

Date: 22 April 2025  
Venue: Keidanren Kaikan



# The 14<sup>th</sup> APAC

## MQS Session

### GMP Inspection Reliance



# GMP Inspection Reliance

## Speakers and Chairs



**Speaker & Panelist**  
**Hng Kim Mi (NPRA)**



**Speaker & Panelist**  
**Lim Li Lian (HSA)**



**Speaker & Panelist**  
**Kentaro Hara (PMDA)**



**Speaker**  
**Makoto Ono (JPMA)**



**Chair**  
**Michihiro Imada**  
**(PMDA)**



**Chair**  
**Miyako Maruyama (JPMA)**

# Panel Discussion

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## Our Expectation

- The promotion of GMP Inspection Reliance will avoid duplicate inspections and allow for optimal resource allocation based on risk.
- The realization of GMP Inspection Reliance will generate more resources for other activities.
- Patient benefit : Early Access and High Quality

# Panel Discussion

## Question 1

What are key points to promote/hinder  
GMP Inspection Reliance?

# Panel Discussion

## Question 2

What is required to realize GMP Inspection Reliance,  
between industries and regulatory authorities,  
or among relevant regulatory authorities?

- especially in cases where GMP issues arise once GMP Inspection Reliance is achieved, how should these be handled?

# Panel Discussion

## Question 3

What GMP compliance evidence is acceptable once GMP Inspection Reliance achieved?



# Panel Discussion

## Question 4

What are the future benefits for the patients and companies of your economy once GMP Inspection Reliance achieved?



# Panel Discussion

## Question 5

What benefits would there be for Asia,  
that materialize GMP inspection reliance in Asia?

# GMP Inspection Reliance

## Conclusion

- GMP Inspection Reliance avoids duplicate inspections and optimize resource allocation based on risk. For low-risk sites, GMP certificates may be accepted instead of having to perform duplicate inspections. GMP inspection reliance support innovation by generating resources for both regulatory authorities and companies.
- Promoting GMP Inspection Reliance requires mutual understanding and trust among authorities through communication, training, assessment. It will lead to maintain a high level of GMP standards in each economy.
- The realization of GMP inspection reliance will contribute to early approval by conducting GMP assessments with minimal resources and time, enabling patients to access high-quality medicines earlier.