

Unit 5: ASEAN, China and Japan

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5.1 ASEAN: one directive, ten markets

The Association of Southeast Asian Nations harmonised its device regulation in the **ASEAN Medical Device Directive**, adopted by the member states and implemented into each national law at its own pace, which is the first thing to understand about it: the directive is a model, and the operative licence is still issued nationally, by the authorities of Singapore, Malaysia, Thailand, Vietnam, the Philippines, Indonesia and their fellow members. The model's contents are the GHTF inheritance entire: the essential principles, the four class A to D risk classification by rules closely following the GHTF set, a common classification and grouping practice that lets families of devices be registered together, and the **Common Submission Dossier Template (CSDT)**, ASEAN's STED shaped dossier, whose chapters carry the device description, the essential principles checklist, the design verification summary, the clinical evidence and the labelling in a form every member state accepts. Registration routes are graded by class in the now familiar proportions, abridged and reliance routes recognising approvals from reference jurisdictions for the lower and middle classes in several member states, with Singapore's Health Sciences Authority operating the region's most developed evaluation routes and Malaysia's Medical Device Authority its registration under the national Medical Device Act. Quality system expectation is ISO 13485 conformity throughout the region, and post market duties follow the member state's vigilance system, with the directive's post market alert framework naming the shared vocabulary. For the regulatory professional the ASEAN lesson is the shape of modern regional harmonisation: one technical spine, national licensing hands, and a dossier written once in CSDT form and readdressed state by state.

5.2 China: the NMPA system

China regulates devices through the **National Medical Products Administration (NMPA)** under the State Council's Regulations for the Supervision and Administration of Medical Devices, with provincial authorities executing parts of the system. Classification runs in the Chinese three tier form: **Class I** low risk, managed by a **filing** with the local authority rather than an approval; **Class II** moderate risk, registered with the provincial authority for domestic products; **Class III** high risk, registered with the NMPA itself, with imported devices registered nationally at Classes II and III. Classification is administered against a published classification catalogue and classification rules in the GHTF spirit, with a formal classification determination available where a novel device fits no catalogue entry. Registration demands a dossier of product technical requirements, type testing by an accredited Chinese laboratory for most products, the risk analysis, clinical evaluation, by literature and equivalence comparison where the rules allow or by a clinical trial conducted for China where they do not, and the quality system evidence, China's device GMP being audited as part of registration for the higher classes. Two China specific disciplines carry examination weight: the **clinical trial catalogue** system, under which defined high risk devices must be trialled in certified Chinese institutions for registration purposes, which makes Chinese registration a programme of local evidence generation rather than a paper reliance exercise for the top of the market; and the post registration duties of adverse event monitoring and re registration on the cycle the regulations set. The direction of travel is convergence, through China's IMDRF membership and the adoption of international standards, from a position that remains distinctly its own.

5.3 Japan: the PMD Act system

Japan's framework, met for drugs in MRA201T, covers devices under the **Pharmaceuticals and Medical Devices Act (PMD Act)**, administered by the Ministry of Health, Labour and Welfare (MHLW) with the review work of the **Pharmaceuticals and Medical Devices Agency (PMDA)**. Classification follows the GHTF four classes, named in the Japanese manner: **general medical devices** (Class I), marketed on **notification** to the PMDA; **controlled medical devices** (Class II), requiring **certification (ninsho)** by a registered certification body against published certification standards where such standards exist; **specially controlled medical devices** (Classes III and IV), requiring ministerial **approval (shonin)** on PMDA review; with in vitro diagnostics distributed through the same structure by their own risk rules. The system's distinctive institution is the separation of the product approval from the licence to do business: a **marketing authorisation holder** licence, graded by class, under which the holder bears the legal duties for the product, including the quality and vigilance duties of the GQP and GVP ordinances, while manufacture itself, domestic or foreign, is separately licensed or accredited, the foreign manufacturer accreditation being the importer's gateway. The quality system ordinance, the QMS ordinance, is built on ISO 13485 and is audited against the device's approval, and PMDA consultations, the pre submission meetings of MRA201T's drug teaching, operate for devices as the standard way to settle classification, evidence and clinical questions before filing. Post market duties run through the re examination and re evaluation machinery and the GVP reporting duties, with the package insert, Japan's controlled labelling document, carrying the approved claims.

ASEAN, China and Japan: three systems side by side

ASEAN	CHINA	JAPAN
AMDD common model	NMPA and provincial authorities	PMD Act; MHLW and PMDA
Classes A to D by rules	Classes I, II and III	Notification, certification, approval
CSDT dossier, written once	Local type testing for registration	Marketing authorisation holder
Licence still issued nationally	Trials in China where catalogued	QMS ordinance on ISO 13485

One GHTF spine, three national hands: the dossier core travels, the licence does not

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Figure: The three systems of Unit 5 compared: ASEAN's common directive and CSDT under national licensing, China's NMPA registration in three classes with local testing and trials, and Japan's PMD Act ladder of notification, certification and approval under the marketing authorisation holder (Unit 5, section 5.3).

5.4 Quality system requirements across ASEAN, China and Japan

The three systems of this unit converge on the point Unit 2 prepared: each demands an ISO 13485 shaped quality system, and differs in how conformity is evidenced and audited. In **ASEAN** member states the registration dossier carries the quality system evidence, an ISO 13485 certificate from an accredited body being the standard exhibit, and several states accept audits performed for other jurisdictions. **China** writes its device good manufacturing practice in national form and audits it domestically, with registration inspection of the quality system for the higher classes, accepting the ISO certificate as supporting rather than substitute evidence. **Japan** audits against its QMS ordinance, harmonised with ISO 13485 in structure, the audit tied to the product approval and conducted by the PMDA or a registered certification body according to class. Standing across all three, and across Units 3 and 4 as well, is the **Medical Device Single Audit Program (MDSAP)**, the IMDRF era programme under which a single audit by a recognised auditing organisation, against ISO 13485 together with the participating jurisdictions' specific requirements,

is accepted by its members, which include the United States, Canada, Brazil, Australia and Japan. MDSAP is the working proof of the harmonisation argument of Unit 1: one system, audited once, read by many regulators.

5.5 Clinical evaluation and investigation in ASEAN, China and Japan

Clinical evidence in the three systems follows the gradient of Unit 2, with local gates that the syllabus's single line unfolds into. **Clinical evaluation**, the appraisal of literature, equivalence data and experience, is the default evidence in all three: ASEAN's CSDT carries a clinical evidence chapter built on evaluation; China's rules permit evaluation by comparison with predicate devices on the market for defined categories; Japan accepts foreign clinical data and literature based evaluation for many approvals. **Clinical investigation** becomes compulsory at the points of genuine novelty and highest risk, and each system gates it in its own law: China through its device GCP and the catalogue of devices requiring trials, with trials conducted at certified Chinese institutions for registration purposes; Japan through its device GCP ordinance, the clinical trial notification to the PMDA for the higher classes, and ethics review at the institutions; ASEAN member states through their national clinical research rules and ethics committees, with ISO 14155 as the referenced standard of conduct. The professional discipline is identical in the three markets and is the unit's closing practical lesson: settle the evidence question, evaluation or investigation, in classification and consultation before the dossier is written, because it is the longest lead item in every one of these registration programmes.

5.6 IMDRF study groups and guidance documents

The syllabus closes this unit, and the subject, by returning to the IMDRF, and the return is structural: the three systems just taught are all, to different degrees, readers of IMDRF's output. The IMDRF works through **working groups** constituted for defined deliverables, the successors in spirit to the GHTF study groups of Unit 1, whose mapping the student should be able to draw: premarket and dossier work descending from Study Group 1, including the regulated product submission table of contents that succeeds the STED; vigilance and adverse event terminology from Study Group 2, whose IMDRF terms and codes are the reporting vocabulary of Unit 2; quality systems and the single audit programme from Study Groups 3 and 4; and clinical evidence from Study Group 5. Its further guidance families address the frontiers the original study groups never faced: software as a medical device, with its classification and clinical evaluation frameworks; personalised and patient matched devices; and good regulatory review practices. The **guidance documents** are not law in any member jurisdiction, and the subject has insisted on the point before: their force is adoption. A manufacturer who writes the dossier in the IMDRF shape, codes events in the IMDRF terminology, and runs the quality system to be auditable under the single audit programme has built one technical core saleable, with local layers, in the United States, Europe, Japan, China and ASEAN alike, which is the entire commercial argument of harmonisation and the note on which the subject properly ends.

Frequently Asked Questions

Q: What distinguishes a medical device from a pharmaceutical product? The primary mode of action. A pharmaceutical achieves its primary intended action by pharmacological, immunological or metabolic means; a medical device achieves its primary action by physical, mechanical, electrical or software means, though it may be assisted by drug action, and is then handled as a combination product led by its primary mode of action.

Q: What are the Essential Principles of safety and performance? They are the harmonised GHTF list of propositions every device must satisfy: safety and performance as intended across its lifetime, risks acceptable against benefits, control of chemical, physical, biological, infection, radiation and measuring hazards, and adequate labelling and information. Conformity with recognised standards is the normal evidence, and the STED dossier is organised to demonstrate them principle by principle.

Q: How does risk based classification work for medical devices? Devices are sorted by rules, weighing duration of body contact, invasiveness, whether the device is active and what its energy does, the body system it touches, and for IVDs the consequence of a wrong result. The GHTF model has four classes, A to D; the US uses Classes I to III, the EU I, IIa, IIb and III, and India and ASEAN the A to D shape, with controls rising with the class.

Q: What is the difference between verification and validation of a device? Verification confirms the design outputs meet the design inputs: the device was built right, shown by test, inspection, analysis or demonstration. Validation confirms the finished device meets the user needs and intended purpose in actual or simulated use: the right device was built, reaching into usability and clinical evidence.

Q: What does ISO 14155 require? ISO 14155 is the good clinical practice standard for clinical investigation of medical devices. It requires an approved clinical investigation plan, ethics committee review, informed consent, qualified investigators, sponsor monitoring, device accountability and the reporting of adverse events and device deficiencies, adapting the Helsinki and GCP tradition to devices, where blinding may be impossible and the device may not be removable.

Q: What is the difference between a 510(k) and a PMA? A 510(k) is a premarket notification showing the device is substantially equivalent to a legally marketed predicate, in intended use and technological characteristics; FDA's act is a clearance, and most Class II devices use it. A PMA is a premarket approval application for Class III devices, which must itself provide reasonable assurance of safety and effectiveness on valid scientific evidence; FDA's act is an approval.

Q: What is a unique device identifier (UDI)? The UDI is the identifier most devices in the US system must bear on label and packaging, in human and machine readable form. Its device identifier part is fixed and names the labeler and model; its production identifier part carries lot or batch, serial number and expiry or manufacture dates as applicable. The record sits in the GUDID database, and the UDI is what makes reports, recalls and registries traceable to the exact device.

Q: How does CE marking differ from FDA clearance or approval? CE marking is a manufacturer's declaration of conformity, resting on an audited quality system and, for the higher classes, on a notified body's examination of the technical documentation or design; it is not a state approval, and it opens every EU member state at once. FDA clearance and approval are acts of the federal agency itself, for the US market only.

Q: What replaced the EU medical device directives? Regulation (EU) 2017/745, the Medical Device Regulation, replaced the Medical Device Directive and the Active Implantable Directive, and Regulation (EU) 2017/746, the IVD Regulation, replaced the IVD Directive. They keep the classification tiers, notified bodies and CE logic while tightening clinical evidence, oversight of notified bodies, UDI and post market duties; the syllabus teaches the directives, and the regulations are the current law.

Q: What is the STED, and why does it matter beyond any one country? The Summary Technical Documentation is the GHTF's standardised summary of the evidence that a device meets the essential principles: description, principles checklist, labelling, design and manufacturing summary, verification and validation, clinical evidence and risk summary. Because adopting regulators accept the same shape, a STED prepared for one jurisdiction can be readdressed to another.

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