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Regulatory Challenges in Supplying APIs to Japan, which differs from European and American Pharmaceutical Systems: focus on GMP compliance, evolving regulatory landscape and harmonization

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Trifarma in the Japanese API Market

- Trifarma has been present into the Japanese market for over 20 years.
- Trifarma is strengthening its presence in the Japanese API market by also joining key industry events such as CPHI Japan, showcasing advanced manufacturing capabilities and technical expertise.
- Several APIs are registered with the PMDA, either via the JDMF (Japanese Drug Master File) or through MAH dossiers, ensuring full compliance with Japan's rigorous regulatory requirements.
- In one of the world's most demanding and high-value pharma markets, Trifarma stands out for quality, reliability, and long-term partnership commitment.

PMDA: Strengths & Opportunities

The **PMDA** is internationally recognized for its **rigor**, **strong scientific foundation**, and unwavering **focus on patient safety**.
In recent years, its procedures have become increasingly **transparent** and **reliable**, further strengthening **trust among global partners**.

→ **Opportunities for continued refinement**

As is the case with all mature regulatory authorities, there may be areas where **efficiency can be further enhanced**.
In addition, **closer alignment with international regulatory standards** could support **smoother global collaboration** and contribute to **even more timely regulatory pathways**.

→ **Overall message**

Japan's regulatory framework is **robust**, **trusted**, and **highly regarded** worldwide, while still offering **meaningful opportunities for continued improvement** that could make an already strong system even more effective.

Regulatory Challenges in Supplying APIs to Japan

Supplying Active Pharmaceutical Ingredients (APIs) to Japan requires navigating a regulatory ecosystem that differs in structure, philosophy, and practical expectations from both EU and U.S. systems. Japan's framework—anchored in the **Pharmaceuticals and Medical Devices Act (PMD Act)**—places significant emphasis on **GMP compliance, MAH-centric quality responsibility, documentary precision, and lifecycle oversight**.

This analysis breaks down the key challenges in three areas:

1. **GMP Compliance Differences**
2. **Evolving Regulatory Landscape**
3. **Harmonization with EU/US Systems**

Improvements Related to GMP Compliance

❑ **Streamlining PMDA GMP Inspections & Expanding Reliance Frameworks**

Japan currently requires extensive PMDA/MHLW inspections for foreign API manufacturers, including Foreign Manufacturer Accreditation (FMA).

Expanding **inspection reliance and mutual recognition** (like PIC/S or EMA–FDA collaboration models) would reduce redundant inspections and accelerate API approvals.

PMDA is already exploring reliance pathways with Asian authorities:

- Joint training programs
- Joint inspections
- Mutual acceptance of inspection

Regulatory improvement: Accelerate the timeline and extend reliance agreements to EU/US authorities.

❑ Simplifying or Digitizing GMP Inspection Documentation

Japan's strong emphasis on comprehensive and perfectly aligned documentation often leads to inspection delays.

Suggested improvements:

- Introduce a standardized digital submission template for **GMP evidence.**
- Allow electronic pre-screening of documents to correct inconsistencies before the official inspection window.

❑ Enhancing Clarity on Data Integrity Requirements

In 2021, Japan strengthened **DI** requirements through a major GMP Ministerial Ordinance revision.

Alignment with PIC/S and ICH principles is improving.

Regulatory improvement: Publish expanded, sector-specific DI guidance tailored to API manufacturers to reduce uncertainty and minimize rework during inspections.

Improvements Related to the Evolving Regulatory Landscape

- **Stabilizing eCTD v4.0 transition timelines**
  - More predictable metadata requirements
  - Longer transition periods
  - Automated validation tools to reduce formatting-related rejections
  - “Grace periods” for minor submission issues

- **Reducing administrative burden**
  - Standardized templates for global API suppliers
  - Smoother dossier preparation
  - Lower risk of administrative delays

❑ Strengthening PMDA–industry communication

- Structured pre-announcement cycles (e.g., 12-month notice)
- Draft guideline consultations before regulatory updates
- Improved predictability for foreign manufacturers

❑ Enhancing transparency & predictability in GMP enforcement

- Expanded publication of inspection observations
- Trend analyses to help manufacturers anticipate frequent deficiencies
- Better risk mitigation and proactive compliance

Improvements Related to Harmonization With EU/US

❑ **Expanding adoption of PIC/S operational standards**

Japan already aligns with PIC/S GMP principles, especially since the 2021 Ministerial Ordinance revision (QRM, PQS, Data Integrity, QA systems).

- Further progress would involve adopting **PIC/S inspection operational standards**, not only GMP principles — enabling Japan to operate inspection programs more consistently with leading regulatory agencies.

This would reduce procedural discrepancies for foreign manufacturers and enhance predictability during FMA renewals.

❑ **Enabling expedited FMA renewal for PIC/S-inspected foreign sites**

Foreign API manufacturers already undergo strong GMP oversight by EU/US/PIC-compliant authorities.

Recognizing **valid PIC/S inspection outcomes** could permit:

- Faster FMA renewal timelines
- Reduced need for duplicate documentation packages
- Shorter queue times for PMDA resources

❑ **Introducing a QP recognition pathway**

Japan does not currently adopt the EU Qualified Person (QP) batch release model.

- A dedicated “QP recognition pathway” for **low-risk APIs** would reduce redundant batch review steps and improve synchronization with EU supply chains.

Improvements Related to Harmonization With EU/US

❑ **Clear guidance on critical vs non-critical inconsistencies**

Japan's MAH-centric documentation model requires extremely tight alignment across all records.

➢ Introducing a **tiered classification system** would help foreign API manufacturers understand which gaps are:

➡ **Critical** (must be corrected before inspection)

➡ **Non-critical** (can be corrected without restarting the inspection cycle)

❑ **Allowing controlled corrections without resetting inspection timelines**

Today, even minor discrepancies can trigger significant delays.

➢ A structured approach to **controlled corrections** would enable:

➡ Limited updates without reopening the entire review cycle

➡ More efficient handling of lifecycle documentation changes

➡ Lower administrative burden on both PMDA and manufacturers

❑ **Expanding standardized SMF templates globally**

Japan already participates in Asian SMF template harmonization efforts.

➢ Extending standard templates to include **EU and US partners** would support:

➡ A single unified SMF for global manufacturers

➡ Better alignment between JDMF, DMF (US), and EU documentation systems

➡ Reduced duplication of effort and fewer inconsistencies among regions

Additional Measures to Improve Supply Chain Stability

❑ **Developing a priority-review pathway for essential APIs**

Similar to how PMDA accelerates drug review timelines, Japan could apply:

- Accelerated evaluation for critical shortage APIs
- Reduced administrative documentation during emergencies

Source: PMDA has already significantly shortened review times, showing capacity for acceleration.

❑ **Increasing transparency on domestic manufacturing capacity**

Japan faces structural shifts (aging population, flat domestic market growth, specialty drug expansion).

A regulatory measure:

- Conduct annual API supply-risk assessments and publish priority lists to guide foreign manufacturers

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Summary of Key Recommended Regulatory Improvements

Area	Key Improvements
GMP Compliance	Inspection reliance; simplified documentation; risk-based re-inspections
Evolving Landscape	Smoother eCTD v4.0 transition; predictable regulatory updates; more transparent GMP trends
Harmonization	PIC/S operational alignment; acceptance of EU QP; standardized documentation templates

Conclusion

To ensure a **stable and resilient API supply**, Japan would benefit from regulatory improvements that focus on:

- **Reducing duplication** (via reliance, harmonized procedures)
- **Increasing predictability** (in inspections, eCTD processing, regulatory updates)
- **Enhancing transparency and communication** (between PMDA, MAHs, and manufacturers)
- **Strengthening international alignment** to minimize friction points for foreign API suppliers.

These measures would not only support supply continuity but also maintain Japan's internationally recognized quality standards.

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Thank you very much for your kind attention and for giving me the opportunity to speak today.
I sincerely appreciate your time and consideration.