Strategies for regulatory convergence including Asian region in Japan

Mari Shirotani, Ph.D.
Division Director
Pharmaceuticals and Medical Devices Agency (PMDA)
Today’s topics

1. International Collaboration
2. Bilateral cooperation
3. PMDA activities in Asia
Globalization of development and marketing of products

- Regulation control of each country
- Different requirement of each country
- Different definition and classification of each country

Deviation and complication between International standards and entrepreneurial development requirements

- International standards, ISO etc.
- Globalization of development and companies
- Complication

Difficulties for resource distribution of regulatory agencies

The situation in which one country cannot address with all issues

Promotion of global harmonization for regulation

- Multilateral correspondence
  Preparation of common standards
- Bilateral correspondence
  Cooperation based on reliability maturity
Management Committee member

IMDRF International Medical Device Regulators Forum

Founding member of GHTF
- Brazil
- Russia
- China
- South Korea
- Singapore

Official Observer:
WHO

Affiliate Organization:
PAHO
APEC AHC LSIF
AHWP
IMDRF Chair

2012 – Australia, TGA
2013 – European Union, European Commission
2014 – USA, Food and Drug Administration
2015 – Japan, MHLW/PMDA
2016 – Brazil, ANVISA
2017 – Canada, Health Canada
2018 – China, NMPA (Previously CFDA)
2019 – Russia, Roszdravnadzor
IMDRF Work Items

1. Medical Device Single Audit Program (MDSAP)
2. Software as a Medical Device (SaMD)
4. Patient Registries
5. Unique Device Identification (UDI) system
6. Regulated Product Submission (RPS)
7. Adverse Event Terminology and Coding (AE)
8. Good Regulatory Review Practice (GRRP)
9. Improving the quality of international medical device standards for regulatory use (Standards)
10. Personalized Medical Device (PMD)
11. Clinical Evaluation
To promote a globally harmonized approach to the application of a UDI system, supporting the principles laid down in the general IMDRF UDI Guidance Document (IMDRF/WG/N7Final:2013).

- IMDRF/UDI WG/N7: 2013 “UDI Guidance - Unique Device Identification (UDI) of Medical Devices”
- IMDRF/UDI WG(PD1)/N48 “Unique Device Identification system (UDI system) Application Guide”
- IMDRF/UDI WG(PD1)/N53 “Use of UDI Data Elements across different IMDRF Jurisdictions”
- IMDRF/UDI WG(PD1)/N54 “Recording Unique Device Identifiers in Electronic Health Sources”

under public consultation till October 12
Adverse Event Terminology and Coding (AE)

IMDRF/AE WG/N43 (Edition3)RI “IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes”

* Annexes E,F are currently under public consultation till October 12
To develop guidance that establishes good regulatory review practices for Regulatory Authorities and/or their Conformity Assessment Bodies and to promote global harmonization in the premarket review processes.

- **IMDRF/GRRP WG/N40: 2017** “Competence, Training, and Conduct Requirements for Regulatory Reviewers”
- **IMDRF/GRRP WG (PD)/N47** “**Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices**”  *to be published soon*
- **IMDRF/GRRP WG(PD1)/N52** “**Principles of Labeling for Medical Devices and IVD Medical Devices**”  *currently under public consultation till September 12*
Improving the quality of international medical device standards for regulatory use

To identify and explore possibilities to improve the process of developing international standards used for regulatory purpose in the medical technology domain.

- IMDRF/Standard WG(PD)/N51 “Optimizing Standards for Regulatory Use”
  *to be published soon*

- Implementation of the N51 document and collaboration with ISO/IEC
- Update the list of international standards recognized by IMDRF members
To develop guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients.

**IMDRF/PMD WG (PD)/N49 “Definitions for Personalized Medical Devices”**

*to be published soon

3 categories of personalized medical device
Regulated Product Submission (RPS)

To establish standards that supports the electronic transmission of regulatory submissions

- Table of Contents (ToC)
- Common Data Elements (CDE)
- Beta Testing (HL7)

**ToC Pilot**
- Pilot ended December 2017.
- Applications that have been received and reviewed to-date by region:
  - Australia: 1
  - Brazil: 7
  - Canada: 2
  - China: 4
  - EU: 1
  - USA: 2
Revision of GHTF SG5 documents focusing on:

1. The Essential Requirements of Demonstrating Equivalence between the Device under Application and the Comparable Device for Clinical Evaluation.

2. The Decision-Making Principals for whether a Medical Device Clinical Trial should be Carried Out.

3. Guidelines for the Acceptance of Overseas Medical Device Clinical Trial Data
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Cooperative Arrangement has been signed between the Interchange Association of Japan and East Asia Relations of Taiwan.
## FY 2017 Completed symposium

(As of August, 2018)

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<tr>
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<th>Country</th>
<th>Contents (Location)</th>
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<tr>
<td>Feb.</td>
<td>Thailand</td>
<td>The 4th Joint Symposium (Bangkok)</td>
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<td>Apr.</td>
<td>India</td>
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<td>May.</td>
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<td>Taiwan</td>
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## FY 2018 Planned symposium

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<td>Jul.</td>
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<td>The 6rd Joint Symposium (Tokyo)</td>
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<td>Brazil</td>
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PMDA Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (ATC)

(1) Help raise the level of regulations in Asia as a whole
(2) Training seminar at PMDA, local prefectures in Japan and Asian with manufacturing site visits
(3) APEC Center of Excellence (COE) for Training (Multi-Regional Clinical Trials and Pharmacovigilance)
International Reputation of Asia Training Center

► Attendance (FY 2017)
  ✓ Nine training seminars and 235 attendees from 27 countries/regions
  ✓ More than 70% of attendees rated as “Very good” according to the questionnaire

 ► Official certificate of APEC LSIF RHSC Training Centers of Excellence for Regulatory Science from APEC
  ✓ Area: Global clinical trials/GCP inspection, pharmacovigilance

► Stipulate utilization of ATC in the Joint Statement of ASEAN-JAPAN Health Ministers (July 15th in 2017)

PMDA contributes to mutual understanding and cooperation in Asia
### Asia Training Center: Training Seminar 2018

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<td>1 Pediatric Review</td>
<td>June 11-14, 2018</td>
<td>Tokyo (PMDA)</td>
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<td>2 Pharmaceuticals Review</td>
<td>June 18-22, 2018</td>
<td>Tokyo (PMDA) and Toyama Prefecture</td>
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<td>3 Good Registration Management (GRM)*</td>
<td>September 26-28, 2018</td>
<td>Taipei</td>
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<td>4 Pharmaceuticals Review</td>
<td>October 15-16, 2018</td>
<td>Naypyidaw, Myanmar</td>
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<tr>
<td>5 Medical Devices Review</td>
<td>November 12-16, 2018</td>
<td>Tokyo (PMDA)</td>
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<tr>
<td>6 Good Manufacturing Practice (GMP)**</td>
<td>November 26-30, 2018</td>
<td>Utsunomiya, Tochigi Prefecture</td>
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<td>7 Pharmaceuticals Review</td>
<td>December 10-13, 2018</td>
<td>Jakarta, Indonesia</td>
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<td>8 Multi-Regional Clinical Trial (MRCT)*</td>
<td>January 21-24, 2019</td>
<td>Tokyo (PMDA)</td>
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<tr>
<td>9 Pharmacovigilance*</td>
<td>February 4-7, 2019</td>
<td>Tokyo (PMDA)</td>
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*APEC-LSIF-RHSC CoE Workshop  **With the support of PIC/S*
● Each country of ASEAN has structured their own regulations by the end of 2020 in order to introduce the ASEAN Medical Device Directives (AMDD), which was established in 2014, to their own domestic regulations.

● PMDA proposed to hold the Workshop for utilization of medical device regulation standards in order to enhance the regulation infrastructures in ASEAN regions as one of approaches for Promotion programs of International Standard Acquisition for Innovative medical device.

● PMDA held the Workshop on the utilization of international standards for medical device reviews in three countries of Vietnam (August), Indonesia (September), and Malaysia (September) in 2017 with the theme of “Essential Principles”.

● PMDA held workshops in Philippines (July) and Thailand (August) in 2018.
Work Together for patients!!

Thank you for your attention