PMDA update and International Cooperation

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices Agency (PMDA)

August 2nd, 2014
1st Brazil-Japan Seminar
Today’s Topics

1. Introduction
2. International Cooperation
3. Conclusion
Regulatory Cooperation: Brazil and Japan

Conclusion of Confidential Arrangement  
(Manaus, November 2012)

Decision of holding Joint Seminar  
(Brasilia, February 2014)

Dr. Tatsuya Kondo (Chief Executive, PMDA)
Pharmaceuticals and Medical Devices Agency

Date of Establishment: April 2004

Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System Securing Nation’s Safety

Dr. Tatsuya Kondo (Chief Executive, PMDA)
PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- We play an active role within the international community by promoting international harmonization.
- We conduct services in a way that is trusted by the public based on our experiences from the past.
Promotion of Regulatory Science

Regulatory Science; Ethical Science for the Society and People

**RS Macroscopic**
Multifactorial Evaluation of Balance

**RS Microscopic**
Improvement of evaluation method
(quality, efficacy, safety)

**RS Engineering**
Regulations on translational research

Results (e.g.)
- Establishment of evaluation method for new technology
- Establishment of guideline
- Establishment of review standards


Dr. Tatsuya Kondo (Chief Executive, PMDA)
Dr. Tatsuya Kondo (Chief Executive, PMDA)
3rd 5-year mid-term plan of PMDA (FY2014-2018)

**Major challenges**

- Shortening the time from early development to approval
  - “Zero” review time lag Support for elimination of development time lag

**Specific measures**

- **Accelerated review process**
  - (Improvement of approval predictability)
- **Improvement of prior assessment**
  - (substantial acceleration of approval review process)
- **Enhanced overseas inspection system**
- **Drastic improvement of consultation service**
  - Active involvement from the early development phase
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service
- Appropriately accommodate the most advanced technologies including personalized medicine and regenerative medicine

**High quality review/consultation services**

- Enhancement of regulatory science research and human resource development
  - Development of advanced review/consultation framework using innovative assessment techniques
  - Cross-products analysis of accumulated large data sets by PMDA using innovative techniques
  - Utilization of Science Board (cooperation with the academia)

**Enhancing safety measures**

- Utilization of medical information database
  - Readiness for introduction of risk management plan

**Globalization**

- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products

**Goal**

- Activation of the industry
- Extending health and life span of Japanese people
- Contribution to global medicine
- Responding to social needs such as Japan Reconstruction Strategy and Health/Medical Care Strategy

**Prerequisites:**

US/EU-equivalent system and human resources with excellent skills

Dr. Tatsuya Kondo (Chief Executive, PMDA)
Today’s Topics

1. Introduction
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Five Important Areas Where RMs are needed

1) Response to advanced science and technology
   • Proactively provide information about the policies for review and scientific consultation of cutting-edge products and recommendation for relevant guideline developments.
   • Introduce progressive analyzing and predictive methods.

2) Improvement of international operation basis
   • Improve the organizational structure enabling wide range international activities and cultivate new internationally minded personnel* in a prompt manner.
     *A personnel who has 1) good command of foreign languages, 2) an international human network, 3) abundant knowledge of his or her related area of expertise, 4) ability to make appropriate decisions under the given circumstances domestically and internationally, and 5) trustworthy international relations.

3) Dissemination of English information on regulatory review of medicinal products, especially publication of review reports in English
   • Increase the number of English version of review reports (aiming to cover all the necessary review reports in English in the future).

4) Dissemination of information and international cooperation on safety measures
   • Enhance exchanging information and establish a system to share evaluation reports with our overseas counterparts.
   • Enrich the contents related to safety information in the English website.

5) Increase of the leverage of Japanese Pharmacopoeia (JP)
   • Publish the newest JP version simultaneously in English and Japanese.
   • Enhance cooperative relationship with the USP, EP, WHO and each Asian pharmacopeia.

As we have been committed to emphasize the activities with ICH, IMDRF and other foreign regulatory agencies, the effort should continue for the future development.

Dr. Tatsuya Kondo (Chief Executive, PMDA)
### Global Activities

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Official Name</th>
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<tbody>
<tr>
<td>Summit</td>
<td>International Summit of Heads of Medicines Regulatory Agencies</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonization</td>
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<tr>
<td>IMDRF</td>
<td>International Medical Device Regulators Forum</td>
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<td>PIC/S</td>
<td>Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme</td>
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<td>HBD</td>
<td>Harmonization By Doing</td>
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<td>APEC LSIF RHSC</td>
<td>APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee</td>
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<td>OECD MAD</td>
<td>OECD Mutual Acceptance of Data</td>
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<td>PDG</td>
<td>Pharmacopoeial Discussion Group</td>
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<td>IDGRP</td>
<td>International Generic Drug Regulators Pilot</td>
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*Dr. Tatsuya Kondo (Chief Executive, PMDA)*
ICH has developed 80 harmonized guidelines regarding technical elements about the evaluation of quality, efficacy and safety, as well as the format of application form and the post-market safety measures, including Common Technical Document (CTD) and their electrical submission system. ICH also directed the development of the Medical Dictionary for Regulatory Activities (MedDRA) Terminology.

MHLW/PMDA have been working as a steering committee member for ICH to harmonize guidelines across different countries and regions to built up the global standard for regulatory administration.

ICH was established in 1990 in order to
• improve efficiency of new drug development and registration process
• promote public health
• prevent duplication of clinical trials in humans
• minimise the use of animal testing without compromising safety and effectiveness

Outcomes of ICH
ICH has developed 80 harmonized guidelines regarding technical elements about the evaluation of quality, efficacy and safety, as well as the format of application form and the post-market safety measures, including Common Technical Document (CTD) and their electrical submission system. ICH also directed the development of the Medical Dictionary for Regulatory Activities (MedDRA) Terminology.

Future of ICH
ICH reform; Membership expansion, Legal entity, New funding etc.
ICH reactivation; Proactive adaption of new topics etc.
Japan Approved Member at the 38th PIC/S Committee Meeting

- Japan (MHLW, PMDA, 47 prefectures)
  GMP Inspectors applied for PIC/S membership on March 2012
- On-site examination on September 9-13, 2013
- Decided to become official membership on July 1st 2014 at the committee meeting on May 15-16, 2014 (Rome)
- 45th member

With PIC/S Chair Dr. Joey Gouws

PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme)
- Cooperative framework between GMP inspectors aimed to achieve harmonized GMP standards within the pharmaceutical area and the international development, enforcement, and conservation of the quality system. PIC/S is emerging to become the world standard in the GMP domain.

Dr. Tatsuya Kondo (Chief Executive, PMDA)
APEC LSIF (Life Science Innovation Forum)

Regulatory Harmonization Steering Committee (RHSC)

Regulatory Members: Canada, China, Japan, Korea, Peru, Chinese Taipei, Thailand, US

Aims for regulatory convergence involving the 21 member economies

Dr. Tatsuya Kondo (Chief Executive, PMDA)
• MOU between the Chinese SFDA (present CFDA) and the Japanese MHLW, under which PMDA supports cooperative activities
• ** MOU concluded between Interchange Association and East Asia Relations Commission, but is being implemented through cooperation of related organizations.
This 3rd PMDA Training Seminar is a good opportunity to share our knowledge and our experiences. It is good to be here participating.

Mr. Guilherme A. Marques Buss, Brazilian Health Surveillance Agency (ANVISA)
Today’s Topics

1. Introduction
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Collaboration with ANVISA

1） Mutual cooperation for improvements in efficiency of the review of pharmaceuticals and medical devices. Promotion of the information exchanges for that purpose.

2） Mutual cooperation for improvements in efficiency of GMP/QMS inspections. The maintenance of the training programs such as accompanying inspections mutually.

3） Recognition of the field of expertise in pharmacopoeia for both parties and promotion of cooperation for mutual pharmacopoeial advancement. e.g. holding a symposium on pharmacopoeia.

4） Implementation of exchange of opinions on the ways and strategies for future international collaboration.

Dr. Tatsuya Kondo (Chief Executive, PMDA)
PMDA for the world

-To create society to receive the essential forefront medicines-

Swift approvals of innovative products

Full measures by use and application of medical information

Convey Japanese technology to the world

Cooperate with all agencies in the world

Swift relief for occurred health damage

Contribute to the world’s medicine

Safety

Japanese citizens

Review

Relief

Regulatory Science

Dr. Tatsuya Kondo (Chief Executive, PMDA)
Thank you for your attention!
Obrigado!!

Pharmaceuticals & Medical Devices Agency

Dr. Tatsuya Kondo (Chief Executive, PMDA)