

MQS Session

GMP Inspection Reliance

22 April 2025
The 14th APAC
JPMA

Session Theme - GMP Inspection Reliance

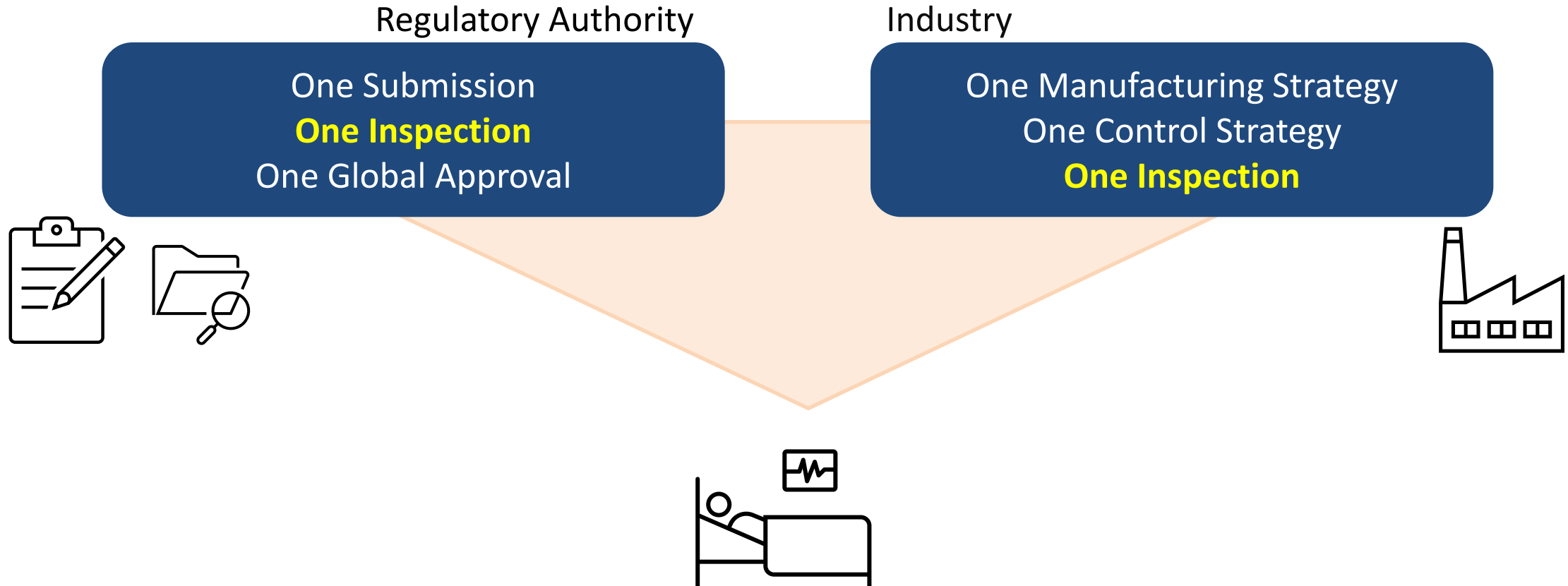
Facilitate faster access of important medicines to patients around the world

**Regulatory Assessment
Reliance**

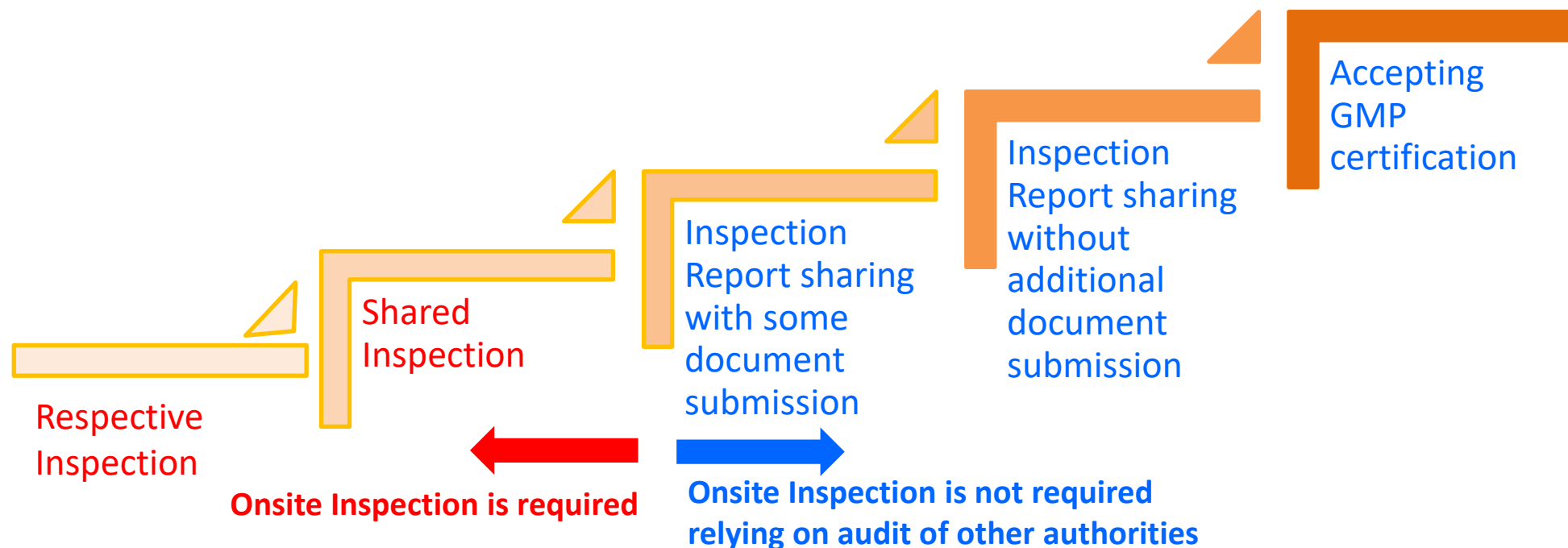
**GMP Inspection
Reliance**



Concept and Vision



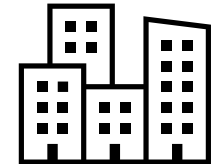
Stages of GMP Inspection Reliance



What is needed?	Capability Building	Standardization (GMP, Inspection)	Information Sharing	Mutual Reliance	Facilitation of mutual recognition
Challenges	-	How to standardize	How to rely How to exchange information (access and platform)	How to evaluate	How to build mechanism How to maintain the mechanism
Frameworks	-	PIC/S	PIC/S Confidential Agreement		MRA, MoU, Other Reliance Framework etc.

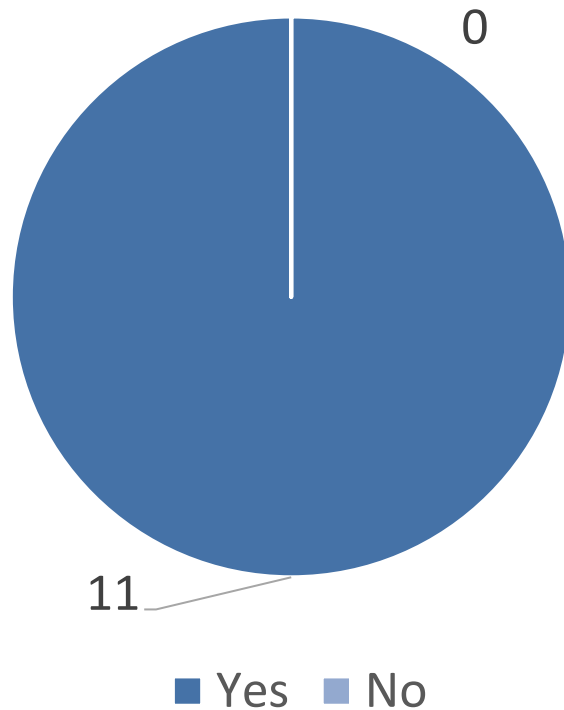
Expectation from Industry - from Survey

- MQS conducted a survey on Industry Voice for GMP Inspection Reliance
- Implementation Period: Oct 2024 (Extended to 25 Nov)
- Respondents: APAC associations (Answers from 11 associations)



Expectation from Industry - from Survey

Q: Do you think GMP inspection reliance framework is beneficial for your country/region?



- ✓ All economies which submit their answer that GMP Inspection Reliance framework is beneficial

Expectation from Industry

Q: What are your expectations for the realization of GMP inspection reliance framework?

Efficiency in GMP inspection reliance

- Recognition of sites audited and conforming to GMP standards by PIC/S members
- Reducing the need for duplicate inspections, saving time and resources
- Streamlining regulatory processes by using inspection reports as supportive information
- Faster GMP approvals

Information Sharing and Cooperation

- Enabling local health authorities to share confidential and non-public inspection information with other competent health agencies.
- Facilitating access to strategic data on the safety, efficacy, and quality of medicines already assessed by one agency to others

Transparency in GMP inspection

- Consolidating the on-site inspections to shorten review and approval timelines for NDA/site transfers
- Minimal documentation requirements
- Simplified procedures related to GMP inspections to enable faster market supply.
- To be accepted digital evidence of GMP status (e.g., FDA Drug Establishment Database & EUDRA GMP) without requiring additional evaluations or wet-ink signatures.

International Trust and Competitiveness

- Increasing confidence in local production facilities.
- Enhancing the international competitiveness of pharmaceutical enterprises.
- Promoting efficient operation of the drug supply chain.

Introduction for MQS Session



Key Points of each presentations

- PMDA (Japan) : Concept and benefit of GMP Inspection Reliance and current activities
- NPRA (Malaysia): ASEAN MRA for GMP and overview of inspection reliance situation in Malaysia
- HSA(Singapore): MRA with South Korea and overview of inspection reliance situation in Singapore

How This Session Will Benefit You

- Gain a deeper understanding of benefits
- Learn practical strategies for facilitating GMP inspection reliance
- Take away from successful cases to build framework

Thank you for your attentions

