APAC
Asia Partnership Conference of Pharmaceutical Associations

MQS Session
GMP Inspection Reliance

22 April 2025
The 14th APAC
JPMA

Session Theme - GMP Inspection Reliance

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Facilitate faster access of important medicines to patients around the world

Regulatory Assessment Reliance

GMP Inspection Reliance

Concept and Vision

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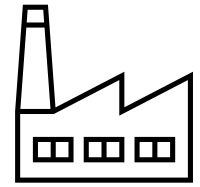
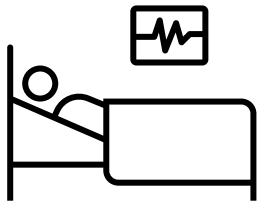
Regulatory Authority

One Submission
One Inspection
One Global Approval

Industry

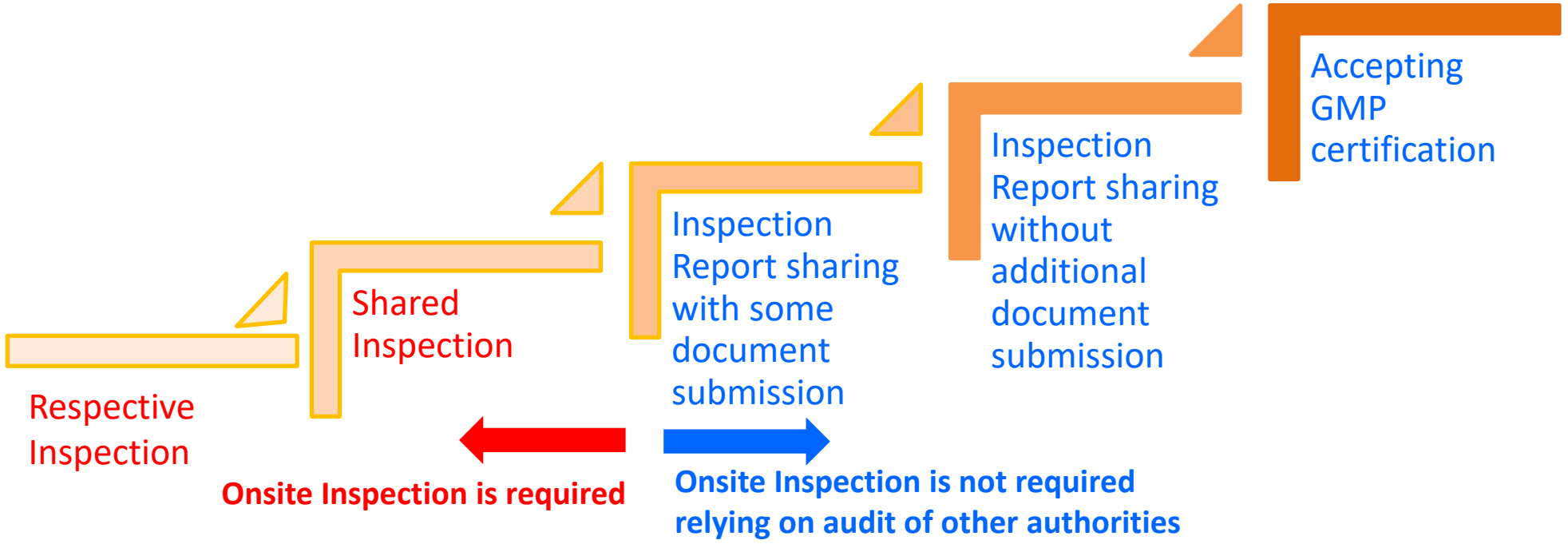
One Manufacturing Strategy
One Control Strategy
One Inspection





Aim for the same goal to achieve our mutual mission for patients

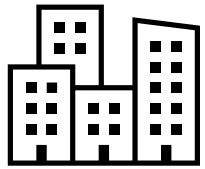
Stages of GMP Inspection Reliance



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

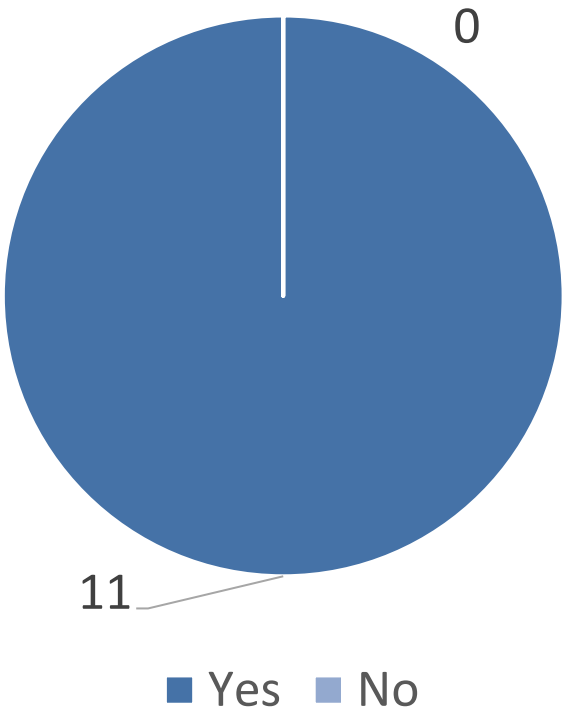
Expectation from Industry - from Survey

- 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

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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

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.

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

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

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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

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Thank you for your attentions