MQS Session Introduction: Advanced Technologies (AT)

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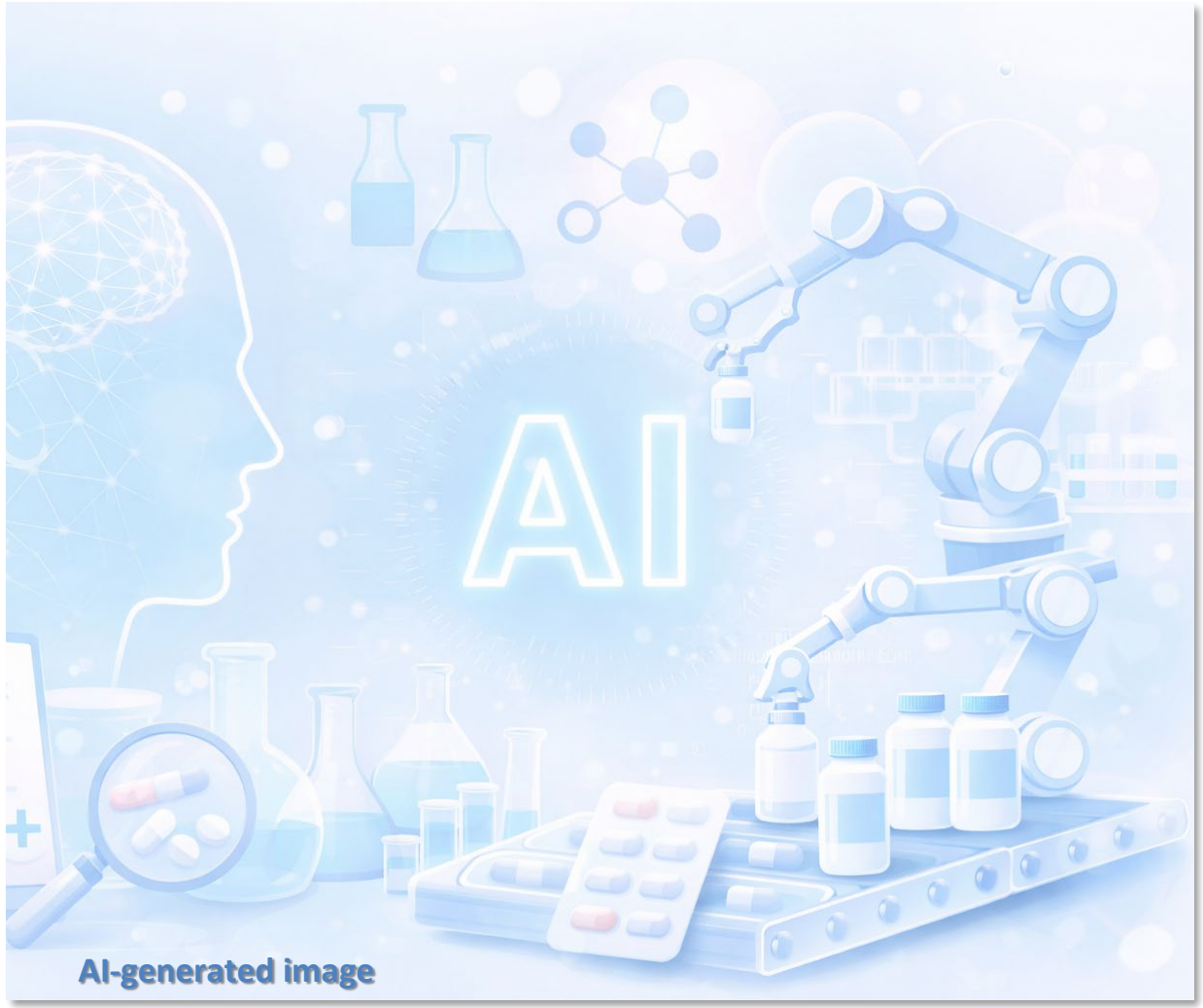

- The 15th APAC (2026)
- JPMA MQS Task Force
- 21 April 2026

MQS Session for the 15th APAC (2026)

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Session Theme

Advanced Technologies

Background

- Advanced technologies (AT) including Artificial Intelligence, and Machine Learning for manufacturing and quality control, and have become a hot topic in the pharmaceutical industry. Draft PIC/S Annex 22 “Artificial Intelligence” and the revised PIC/S Annex 11 “Computerized Systems” have been published, and detailed discussions are taking place among authorities and industries.
- However, significant challenges remain in adopting AT, including global regulatory harmonization, uncertainties in the practical application of new technologies, and the development of skilled human resources.
- Therefore, its implementation is not progressing smoothly.

Survey Results on AT from APAC-Related Associations

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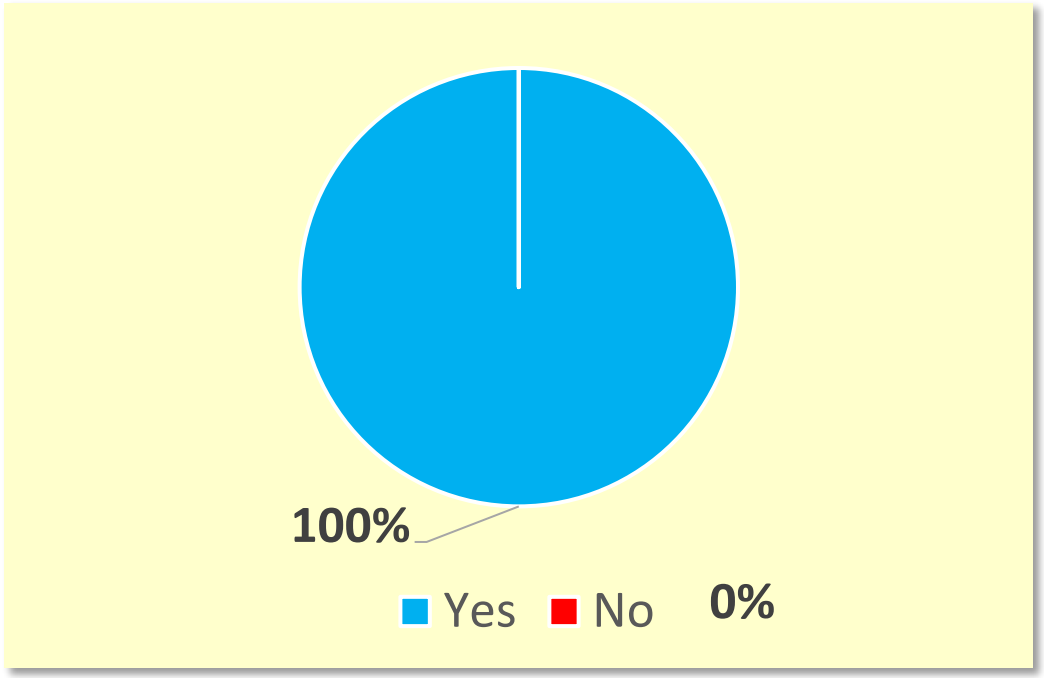

- Interest in AT: expressed by all respondents
- Details in the following slides

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Industry Interest in AT

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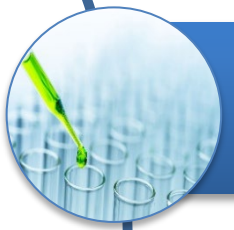
Enhancing productivity and manufacturing efficiency



Accelerating development timelines

Strengthening product quality

Driving innovation

Key Challenges to Implementation

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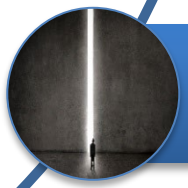
Regulatory uncertainty in practical application

Lack of international harmonization

Limited regulatory experience

Digital infrastructure gaps



Organizational and cultural barriers

Industry Expectations for Regulators

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Science-based regulatory approaches

Early communication and dialogue with regulators.

Greater international harmonization

Clear guidance for advanced technologies

Regulatory capacity building

Purpose of MQS Session

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Purpose of This Session

- Share perspectives on advanced technologies
- Discuss regulatory trends and challenges
- Explore practical approaches to implementation
- Strengthen collaboration between regulators and industry

Your Key Takeaways

- A clear view of the global regulatory landscape shaping AT
- Practical approaches to managing risks associated with AT development
- Insights into overcoming implementation challenges
- Earlier and stronger engagement between regulators and industry

Time Schedule of MQS session

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No	Title	Presenter	Time
1	Opening and Introduction	Dr. Ikuo Kushida (JPMA)	10 min
2	AI/ML in Pharmaceutical Manufacturing	Ms. Na Lim (HSA)	20 min
3	Application of AI in Pharmaceutical Manufacturing	Dr. Srinivasan Kellathur (PhAMA)	20 min
4	Toward the Implementation of Advanced Technologies in Pharmaceutical Manufacturing	Mr. Nobuhiro Shimizu (PMDA)	20 min
5	Panel Discussion	Dr. Kentaro Hara (PMDA) Mr. Yuki Marumo (PMDA) Ms. Na Lim (HSA) Dr. Srinivasan Kellathur (PhAMA)	15 min
6	Closing	Mr. Keiichi Kodama (JPMA)	5 min

Thank you for your attention

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Advanced Technologies

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Appendix

What Advanced Technologies Can

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- **Accelerated Development**
  - ✓ Faster R&D project completion through AI-driven approaches
  - ✓ Faster initial shelf-life setting using predictive modeling
- **Cost Reduction**
  - ✓ Reduced testing and validation costs through Real-Time Release Testing (RTRT)
- **Improved Product Quality and Consistency**
  - ✓ Real-time quality monitoring using Process Analytical Technology (PAT)
  - ✓ Enhanced defect detection through AI-based visual inspection
  - ✓ Reduced process variability
- **Increased Manufacturing Flexibility**
  - ✓ Greater adaptability through continuous manufacturing
  - ✓ Better support for small-batch and multi-product production
- **Advanced Data Utilization**
  - ✓ AI/ML-enabled data analytics and process modeling
  - ✓ Improved predictive capabilities
- **Higher Productivity**
  - ✓ Streamlined processes through automation
  - ✓ Significant time savings in data analysis
- **Stronger Regulatory Alignment**
  - ✓ Enhanced compliance with global standards
  - ✓ Improved data integrity