

Curia's Approach to Regulatory Compliance in Korea



Korea is a key pharmaceutical market in Asia, with a rigorous MFDS framework for API quality, manufacturing control, data integrity, and lifecycle compliance. For global API manufacturers, navigating these requirements effectively is essential to reduce regulatory risk, support timely submissions, and enable reliable commercial supply.

Curia helps customers pursue API registration and market access in Korea through global regulatory experience, strong CMC expertise, and established quality systems. Working with local partners and regulatory stakeholders, Curia supports MFDS-aligned documentation, site registration, GMP compliance, and lifecycle management.

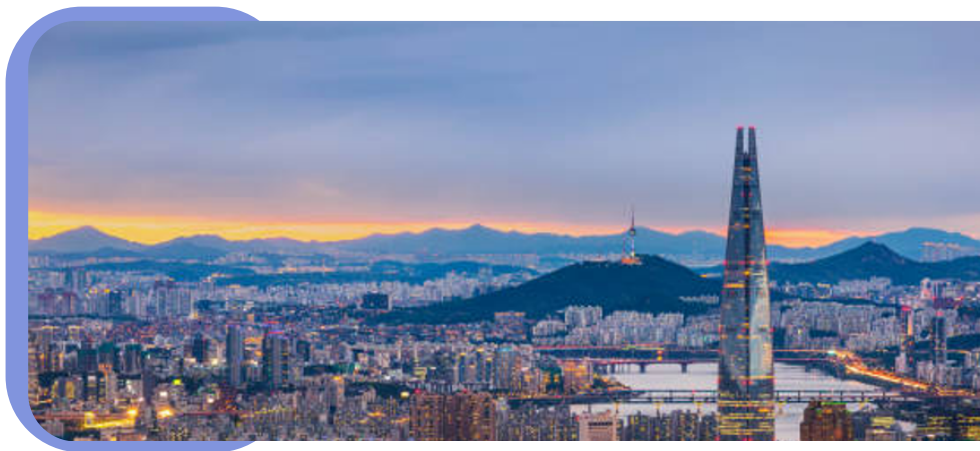
Korea's Regulatory Framework for Active Pharmaceutical Ingredients (APIs)

1. Korean Drug Master File (K-DMF) Registration

A central component of Korea's regulatory framework is the Korean Drug Master File (K-DMF) system, administered by the Ministry of Food and Drug Safety (MFDS). API manufacturers can register confidential manufacturing and quality information through a K-DMF submission, supporting marketing authorization applications by Korean pharmaceutical companies.

The K-DMF typically includes:

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



The MFDS conducts a scientific review of the submitted information and may issue deficiency questions during the evaluation process.

2. Foreign Manufacturer Registration

Foreign API manufacturers supplying the Korean market must register their manufacturing sites with the MFDS. This registration confirms that the facility is recognized by the Korean authority for the relevant manufacturing activities and that it operates in accordance with applicable regulatory and quality expectations. It is a key prerequisite for enabling API supply into Korea and supporting marketing authorization applications that reference the manufacturing site.

The registration process typically involves:

- Submission of detailed facility information
- Description of manufacturing activities
- Quality management documentation
- Identification of responsible personnel
- Periodic renewal and reporting of significant changes

Because the process links regulatory status directly to the manufacturing site, consistency between facility information, CMC documentation, GMP records, and local submissions is essential.

3. Good Manufacturing Practices (GMP) Compliance

Manufacturers supplying APIs to Korea must comply with Korean GMP requirements, which are harmonized with international standards such as ICH and PIC/S guidelines. The MFDS places emphasis on:

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

MFDS inspectors may conduct on-site inspections of foreign facilities or review inspection reports from recognized regulatory authorities. A strong inspection history with agencies such as FDA, EMA, or MFDS can facilitate market access. Additionally, compliance with Korean GMP requirements is reviewed during customers on-site audits.

4. Regulatory Fees and Review Process

Applicable Korean regulations define fees for certain pharmaceutical approval, review, inspection, and administrative procedures; however, such fees do not initially apply to K-DMF new submission.

The process typically involves:

- K-DMF submission and maintenance
- Foreign manufacturer registration
- MFDS scientific review
- Potential GMP inspections
- Lifecycle management activities

Korea's review process may include rounds of technical questions and clarification requests.

5. Registration Process for Imported APIs

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

Preparation of Registration Documentation

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

Appointment of a Korean Representative

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

K-DMF Registration

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

Foreign Manufacturer Registration

The manufacturing facility obtains or maintains MFDS registration for the applicable manufacturing activities.

Technical Review and GMP Assessment

MFDS 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 K-DMF is approved, the API may be legally supplied to support commercial manufacturing in Korea.



Curia's Journey in Korea

Korea represents an attractive but highly regulated market for pharmaceutical companies seeking to introduce APIs into commercial supply chains. Successful access requires early planning, high-quality technical documentation, alignment with MFDS expectations, and proactive management of K-DMF registration, foreign manufacturer requirements, GMP compliance, and lifecycle obligations.

Curia is well positioned to support customers through this process by combining strong regulatory expertise with +15 KDMFs, robust CMC capabilities, and established global quality systems. By working closely with local partners and regulatory stakeholders, Curia helps customers navigate the Korean regulatory pathway efficiently, reduce compliance-related risks, and support reliable API supply for the Korean market.

Ultimately, Curia's integrated approach enables customers to enter and operate in Korea with greater confidence, regulatory readiness, and long-term supply continuity.

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