For Future Innovation in Asia

~Beyond Global Environmental Change~

PMDA
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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APAC
Asia Partnership Conference of Pharmaceutical Associations

Today's Topics

1. Global Environmental Changes
2. PMDA's Responses
3. Collaboration in Asia through Regulatory Science: Key Considerations
4. The Future of Working Together

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Global Environmental Changes

A gradual shift toward more **nationally focused approaches**

Prioritized Topics in Asia

◆ Promoting **domestic access** to medicinal products
- Expansion of reliance pathways
- Establishment of **expedited review pathways**
- Encouragement of **clinical trials**

◆ Securing and strengthening **national supply chains**
- Active ingredients, essential pharmaceuticals, vaccines
- **GMP inspections** of manufacturing sites

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Current Agenda

Fundamental capabilities

- Regulatory science-based decision making
- Implementation of international guidelines
- Flexible, needs-oriented regulations
- Consistent and predictable regulatory operations
- Transparent communication with stakeholders

Advancing

- ☐ Pharmaceutical regulatory systems
- ☐ The pharmaceutical Industry across Asian countries

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Promoting New Drug Development

◆Create Early Consideration

- Sharing initial position even when scientific knowledge is not fully accumulated
- To promote:
  - Practical application of **new technologies** and **innovations**
  - Development of **innovative** pharmaceuticals

◆Further Promote Multi-Regional Clinical Trials (MRCT)

- Clear guidance on:
  - Situations where **Phase I studies in Japanese subjects are not required**
  - Cases where **Japanese patient data are required at pivotal trials**, particularly for rare diseases when trials are conducted exclusively overseas

◆Outreach and consultation

- Outreach activities
  – Engagement with overseas start-up companies through scientific conferences
- Consultation and support services
  – Provided for start-up companies through the **PMDA Washington, D.C. Office**

Washington D.C. Office

Improving Japanese Clinical Trial Environment

- **Implement "ICH-E6 (R3)" Principles and Annex 1**
  [Adopted on 06 January 2025]
  - Guidance on **clinical development life cycle**
  - Interpreting "Quality in Clinical Trials" as **fitness for purpose**
  - Introduction of **Quality by Design** (QbD)

- **Promote Clinical Trial Ecosystem**
  Reducing costs/procedural burdens to enable **efficient clinical trials**

  Examples:
  - **Standardization of single IRB review**
  - **Standardized document formats** prepared by medical institutions
  - **Strengthening expertise** of sponsors and clinical trial sites
  - Encouraging IRBs **to accept English** meeting materials

Revised GCP Ministerial Ordinance in FY 2026, together with related notifications

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Dialogue on Reliance with ASEAN

PMDA Reliance meeting – 20 April, 2026

- In cooperation with **WHO and ASEAN**
- High-level session for **policy-level dialogue**
  - Application of Reliance approaches within national regulatory systems
  - Role of reliance approaches in decision-making at product assessments
  - Interaction between reliance approaches and regulatory science

PMDA-ATC

- Working-level session identifies practical enablers for reliance in ASEAN

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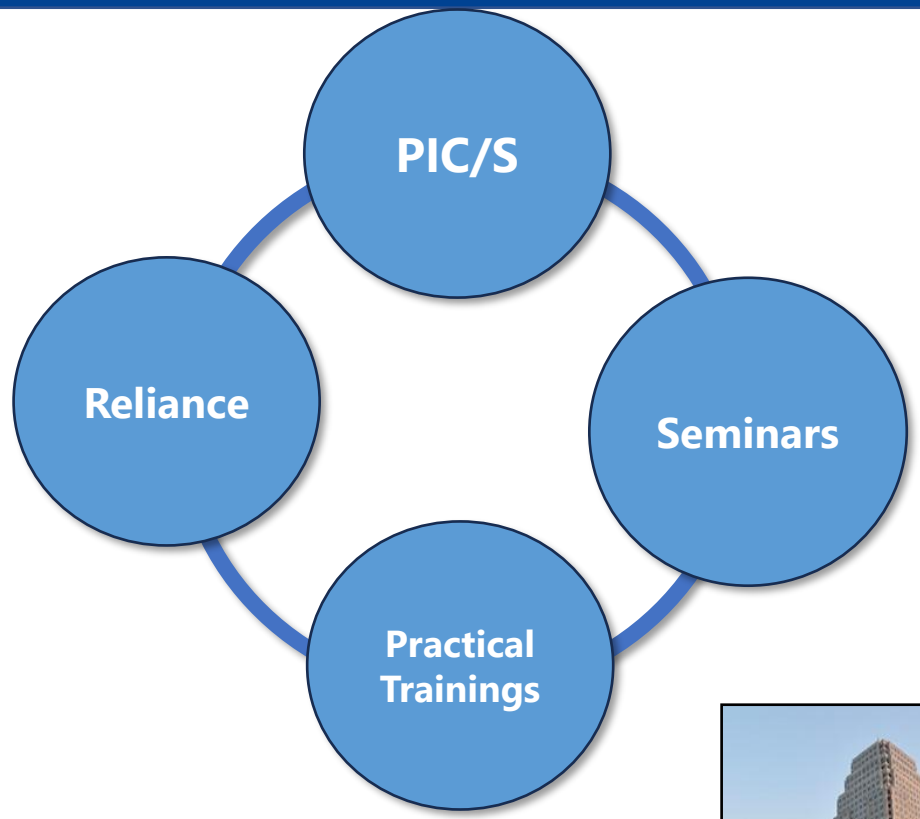
Inspection Reliance/Collaboration

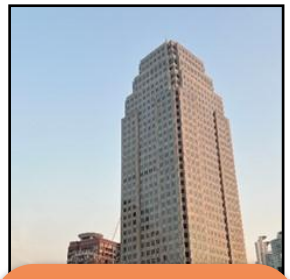
- **GMP inspection reliance**
  - Workshop based on the PIC/S guideline (drafted by ICMRA)
    "Informed decisions on the GMP compliance of a manufacturing facility can be made, in certain circumstances, based on the outcome of work by another regulatory authority or authorities."
  - PMDA's reliance activities: **ongoing**

- **GCP inspection collaboration**
  - PMDA starts first-step collaboration
  - Exploring future collaboration with Asian countries

GMP inspection reliance



- Active commitment to PIC/S as core international collaboration
- Development of GMP reliance frameworks with Asian countries
- PMDA-ATC GMP inspection Seminars as a pre-leaning of PIC/S training
- Practical GMP trainings programs organized by the PMDA Asia office



Asia Office, Bangkok Est. July 2024

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Clinical Trial/GCP Inspection Collaboration

- **Regulatory Symposium**
  hosted by PMDA/Academia
  - Regional collaboration to promote clinical trials in Asia
  - Regional dialogue among regulators, academia, and industry
  - **26th or 27th November 2026**, Bangkok, Thailand

- **Clinical trial and GCP inspection workshop**
  hosted by Clinical Research Malaysia (CRM)/PMDA
  - To exchange views on promoting clinical trials among regulators
  - **6th May 2026**, Kuala Lumpur, Malaysia
    - Back-to-back with the CRM Trial Connect 2026

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PMDA Asia Training Center

April 2026

10 years
PMDA-ATC

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia
through regulatory harmonization in the Asian region from capacity building

2016－2025

Participation from **76** countries and regions

Total participants **4,003** / Participants from Asia **3,460**

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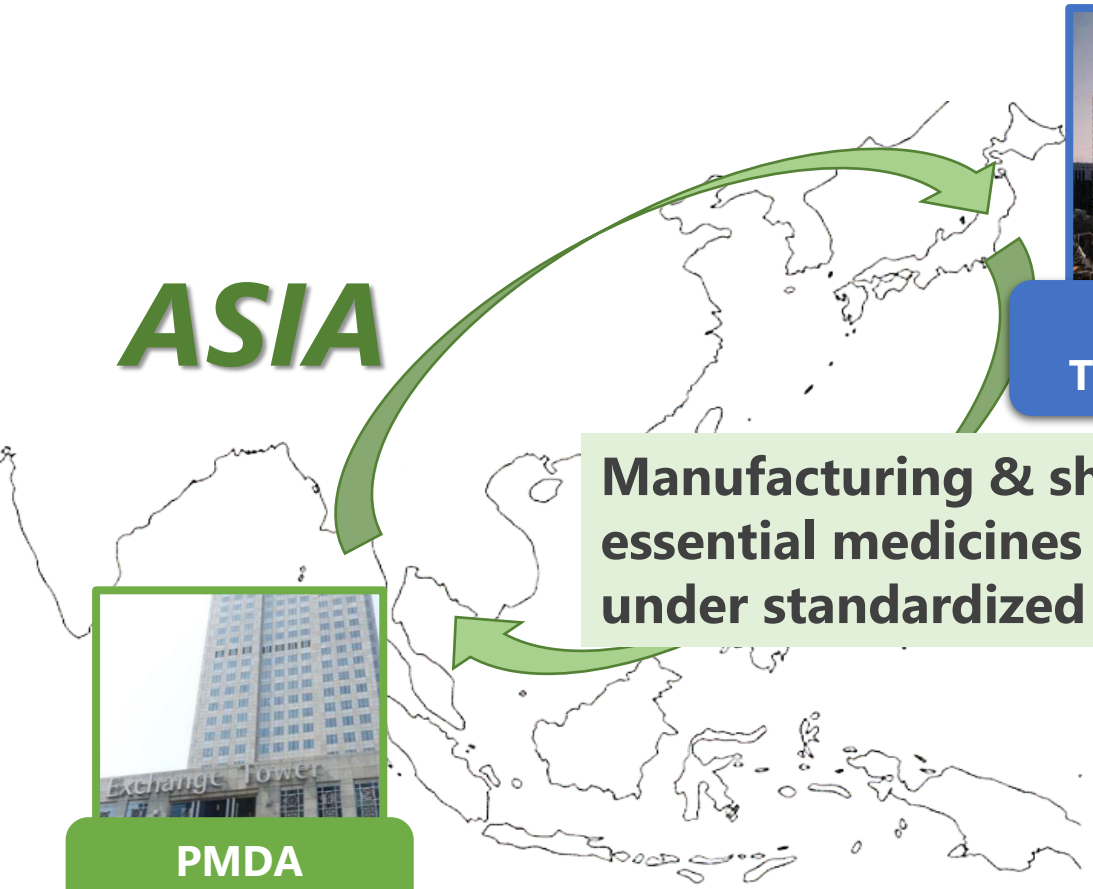
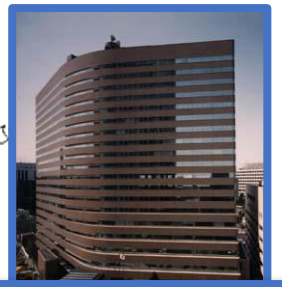
Stable Access to Pharmaceuticals across Asia





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Tokyo Office

Outreach to start-up companies

Manufacturing & sharing
essential medicines
under standardized quality

Incorporation of drug development
into Japan

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Thank you for your attention

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