Forward-looking approaches & its Experiences of PMDA's ATC

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PMDA International Strategic Plan 2015
PMDA International Strategic Plan 2015

**Introduction**

- **PMDA’s primary responsibility**: Providing a reliable environment which affords quicker access to more effective and safer medical products
- **Change of environment surrounding PMDA**: Globalization of research, development, manufacture, and distribution of the products, Expectation to PMDA for International Contribution

**3 Visions**

- **VISION I**
  - To contribute to the world through regulatory innovation
- **VISION II**
  - To maximize the common health benefits to other countries/regions
- **VISION III**
  - To share the wisdom with other countries/regions

**5 Strategies**

1. **Strategy 1**: Taking the lead, and disseminating the information around the globe
   - With be Established “Regulatory Science Center”

2. **Strategy 2**: Promotion of international regulatory harmonization and global cooperation

3. **Strategy 3**: Increase efficiency of inspections that may lead to future international work-sharing

4. **Strategy 4**: Contribution to international regulatory harmonization activities

5. **Strategy 5**: Provision of information and training programs that are essential for building regulatory capacity in partner countries
   - With be established “Asian Training Center”

**Solid basis to implement strategies**

- Cultivation of human resources
- Strengthening of translation, dissemination of information, and information analysis
Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

Established on 1 April, 2016
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 raise the level of regulations in Asia as a whole.

(1) Training seminar by PMDA, local prefectures and industry

(2) Assign to local site

(3) APEC Training Centre for Clinical Trial and Pharmacovigilance
PMDA-ATC seminars held in FY2016

<table>
<thead>
<tr>
<th>Theme</th>
<th>Date</th>
<th>Place</th>
<th>Participants</th>
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</thead>
<tbody>
<tr>
<td>1 Pharmaceuticals Review</td>
<td>July 25-29, 2016</td>
<td>Tokyo (PMDA)</td>
<td>13 from 7 countries/regions</td>
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<tr>
<td>2 Pharmaceuticals Review</td>
<td>September 26-29, 2016</td>
<td>Bangkok</td>
<td>13 from Hong Kong and Thailand</td>
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<tr>
<td>3 Medical Device</td>
<td>November 7-11, 2016</td>
<td>Tokyo (PMDA)</td>
<td>28 from 13 countries/regions</td>
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<tr>
<td>4 Good Registration Management (GRM)</td>
<td>November 15-17, 2016</td>
<td>Taipei</td>
<td>28 from 10 countries/regions</td>
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<tr>
<td>5 Good Manufacturing Practice (GMP) Inspection*</td>
<td>December 5-9, 2016</td>
<td>Toyama</td>
<td>19 from 12 countries/regions</td>
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<tr>
<td>6 Multi-Regional Clinical Trial (MRCT)**</td>
<td>January 23-26, 2017</td>
<td>Tokyo (PMDA)</td>
<td>32 from 14 countries/regions</td>
</tr>
<tr>
<td>7 Pharmacovigilance**</td>
<td>February 6-9, 2017</td>
<td>Tokyo (PMDA)</td>
<td>28 from 15 countries/regions</td>
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*With the support of PIC/S, **APEC-LSIF-RHSC CoE Pilot Workshop
## PMDA-ATC seminars planned in FY2017

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<tr>
<td>3. Good Manufacturing Practice (GMP) Inspection*</td>
<td>July 31-August 4, 2017</td>
<td>Hikari</td>
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<td>4. Anti-infective</td>
<td>October, 2017</td>
<td>Hanoi</td>
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<tr>
<td>5. Medical Device</td>
<td>November, 2017</td>
<td>Tokyo (PMDA)</td>
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<td>February, 2018</td>
<td>Tokyo (PMDA)</td>
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*With the support of PIC/S, **APEC-LSIF-RHSC CoE Workshop
Project Teams established by PMDA staffs

Pharmaceuticals Review

Pharmaceuticals Review in Thailand

Medical Devices

Review Offices

Standards Office

Compliance Offices

Safety Offices

Relief Funds Office

GMP Inspection*

Good Review Management

Multi-Regional Clinical Trial

Pharmacovigilance
What we do at PMDA-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
Purpose of PMDA-ATC

• Well Communication
  • Information/Experience sharing based on other regulator’s needs
  • Building trust relationship with Asian regulators to work for Asian citizen

• Win-Win relationship
Our plans for the future

1. Continue holding PMDA-ATC Seminars at PMDA.
2. Increase the number of PMDA-ATC Seminars held Japan/overseas to provide more chances to “train the trainer”.
3. Plan PMDA-ATC Seminars with more flexibility.
   • theme, duration, mock review etc.
4. Conduct hearings to find out the training needs.
5. Work collaboratively with training providers for regulatory convergence
PMDA – future direction in Asia

- Disseminate PMDA’s accumulated knowledge and experiences to promote regulatory science.
- Provision of hints for betterment of the regulations in participants' regulatory authority.
- More contribution to public health as a result of improvement in regulations.

PMDA will contribute to promote Capacity Building Activities in Asia
PMDA – Future direction

PMDA’ Knowledge & Experience

Public Health in Asia

Level of Regulation in Asia

13
PMDA will contribute to promote Capacity Building Activities in Asia