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

The 14th APAC
MQS Session: GMP Inspection Reliance

GMP Inspection Reliance in Asia

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The 14th Asia Partnership Conference of Pharmaceutical Associations

Date: April 22 (Tue), 2025

Venue: Keidanren Kaikan, Tokyo, Japan

Theme : Achieving a healthier future for Asia through trust and collaboration

URL: https://14th-apac.com/index.html

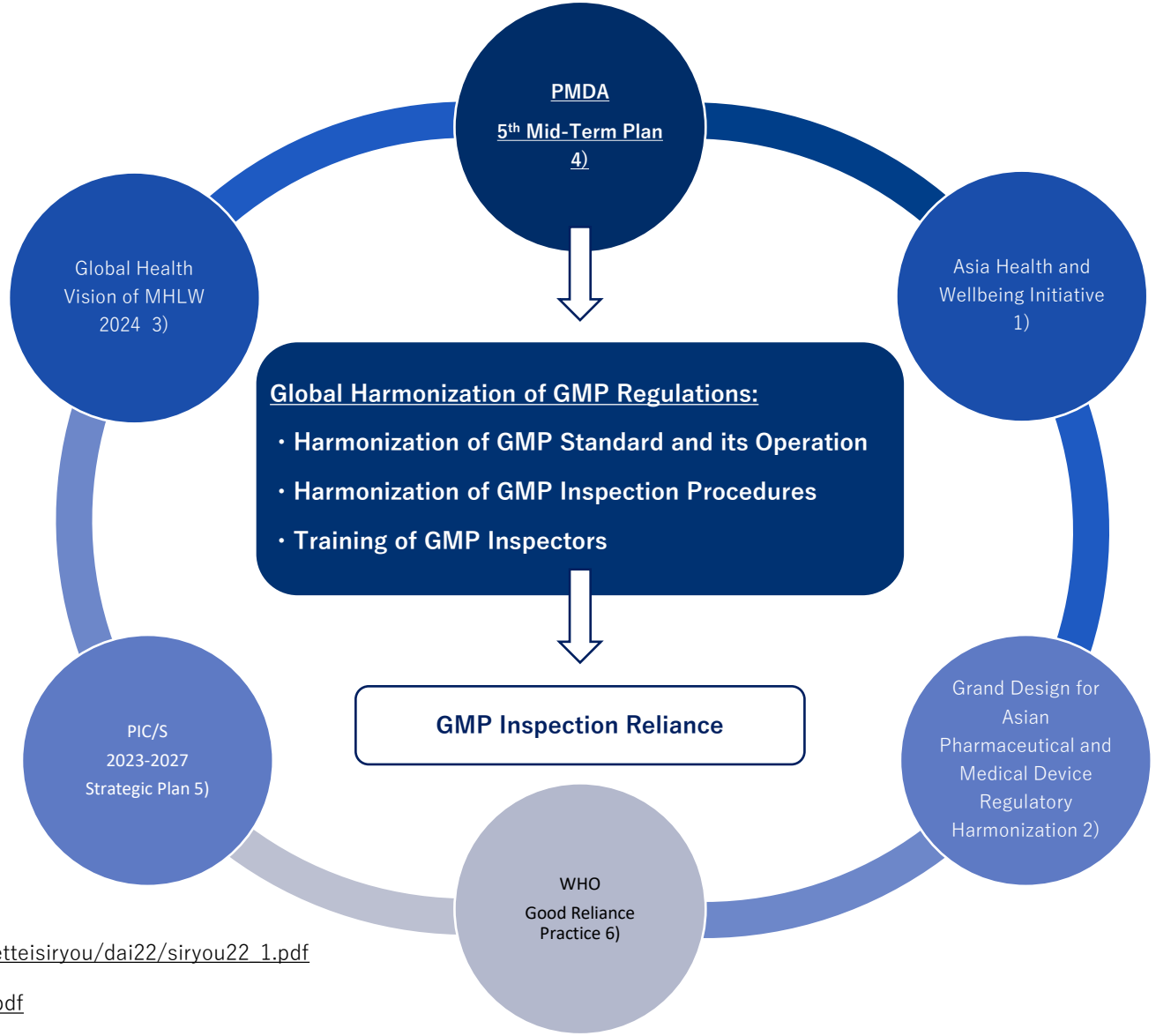
BUILD A QUALITY
DEVELOP THE GMP

Agenda

GMP Inspection Reliance in Asia

1. Basic Policy and Benefit
2. Current Activities by PMDA
3. Our Challenges

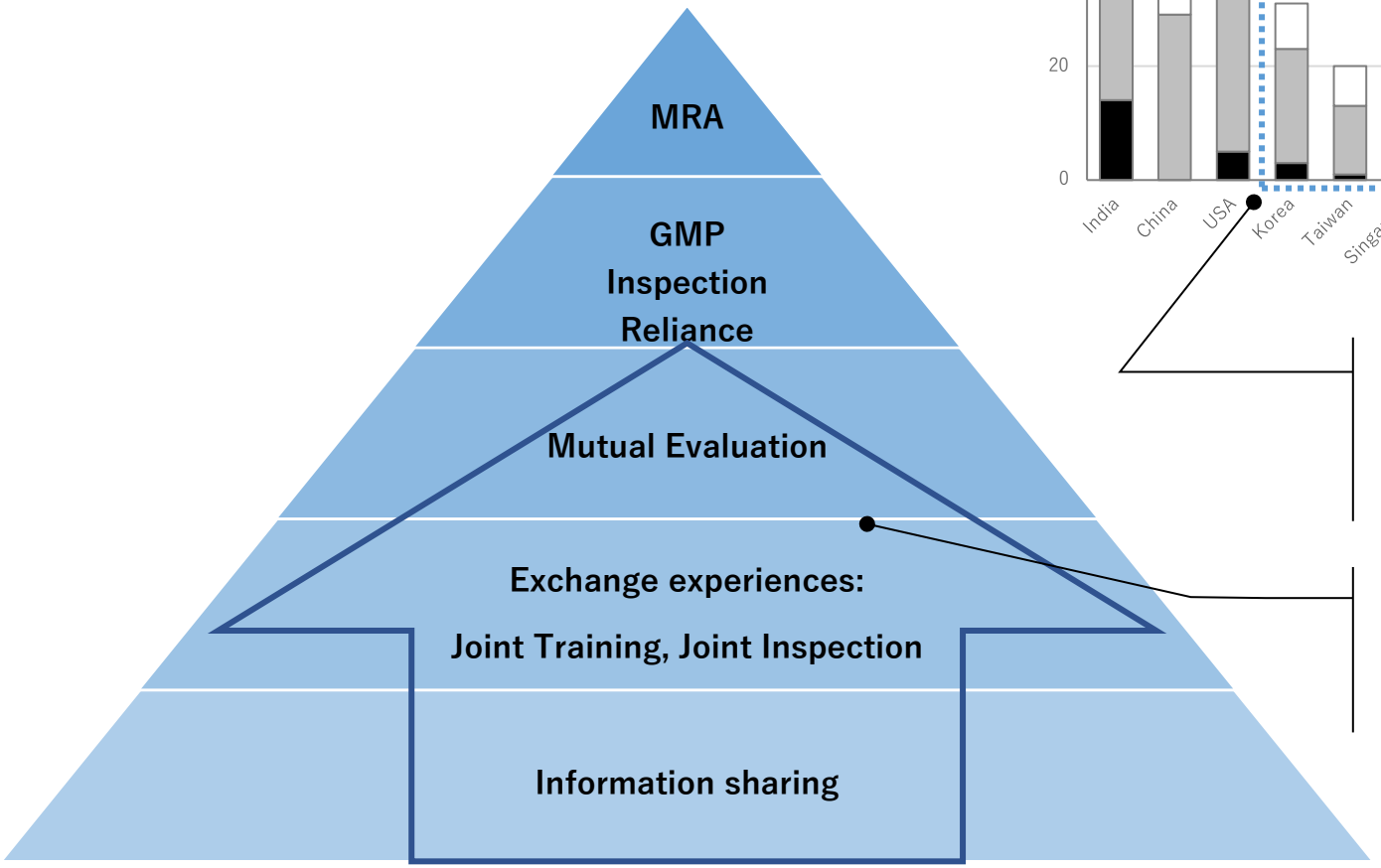
Basic Policy and Benefit

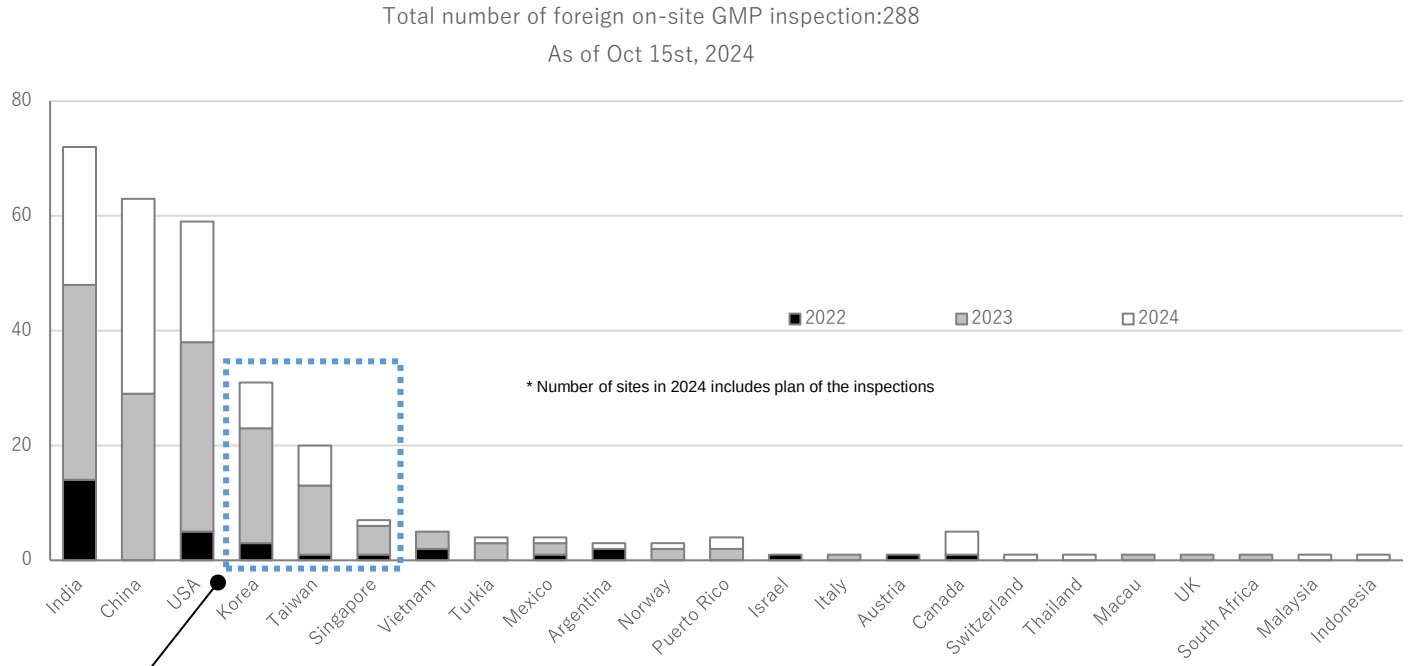


References

1) https://www.kantei.go.jp/jp/singi/kenkouiryou/suisin/ketteisiryou/dai22/siryou22_1.pdf
2) https://www.pmda.go.jp/files/000270752.pdf
3) https://www.mhlw.go.jp/content/10501000/001294429.pdf
4) https://www.pmda.go.jp/files/000267756.pdf
5) https://picscheme.org/en/publications
6) https://www.who.int/publications/m/item/annex-10-trs-1033

Basic Policy and Benefit

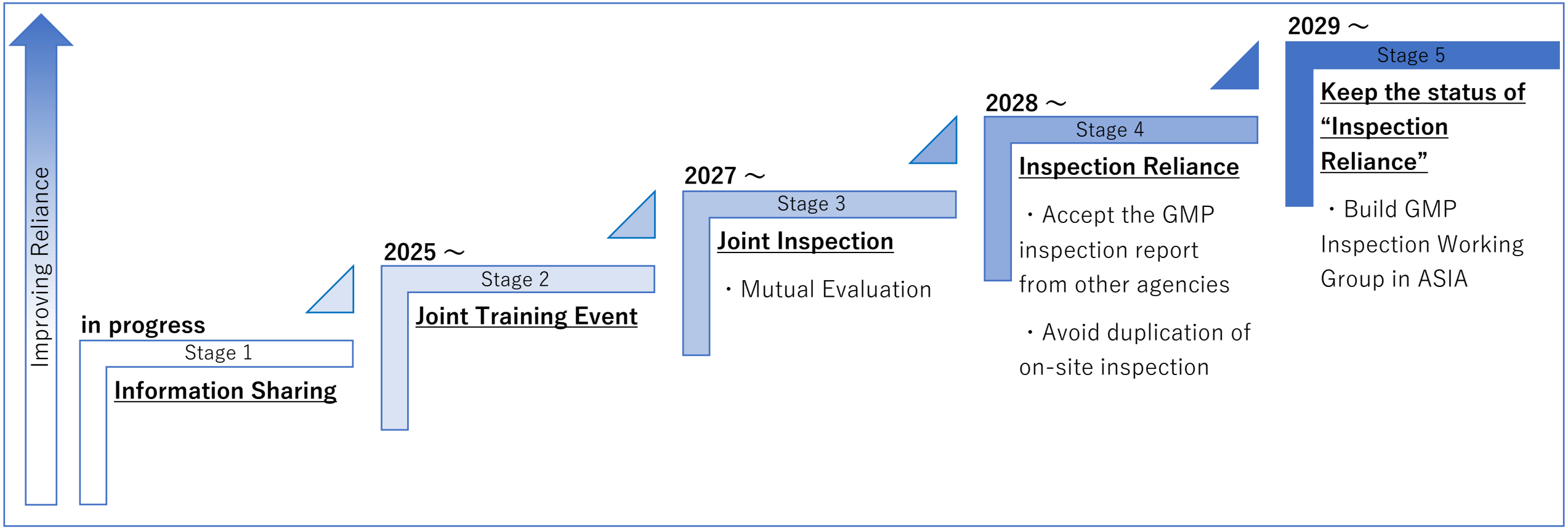




Discussion regarding the possibility of mutual acceptance of inspection results with the GMP authorities where on-site inspections are frequently conducted.

Sharing our vision on the mutual development in the field of manufacturing and quality control in Asia

Basic Policy and Benefit



Improve inspection skills of inspectors

Building Trust of Regulatory Agencies in Asia

Decrease inspection "burden"

Improve the quality and stable supply of pharmaceuticals: Patients Benefit

Agenda

GMP Inspection Reliance in Asia

1. Basic Policy and Benefit
2. **Current Activities by PMDA**
3. Our Challenges

Current Activities by PMDA

EMA GMP/GDP Inspectors Working Group

URL: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/good-manufacturing-practice-gmp-distribution-practice-practice-gdp-inspectors-working-group

Frequency: Four times a year

Participants: GMP inspectorates of the European Economic Area Member States, European Commission (DG Enterprise and Industry) and observers from EDQM, WHO and the inspectorates of the countries accessing to the EU, and MRA and other trade co-operation partner countries

Theme:

The meetings consider new and revised GMP and GDP - related guidance, normally developed by drafting groups, work related to MRA, how new legislation impacts GMP and GDP inspection activity and harmonisation of GMP and GDP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Union Procedures are developed. The group interacts with other bodies e.g. MRA Partners, PIC/S, WHO and EDQM. GMP related issues concerning centrally authorised products and GMP inspections co-ordinated by the EMA in connection with these, are also considered at the meetings.

PIC/S Seminar

URL: https://picscheme.org/en/events

Frequency: Once a year

Duration: 3 days

Number of participants: 150-200 inspectors (Regulatory Only)

Theme:

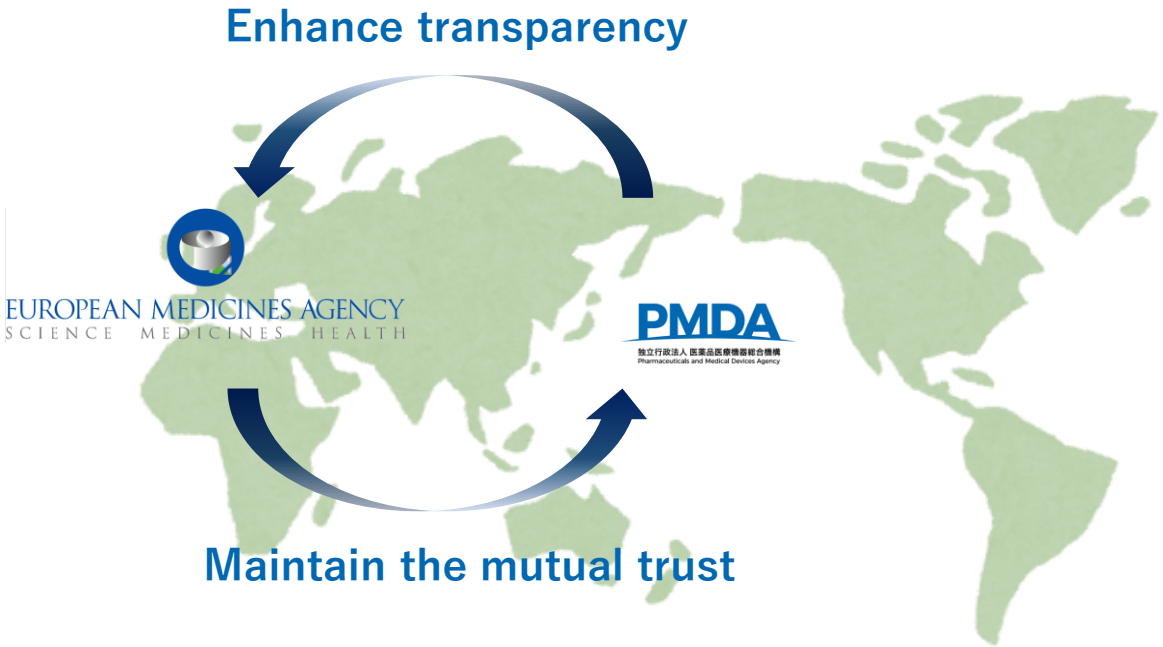
(2025, Hong Kong) Advanced technologies in Pharmaceutical Manufacturing

(2024, Brasilia) Annex I Unveiled: Shaping the Future of Sterility

(2023, Bangkok) Soft Skills that make a Good GMP/GDP inspector

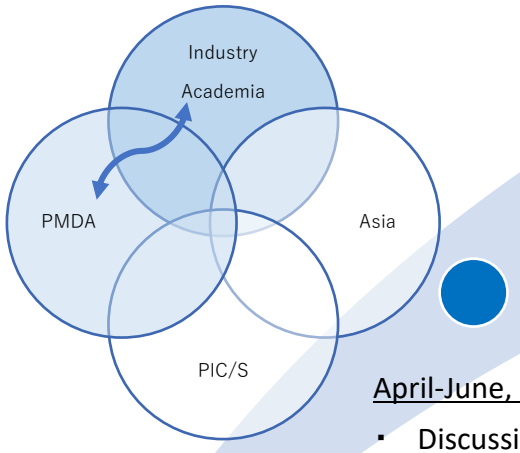
(2022, Dublin) Inspection of the Pharmaceutical Quality System

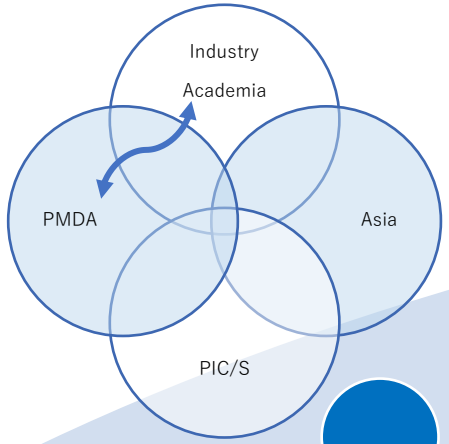
EMA GMP/GDP Inspectors Working Group

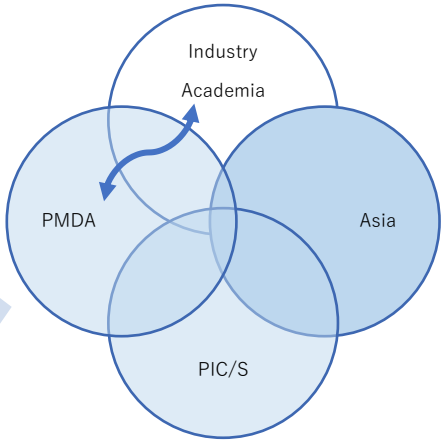


1. **Enhance transparency and maintain the mutual trust as an MRA partner**
2. **Clarify challenges of Japanese GMP regulations**
3. **Find weakness of PMDA inspectors**
4. **Expand the communication network with European regulators**
5. **Understand a global trend of the GMP regulation and predict future GMP regulation**

PIC/S Seminar 2025: Advanced Technologies in Pharmaceutical Manufacturing







January-March, 2025

- Communication with industry
- Identify our challenges and establish our future vision

April-June, 2025

- Discussion with industry
- Considerations the contents of PMDA ATC GMP Seminar and PIC/S Seminar

July-September, 2025

- Study sessions with industry
- Make presentation scenarios in the PMDA ATC GMP Seminar and PIC/S Seminar
- Participate in the PIC/S WG on Advanced Technologies

September, 2025

- PMDA ATC GMP Seminar in Tokyo
- Preparation for the PIC/S Seminar in collaboration with GMP authorities in Asia

November, 2025

- PIC/S Seminar in Hong Kong

Documentation of PMDA Discussion paper on AI in manufacturing

Agenda

GMP Inspection Reliance in Asia

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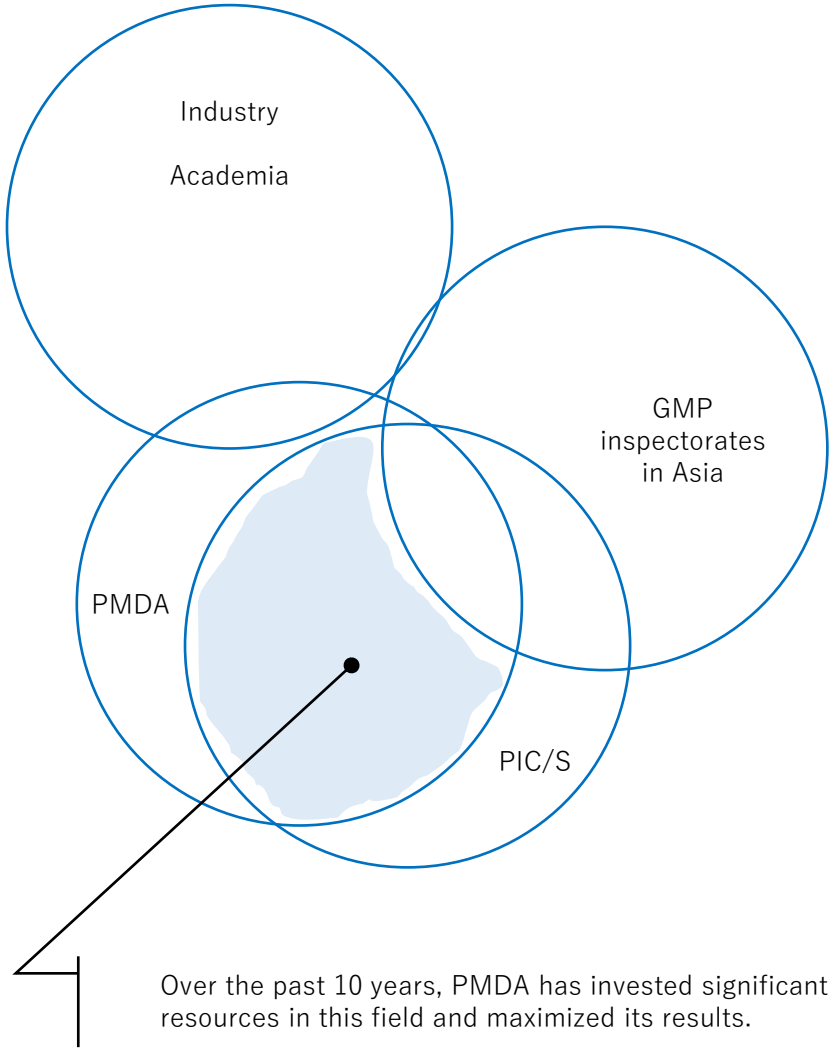
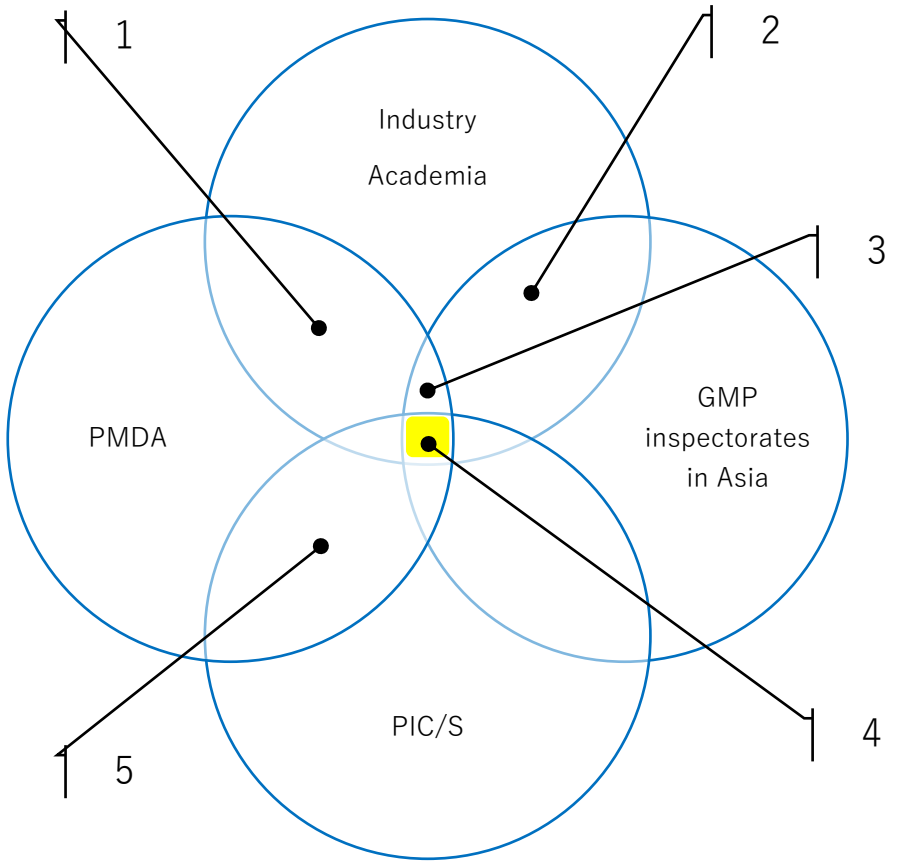
2. Current Activities by PMDA
3. **Our Challenges**

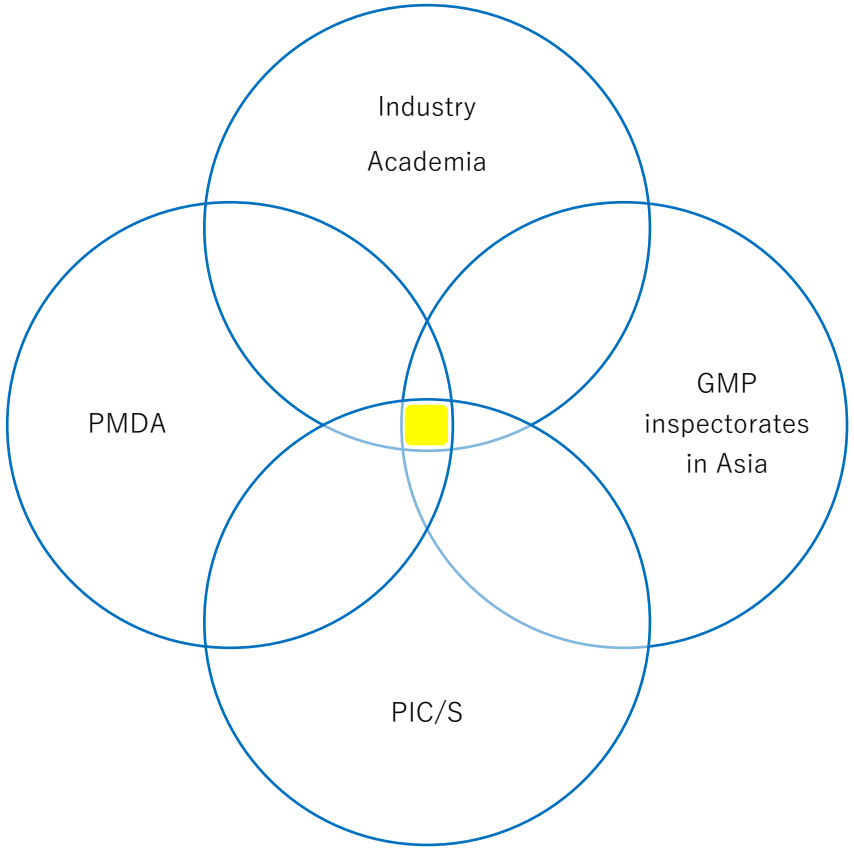
Effective collaborations maximize benefits

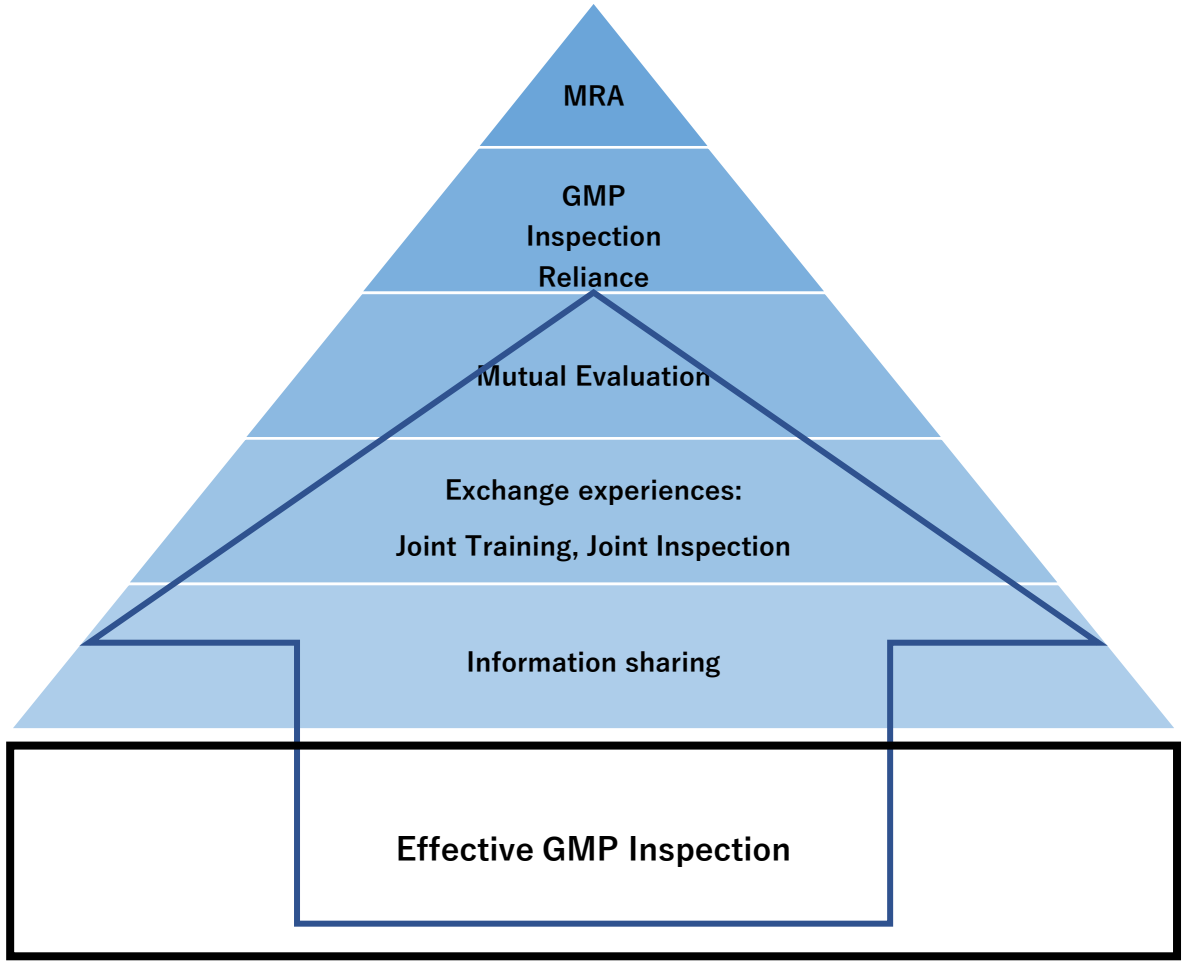


Over the past 10 years, PMDA has invested significant resources in this field and maximized its results.



Conclusion: Message from PMDA





1. Share the future vision of GMP inspection Reliance in Asia
2. Make the effective pathway for mutual acceptance of GMP inspection results
3. Improve the inspection capability and mutual acceptance of inspection results to achieve regulatory approval of pharmaceutical products in a short time.
4. Maintain the quality and stable supply of pharmaceutical products: Patients Benfit

PMDA

Making everyone’s lives brighter together