International Regulatory Cooperations

TAKANASHI, Fumihito

Medical Device Evaluation Division,

Ministry of Health Labour and Welfare, Japan

厚生労働省
Ministry of Health, Labour and Welfare

Environment Surrounding Medical Device Regulations

- Development of products, globalization of market

Regulations in each country

Different definition, categorization in each country

Overlap

Different requirements in each country
quality
non-clinical
clinical etc.

Promoting harmonization of international regulations

- multilateral correspondence
  creating common standards
- bilateral correspondence
  collaboration based on development of relationship

- Divergence and complication of international standard and company development requirement

International standard ISO etc.

sophisticated

Company globalization

- lack of regulatory authorities resource
  Situations where it's difficult to handle everything in one country

WHO

WHA 67.20 Regulatory system strengthening (2014)
~ Call for regulatory cooperation to strengthen NRAs ~

SIXTY-SEVENTH WORLD HEALTH ASSEMBLY **WHA67.20**

Agenda item 15.6 **24 May 2014**

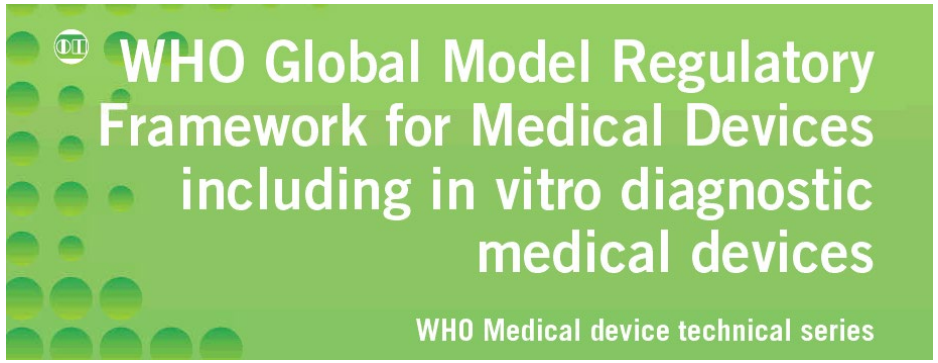
Regulatory system strengthening for medical products

Following measures by WHO to promote "***Reliance***":

- Global Benchmarking Tool (GBT)
- WHO Listed Authorities (WLA)
- Collaborative Registration Procedures (CRP)
- Support for harmonization networks

WHO

WHO Global Model Regulatory Framework for MDs including IVDs (2017)



Global atlas of medical devices (2017)

International Regulators Forum - IMDRF

GHTF: 1992-, IMDRF: 2011-

IMDRF International Medical Device Regulators Forum

Management Committee: MC

Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, the United States

Official Observer

WHO

Regional Harmonization Initiatives

APEC LSIF RHSC

AHWP

PAHO

Stakeholders

Industries, Academia, etc.

WG Chair: Japan

- Working Group: AE Terminology
- WG: GRRP
- WG: Standard
- WG: RPS
- WG: Personalized MD
- WG: Cyber-Security
- WG: Clinical Evaluation
- WG: IVD

US/Japan Regulatory Collaboration

FDA

Search

IN THIS SECTION: CDRH International Programs

← CDRH International Programs

US/Japan Regulatory Collaboration

Share | Tweet | Linkedin | Email | Print

Through the U.S. - Japan Medical Device Harmonization by Doing (HBD), the FDA, Japanese regulators, academia, and industry developed internationally agreed upon standards for global clinical trials related to cardiovascular devices, and addressed regulatory barriers that may delay timely medical device approvals in both countries.

The U.S. and Japan are also committed partners in the International Medical Device Regulators Forum, which is a group that works together to accelerate international medical device regulatory harmonization and convergence.

HBD East 2019 Think Tank Meeting will be held in Tokyo on December 11, 2019.
http://www.pmda.go.jp/english/int-activities/int-harmony/0004.html

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

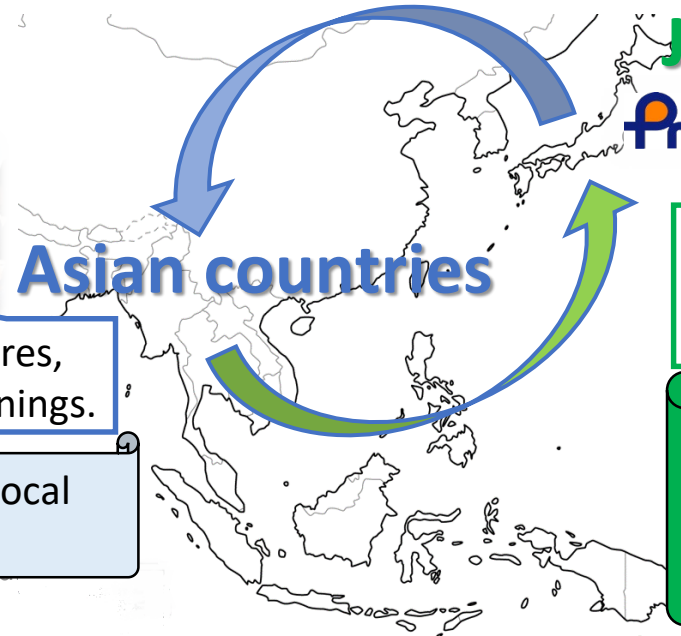
- PMDA-ATC was established (April 2016). PMDA-ATC has also been approved as Centers of Excellence (CoE).
- Promote capacity building and human resource development through training seminars for Asian regulators.

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

Visits sites and conducts lectures, case studies and practical trainings.

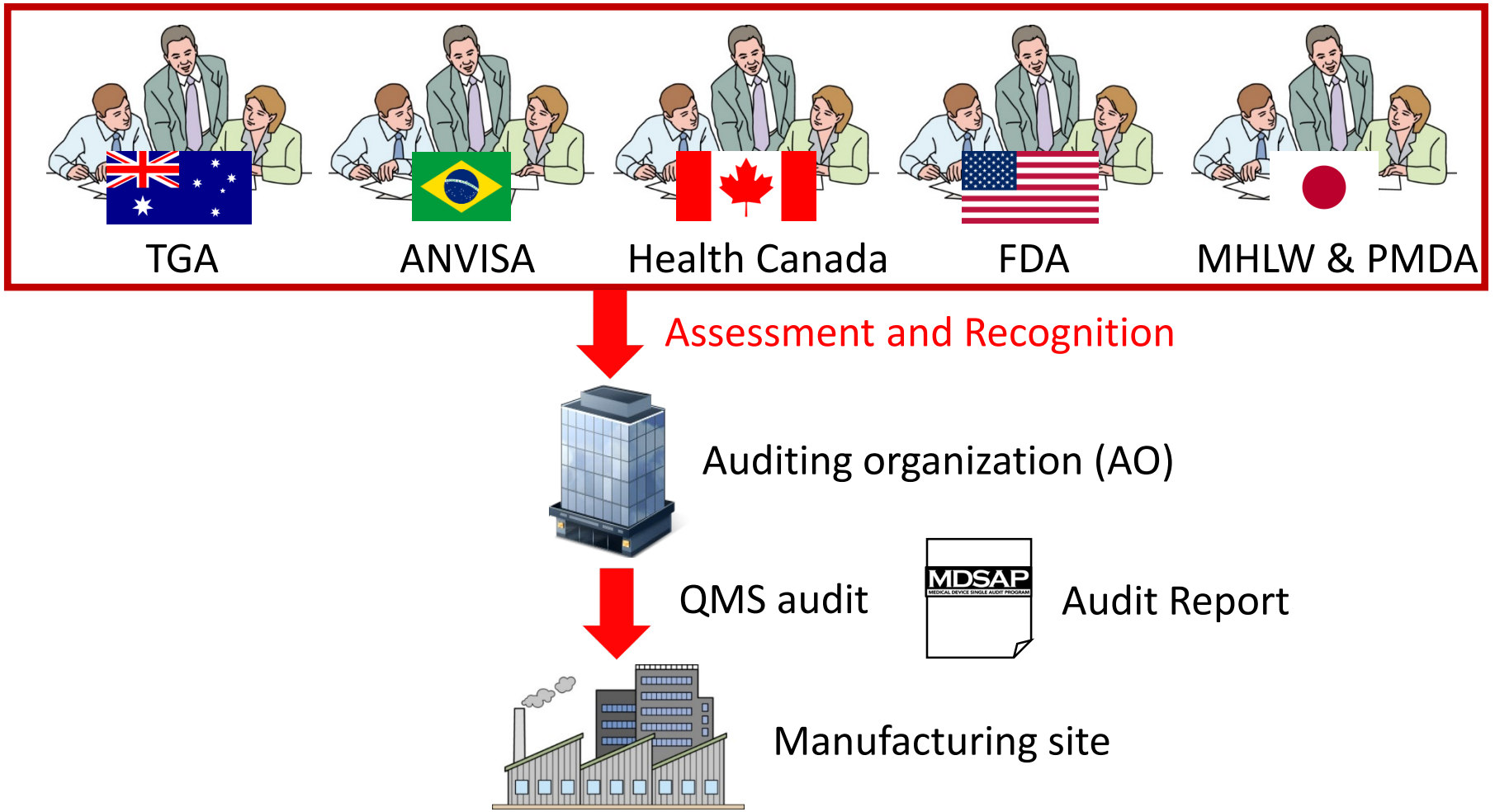
Provides trainings tailored to local needs for more people.



Invites Asian regulatory representatives and offers training seminars.

Shares Japanese knowledge and experiences in the regulation of pharmaceuticals and medical devices with Asian countries.

Medical Device Single Audit Program



New MDSAP Membership Category: Affiliate Membership

- Regulatory requirements of the Affiliate Member are not included in the audit model
- Audit reports will need to be obtained from medical device manufacturer by request
- Benefits:
  - Training on MDSAP
  - Ability to utilize MDSAP reports in jurisdiction
  - Receive a routine list of MDSAP audits conducted, dates, location, and auditing organization
  - Listed on MDSAP website as an Affiliate Member
  - Participate in yearly MDSAP Forum meetings

Affiliate Membership Criteria

- Membership for Regulatory Authorities
- Criteria includes:
  - Laws and regulations in place for evaluating a medical device manufacturer's QMS based on GHTF and IMDRF foundations and principles
  - Other laws and regulations that build on GHTF and IMDRF foundations and principles (ex: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance)
  - Completion of MDSAP on-line training modules
  - Objectives for becoming an Affiliate Member
  - Contributions to MDSAP
  - Implementation of MDSAP documents

- MDSAP Affiliate Membership Document https://www.fda.gov/media/127697/download

Summary

1. International regulatory cooperation, including through *reliance*, is recommended by WHO for Regulatory system strengthening.
2. There are multiple channels of regulatory cooperation. Multi-faced approach is required.
   - *MDSAP Affiliate Membership* is specially featured.
3. MHLW&PMDA, Japan is expecting further collaborations with all the AHWP participating regulatory authorities.

厚生労働省
Ministry of Health, Labour and Welfare