# JPTA Symposium at CPHI Japan 2026

## Navigating Japan’s Evolving Pharmaceutical Regulatory Landscape: a Global API Manufacturer’s perspective

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# About Icrom

Your boutique for *hi-tech* APIs

Icrom is a trusted Italian CDMO specialized in development and GMP manufacturing of hi-tech APIs.

Headquartered in Concorezzo (Monza), Icrom supports pharma & biotech companies from early-development to commercial production.

- 50 years + in the pharma industry as CDMO and API manufacturer
- 2 R&D centers, 1 GMP Manufacturing site with 6 diversified production units
- Global presence in business operations in more than 30 Countries Worldwide

## Experience in Japan

- Active collaborations with Japanese pharmaceutical partners
- Experience in Japanese regulatory pathways
- Engagement with evolving regulatory frameworks


This perspective provides a practical view on how the 2025 PMDA pharmaceutical reform may influence international pharmaceutical development and market access in Japan

# Overview of Today's Discussion

- Context & Perspective
- Areas Where EU API Manufacturers Perceive Complexity
- Strategic Considerations for Global API Manufacturers
- Outlook: Opportunities for Further Collaboration
  - Possible areas for continued dialogue
  - Question for discussion
  - Closing

# Context and Perspective

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## Japan as a high-quality, compliance-driven pharmaceutical market

- What Global Manufacturers Value About Japan:
    - Technical competence
    - High level of professionalism
    - Long-term relationships
    - Strong quality culture

- Within the evolving Yokki ho 2025 framework, and in comparison with some foreign guidelines (e.g. Italian standards), stakeholders note opportunities for regulatory alignment and simplification

# Two Traditions of Harmony

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different design, same purpose

# Areas where EU API Manufacturers perceive complexity

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## Foreign Manufacturer Accreditation

- Accreditation process and timelines
- Perceived overlap with EU-GMP
- Post-approval changes
- Communication flow, documentation and language

# Strategic Considerations for Global API Manufacturers

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When evaluating long-term engagement in Japan, companies often evaluate:

- Market dynamics
- Operational complexity
- Investment required to serve the Japanese market
- Ability to maintain globally integrated supply chains

# Outlook: Opportunities for Further Collaboration - 1

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## Possible areas for continued dialogue

| Key Area | Stakeholder Perspective | Suggested Way Forward |
|---|---|---|
| Accreditation process | Timelines and procedural complexity remain a concern for stakeholders | Further alignment with ICH principles to support streamlined and predictable processes |
| Interaction with EU-GMP framework | Perceived overlap between accreditation requirements and EU-GMP expectations | Strengthened technical dialogue between API suppliers, MAHs, and competent authorities to clarify interfaces |
| Post-approval changes | Need for greater predictability in change management requirements | Clearer regulatory guidance and expectations for post-approval change management |
| Communication and documentation | Communication flows and documentation processes could be more efficient | Continued efforts towards transparency, improved communication channels, and further digitalization |

# Outlook: Opportunities for Further Collaboration - 2

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## Question for discussion

How can Japan remain highly rigorous while facilitating broader global participation?


## Closing

Global manufacturers do not seek lower standards but greater predictability, proportionality, and dialogue.

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# Thank you for your attention

*with special thanks to the organizers, coordinators and audience*

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