Date: 22 April 2025
Venue: Keidanren Kaikan

APAC
Asia Partnership Conference of Pharmaceutical Associations

The 14th APAC

MQS Session
GMP Inspection Reliance

GMP Inspection Reliance

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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)

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Panel Discussion

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

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Question 1

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

Panel Discussion

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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

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Question 3

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

Panel Discussion

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Question 4

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

Panel Discussion

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Question 5

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

GMP Inspection Reliance

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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.