Japan Update

IMDRF Open Stakeholder Forum
September 14, 2016
- 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
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)

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)
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.
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.
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
- 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
Thank you