PMDA International Vision and Cooperation with Asian Drug Regulatory Authorities

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Contents

1. Generally on International Activities
2. International Master Plan
3. PMDA EPOCH
4. PMDA’s Activities in Asia
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1. Generally on International Activities
2. International Master Plan
3. PMDA EPOCH
4. PMDA’s Activities in Asia
Generally on International Activities (1)

Int’l Activities by Drug Reg. Authorities must...

1. Serve the DRA’s needs
2. Construct win-win situation w. foreign DRAs
3. Synergize (or at least be compatible) with domestic measures
4. (sometimes) employ diplomacy to gain influence
Random “international Cooperation” sounds nice but leads to waste

International Activities need to be consciously designed and conducted to achieve certain goals related to the DRA’s (a) desired international status, and (b) overall goal.
International Mater Plan

Need for Master Plan
Philosophy, Vision, and Roadmap

Current Situation

PMDA Philosophy

Desired Achievements

Roadmap

Int’l vision

Time

2020
Contents
Concrete goals for PMDA to attain by 2020 as one of world’s top three medical products regulatory agencies comparable to USFDA and EMA

(Published in November 2011)
Secure the highest level *E*xcellence in *P*erformance in the following aspects:

- A) Quality and speed in product reviews, safety measures, and relief services (PMDA’s Safety Triangle)
- B) Quality and quantity of regulatory science research
- C) Quality, quantity and speed of information transmission to the world

Maintain close *P*artnership with the *O*rient for common benefits through:

- A) Cooperating to improve the level of medical products regulation across Asia.
- B) Communication of information and opinions to the world as a member of the Asian community

Actively *C*ontribute to International *H*armonization of regulations, guidelines, and standards for the benefit of both Japan and the world
What is PMDA EPOCH? (1)

1. Secure the highest level Excellence in Performance in:
   A) Product review, Safety Measures, and Relief Services
   B) Regulatory Science Research
   C) Information transmission to the world
Does Japan count as one of the Top 3?
Human Resource Development Plan (Training) to Improve Knowledge & Skills of PMDA staff

- Basic Training (human skills, languages, etc.)
- On-site Training (hospitals, factories)
- Specialized Training (case studies, etc.)
- Special Training (latest scientific topics)

Challenges for the Future
1. Increase of training for mid-level and management-level staff (Leader Development)
2. Increase of long-term dispatches to overseas regulatory authorities
3. Increase of long-term dispatches to universities or other education institutions (provision of the opportunity to obtain a Ph.D)

International academic societies, international meetings: ICH, GHTF, DIA, etc.

Participation, discussion

Overseas organizations
FDA, EMA, OECD

Universities, institutions in Japan

Long-term dispatch

Confidentiality Arrangements

Must
- cooperate to excel
- excel to cooperate
- build Win-Win Situation

EC/EMA
US FDA
MHRA (U.K.)
Swissmedic (Switzerland)
HAS (Singapore)
Health Canada
IMB (Ireland)
TGA (Australia)
Cooperation across Atlantic / Pacific

EMA-MHLW/PMDA, EMA-FDA Interactions
January 2009 – August 2011

EMA-MHLW/PMDA
EMA-FDA

DIA 年鑑「The Liaison Placements Concept - Introduction」 by Emmer Cookeより抜粋・加工
2. Maintain close **P**artnership with the **O**rient for common benefits
Asia as Japan’s Future

Strengthen Partnership with Asian Countries
3. Actively **C**ontribute to International **H**armonization of regulations, guidelines, and standards.
Current Harmonization Activities
International “Regulatory” Harmonization
Coming Soon!

PMDA Roadmap toward 2020
Structure of Roadmap (planned)

<table>
<thead>
<tr>
<th>Time (Year)</th>
<th>Product Review</th>
<th>Safety</th>
<th>Others</th>
<th>Item of Vision</th>
</tr>
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<tbody>
<tr>
<td>EPOCH</td>
<td>2012</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2016</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td></td>
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</table>

PMDA Functions
PMDA Activities in Asia
China/Korea/Japan Tripartite Cooperation

Health Ministers’ Joint Statement among China, Korea & Japan (April 8, 2007)
Three Joint Projects
2011 China-Korea-Japan Tripartite Meeting
APEC, LSIF, and RHSC

APEC Member Economies

Leaders Meeting
Ministerial Meeting
Senior Officials Meeting
Committee on Trade and Investment

LSIF (Life Science Innovation Forum)

Regulatory Harmonization Steering Committee (RHSC)

Member: Canada, China, Japan, Korea, Peru, Taiwan, Thailand, USA
**Goal:** To facilitate MRCTs and acceptance of MRCT results for drug review by regulatory authorities in APEC region.

APEC Multi-Regional Clinical Trial Workshop
(Sep. 13-15, 2010, Seoul, Korea)
APEC Multi-Regional Clinical Trial Workshop
(Nov. 1-2, 2011, Tokyo Japan)
China-Japan Bilateral Meeting

Starting from 2010 for the purpose of:
## Project 1: GCP Comparison Table

<table>
<thead>
<tr>
<th>Category</th>
<th>Item</th>
<th>Japan</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application Form</td>
<td>Yes: Clinical Trial notification form (in Japanese)</td>
<td>Yes (in Chinese) Huge IND materials required</td>
</tr>
<tr>
<td></td>
<td>Informed Consent form</td>
<td>Yes (in Japanese)</td>
<td>IND Application Materials</td>
</tr>
<tr>
<td></td>
<td>Investigator’s CV</td>
<td>No</td>
<td>No (Submit list to the local authority for the medical sites application)</td>
</tr>
</tbody>
</table>

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*Note: The table details the requirements for GCP (Good Clinical Practice) in Japan and China.*
China-Japan Symposium

To promote dialogue and cooperation between the agencies

2010 May

2011 March

2012 March
PMDA Training Seminar

2010 November – December
PMDA’s role in regulation, and Scientific review process on new drug applications biological applications

35 trainees participated from Indonesia, Singapore, China, Taiwan, Korea and Nigeria

2011 December
Pharmaceutical GMP inspection

27 trainees participated from Korea, India, Indonesia....
Trainings for individual Trainees

Dr. Kondo with Trainees from KFDA

Dr. Kondo with Trainees from Taiwan FDA
Our goal is to...

Promote Global & Domestic Public Health through International Activities
Thank you!