

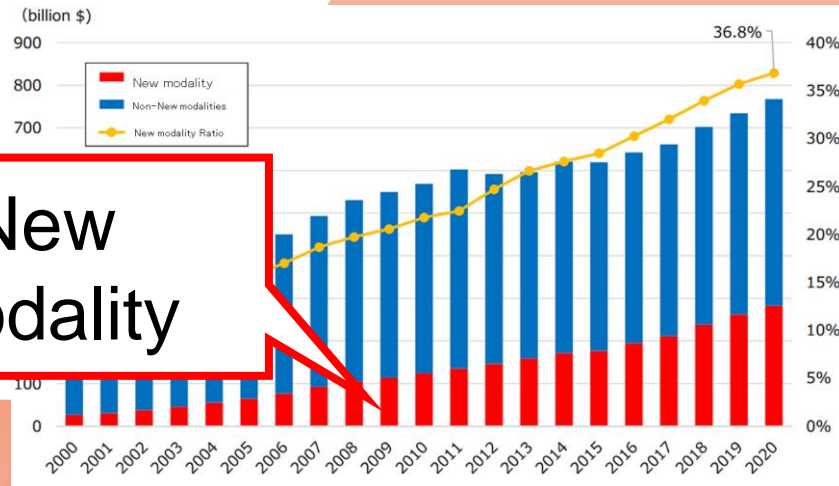
# Challenges for Capacity Building of Asian Regulatory Authorities

## - Utilization of PMDA-ATC for the Asian Region -

**Jun Kitahara, Ph.D.**  
Head , PMDA Asia Office

# Change in Global Trend

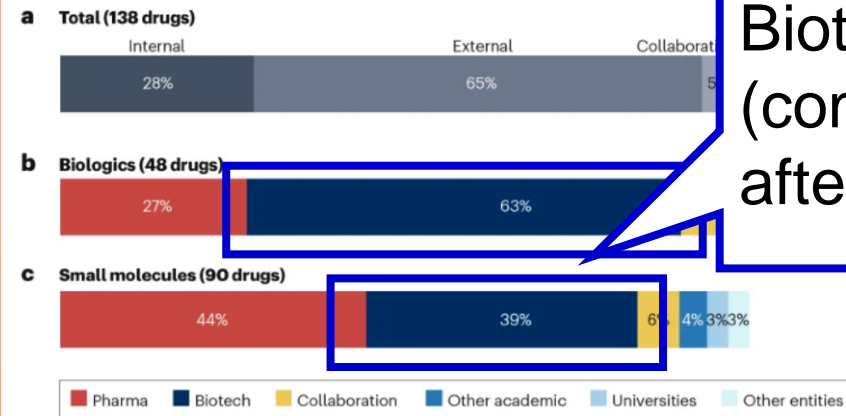
## Trend of New modality global pharmaceutical sales



New modality

<https://www.mhlw.go.jp/content/10800000/000831974.pdf>

## Origins of Pharmaceutical Innovation



Biotech companies (companies founded after 1976)

Fig. 1 | Origins of FDA-approved new drugs filed by the top 20 biopharma companies between 2015–2021.

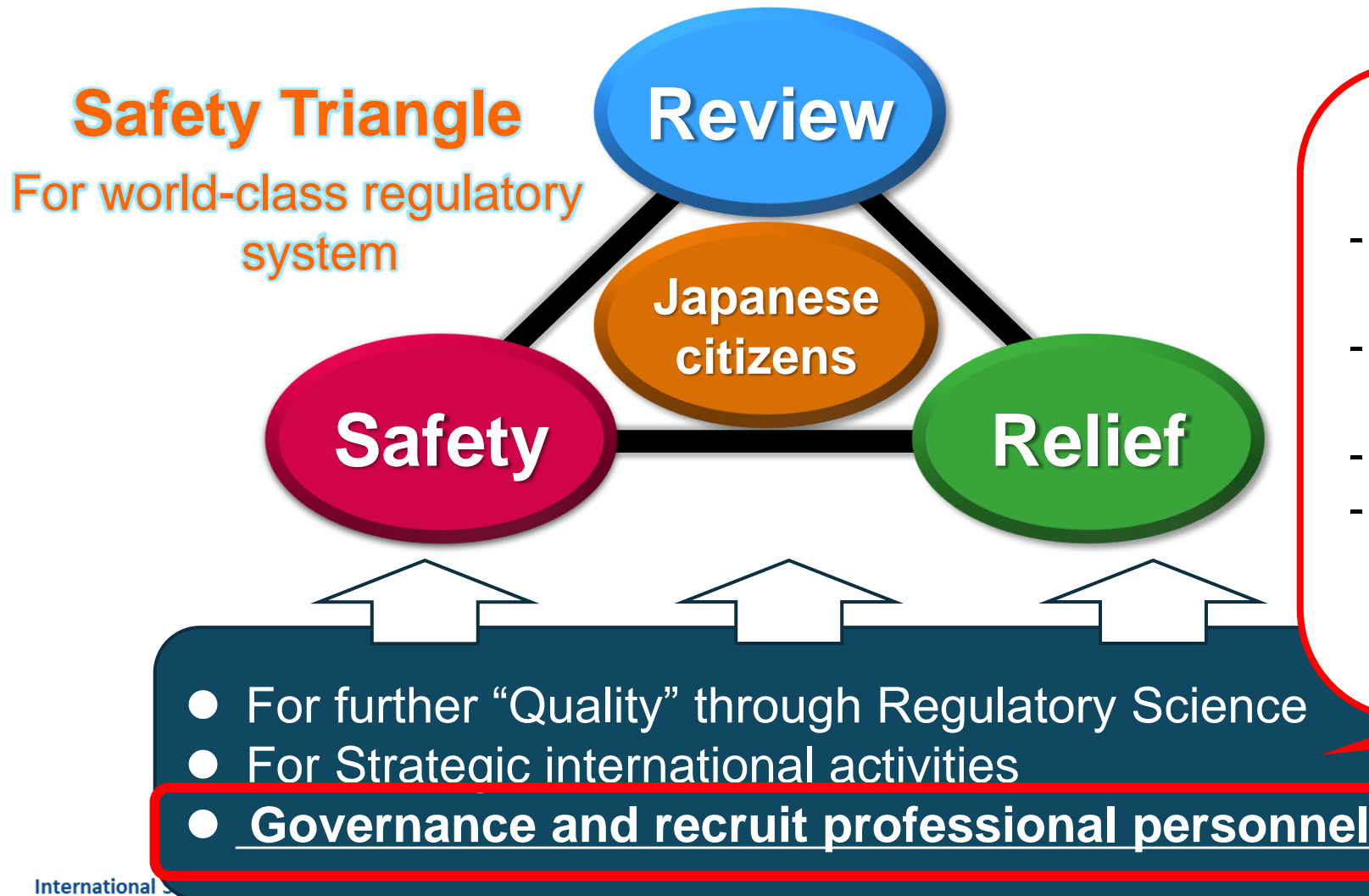
Nat Rev Drug Discov 22:781–782, 2023 (Oct) doi: <https://doi.org/10.1038/d41573-023-00102-z>

New regulation/measures

## Regulators need:

- Capacity building
- Strengthening adaptability/ Flexibility

# PMDA 5<sup>th</sup> Mid-term plan [FY2024-2028]



## Promoting Regulatory Science

- expansion of training programs for employees
- implementation of research on PMDA’s three services
- Utilization of the Science Board
- Education by way of the Collaborative Graduate School Program

(PMDA website)

# Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization

## Action 1

### Establishing a system and framework

- Creating Platform
- Promotion and cooperation of industrial activities
- Identification of needs and establishment of utilization schemes
- Strengthening the system

## Action 2

### Enhancement of clinical trial system

- Support for maintenance of clinical trial sites

## Action 3

### Promotion of harmonization including capacity building

- International standardization, Promotion of reliance
- Human resource development

## Action 4

### Specific actions for

- Drugs
- MD/IVD
- Regenerative Medicines

# PMDA Asia Training Center Performance



- Established in April, 2016.
- Endorsed as Centers of Excellence (CoE) of APEC-SCSC-RHSC.
- Promote capacity building and human resource development through training seminars for Asian regulators.

## Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

2016 – 2023

Participated from **69** countries/regions

All Participants **3,155** / Participants from Asia **2,736**

# PMDA-ATC training seminar FY2024

## For multiple countries

PMDA-ATC & U.S. FDA Pediatric Review Seminar 2024	APEC CoE Good Registration Management (GRM) Taiwan FDA	PMDA-ATC GMP Inspection Seminar 2024	APEC CoE/PMDA-ATC Medical Devices Webinar	PMDA-ATC Herbal Medicine Seminar 2024	PMDA-ATC Pharmaceuticals Review Webinar 2024	PMDA-ATC MRCT Seminar 2024	PMDA-ATC Pharmacovigilance Seminar 2024
July	September	October	October /November	November	December	January	February

## For ASEAN or specific countries

PMDA-ATC Pharmaceuticals review Seminar 2024	PMDA-ATC Cell therapy and Gene therapy products Webinar 2024	More...					
June	June		<p>Go to our website for more information ⇒ <a href="https://www.pmda.go.jp/english/int-activities/training-center/0004.html">https://www.pmda.go.jp/english/int-activities/training-center/0004.html</a></p>				



# PMDA-ATC

## Pharmaceuticals Review Seminar 2024 for ASEAN

First training seminar specific to new drug evaluation

- To strengthen evaluation skill of regulators in ASEAN, the training focused on practical case studies.



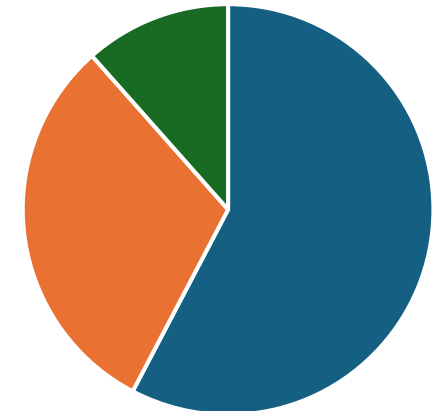
Well experienced reviewers in new drug office,

- shared points to consider in a new drug review
- explained how data is evaluated in PMDA

### Overall Satisfaction

Answered 26

Excellent	58%
Very Good or more	88%
Good or more	100%

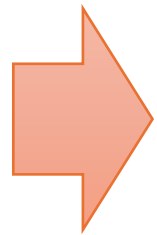


■ Excellent ■ Very Good ■ Good

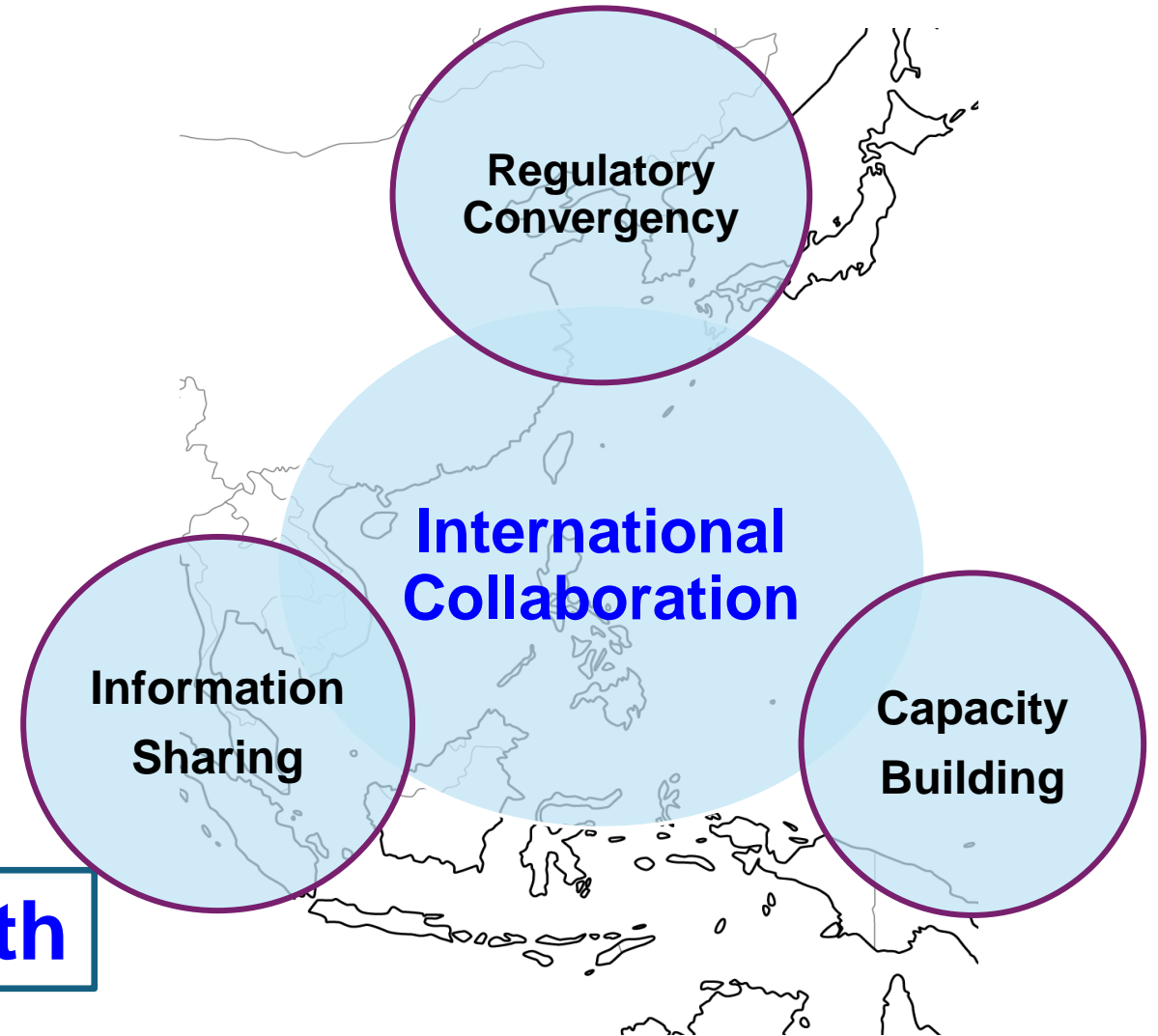
# International Collaboration

**Significantly important than ever before**

- Globalisation of supply chain
- Emergence of new technologies
- Limited human resources
- Response and Preparedness for pandemic (COVID-19 and the Next), etc...

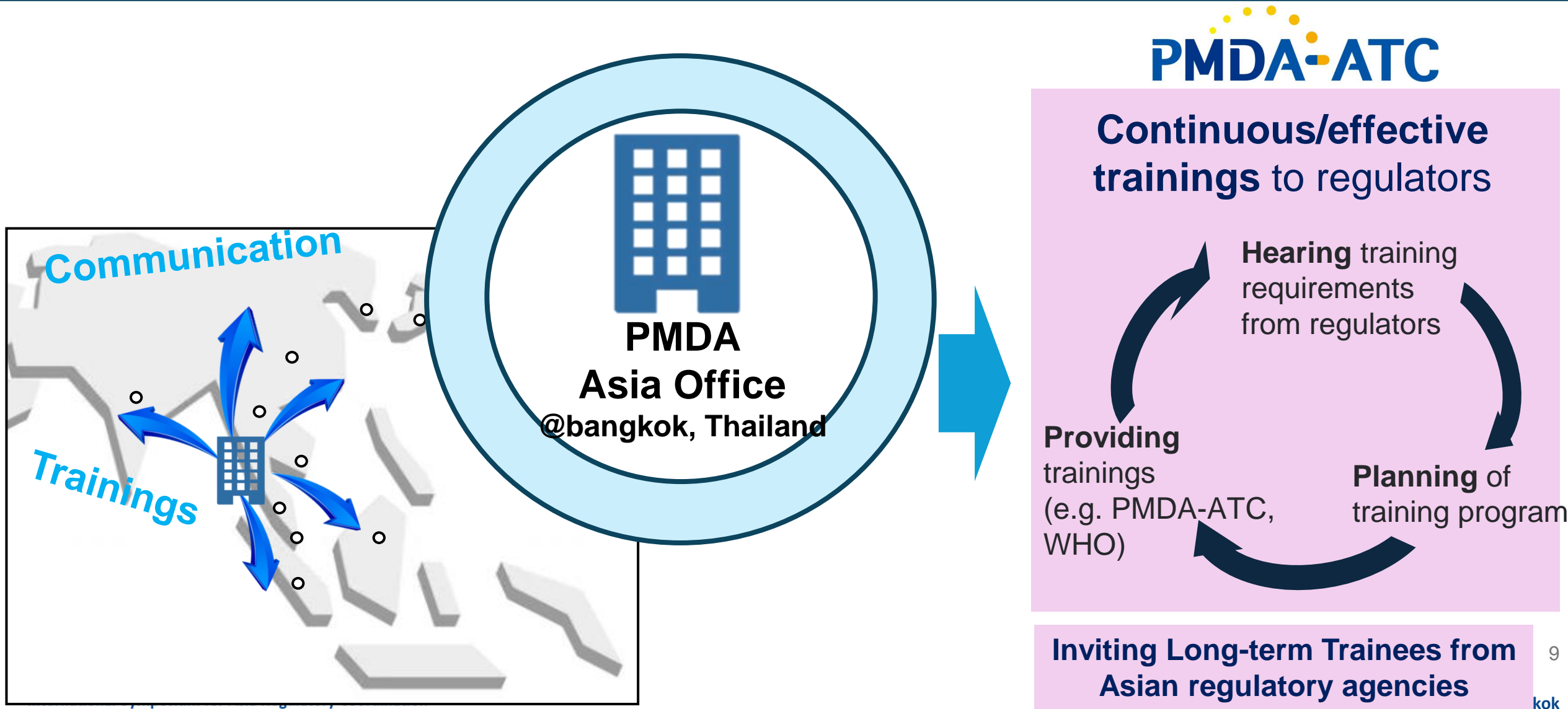


**Improving Public Health**





# PMDA-ATC Training and Asia office



The background features a complex geometric pattern of overlapping triangles in various shades of blue, ranging from light sky blue to deep navy blue. These triangles are arranged in a way that creates a sense of depth and movement, with some triangles pointing upwards and others downwards. The pattern is most dense on the left side of the image and fades out towards the right, where the background is a solid, very light blue. The text "Thank you!" is centered in the middle of the image, overlaid on the geometric pattern.

Thank you!