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

Decision of holding Joint Seminar
(Brasilia, February 2014)

Conclusion of Confidential Arrangement
(Manaus, November 2012)

Tatsuya KONDO (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

Review

Japanese citizens

Safety

Relief

Tatsuya KONDO (PMDA)
Our Philosophy

(September, 2008)

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

Benefit vs. Risk

DB


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Number of Approvals and Review Time

New Drugs

- No. of approvals
- Priority review

Medical Devices

- No. of approvals
- Standard review

Tatsuya KONDO (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

High quality review/consultation services

Enhancing safety measures

Globalization

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

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)

Utilization of medical information database

Readiness for introduction of risk management plan

Goal

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

- 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

Tatsuya KONDO (PMDA)
Today’s Topics

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Roadmap for the PMDA International Vision

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 safely 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.
<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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<tr>
<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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<tr>
<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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<tr>
<td>PDG</td>
<td>Pharmacopoeial Discussion Group</td>
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<tr>
<td>IGDRP</td>
<td>International Generic Drug Regulators Pilot</td>
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and more...
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.

Outcomes of ICH

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

Future of ICH

ICH reform; Membership expansion, Legal entity, New funding etc.
ICH reactivation; Proactive adaptation 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 1\(^{st}\) 2014 at the committee meeting on May 15-16, 2014 (Rome)

- 45\(^{th}\) 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.
APEC LSIF (Life Science Innovation Forum)

Aims for regulatory convergence involving the 21 member economies

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

Tatsuya KONDO (PMDA)
Tatsuya KONDO (PMDA)
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)

2014 October 6-10: 5th PMDA Training Seminar (Reviewing New Drugs (including biopharmaceuticals and tissue and cellular products))

2014 February 3-7: 4th PMDA Training Seminar (Reviewing Generic Drugs)

17 participants (Korea 3, Saudi Arabia 3, Taiwan 2, Indonesia 2, Yemen 1, Russia 1, WHO 1, Vietnam 4*) *WHO Fellows

2013 January 21-25: 3rd PMDA Training Seminar

2014 March 3-7: 1st PMDA Medical Devices Training Seminar

19 participants (Taiwan 4, Malaysia 4, Korea 3, Singapore 3, Saudi Arabia 2, Hong Kong 1, Switzerland 1, Uganda 1)

2014 February 2-6: 2nd PMDA Medical Devices Training Seminar

Website: http://www.pmda.go.jp/english/seminar/
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.
PMDA for the world

-To create society to receive the essential forefront medicines-

Swift approvals of innovative products
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

Full measures by use and application of medical information

Safety
Japanese citizens
Review
Relief

Regulatory Science

Tatsuya KONDO (PMDA)
Thank you for your attention!
Obrigado!!