ASEAN, China & Japan

Medical Devices and IVDs (ASEAN, China & Japan)

- Medical devices are instruments, apparatus, software, or materials used for diagnosis, prevention, monitoring, or treatment of diseases in humans.
- In vitro diagnostic (IVD) devices are medical devices used to examine specimens such as blood, urine, or tissues outside the human body.
- ASEAN countries, China, and Japan have separate but structured regulatory systems to ensure safety, quality, and performance of both medical devices and IVDs.



ASEAN, China and Japan use different medical-device classification systems

First Hope

ASEAN Region

1. Definition and Classification

- ASEAN follows a harmonized medical device directive framework.
- Devices are classified based on risk into Class A (low risk) to Class D (high risk).
- IVDs are also classified based on risk level and intended use.

2. Regulatory Approach

- ASEAN Medical Device Directive (AMDD) provides a common structure.
- Each member country implements the rules through its own authority.

China

A. Definition and Classification

- Medical devices and IVDs are regulated by the National Medical Products Administration (NMPA).
- Devices are classified into Class I, II, and III based on risk.

B. Regulatory Approach

- Class III devices are high risk and require strict pre-market approval.
- IVDs have separate classification but follow similar risk-based principles.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

Japan

1. Definition and Classification

- Medical devices and IVDs are regulated under the Pharmaceuticals and Medical Devices Act (PMDA/MHLW).
- Devices are classified into Class I to Class IV depending on risk.

2. Regulatory Approach

- Higher-risk devices require approval from PMDA.
- Lower-risk devices may require certification by registered bodies.

Importance

- Ensures patient safety and device effectiveness.
- Provides standardized regulatory control across regions.
- Facilitates international trade and market access.

Regulatory Registration Procedures (ASEAN, China & Japan)

Basic Idea

- Regulatory registration procedures are formal steps required to obtain approval before a medical device or IVD can be marketed in a country.
- These procedures ensure that devices meet safety, performance, and quality standards.

ASEAN Registration Procedure

1. Preparation Stage

- Device classification is determined according to risk.
- Technical documentation is prepared.

2. Conformity Assessment

- Evidence of compliance with ASEAN Common Submission Dossier Template (CSDT) is required.
- Quality system certification is often needed.

3. Submission to Regulatory Authority

- Application is submitted to the national authority of each ASEAN country.

4. Review and Approval

- Authorities review technical and safety data.
- Approval or registration certificate is issued.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

China Registration Procedure

A. Classification and Testing

- Device is classified into Class I, II, or III.
- Type testing in approved laboratories is required for higher classes.

B. Clinical Evaluation

- Clinical data or trials may be required depending on risk.

C. Submission to NMPA

- Technical dossier and testing reports are submitted.

D. Review Process

- NMPA conducts technical and administrative review.
- Registration certificate is granted upon approval.

Japan Registration Procedure

1. Pre-Submission Requirements

- Device classification and QMS compliance are confirmed.

2. Approval or Certification Path

- High-risk devices require PMDA approval.
- Medium-risk devices may go through third-party certification.

3. Submission of Application

- Detailed technical documentation is submitted.

4. Review and Decision

- Scientific and safety review is conducted.
- Marketing authorization is issued.

Importance

- Ensures legal compliance before marketing.
- Prevents unsafe devices from entering the market.
- Standardizes evaluation of device safety and performance.

Quality System Requirements (ASEAN, China & Japan)

- Quality System Requirements (QSR) ensure that medical devices are consistently designed, manufactured, and controlled to meet safety and performance standards.
- They cover all stages from design to post-market surveillance.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

ASEAN Quality System Requirements

1. General Requirements

- Manufacturers must follow ISO 13485 standards.
- Emphasis on risk management and documentation.

2. Key Elements

- Design control systems.
- Production and process control.
- Corrective and preventive actions (CAPA).
- Complaint handling systems.

China Quality System Requirements

A. Regulatory Framework

- China Medical Device Good Manufacturing Practice (GMP) applies.
- Compliance is mandatory for manufacturers.

B. Key Elements

- Facility and environmental control.
- Production process validation.
- Quality control testing.
- Traceability of products.

First Hope

Japan Quality System Requirements

1. QMS Ordinance

- Based on international ISO standards with local adaptation.
- Required for all manufacturers.

2. Key Elements

- Design and development control.
- Supplier control and management.
- Internal audits and inspections.
- Post-market safety monitoring.

Importance

- Ensures consistent product quality.
- Reduces manufacturing defects and risks.
- Builds regulatory trust and market access.

Copyright by Engacy Learning Private Limited. All rights reserved. Reproduction or distribution without written consent is strictly prohibited.

First Hope

FREE PREVIEW

Click here to visit our website

PHARMACY PREMIUM NOTES

Complete subject and semesters are available on FirstHope app only.

Scan or click here

Click here to get the app >

Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram >

Scan or click here

@FirstHopeNotes

Instagram

@firsthope.official

Click here to follow >

YouTube channel

FirstHope-Pharmacy / Live streams

Click here to watch >

WhatsApp channel

Follow FirstHope on WhatsApp

Click here to join >

FirstHope website

firsthope.co.in

Click here to visit >

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.