

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

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PMDA International Strategic Plan 2015

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PMDA 国際戦略 2015 2015年06月26日

PMDAの第一の責務は、レギュラトリーサイエンスに基づき、よりよい医薬品・医療機器・再生医療等製品などが、より早く、より安心して使用できる環境を日本国民のために創出することである。グローバル化が進展し、医薬品・医療機器・再生医療等製品などが、地域を超えて世界規模で開発・製造・流通するようになった今日、日本国民の保健衛生・健康寿命の更なる向上を図るためには、我が国自らが努力することはもちろんのこと、他の国・地域の規制当局、企業、アカデミアと緊密に協力することが不可欠である。このような状況の下、PMDAは、厚生労働省の国際事業規制調和戦略(平成27年6月)も踏まえ、おおむね第3期・第4期国際活動を以下のように定めて積極的に取り組んでいく。

ビジョン1. 先駆的な取組みによりPMDAは、レギュラトリーサイエンス及び健康被害救済に取り組む、健康な暮らしに貢献する。

PMDA International Strategic Plan 2015 June 26, 2015.

The primary responsibility of the Pharmaceuticals and Medical Devices Agency (PMDA) is to provide a reliable regulatory environment that enables quicker access to more effective and safer medical products including pharmaceuticals, medical devices, and cellular and tissue-based products for the people of Japan. Regulatory science forms the basis of PMDA's activities. As the development, manufacture, and distribution of products are becoming increasingly globalized, PMDA must increase its efforts to cooperate closely with foreign regulatory authorities, as well as industry and academia. Such collaboration to overcome common public health issues will greatly promote public health in Japan and globally.

In view of the abovementioned situation as well as the Regulatory Strategy Initiative set forth by the Ministry of Health, Labour and Welfare (MHLW) in June 2015, PMDA has established the following strategic plan on international activities that will be conducted in the period defined in the 3rd and 4th Mid-term Plans (FY 2014-2015). PMDA will strive to implement the strategic plan in order to maximize the health benefits to Japan and the world, by effectively utilizing its human resources, scientific knowledge, electronic information, and by other means.

Vision 1: To contribute to the world through regulatory innovation

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

VISION I To contribute to the world through regulatory innovation

3 Visions

Vision II To maximize the common health benefits to other countries/regions

Vision III To share the wisdom with other countries/regions

Strategy 1: Taking the lead, and disseminating the information around the globe

→ With be Established **"Regulatory Science Center"**

Strategy 2: Promotion of international regulatory harmonization and global cooperation

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

Strategy 4: Contribution to international regulatory harmonization activities

Strategy 5: Provision of information and training programs that are essential for building regulatory capacity in partner countries

→ With be established **"Asian Training Center"**

5 Strategies

- Cultivation of human resources
- Strengthening of translation, dissemination of information, and information analysis

Solid basis to implement strategies

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

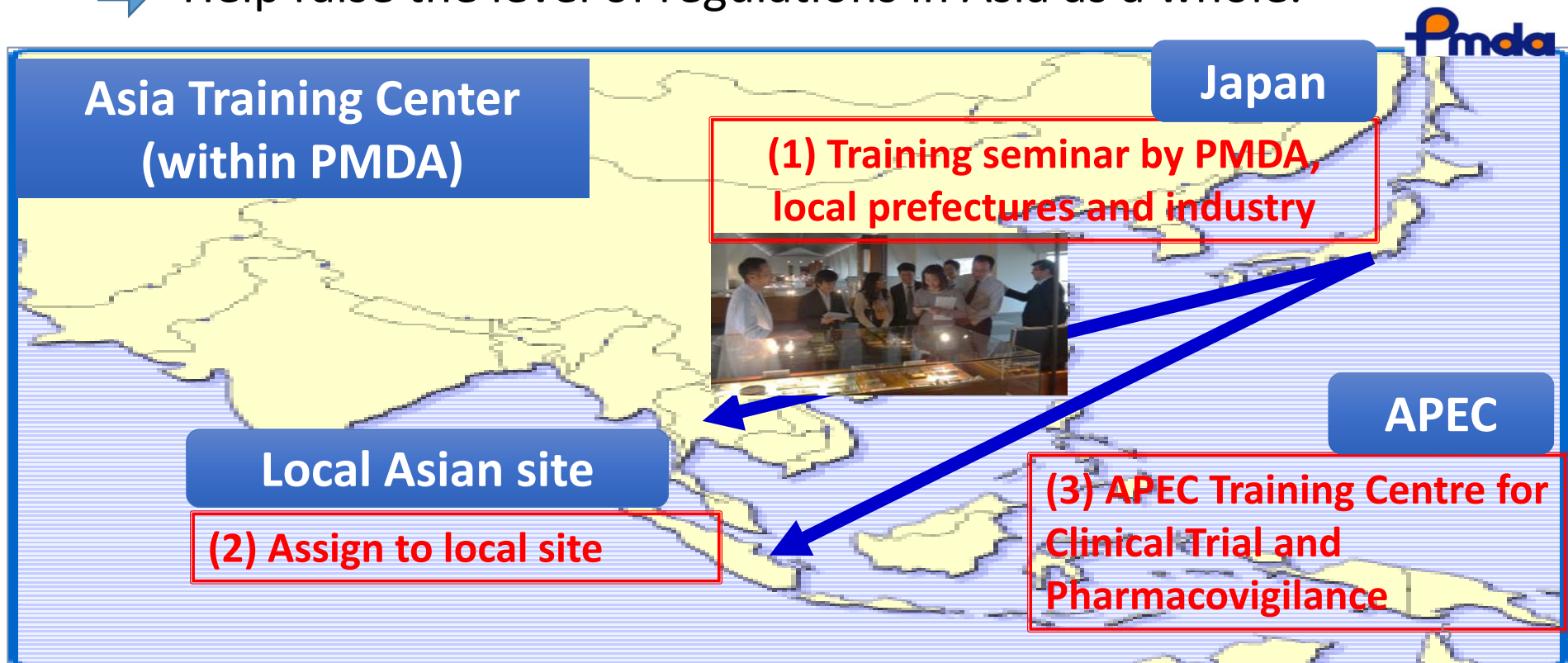
Established on 1 April, 2016



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.



PMDA-ATC seminars held in FY2016

| | Theme | Date | Place | Participants |
|---|---|-----------------------|--------------|--------------------------------|
| 1 | Pharmaceuticals Review | July 25-29, 2016 | Tokyo (PMDA) | 13 from 7 countries/regions |
| 2 | Pharmaceuticals Review | September 26-29, 2016 | Bangkok | 13 from Hong Kong and Thailand |
| 3 | Medical Device | November 7-11, 2016 | Tokyo (PMDA) | 28 from 13 countries/regions |
| 4 | Good Registration Management (GRM) | November 15-17, 2016 | Taipei | 28 from 10 countries/regions |
| 5 | Good Manufacturing Practice (GMP) Inspection* | December 5-9, 2016 | Toyama | 19 from 12 countries/regions |
| 6 | Multi-Regional Clinical Trial (MRCT)** | January 23-26, 2017 | Tokyo (PMDA) | 32 from 14 countries/regions |
| 7 | Pharmacovigilance** | February 6-9, 2017 | Tokyo (PMDA) | 28 from 15 countries/regions |

*With the support of PIC/S, **APEC-LSIF-RHSC CoE Pilot Workshop

PMDA-ATC seminars planned in FY2017

| | Theme | Date | Place |
|---|---|------------------------|--------------|
| 1 | Risk Management Plan (RMP) | May 18-19, 2017 | Jakarta |
| 2 | Pharmaceuticals Review | June 26-30, 2017 | Tokyo (PMDA) |
| 3 | Good Manufacturing Practice (GMP) Inspection* | July 31-August 4, 2017 | Hikari |
| 4 | Anti-infective | October, 2017 | Hanoi |
| 5 | Medical Device | November, 2017 | Tokyo (PMDA) |
| 6 | Good Registration Management (GRM) | November, 2017 | Taipei |
| 7 | Pharmaceuticals Review | December, 2017 | Bangkok |
| 8 | Multi-regional Clinical Trial (MRCT)** | January, 2018 | Tokyo (PMDA) |
| 9 | Pharmacovigilance** | February, 2018 | Tokyo (PMDA) |

*With the support of PIC/S, **APEC-LSIF-RHSC CoE Workshop

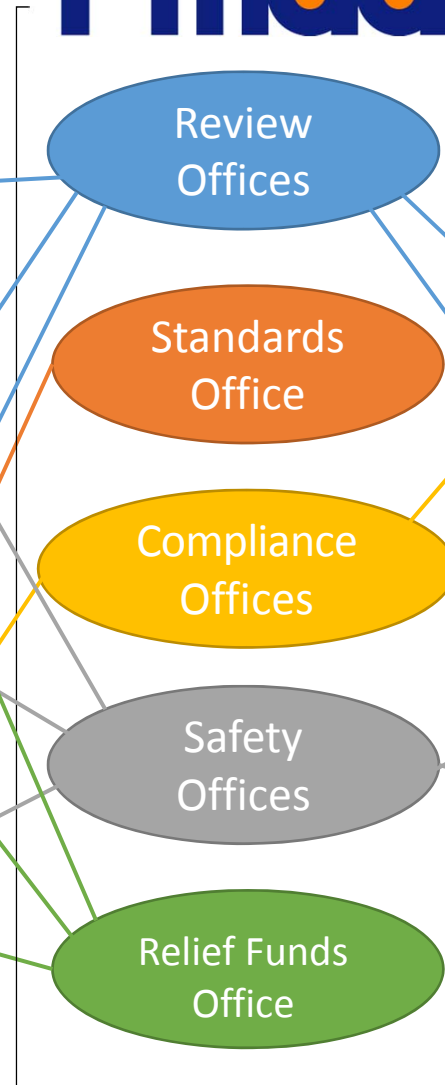
Project Teams established by PMDA staff



Pharmaceuticals
Review

Pharmaceuticals
Review in Thailand

Medical Devices



GMP Inspection*

With the support of



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

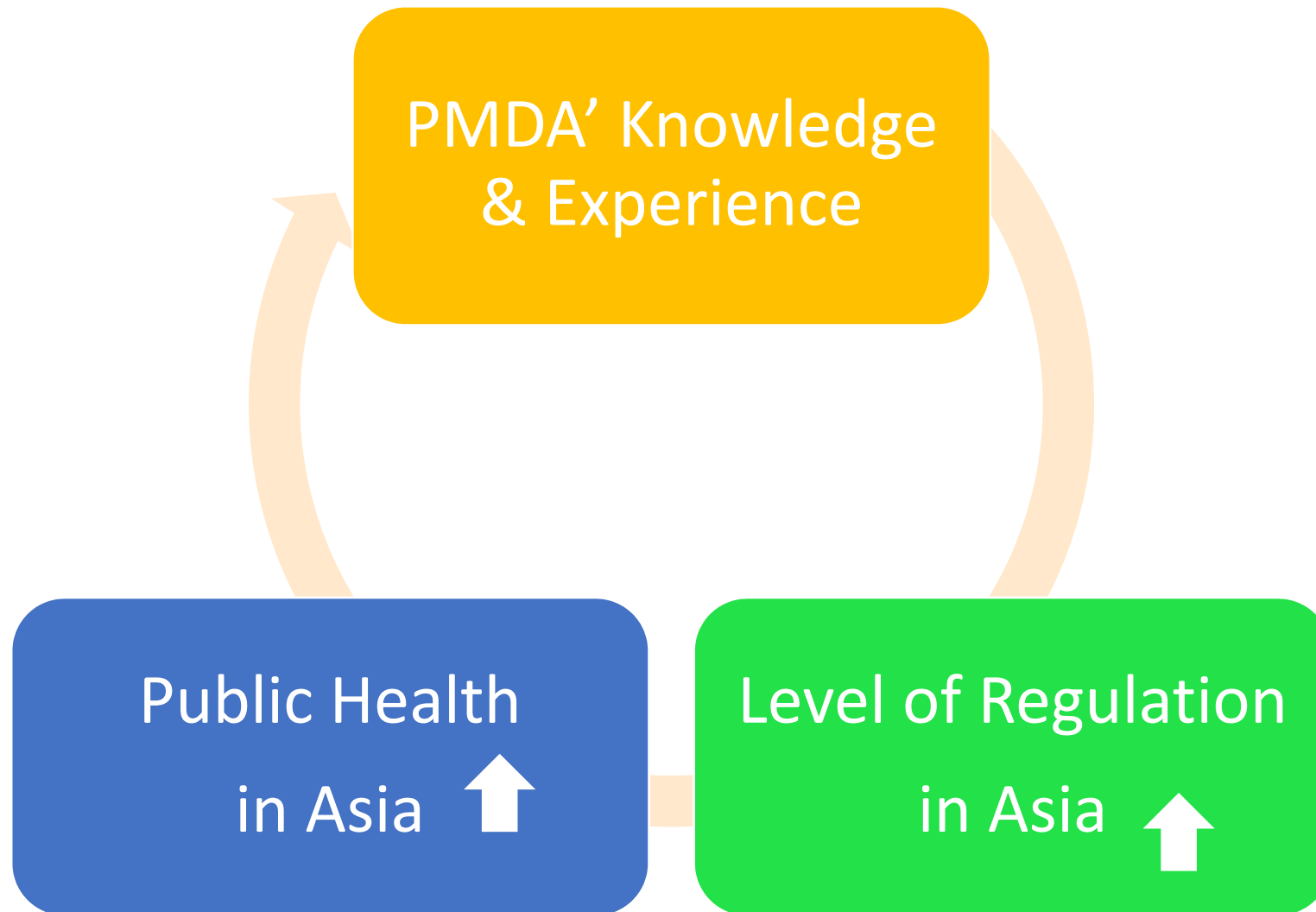
PMDA – future direction in Asia

- ▶ 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 will contribute to promote Capacity Building Activities in Asia

