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

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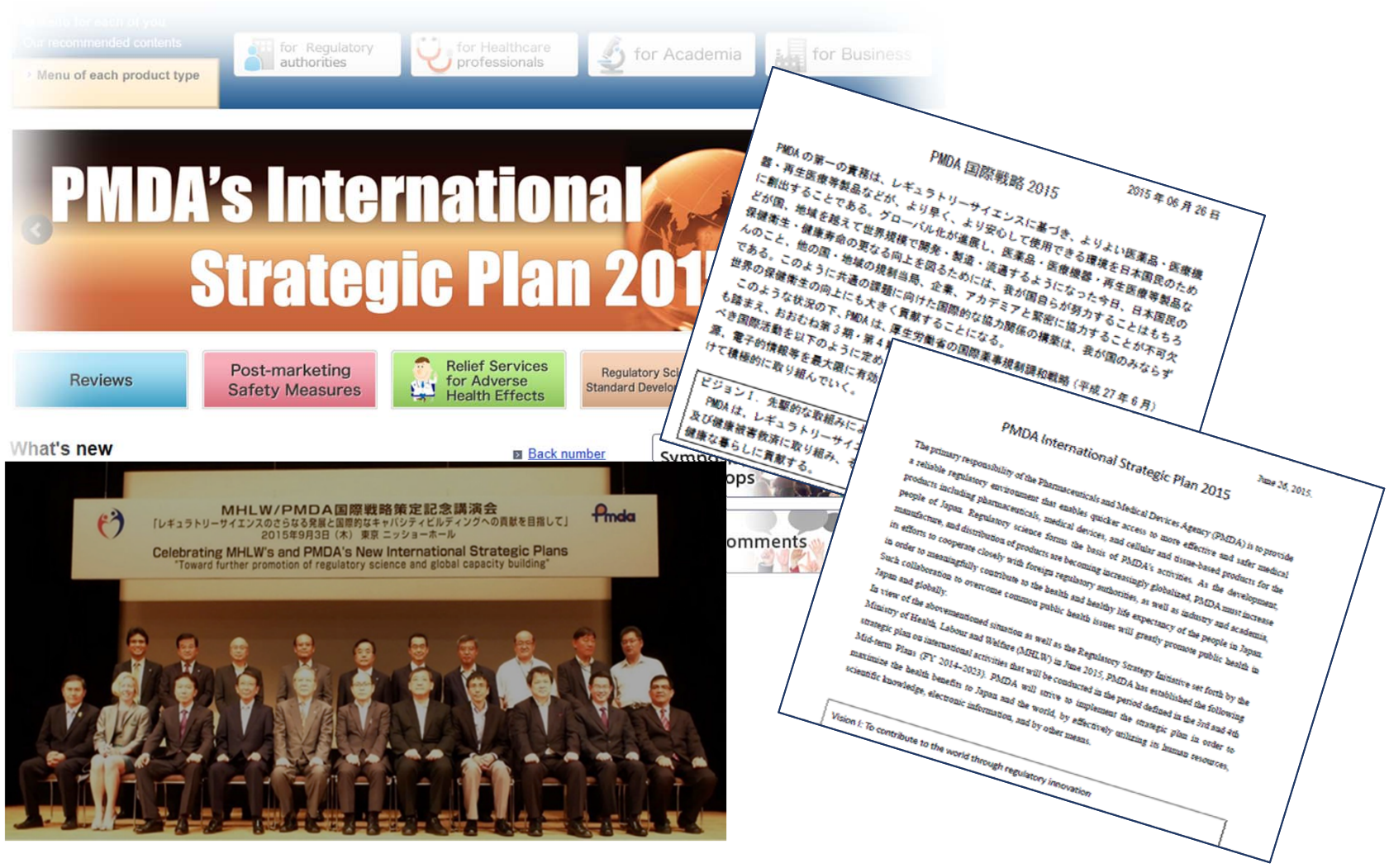
PMDA International Strategic Plan 2015



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

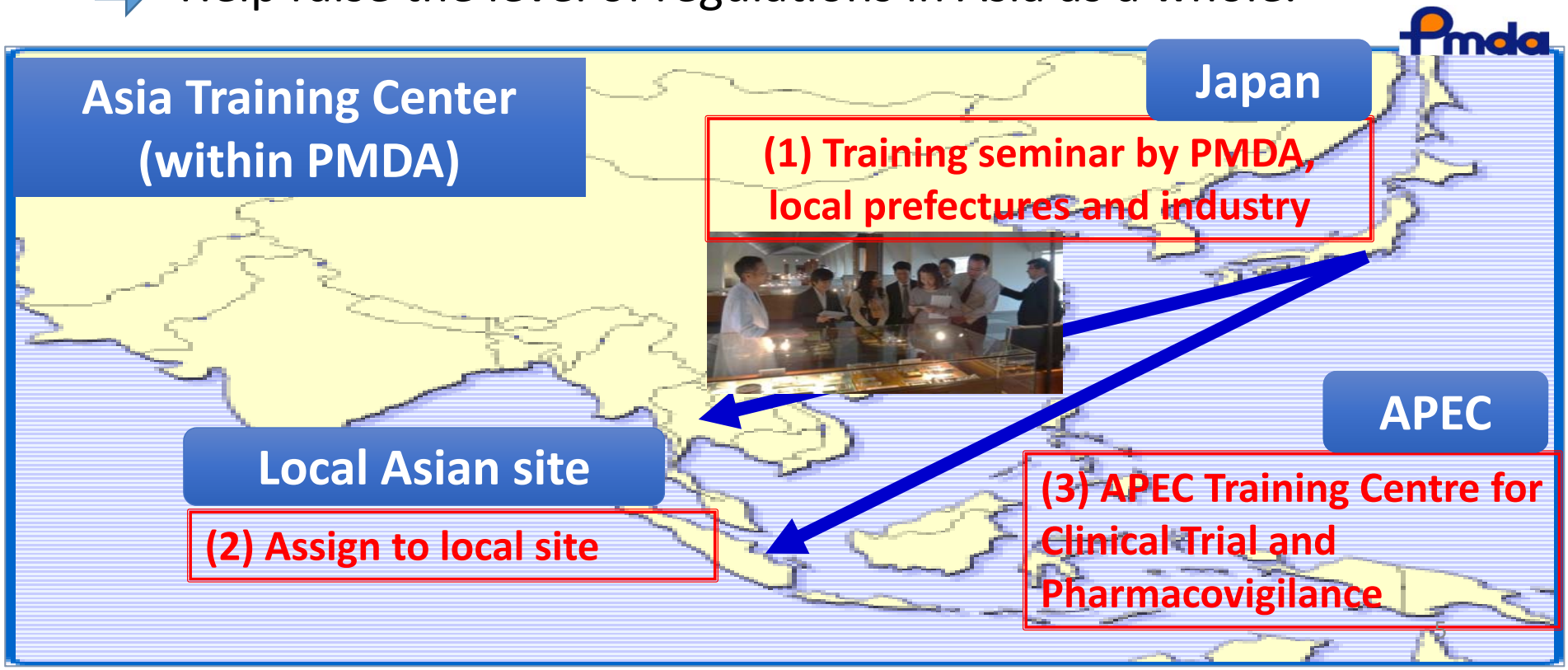
Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

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 staffs

Pharmaceuticals Review

Pharmaceuticals Review in Thailand

Medical Devices

pmda

Review Offices

Standards Office

Compliance Offices

Safety Offices

Relief Funds Office

GMP Inspection*

With the support of PIC/S

Good Review Management

Multi-Regional Clinical Trial

Pharmacovigilance

APEC Asia-Pacific Economic Cooperation

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

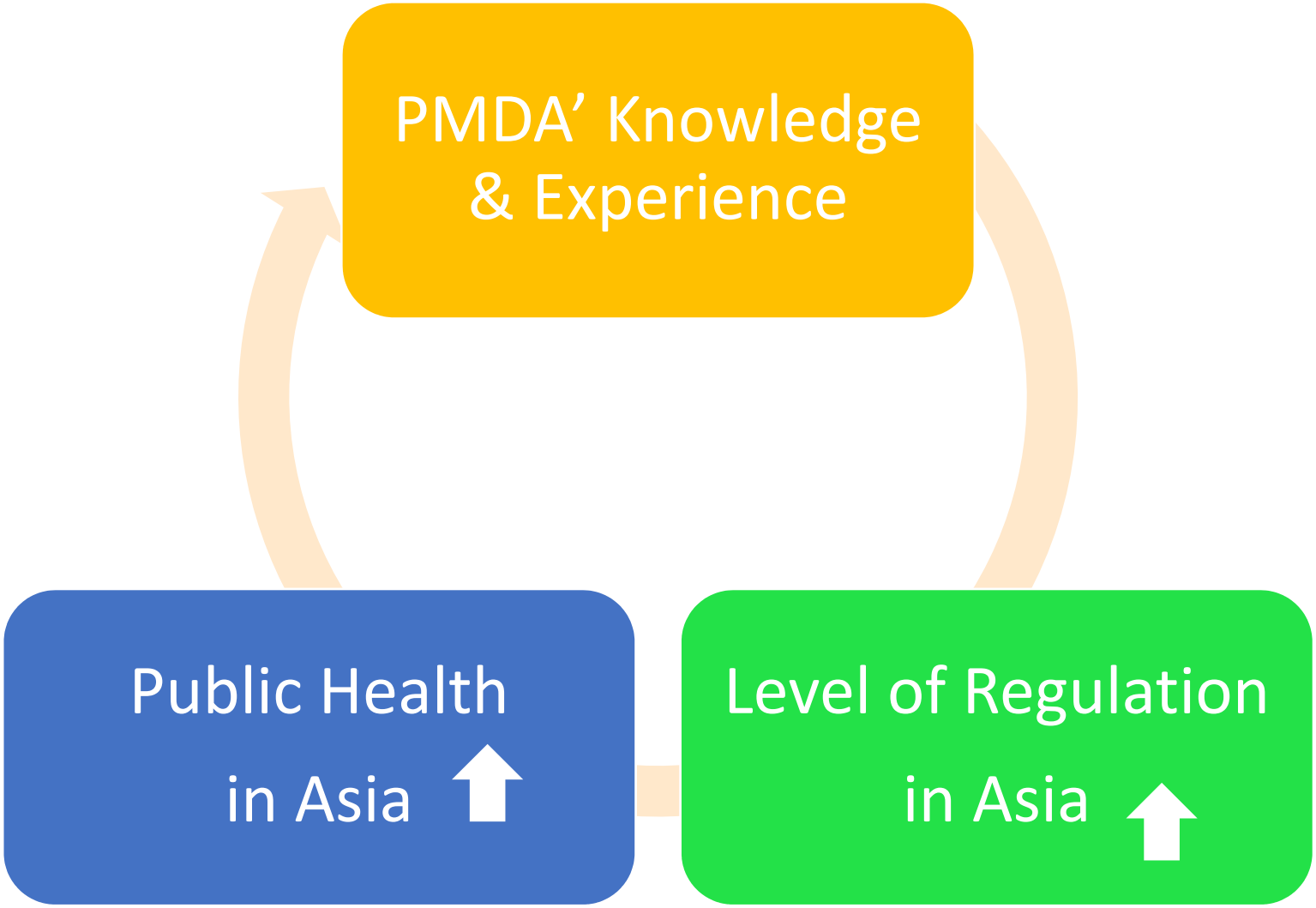
1. Continue holding PMDA-ATC Seminars at PMDA.
2. Increase the number of PMDA-ATC Seminars held Japan/overseas to provide more chances to “train the trainer”.
3. Plan PMDA-ATC Seminars with more flexibility.
   - theme, duration, mock review etc.
4. Conduct hearings to find out the training needs.
5. 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