

Curia's Approach to Regulatory Compliance in Japan



As a global leader in CDMO services, Curia has proactively embraced the highly regulated pharmaceutical environment of Japan. Leveraging decades of experience in supporting regulatory submissions worldwide, Curia has developed strong expertise in navigating the specific requirements established by the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA).

Our regulatory teams work closely with customers and local Japanese partners to ensure efficient market access strategies, successful submissions, and ongoing compliance. Through extensive experience supporting global registrations and regulatory inspections, Curia helps customers overcome the complexities associated with one of the world's most demanding pharmaceutical markets.

Japan's regulatory framework is recognized for its rigorous focus on product quality, manufacturing controls, and supply chain oversight. While the requirements can be demanding, they provide a transparent pathway for high-quality API manufacturers seeking access to the Japanese market.



Japan's Regulatory Framework for Active Pharmaceutical Ingredients (APIs)

1. Japanese Drug Master File (J-DMF) Registration

A central component of the Japanese regulatory framework is the Japanese Drug Master File (J-DMF) system administered by the PMDA.

API manufacturers can register confidential manufacturing and quality information through a J-DMF submission, allowing proprietary information to remain protected while supporting marketing authorization applications submitted by Japanese pharmaceutical companies.

The J-DMF includes detailed information regarding:

- Manufacturing process and controls
- Specifications and analytical methods
- Impurity profiles
- Stability data
- Process validation information
- Packaging and storage conditions

The PMDA performs extensive scientific review of submitted information and may issue deficiency questions during the evaluation process.

2. Foreign Manufacturer Accreditation (FMA)

Foreign API manufacturers supplying the Japanese market must obtain Foreign Manufacturer Accreditation (FMA) from the MHLW.

This accreditation confirms that the manufacturing facility operates in accordance with Japanese regulatory expectations and is a prerequisite for products supplied to Japan.

The accreditation process involves:

- Submission of detailed facility information
- Identification of responsible personnel
- Description of manufacturing activities
- Periodic renewal requirements
- Quality management documentation

Any significant manufacturing changes must be reported to maintain compliance.

3. Good Manufacturing Practices (GMP) Compliance

Manufacturers supplying APIs to Japan must comply with Japanese GMP requirements, which are closely aligned with PIC/S and ICH guidelines.

Japanese authorities place particular emphasis on:

- Data integrity
- Supplier qualification
- Quality management systems
- Validation activities
- Change control procedures
- Deviation management

PMDA inspectors may conduct on-site inspections of foreign facilities or review inspection reports from recognized regulatory authorities.

Strong inspection histories from agencies such as FDA, EMA, PMDA and ANVISA can support regulatory confidence and facilitate market access.

4. Regulatory Fees and Review Process

Regulatory costs in Japan vary depending on the type of submission, review category, and whether inspections or accreditation activities are required.

The registration process generally includes:

- J-DMF submission and maintenance
- Potential GMP inspections
- Foreign Manufacturer Accreditation
- Lifecycle management activities
- PMDA scientific review

Japan's review process is known for its scientific rigor and frequently includes multiple rounds of technical questions and clarification requests.

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5. Registration Process for Imported APIs

For international API manufacturers wishing to enter the Japanese market, the registration process typically involves several critical steps:

Preparation of Registration Documentation

Manufacturers compile technical, quality, and manufacturing information according to Japanese requirements and applicable ICH guidelines.

Appointment of a Japanese Representative

A local Japanese representative is required to facilitate communications with regulatory authorities and support regulatory submissions.

J-DMF Registration

The API manufacturer submits the J-DMF dossier to PMDA, providing complete manufacturing and quality information while protecting confidential know-how.

Foreign Manufacturer Accreditation

The manufacturing facility obtains or maintains MHLW accreditation for the applicable manufacturing activities.

Technical Review and GMP Assessment

PMDA conducts scientific review of the dossier and may require additional information or perform GMP evaluations to verify compliance.

Approval and Commercial Supply

Once the drug product application referencing the J-DMF is approved, the API may be legally supplied to support commercial manufacturing in Japan.



Curia's Journey in Japan

Curia has extensive experience supporting regulatory filings across major pharmaceutical markets, including Japan with +20 Japanese Master Files. Our global regulatory organization provides customers with strategic guidance throughout the registration lifecycle, from early development through commercial supply.

Our expertise in Chemistry, Manufacturing and Controls (CMC), GMP compliance, inspection readiness, and lifecycle management enables customers to navigate complex Japanese regulatory requirements with confidence.

By combining strong quality systems, proven manufacturing capabilities, and decades of regulatory experience, Curia continues to support customers seeking successful market entry into one of the world's most important pharmaceutical markets.

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