IMDRF International Medical Device Regulators Forum

Japan Update

IMDRF Open Stakeholder Forum

September 14, 2016

厚生労働省
Ministry of Health, Labour and Welfare

pmda

IMDRF International Medical Device Regulators Forum

- Regulatory Authorities in Japan -

MHLW

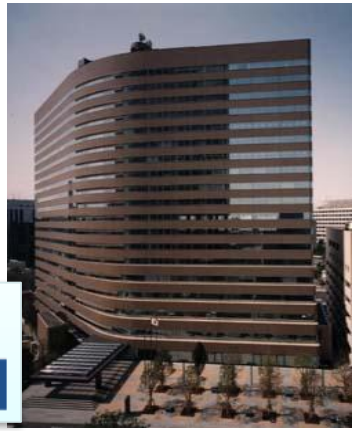
Ministry of Health, Labor and Welfare

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

PMDA

Pharmaceuticals and Medical Devices Agency

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



Topics

1. Launch of Asia training center for Pharmaceuticals and Medical Devices Regulatory Affairs

2. Outcomes from Science Board

IMDRF International Medical Device Regulators Forum

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

- Plan, design and coordinate training for Asian regulatory authority staff
- Provide **training opportunities** including **on-site training**

➡ Help to raise the level of regulations in Asia as a whole.

WHAT WE DO at PMDA Asia Training Center (ATC)

- Organize Training programs held at PMDA and overseas
- Exchange staff members for on-the-job training
- Training themes:
  - Best Regulatory Practices in Product Review, Safety Info Analysis, etc.
  - ICH, IMDRF, IGDRP, ICCR, PIC/S Guidelines
  - Specific topics per request by partner country

Training Seminars in FY2016

Pharmaceuticals Review Seminar (July 25-29, Tokyo) Finished

Pharmaceuticals Review Seminar (Sep 26-29, Bangkok)

Medical Devices Seminar (Nov 7-11, Tokyo)
https://www.pmda.go.jp/english/symposia/0092.html
- Registration will close on September 30, 2016

GMP Inspection Seminar* (Dec) * co-hosted with PIC/S

APEC MRCT/GCP (Jan - Mar, 2017)

APEC Pharmacovigilance (Jan - Mar, 2017)

(Reference) 3rd PMDA Medical Device Training Seminar for regulators in other jurisdictions

The seminar was held in cooperation with Japanese industries on 15 – 19 February, 2016 at PMDA (Tokyo, Japan).

- Topics such as pre-market review, QMS, PMS, manufacturing site visit, collaboration among stakeholders and group works for review were provided in the 2016 seminar.
- 31 officials from the following jurisdictions were participated:
  - ✓ Bahrain
  - ✓ Chinese Taipei
  - ✓ Ghana
  - ✓ Hong Kong
  - ✓ India
  - ✓ Indonesia
  - ✓ Iran
  - ✓ Malaysia
  - ✓ Myanmar
  - ✓ Saudi Arabia
  - ✓ Singapore

(Reference) Establishment of new international regulatory harmonization strategies by MHLW and PMDA

International Regulatory Harmonization Strategy by MHLW and *PMDA International Strategic Plan 2015 by PMDA* have been published on 26 June 2015.
Based on the *mutually complementary* strategies, the following measures will be taken:

A) Promotion of Regulatory Science

Guidelines related to medical device regulations in Japan will be prepared and internationally announced.

B) Establishment of Training Center for regulatory matters

PMDA will provide regulators outside Japan with training for capacity building.

C) Active commitment to IMDRF as well as advancement of bilateral collaboration

IMDRF has been reaffirmed as one of the most important activities.

Basic Research

Seeds of new drug / medical devices

Quality Tests → Non-clinical tests → Clinical Trial → Review → Approve → Post Marketing

Pharmaceutical consultation on R&D Strategy | Clinical Trial Consultation | Review | Post Marketing Safety Measure

Offices of Review (Drugs & Medical Devices), Office of Safety

Practical use

Innovative medical products

Office of Review Innovation

Science Board

The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced science & technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.

Board members

Academia

Outcome documents of the Science Board

Regulatory Science/The Science Board/Standard Development

- Regulatory Science
- The Science Board
  - Outline
  - The Science Board
  - **Outcome documents of the Science Board**
  - The Second Term (2014 April -) Subcommittees
  - The First Term (- 2014 March) Subcommittees
- Standard Development

Outcome documents of the Science Board

The Second Term (April, 2014-) Subcommittees

- Report on the Use of Numerical Analysis for Strength Evaluation of Orthopedic Implants
- Current Status and Perspectives of Placebo-controlled Studies
- Report on the use of non-clinical studies in the regulatory evaluation of oncology drugs (*Cancer Sci.*, 107(2):189-202, February 2016)
- Discussions on Evaluation of Medical Devices in Pediatric Use
- Proposal on Basic Principle to Quality Assurance of Cell Therapy (CT) Products

The First Term (-March, 2014) Subcommittees

- Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from induced Pluripotent Stem Cells (iPSCs) and iPSCs as Their Starting Materials
- Summary of Discussion on Non-clinical Pharmacology Studies on Anticancer Drugs
- Summary of discussion on the assessment of the current status of personalized medicine related to development and regulatory review

https://www.pmda.go.jp/english/rs-sb-std/sb/outcome-docs/0001.html

Thank you

MHLW

PMDA