Devices notified as Drugs
- Regulations for Import, Manufacturing, Sales and Clinical Trials
- 8 Devices regulated as “substances” under sub clause (ii) of section 3(b) of D&C Act, 1940

15 NOTIFIED MEDICAL DEVICES

S.No	Name of the device	Notification Date
1	Disposable Hypodermic Syringes	17-03-1989
2	Disposable Hypodermic Needles	17-03-1989
3	Disposable Perfusion Sets	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV	01-09-2002
5	Cardiac Stents	06-10-2005
6	Drug Eluting Stents	06-10-2005
7	Catheters	06-10-2005
8	Intra Ocular Lenses	06-10-2005
9	I.V. Cannulae	06-10-2005
10	Bone Cements	06-10-2005
11	Heart Valves	06-10-2005
12	Scalp Vein Set	06-10-2005
13	Orthopedic Implants	06-10-2005
14	Internal Prosthetic Replacements	06-10-2005
15	Ablation Devices	25-01-2016

8 DEVICES REGULATED AS SUBSTANCES

S.No	Name of the device
1	Blood Grouping Sera
2	Ligatures, Sutures and Staplers
3	Intra Uterine Devices (Cu-T)
4	Tubal Rings
5	Surgical Dressings
6	Umbilical Tapes
7	Blood / Blood Component Bags
8	Condoms

SALIENT FEATURES OF PROPOSED REGULATION FOR INDIA

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

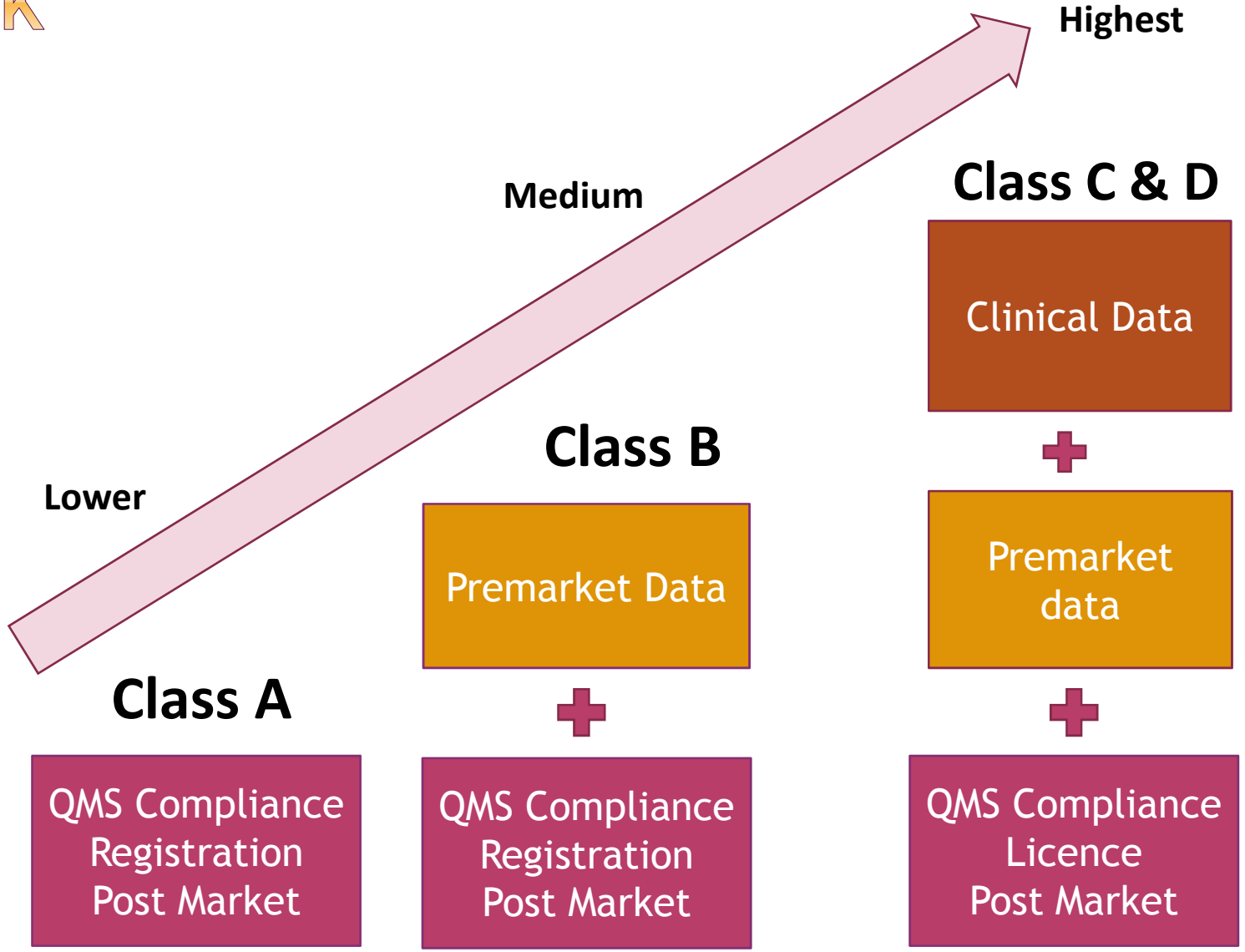
CLASSIFICATION IN OTHER COUNTRIES

Risk Criteria	India (Proposed)	USFDA	EU	Japan	Singapore	IMDRF
Low	Class A	I	I	I	A	A
Low-Moderate	Class B	II	IIa	II	B	B
Moderate-High	Class C	III	IIb	III	C	C
High	Class D		III	IV	D	D

PROPOSED CLASSIFICATION

Risk Criteria	India (Proposed)	IMDRF	Regulatory Authority
Low	Class A	Class A	Notified Body*
Low-Moderate	Class B	Class B	Notified Body*
Moderate-High	Class C	Class C	CDSCO
High	Class D	Class D	CDSCO
* Electronic online system – Random Selection			

REGULATORY SCRUTINY INCREASES WITH RISK



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.**

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**

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

Regulatory Compliance	Class A	Class B	Class C	Class D
QMS	✓	✓	✓	✓
Electrical Safety/EMI/EMC testing data	*✓	*✓	*✓	*✓
Risk Analysis Report	✓	✓	✓	✓
Device Master File		✓	✓	✓
Biocompatibility data		**✓	**✓	**✓
Animal Testing			**✓	**✓
Clinical Data			***✓	***✓

* Only for Electrical supply based devices
**Only for invasive or implantable devices
***Only for Investigational devices

REGULATIONS FOR IMPORT

- In case of products approved by any one of the GHTF countries, FSC/CFG from GHTF countries is to be insisted upon. [Class A, B,C, D]
- In case of others the Certifying Bodies should be accredited by International accreditation forum or by NABCB with FSC.
- Others in accordance with the system to be put in place by CDSCO.

REGULATORY AUTHORITIES

Scope of Regulation		Reviewer / Auditors	Regulatory Body
Clinical Investigation and approval of investigational medical devices		Medical Device Officer (MDO)/ Drugs Inspector (DIs)/ External subject experts	CDSCO
Import	All Class	MDO/ DI	CDSCO issue licence/ certificate
Manufacture	Class A&B	Notified Body	CDSCO
	Class C&D	MDO/ DI	
Sales		MDO/ DI (State officers)	State Licensing Authority

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 licence 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 upto a maximum period of two months. After 2 months licence 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:
  1. Raw Material 2. Process 3. Product
  4. Labelling
- 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 Drug 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

WORLD CLASS REGULATORY FRAME WORK- A COMMITMENT

- Leverage:
  - Japanese Technology
  - Indian demographic dividend, enterprise, scale and cost competitiveness
  - Indo Japanese qualities head and heart
  - Knowledge from across the world
- Build a hub for meeting world requirements of quality medical devices at affordable cost

THE JOURNEY

- Draft Rules prepared/discussed with stake holders
- Final round on 24th May 2016
- Placing in Public domain
- DTAB consultation
- Expert committee for finalising classification and inclusion of devices

REACHING DESTINATION

- Survey undertaken
- Stake holders to suggest:
  - What it requires to do business with ease and integrity
  - Ensuring quality, safety, performance and affordability
- Jointly build the highway
- Government to concretise the highway
- Zoom on the highway at the speed you choose


Thank you

Keynote Speech II

Latest trend of medical device regulations in Japan

1st India-Japan Medical Products Regulation Symposium

19th May 2016

Toshiyoshi Tominaga, Ph.D.
Associate Executive Director for International Programs,
Pharmaceuticals and Medical Devices Agency (PMDA)

JAPAN

Overview of Medical Device Regulations in Japan

History of medical device regulations in Japan – recent big amendments (1/2)

Medical Device has been regulated since 1948 in Japan. Regulations under current Act started in 1960 and there have been 2 big amendments for the regulations recently;

1. Amendment in 2005
   - ① Introduction of Marketing Authorization Holder system
   - ② Introduction of Third Party Certification system
   - ③ Introduction of medical device classification based on the GHTF Classification Rule
   - ④ Introduction of STED and Essential Principles
   - ⑤ Introduction of GCP as a ministerial ordinance
   - ⑥ Introduction of QMS, instead of GMP

History of medical device regulations in Japan – recent big amendments (2/2)

Medical Device has been regulated since 1948 in Japan. Regulations under current Act started in 1960 and there have been 2 big amendments for the regulations recently;

2. Amendment in 2014
   - ① Amendment of Third Party Certification system, including expansion of scope
   - ② Improvement of regulations on manufacturer
   - ③ Improvement of QMS inspection
   - ④ Application of medical device regulations on SaMD (Software as a Medical Device)
   - ⑤ Establishment of a new category, Regenerative Medicine Product

Medical Device Regulations

EU	Japan	US
Pre-market review		
Notified body certification (requirements depend on device classification)	Class III, IV: Minister's approval Class II and a few Class III: Third Party Certification by Registered Certification Body Class I: Marketing Notification	Class III: PMA Approval Class II: 510(k) clearance, Class I: Listing

Governmental approval/license | Notified body review/certification | Self declaration/exemption

Legal structure for medical device/IVD regulations

Act	Pharmaceutical and Medical Device Act (PMD Act), 1960
Cabinet Ordinance	Cabinet Ordinance on PMD Act, 1961
Ministerial Ordinance	Ministerial Ordinance on PMD Act, 1961 GCP for medical device, 2005 Good Vigilance Practice (GVP) Quality Management System (QMS) etc.
Ministerial Notification	Essential Principles Certification standards for class II/III devices Classification of medical devices List of orphan designation etc.
Notification	Information on application procedures Guidelines for clinical evaluation etc.

Scope of regulations on medical device/IVD marketing in Japan under PMD Act

Product

Minister's Approval for marketing or,
Certification by a Registered Certification Body or,
Marketing Notification

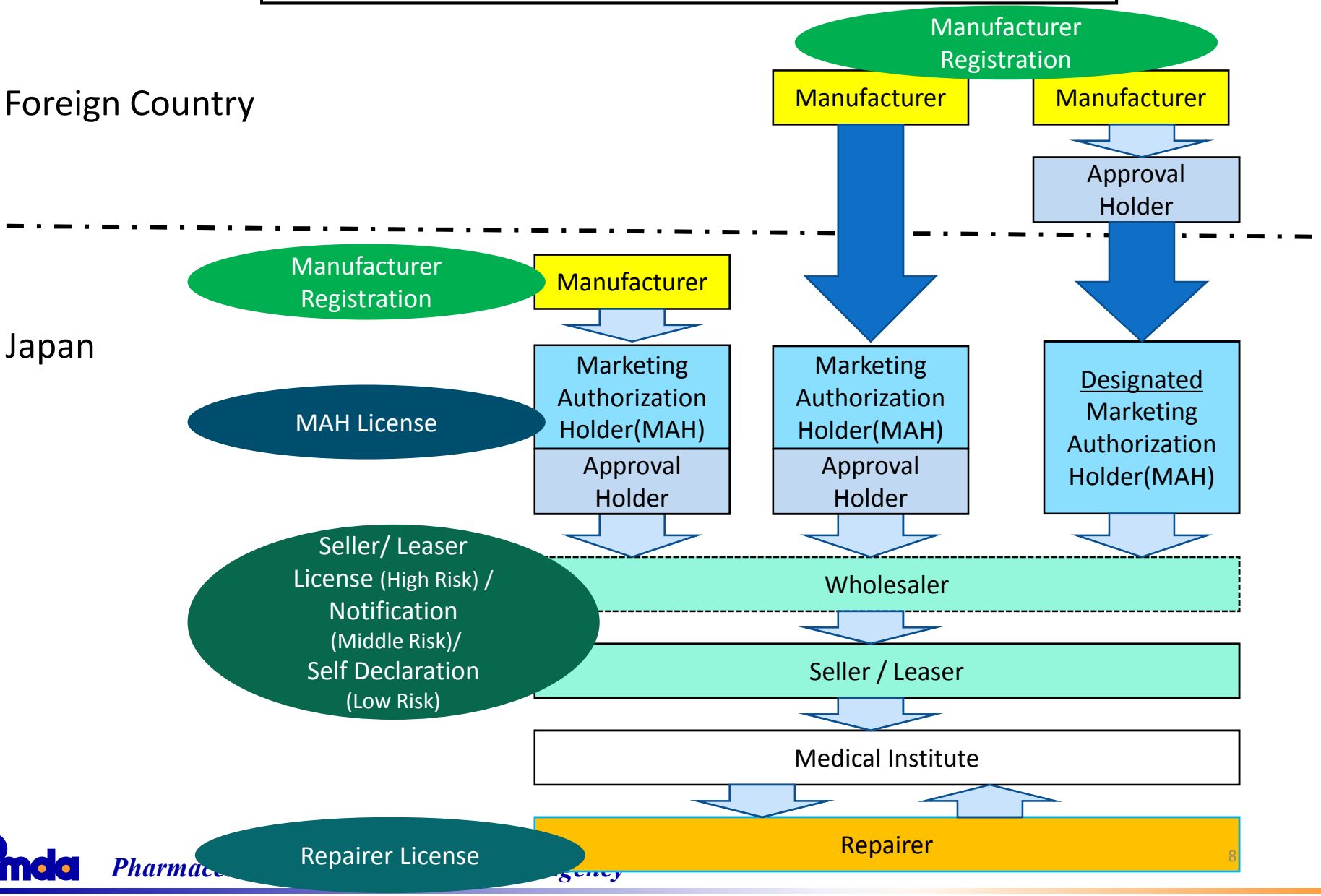
Company

License of Marketing Authorization Holder (MAH)

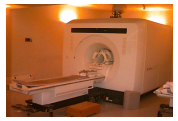
Plant

Registration as a Manufacturer

Supply Chain Regulations in Japan

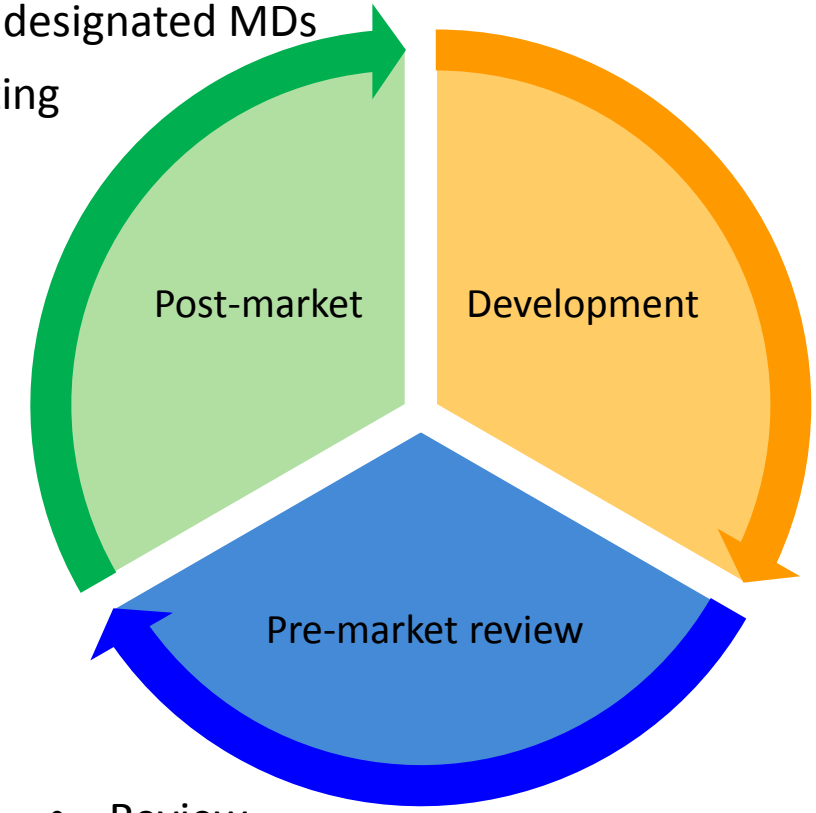


Device classification

<table>
<tr><th colspan="2" rowspan="2">GHTF Classification</th><th colspan="3">PAD Act classification</th></tr>
<tr><th>Category</th><th>Regulatory requirements</th><th>Japanese MD Nomenclature</th></tr>
<tr><td>Class A
  </td><td>Extremely low risk
e.g., X-ray film</td><td>General MDs (Class I)</td><td>Self declaration
Approval of the product is not required, but marketing notification is necessary.</td><td>1,195</td></tr>
<tr><td>Class B
  </td><td>Low risk
e.g., MRI, digestive catheters</td><td>Controlled MDs (class II)</td><td>Third party Certification
Certification by a registered certification body is required.
・Certification standard
Certification (Review by CB) | Minister’s Approval (Review by PMDA)</td><td>1,972 (1,519 for 3rd Party)</td></tr>
<tr><td>Class C
  </td><td>Medium risk
e.g., dialyzer</td><td rowspan="2">Specially Controlled MDs (class III & IV)</td><td rowspan="2">The Minister's approval for the product is required.
・Approval standard
・Review guideline</td><td>771</td></tr>
<tr><td>Class D
  </td><td>High risk
e.g., pacemaker</td><td>350</td></tr>
</table>

Overview of Medical Device Regulations in Japan

- Use result survey for designated MDs
- Adverse Event reporting
- QMS inspection



- Clinical Trial Notification
- Registration of manufacturing site
- Consultations

- Review
- QMS inspection
- Data integrity inspection
  - GCP inspection on clinical trial data
  - Integrity inspection on non-clinical safety data

Number of approvals of Medical Devices

		FY2010	FY2011	FY2012	FY2013	FY2014
Medical devices (total)		1,634	1,227	1535	1,347	1,235
Priority review items (included in total)		3	6	5	14	5
Breakdown	Band-new MDs	18	33	46	94	67
	Others (e.g. Improved MDs w/wo clinical data, Me-too MDs)	1,616	1,194	1,489	1,253	1,168

Number of certifications by registered certification bodies

Certification (including partial change certification)	2,298	2,369	2,350	2,417	2,276

Acceptance of Foreign Clinical Data

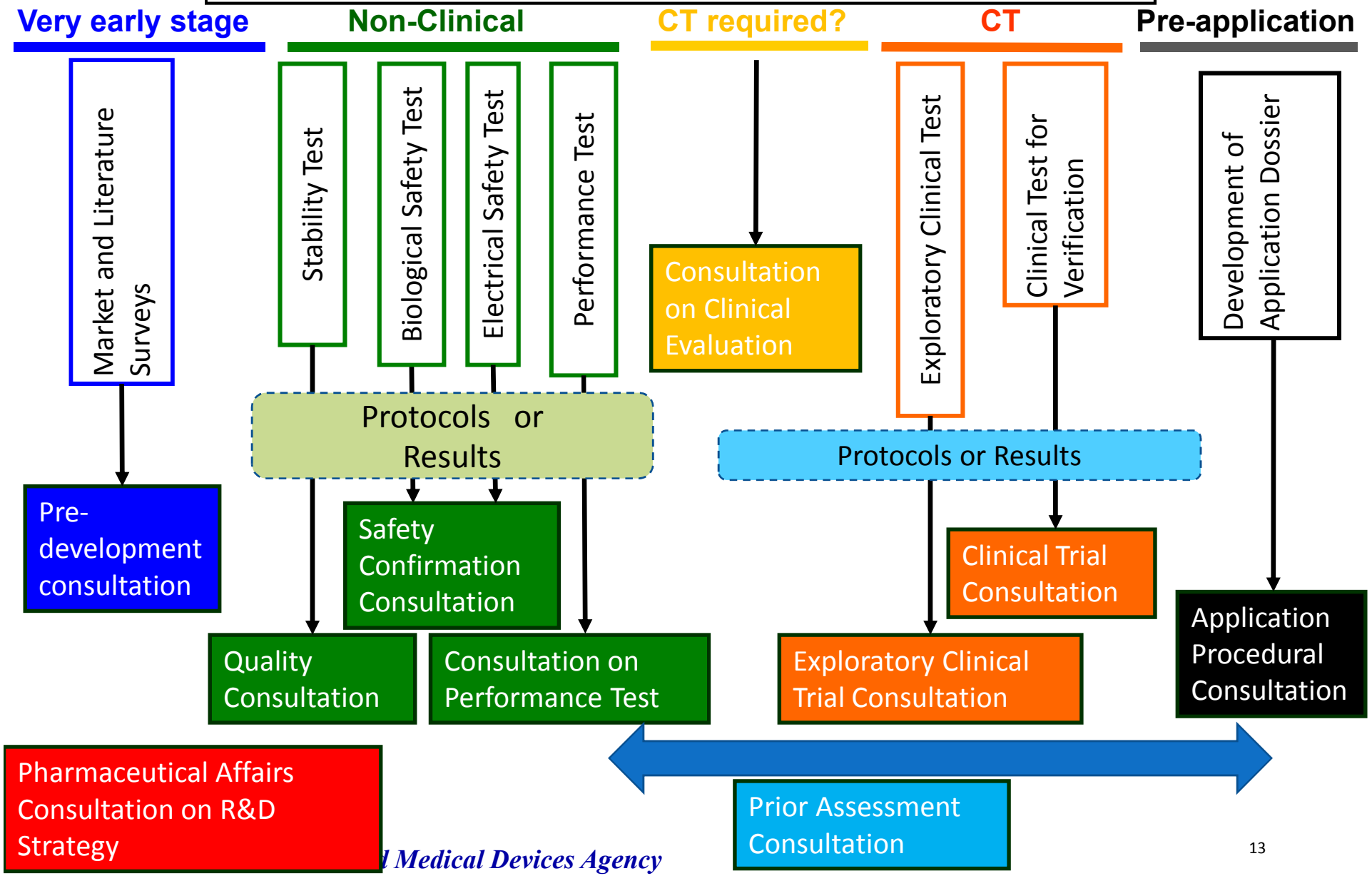
MHLW/PMDA have been accepting foreign clinical data for years if it is good enough to evaluate a device's clinical safety and efficacy on Japanese population under Japanese medical practice/environment.

Number of devices approved after review with clinical data

	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014
Foreign clinical data only	32	29	38	23	34	28
Both foreign and Japanese clinical data	6	2	5	3	8	2
Japanese Clinical data only	14	19	14	23	24	11

(Source: PMDA Annual Report FY2014)

PMDA's Consultation Menu

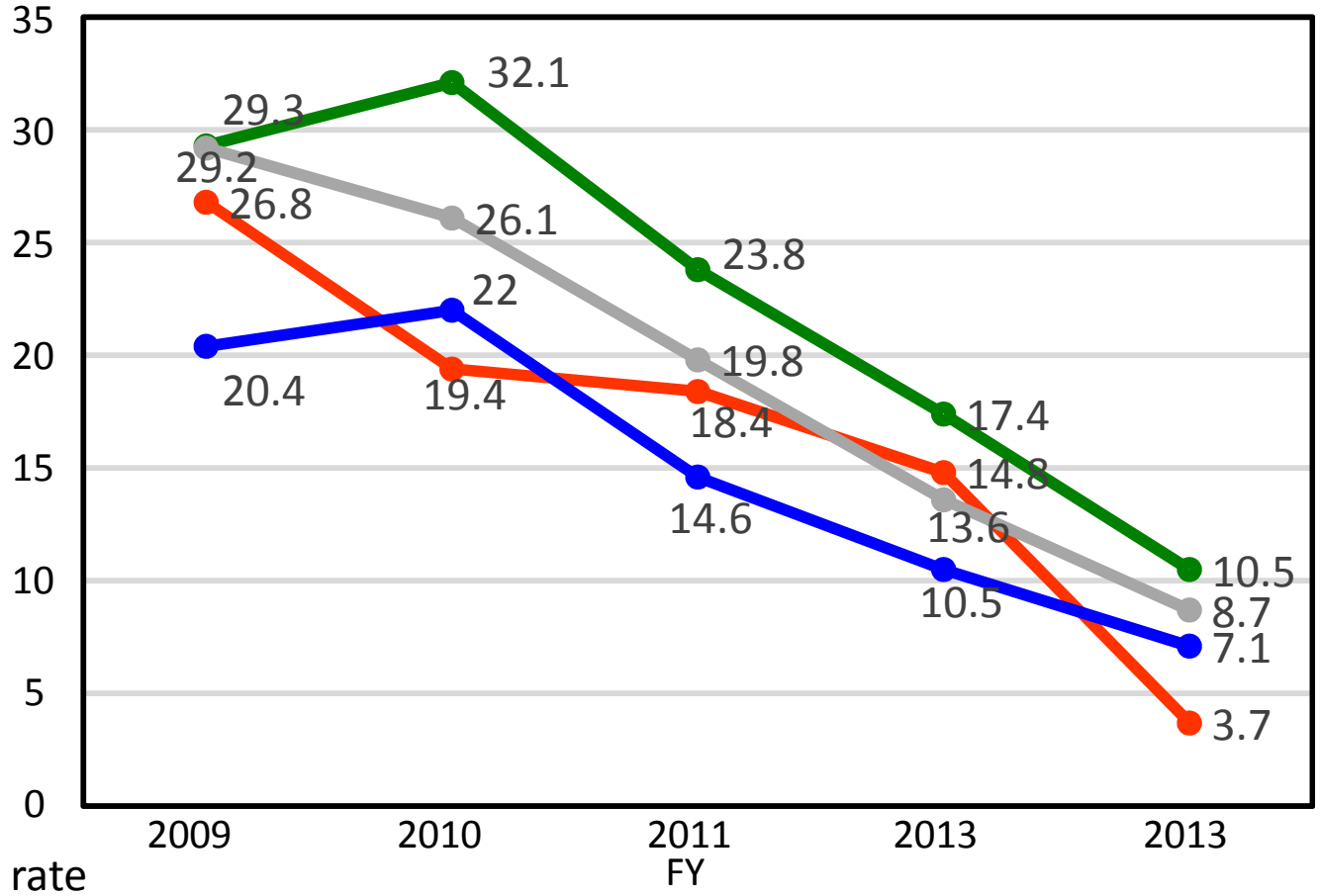


Collaboration among Stakeholders

Shortening of medical device review period - Collaboration with Industry -

- Action Program for Acceleration of Medical Device Reviews (FY2009～FY2013)
- Collaboration Plan for Acceleration of Medical Device Review（FY2014～FY2018）

90% Tile Review Times for Medical Devices
(Total time in submission cohort)



Completion rate

Category	FY	2009	2010	2011	2012	2013
New		100%	92.0%	95.2%	96.3%	46.9%
Improved (w clinical data)		100%	96.1%	96.0%	100%	75.0%
Improved (w/o clinical data)		100%	95.7%	94.2%	88.9%	44.8%
Generic (me-too)		98.4%	96.2%	97.2%	95.6%	63.9%

Collaboration Plan for Acceleration of Medical Device Review（FY2014～FY2018）

New Performance Goal towards FY2018*

(Total Time)

- New Medical Device
  - Standard items: 12 months
  - Priority items: 9 months
- Improved Medical Device
  - With clinical data: 9 months
  - Without clinical data: 7 months
- Generic Medical Device
  - New application: 5 months
  - Partial change application: 4 months

* In order to set higher target, 80 percentile figures are adopted instead of median

IMDRF International Medical Device Regulators Forum

Management Committee member

Founding member of GHTF

Brazil Russia China

Official Observer

World Health Organization

APEC LSIF RHSC

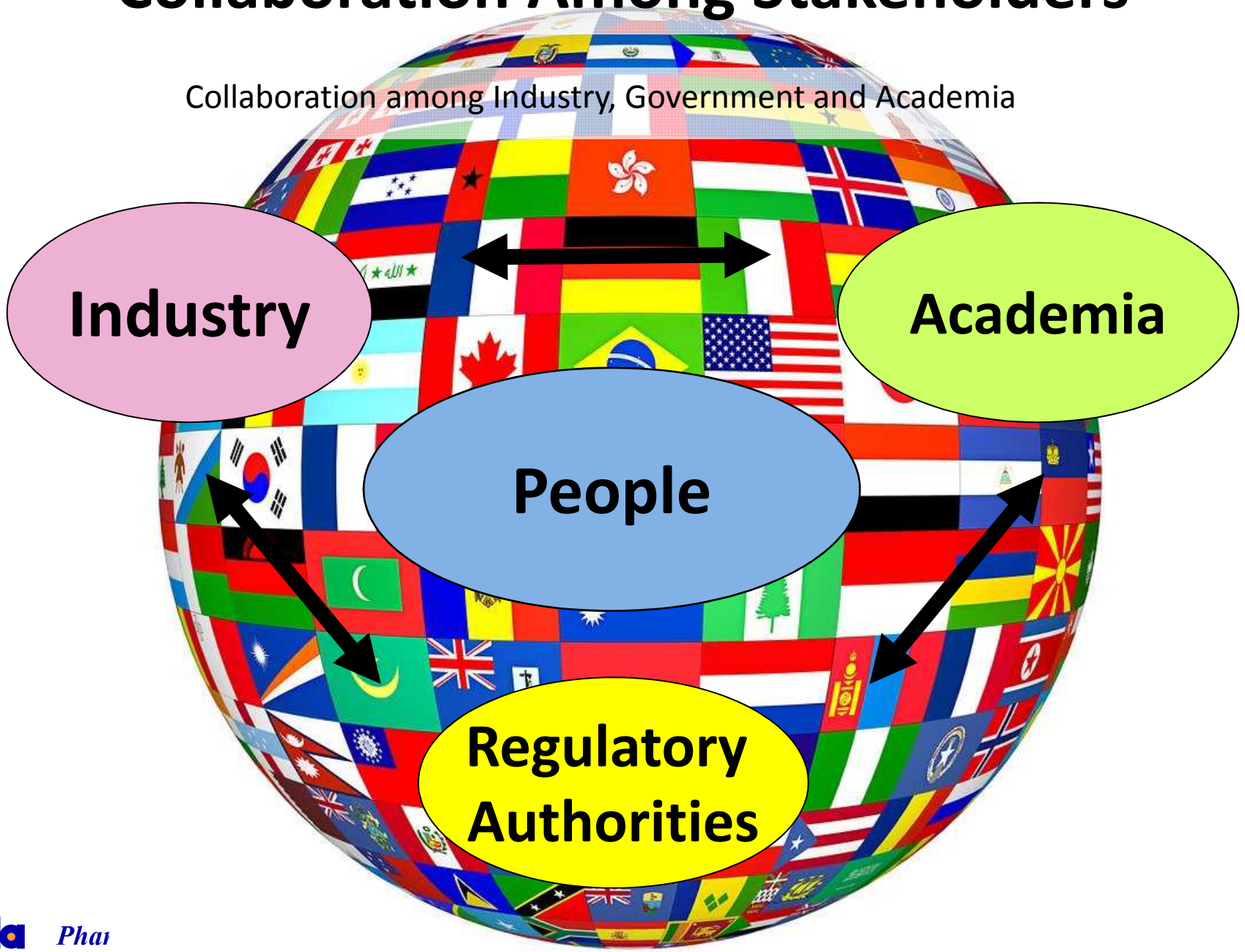
Affiliate Organization

AHWP Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Pan American Health Organization

Collaboration Among Stakeholders

Collaboration among Industry, Government and Academia



Thank you for your attention

Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
http://www.pmda.go.jp/
http://www.pmda.go.jp/english/index.html

1st India – Japan Medical Products Regulation Symposium

Probir Das
Chair – FICCI Medical Devices Forum

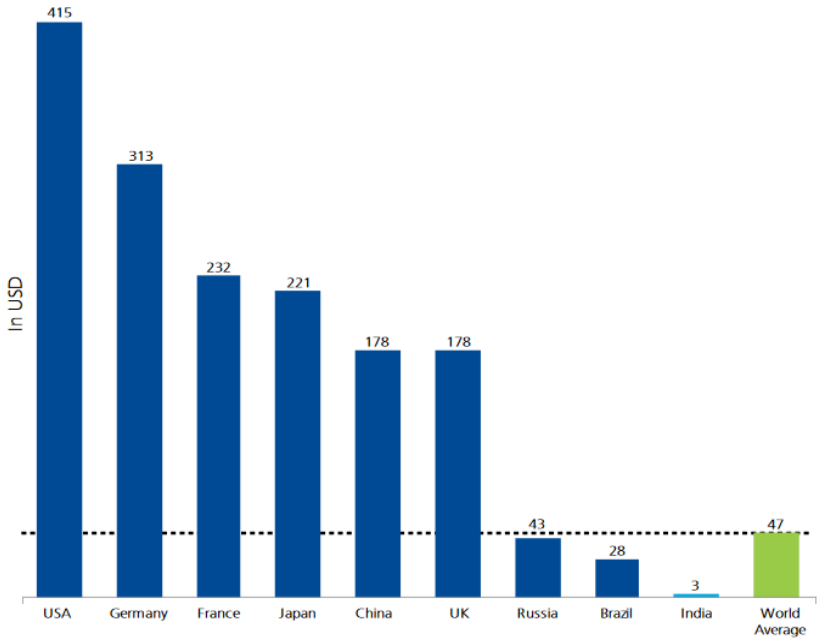
Natural allies

© Vilas Nayak & Terumo India Pvt. Ltd.

- Our histories and cultures are intricately linked
- 4th largest FDI contributor to India;
  May 2015 agreement to double investment in 5 yr
- Ministry of Commerce (DIPP) ‘Japan Plus’ fast track
- Regulator to Regulator collaboration – great step forward

FICCI

Need for collaboration



© Deloitte & NATHEALTH – Making In India Report

- Japanese Med Tech $30B & Pharma $97B
- 3rd Biggest medical device market
- GHTF founding nation; highly respected Regulators
- Cardiac, cancer, pain, regenerative med, self care … best in world solutions
- Reasonably flat domestic market; interests high in hyper growth Indian healthcare

Young relationship, but scaling up

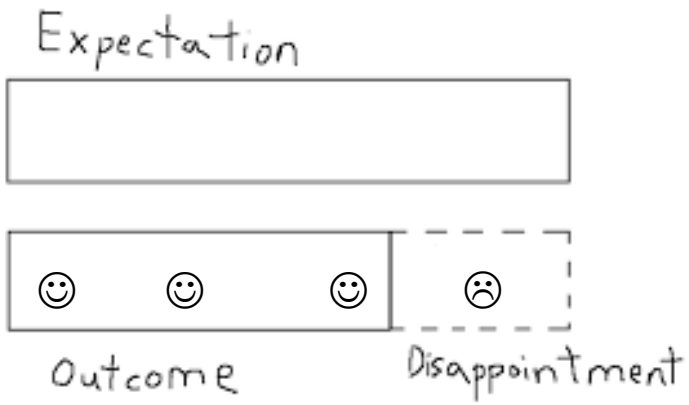
- Started in 2014 !!!
- Several G2G missions and interactions
- July 2015 onwards PMDA approval accepted independently
- Feb 2016 – Indian Regulator @ PMDA training
- In 2 years we have come a long way …
  But a long march ahead.

FICCI

Industry commitment

- Support to the various engagement platforms
- Skill building partnerships
- “Make in India” commitment
- Beyond Regulatory / QMS …
  Clinical best practices collaborations

Some requests



- Completely distinct treatment from Pharma
- Stitched “one policy” towards industrial interest to drive ‘Make In India’
- Increase healthcare spend & combine with global fiscal competitiveness
- Regulatory streamlining
  - ❖ Logical timelines post new Act
  - ❖ e-Sugam roll out should not delay pending registrations
  - ❖ ‘Fast track’ provision