

Implementation of Advanced Technologies in Pharmaceutical Manufacturing in Japan

Nobuhiro SHIMIZU, Yuki MARUMO, Kentaro HARA

Office of Manufacturing Quality for Drugs

Pharmaceuticals and Medical Devices Agency (PMDA) , Japan

15th APAC Conference MQS (Manufacturing, Quality Control and Supply) Session 15:10-15:30 on 21 April 2026



Agenda

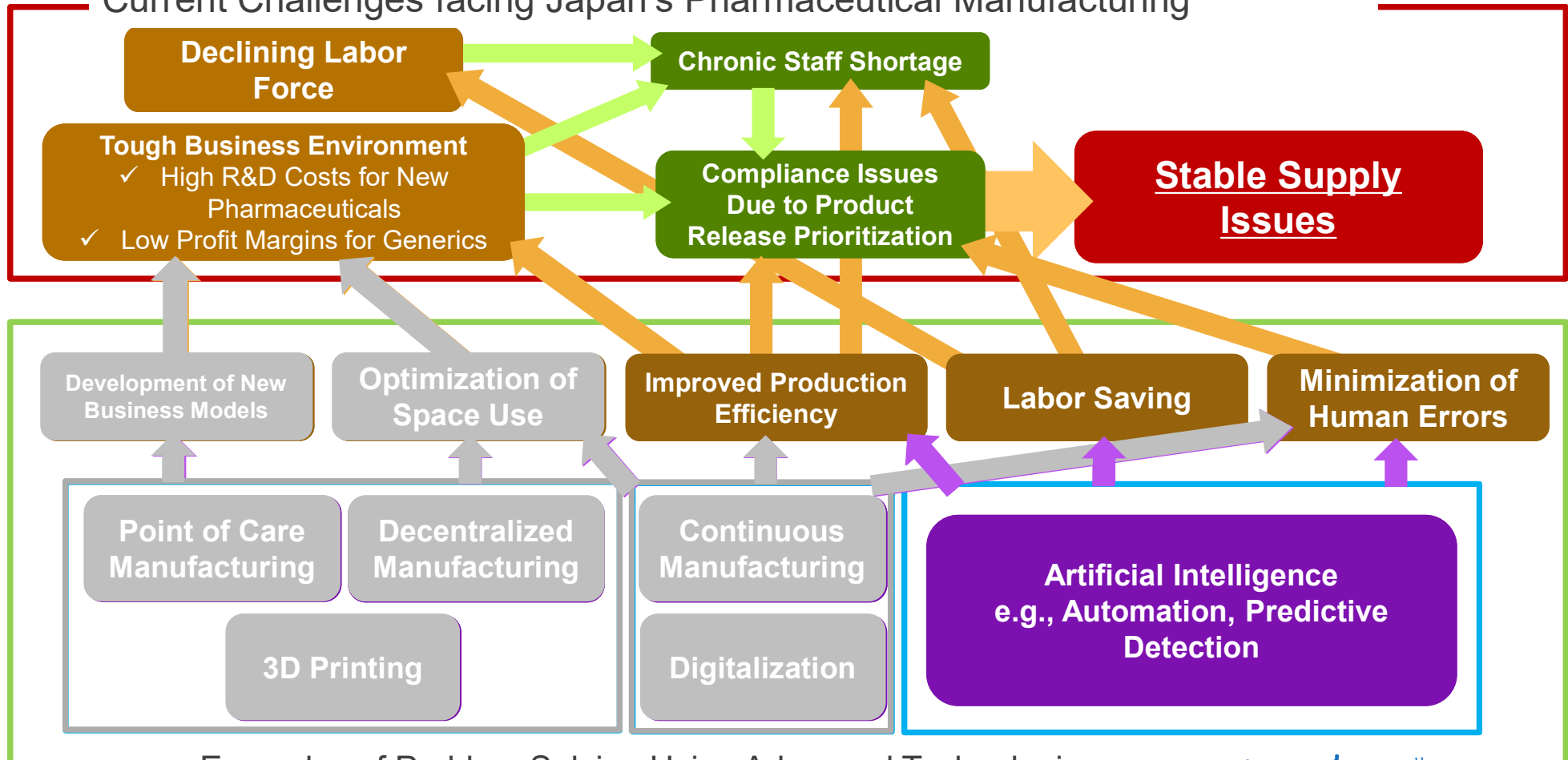
- PMDA's challenges
- PMDA's proposal
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- Status of Draft Use Case Development
- Future plans

Agenda

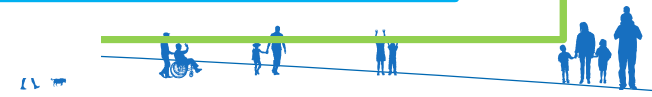
- PMDA's challenges
- PMDA's proposal
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- Status of Draft Use Case Development
- Future plan

Expectations for the adoption of AT in Pharmaceutical Manufacturing

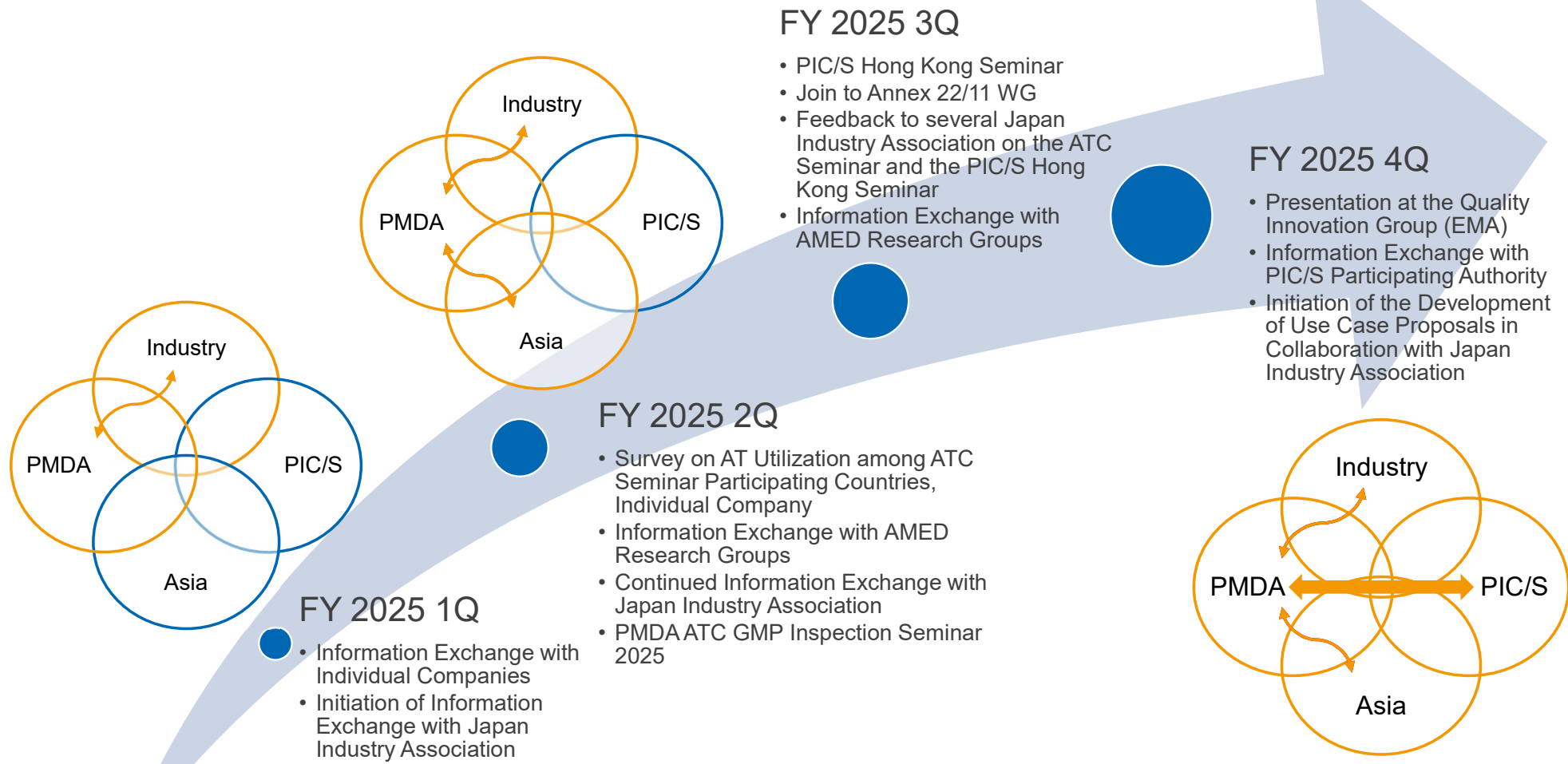
Current Challenges facing Japan's Pharmaceutical Manufacturing



Examples of Problem Solving Using Advanced Technologies



Progress and Activities in Fiscal Year 2025



Agenda

- PMDA's challenges
- **PMDA's proposal**
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- Status of Draft Use Case Development
- Future plan

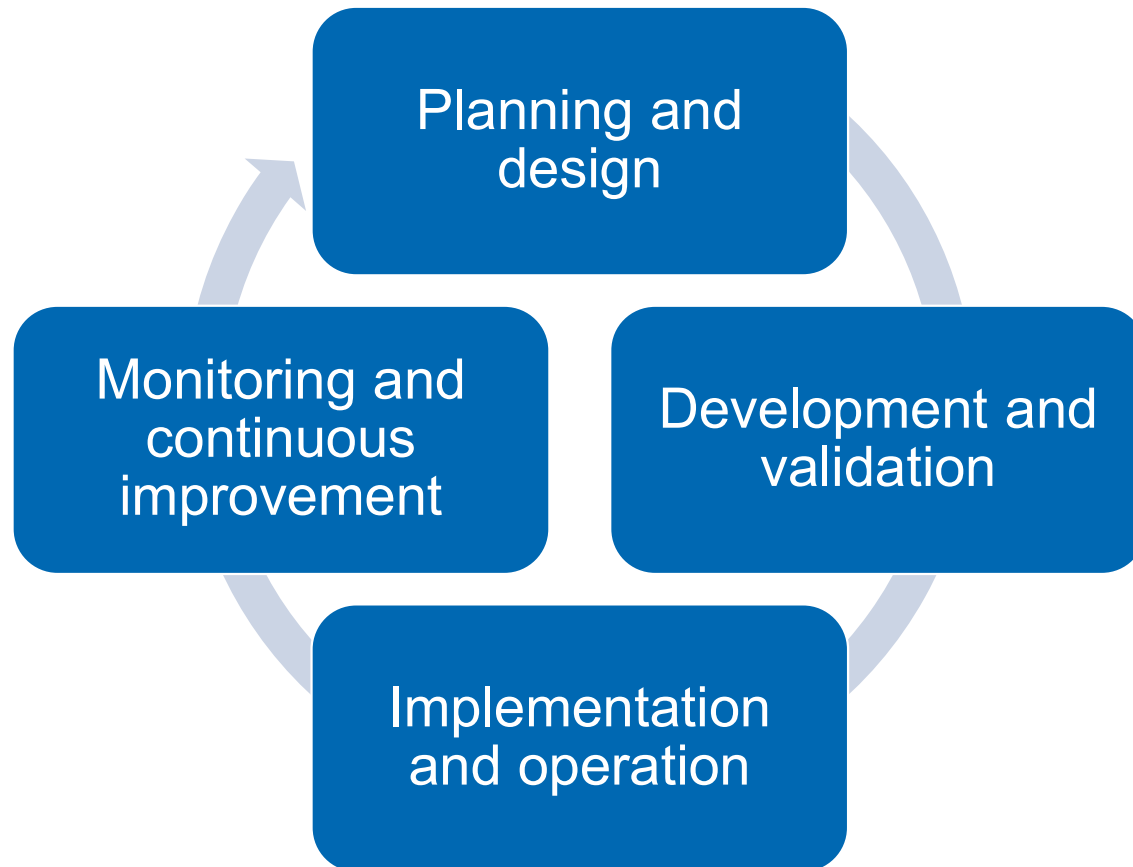
Key messages

Use cases are essential for the proper implementation of Annex 22



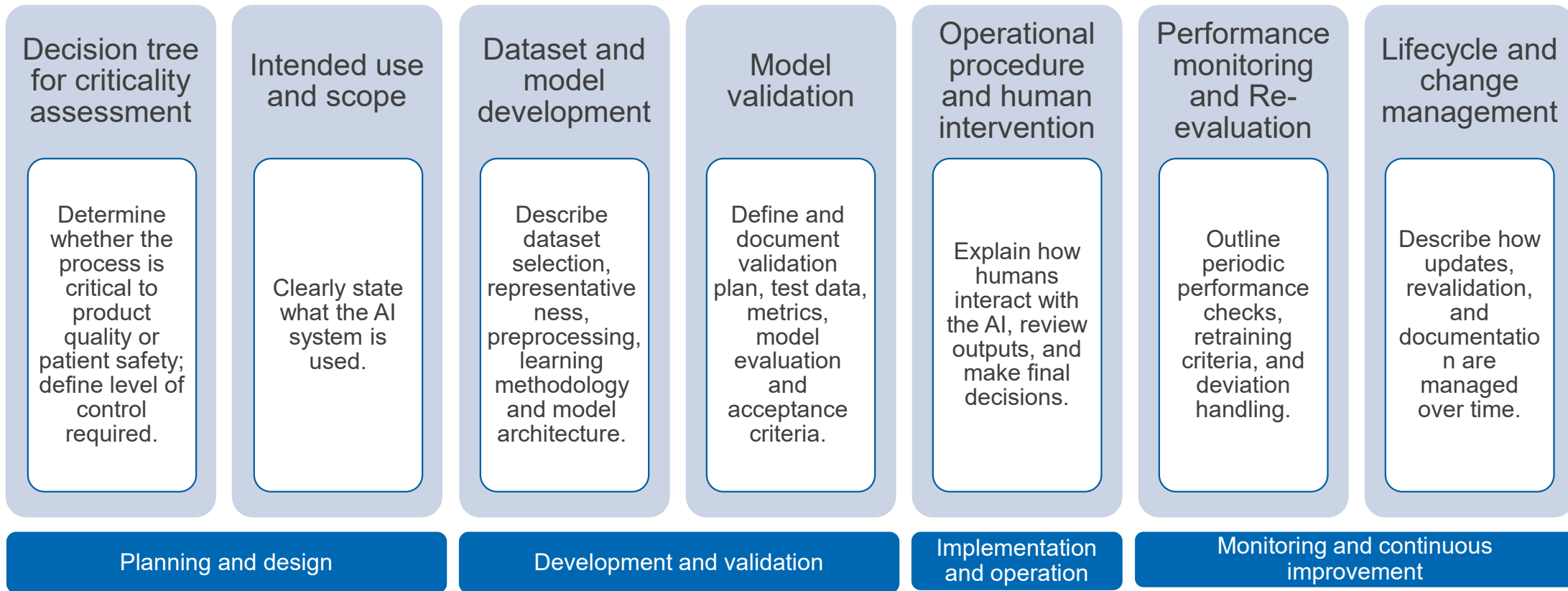
PMDA's proposal – Use cases format: Lifecycle based structure

To demonstrate how Annex 22 is applied properly across the model lifecycle



PMDA's proposal – Use cases format: Lifecycle based structure

Expected direction for developing lifecycle based use case format



Discussion points to share with participants

Should the use cases be included as an appendix of Annex 22, or as separate training material?



Appendix:

- Ensures official reference and regulatory consistency
- But may require longer revision procedures

Training material:

- Allows flexibility and frequent updates
- But may lack formal status or global alignment

Agenda

- PMDA's challenges
- PMDA's proposal
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- Status of Draft Use Case Development
- Future plan

Nov 2025: PMDA Joined the Annex 11/22 Working Group

EU (EEA) and PIC/S countries

- Australia
- Austria
- Canada
- Denmark (chair)
- Finland
- France
- Germany
- Italy
- Netherlands
- Norway (from Aug 2025)
- Switzerland
- Turkey (from Aug 2025)
- USA
- Japan (from Nov 2025)
- Taiwan (from Nov 2025)
- Brazil (from Nov 2025)



GMP Annex 11 and 22 Drafting Group

Current situation in Drafting group

Most comments request clarification on whether generative AI and LLMs should be included within the scope of Annex 22, as well as the addition of how-to guidance.

The requested how-to content is use case dependent and cannot be comprehensively addressed within the main body.

PMDA approaches

PMDA plans to develop representative use cases through dialogue with industry and to present them as an appendix to support the understanding of Annex 22, which PMDA intends to propose and communicate within PIC/S.

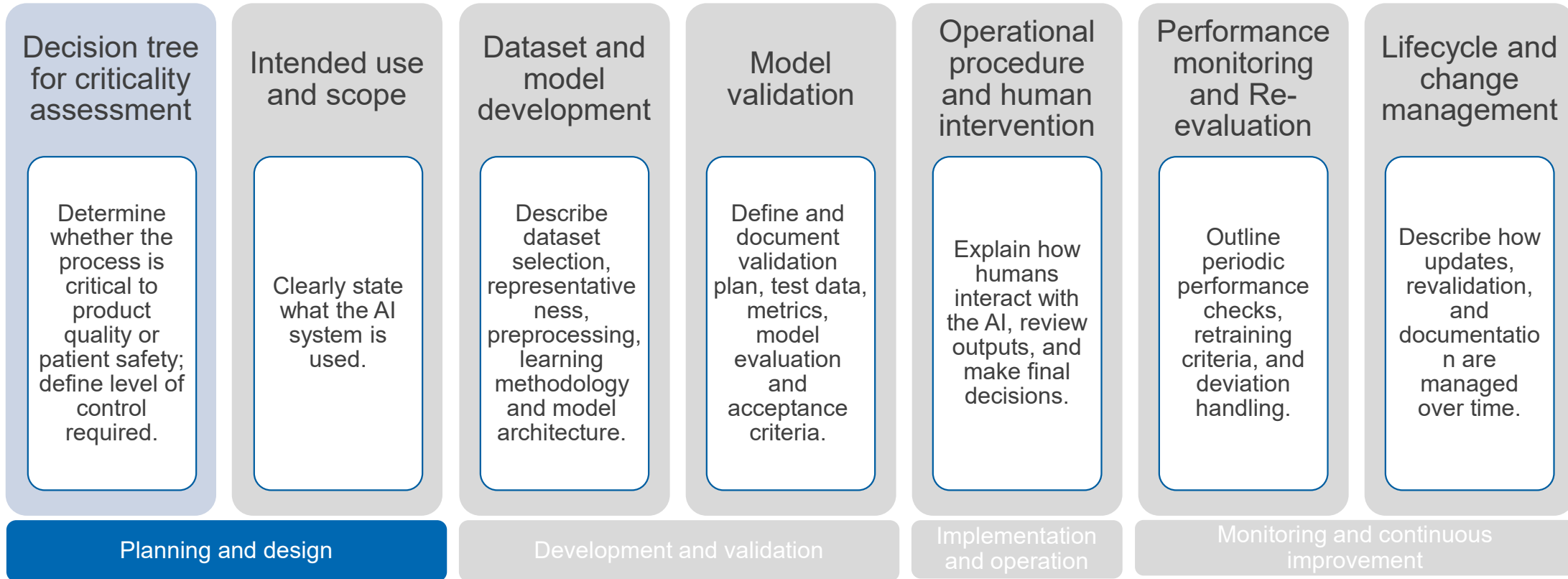
Agenda

- PMDA's challenges
- PMDA's proposal
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- **Status of Draft Use Case Development**
- Future plan



Elements Under Consideration for Inclusion in the Use Cases

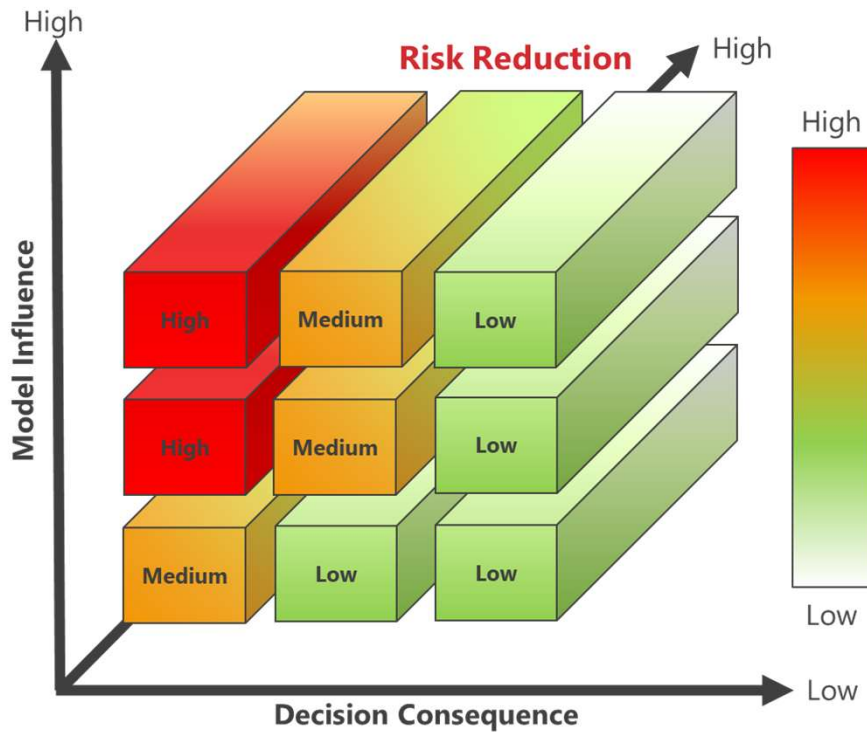
Expected direction for developing lifecycle based use case format



This presentation proposes the following approach.

Under consideration – How to assess ‘AI criticality’

Don't assess the model alone, assess the whole process that uses the model



AI criticality

Model Influence

Decision Consequence

Risk Reduction

how much the GMP decision depends on the model output

how serious it is if the decision is wrong

Where human review is placed, whether errors are detectable/can be reduced before batch release

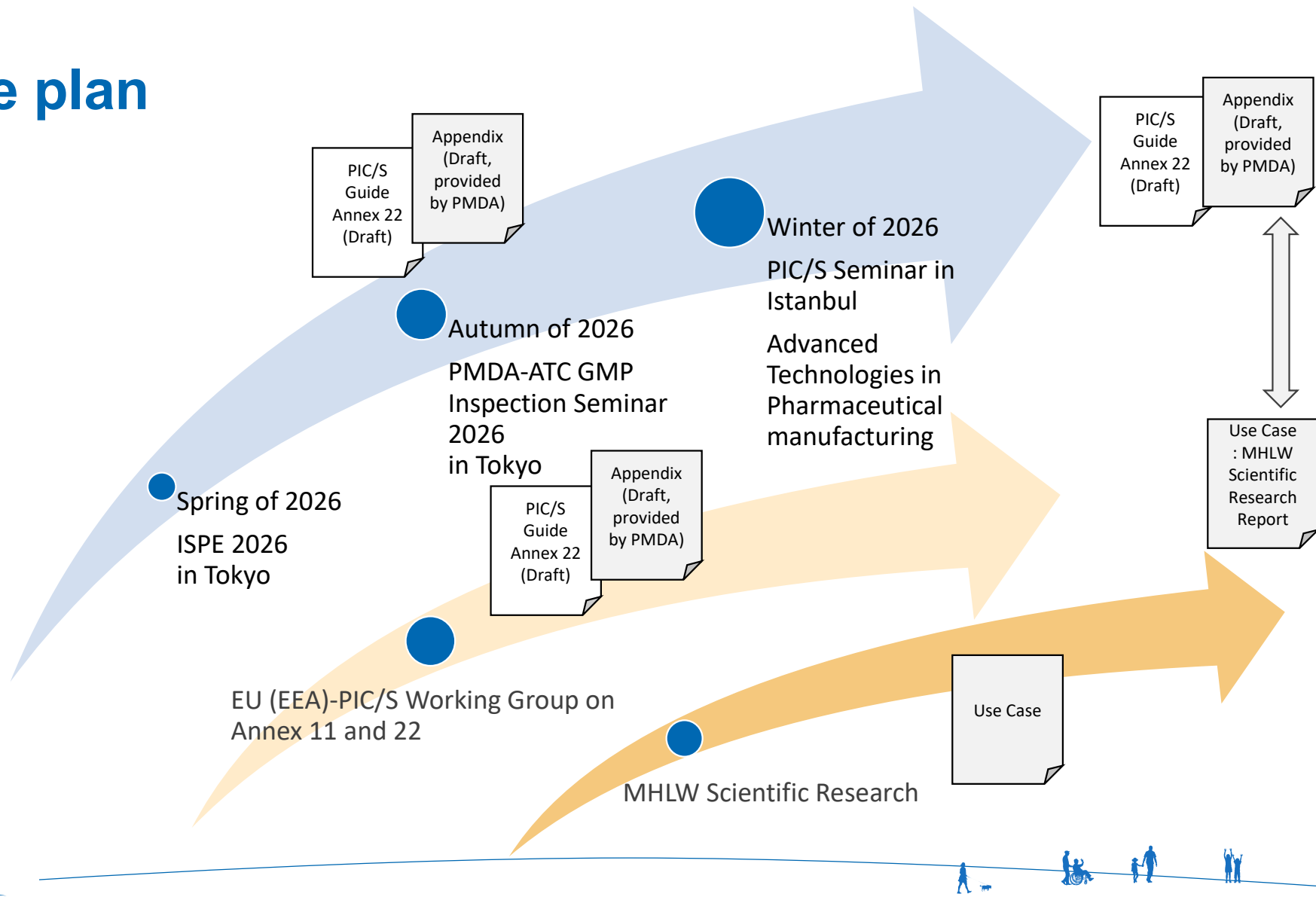


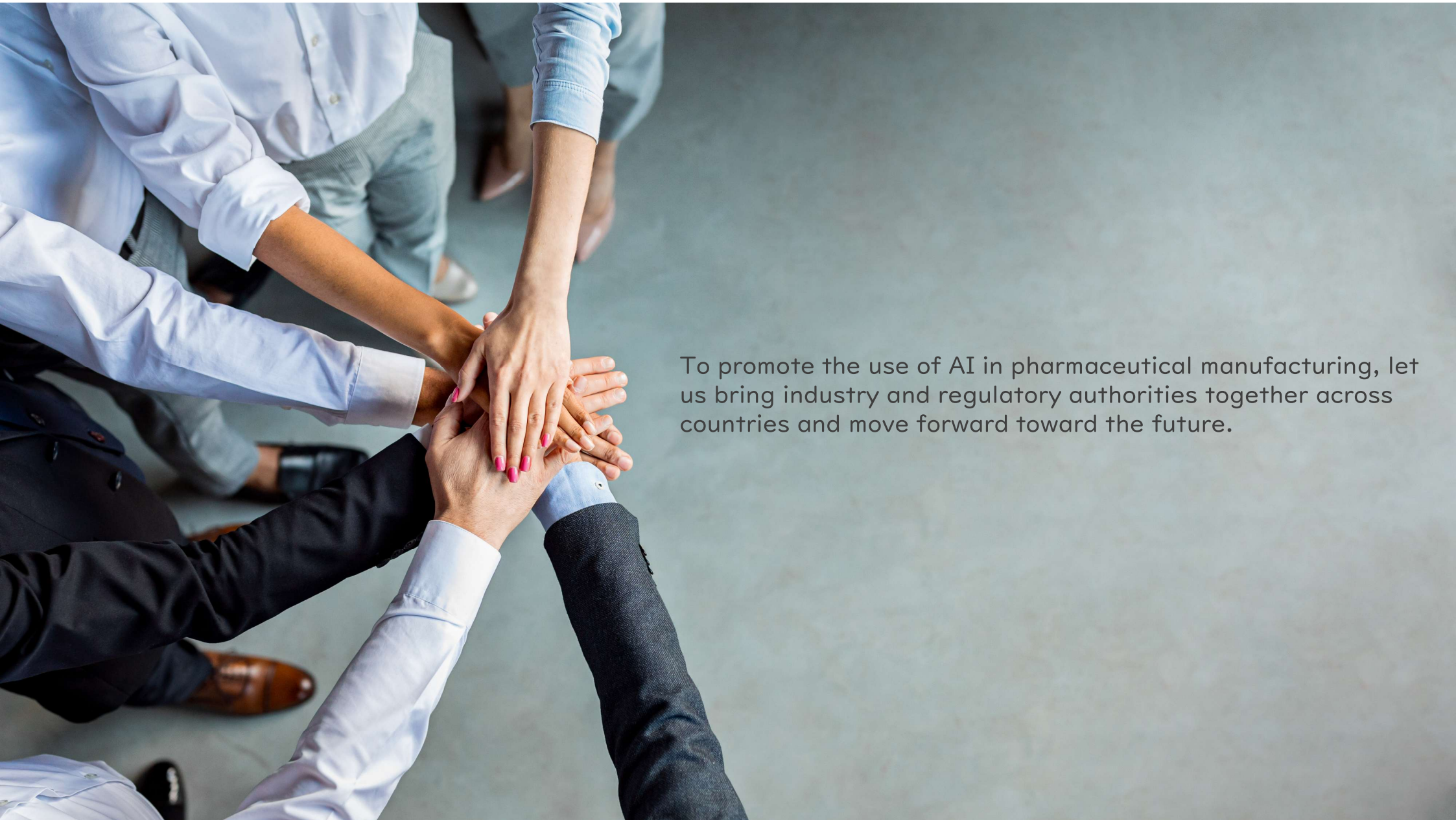
Agenda

- PMDA's challenges
- PMDA's proposal
- Participation in the Annex 22 WG and Topics Currently Under Consideration
- Status of Draft Use Case Development
- **Future plan**



Future plan





To promote the use of AI in pharmaceutical manufacturing, let us bring industry and regulatory authorities together across countries and move forward toward the future.

PMDA

健やかに生きる世界を、ともに



Copyright © Pharmaceuticals and Medical Devices Agency, All Rights Reserved.