

Unit 1: Medical Devices, Introduction

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Regulatory Aspects of Medical Devices, subject code MRA203T, is the third core subject of M.Pharm Regulatory Affairs, Semester 2. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks. The two subjects before it regulated products that are swallowed, injected or applied: drugs, whose identity is chemical, and biologics, whose identity is bound up with a living process. This subject regulates the third great family of medical products, the ones that act on the body without being metabolised by it: the instruments, machines, implants, software and laboratory tests of modern medicine. A medical device is regulated differently from a drug for a reason that runs through every unit of this course. Its performance is an engineering property, proved by design control, bench testing and standards conformity, with clinical evidence scaled to risk, rather than by the pharmacological trial programme of a medicine; its failures are mechanical, electrical and usability failures as much as biological ones; and its makers range from global engineering firms to a workshop with one lathe, so the law is built on classification by risk and on quality systems rather than on product by product proof of efficacy. This course is designed to impart fundamental knowledge on medical devices and in vitro diagnostics, the basis of classification and the product life cycle of medical devices, and the regulatory requirements for approval of medical devices in regulated countries like the US, EU and Asian countries along with WHO regulations, covering in detail the harmonization initiatives, and the quality and ethical considerations, for marketing devices and IVDs. The units follow the architecture of the field. Unit 1 builds the global foundation: what a medical device is, the essential principles every device must meet, risk based classification, how devices, IVDs and combination products differ from pharmaceuticals, the history and the product life cycle, and the harmonisation machinery of the GHTF and its successor the IMDRF, with its two great tools, the STED dossier format and the GMDN nomenclature. Unit 2 takes the ethical and quality spine: clinical investigation of devices under ISO 14155, the ISO 13485 quality system, ISO 14971 risk management, design verification and validation, and adverse event reporting. Unit 3 studies the United States: classification into Classes I, II and III, the 510(k) notification, premarket approval, the investigational device exemption, the Quality System Regulation of 21 CFR Part 820, labelling under Part 801, post market surveillance and the Unique Device Identification system, closing with IVDs. Unit 4 studies the European Union through the directives the syllabus names, the Medical Device Directive, the Active Implantable Medical Device Directive and the In Vitro Diagnostic Directive, with the CE certification process and IVD classification; because those directives have since been replaced by the Medical Device Regulation 2017/745 and the IVD Regulation 2017/746, the unit teaches the directive framework in full and states the current position beside it, in the two layer manner used throughout this branch. Unit 5 studies ASEAN, China and Japan: registration procedures, quality system requirements and clinical evaluation and investigation, closing with the IMDRF study groups and guidance documents. One honest note belongs here at the start: the course objectives name India among the countries whose approval process the student shall know, but the printed units assign no unit to India. The Indian framework, the Medical Devices Rules 2017 with their classes A to D and the CDSCO licensing machinery, is taught in this branch in MRA104T, and Unit 1 of this subject places the Indian classes inside the global classification picture; this subject then follows its printed units. The habit that pays off throughout: classify first. Almost every regulatory question about a device, which dossier, which evidence, which authority, which vigilance duty, is answered by the class the device falls in and the jurisdiction it is sold in, and the two together.

1.1 Introduction: a third family of medical products

A medical device can be almost anything in a hospital that is not a drug or a pair of hands: a scalpel, a hip implant, an MRI scanner, a blood glucose test, a surgical glove, a pacemaker, a phone application that reads a heart rhythm. The family is defined not by what its members are made of but by how they achieve their purpose, through physical, mechanical, electrical or software action rather than through pharmacological, immunological or metabolic means. That single distinction drives the whole regulatory design of this subject. Because a device's action is engineered, its safety and performance can to a large extent be designed in, specified, tested on the bench and audited through the manufacturer's quality system; because devices iterate quickly and are used by operators whose skill varies, regulation must also govern design change, usability and the information supplied to the user. The regulatory professional's work in this field is therefore classification, standards, quality systems and vigilance, wrapped around clinical evidence proportionate to risk.

1.2 Definition of a medical device

Definitions decide jurisdiction, so they are drafted with care and examined accordingly. The harmonised definition, carried by the GHTF and echoed in law worldwide, runs in substance as follows: a **medical device** is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more specific medical purposes: the diagnosis, prevention, monitoring, treatment or alleviation of disease; the diagnosis, monitoring, treatment, alleviation of or compensation for an injury; the investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; the control of conception; the disinfection of medical devices; or providing information by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. Three elements do the work. **Intended purpose**, as stated by the manufacturer in labelling, instructions and claims, decides whether an article is a device at all: the same software is a wellness product or a regulated device according to the medical purpose claimed for it. **Mode of action** separates devices from drugs at the border: a wound dressing that merely covers is a device, while one whose primary action is an antimicrobial drug effect crosses toward the drug side, the combination product problem of section 1.5. And the definition deliberately includes **software and in vitro reagents**, which is why the syllabus treats IVDs inside the device family throughout. An **in vitro diagnostic medical device (IVD)** is a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body, solely or principally to provide information for diagnostic, monitoring or compatibility purposes: reagents, calibrators, control materials, specimen receptacles, instruments and test kits, from a pregnancy test to a blood bank screening assay.

1.3 Essential principles of safety and performance

Every regulatory system in this subject is, at bottom, a machine for demonstrating one short list of propositions about a device, and the GHTF codified that list as the **Essential Principles of Safety and Performance**. In substance they require that devices be designed and manufactured so that, when used as intended, they do not compromise the health or safety of patients, users and others; that the risks be acceptable when weighed against the benefits; that performance claimed by the manufacturer be achieved, over the device's lifetime, under normal conditions of use; that design take account of the state of the art, of the environment of use and of the knowledge and skill of the intended user; and that specific families of hazards be controlled: chemical, physical and biological properties, including material safety and contamination; infection and microbial contamination; manufacturing and environmental properties; devices

with a measuring function, which must be accurate and stable; protection against radiation, where the device emits or uses it; and the information supplied with the device, labelling and instructions for use, which is itself treated as a safety feature. Conformity with **recognised standards** is the normal evidence: a device built and tested to the applicable harmonised or consensus standards is presumed to meet the corresponding essential principles, which is why standards literacy, met for quality in ISO 13485 and for risk in ISO 14971 in Unit 2, is a regulatory skill and not an engineering extra. The essential principles also explain the shape of the STED dossier of section 1.10: its device description, design verification and clinical evidence sections exist to demonstrate, principle by principle, that this device meets the list.

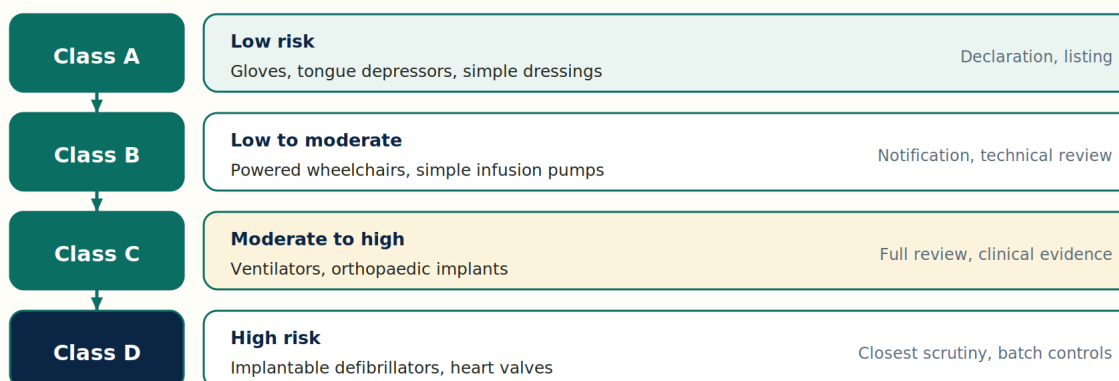
1.4 Risk based classification

Classification is the master key of device regulation because the class assigns the weight of every other control: the conformity route, the depth of clinical evidence, the audit intensity and the vigilance duties. The GHTF model, which most of the world now follows in shape, sorts devices into four classes, A, B, C and D, in ascending risk, assigned by **rules** applied to the device's characteristics rather than by case by case discretion. The rules weigh a consistent set of factors: the **duration of contact** with the body (transient, short term, long term); the **invasiveness** of the device and the body orifice or tissue it reaches, with surgically invasive and implantable devices weighted above surface devices; whether the device is **active**, depending on a source of energy, and what that energy does, administering or exchanging substances or radiation being weighted most heavily; the **centrality of the body system** touched, devices acting on the central circulatory or nervous system carrying the highest weight; and for IVDs, the **consequence of a wrong result**, for the individual and for public health, which is why a test for a transmissible agent in blood donations outranks a test whose error merely inconveniences. The regulatory logic is proportionality stated as a table.

Class (GHTF model)	Risk level	Illustrative devices	Weight of control
A	Low	Examination gloves, tongue depressors, simple dressings	Manufacturer declaration, quality system basics, registration and listing
B	Low to moderate	Powered wheelchairs, infusion pumps of simple design, most diagnostic ultrasound	Notification or review of technical documentation by the authority or a designated body
C	Moderate to high	Ventilators, orthopaedic implants, blood glucose monitoring systems	Full technical review, clinical evidence examined, quality system audited
D	High	Implantable defibrillators, heart valves, tests for transfusion transmitted infection	The closest scrutiny: full review, clinical investigation evidence, batch and post market controls

The named jurisdictions translate this model into their own labels, the subject of Unit 3, Unit 4 and section 1.8 below: the United States uses Classes I, II and III; the European directives used I, IIa, IIb and III; India, ASEAN, China and Japan follow the four letter A to D shape most closely.

Risk based classification: the four class ladder



Risk rises with invasiveness, duration of contact and consequence of failure; control rises with it

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Figure: The GHTF four class ladder of section 1.4: risk rises with invasiveness, duration of contact and consequence of failure, and the weight of regulatory control rises with it, the model the working systems of section 1.8 translate into local labels (Unit 1, section 1.4).

1.5 Devices, IVDs and combination products, and the line against pharmaceuticals

Borderline judgment is a daily regulatory task, and the syllabus lists the differentiations explicitly. A **pharmaceutical** achieves its primary action by pharmacological, immunological or metabolic means and is regulated on chemical or biological identity plus clinical trial proof of efficacy. A **medical device** achieves its primary action by physical or mechanical means and is regulated on classification, design control and performance evidence. An **IVD** never touches the patient at all: it examines a specimen taken from the body, and its performance is measured in analytical and diagnostic accuracy, sensitivity and specificity, rather than in therapeutic effect, which is why a false result, not a toxic effect, is its characteristic harm. A **combination product** combines two or more of the families in one article: a drug eluting stent (device frame, drug action), a prefilled syringe (drug in a device), an antimicrobial catheter. Combination products are assigned by their **primary mode of action**: the component that achieves the principal intended purpose decides the lead regulatory framework, and the other component's requirements are then applied on top, so a drug eluting stent is led as a device with the drug constituent assessed to drug standards. In the United States a dedicated office assigns the lead centre, CDRH, CDER or CBER, by that test; in the EU a device incorporating a medicinal substance whose action is ancillary is regulated as a device with a medicines authority consulted on the substance. The examination point is the test itself: primary mode of action decides the lead, and both sets of rules then apply to their own parts.

Point	Pharmaceutical	Medical device	IVD
Primary action	Pharmacological, immunological or metabolic	Physical, mechanical, electrical or software	None on the body: examination of a specimen
Proof of performance	Clinical trials of efficacy and safety	Design verification, bench and performance testing, clinical evidence by risk	Analytical and clinical performance: accuracy, sensitivity, specificity
Characteristic harm	Adverse drug reaction	Malfunction, mechanical or electrical failure, use error	A false result leading to a wrong decision
Regulatory key	Composition and trials	Classification and quality system	Classification by consequence of error
Change discipline	Variations to a marketing authorisation	Design control under the quality system	Change control of reagents, calibrators and software

1.6 History of medical device regulation

Device law is younger than drug law, and its landmarks are reactions to harm, in the pattern MRA103T traced for clinical research ethics. Early twentieth century law treated devices, where it noticed them at all, as ordinary goods: the original US Food, Drug, and Cosmetic Act of 1938 gave the FDA authority over adulterated and misbranded devices but no power to require proof before marketing, and most countries had less. The gap showed in a series of failures, of which the **Dalkon Shield** intrauterine device in the 1970s, marketed without premarket testing and followed by pelvic infections, infertility and deaths, is the standard teaching case: it taught legislators that a device could injure at scale while no authority had ever examined it before sale. The American answer was the **Medical Device Amendments of 1976**, the foundation of the modern system: classification into three classes, general controls for all devices, premarket notification for the middle class and premarket approval for the highest, with investigational device exemptions for clinical study, the machinery Unit 3 teaches. Europe built later and differently: the directives of the 1990s (the Active Implantable Directive of 1990, the Medical Device Directive of 1993, the IVD Directive of 1998) created the CE marking system of Unit 4, delegating conformity assessment to notified bodies rather than a central agency. The harmonisation era followed: the **Global Harmonization Task Force**, founded in 1992 by the regulators and industry of the US, EU, Japan, Canada and Australia, wrote the shared grammar of the field, the essential principles, the classification rules, the STED; and when its work was judged ready to pass to regulators alone, the **IMDRF** succeeded it in 2011. The most recent turn is tightening after failure: the PIP breast implant scandal, in which a manufacturer fraudulently used industrial grade silicone while holding a CE mark, drove the EU from directives to the directly applicable, stricter MDR and IVDR of 2017, with notified bodies themselves more heavily supervised.

1.7 Product lifecycle of medical devices

A device's regulated life runs longer and changes faster than a drug's, and the syllabus names the product lifecycle as a topic because each stage carries its own regulatory instruments. It opens in **conception and design**: intended purpose is fixed, the classification is determined, the applicable standards and essential principles are mapped, and design control under the quality system begins, because in device regulation the design file is a legal document. **Design verification and validation** follow, bench, software, usability and where required animal and clinical work, governed for investigations by ISO 14155 (Unit 2). **Regulatory submission and market authorisation** convert the design dossier, in STED shape where accepted, into the right to sell, through the routes of Units 3 to 5. **Manufacture and release** run under the audited quality system, with the device history records that let every unit be traced to its materials and process. **Distribution and use** add labelling, installation, training and servicing duties, and for the higher classes the unique device identification that Unit 3 covers. **Post market surveillance and vigilance** then operate for the whole market life: complaint handling, adverse event reporting, field safety corrective actions and the periodic reassessment of the risk file, because a device's risk profile is learned in use and its design is expected to improve. **Change and obsolescence** close the loop: design changes are graded by their effect on safety and performance and may need fresh notification or approval, and end of life brings withdrawal, recall where required, and record retention. The contrast with the drug lifecycle of MRA102T is instructive: a medicine's identity is frozen at authorisation and defended by variations control, while a device is expected to evolve under design control, and its regulator therefore audits the system that controls change as much as the product that results.

The regulated lifecycle of a medical device
Conception: intended purpose fixed, classification determined
|
Design and development under design control (ISO 13485)
|
Verification and validation; clinical investigation where
the class requires it (ISO 14155)
|
Submission (STED shaped dossier) and market authorisation
|
Manufacture and release under the audited quality system
|
Distribution and use: labelling, UDI, training, servicing
|
Post market surveillance, vigilance, corrective action
|
Change under design control, or obsolescence and withdrawal
(and the loop returns to design)

1.8 Classification of medical devices: the working systems

Section 1.4 gave the model; this section gives the labels the market actually uses, which Units 3 to 5 then spend. The **United States** classifies into Class I (low risk, general controls, many exempt from premarket notification), Class II (moderate risk, general plus special controls, normally the 510(k) route) and Class III (high risk, normally premarket approval), assigned device type by device type in the classification regulations. The **European directives** classified by eighteen rules into Class I, IIa, IIb and III, the MDR keeping the four tiers and widening several rules so that some devices moved up a class. **India's Medical Devices Rules 2017** follow the GHTF shape exactly: Class A low, B low to moderate, C moderate to high, D high risk, with the licensing split MRA104T teaches, State Licensing Authority for Classes A and B manufacture, Central Licensing Authority for C and D and for all imports. **ASEAN** under its Medical Device Directive, **China** under the NMPA (with its own Class I, II and III labels), and **Japan** under the PMDA Act (general, controlled and specially controlled devices, aligned to the four GHTF classes) complete the Unit 5 picture. Two professional habits follow. Classification is **rule based and intended purpose based**, so the same physical article can change class with its claims; and classification must be settled **before** any other regulatory planning, because dossier, evidence, route and audit all hang from it.

1.9 IMDRF and GHTF: the harmonisation machinery

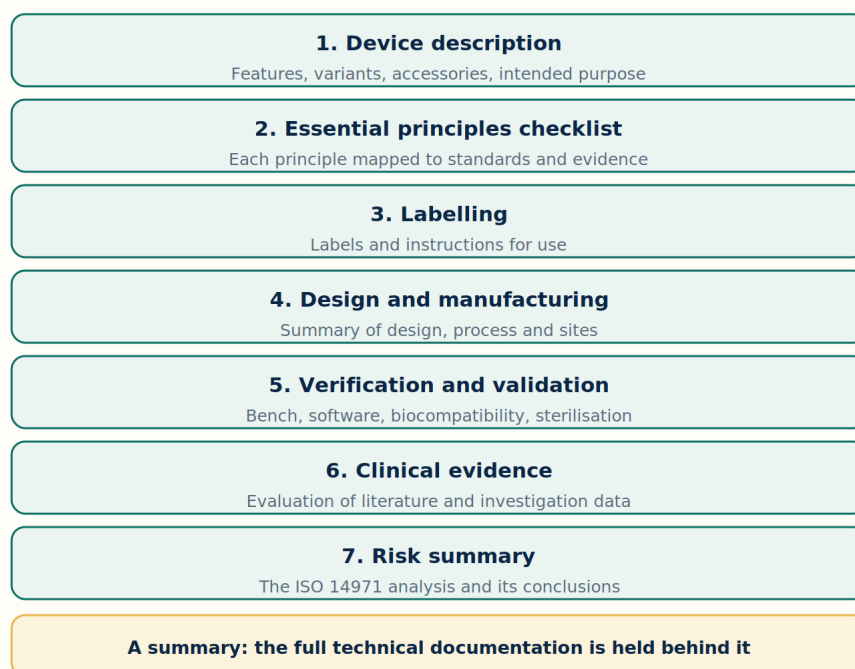
The **Global Harmonization Task Force (GHTF)** was founded in 1992 as a voluntary partnership of the regulatory authorities and the regulated industry of five jurisdictions, the United States, the European Union, Japan, Canada and Australia, to converge device regulation worldwide: one set of essential principles, one classification model, one dossier shape, so that a device assessed once could travel. It worked through five **study groups**, each owning a territory: Study Group 1, premarket evaluation, which wrote the essential principles and the STED; Study Group 2, post market surveillance and vigilance, which wrote the adverse event terminology and reporting guidance met in Unit 2; Study Group 3, quality systems; Study Group 4, auditing of quality systems; and Study Group 5, clinical safety and performance. In 2011 the regulators judged that convergence work should be led by regulators alone, wound the GHTF down, and founded the **International Medical Device Regulators Forum (IMDRF)** as its successor, a voluntary group of device regulators, chaired in rotation, working through working groups on the same convergence agenda, with a management committee of the member authorities and the WHO and harmonisation bodies such as the Asian Harmonization Working Party participating as observers. IMDRF's products are guidance documents (its adverse event terminology is the global coding standard of Unit 2, section 2.7), the regulated product submission table of contents that succeeds the STED, and frameworks such as the Medical Device Single Audit Program, under which one quality system audit serves several jurisdictions, used again in Unit 5.

Neither body makes law: their power is that national systems, India's 2017 Rules and ASEAN's directive among them, adopt their models wholesale, so a student who knows the GHTF grammar can read most national device rules as dialects of it.

1.10 Summary Technical Documentation: the STED

The **Summary Technical Documentation**, universally shortened to **STED**, is Study Group 1's answer to the dossier problem: a standardised summary of the evidence that a device complies with the essential principles, organised so that any adopting regulator can review the same package. Its contents follow the lifecycle of the proof: a device description and features, including variants and accessories, and the intended purpose; the essential principles checklist, mapping each applicable principle to the standards applied and the evidence held; labelling and instructions for use; design and manufacturing information, at summary level; the verification and validation evidence, bench, software, biocompatibility, sterilisation and stability as applicable; the clinical evidence and its evaluation; and the risk analysis and management summary drawn from the ISO 14971 file. The crucial word is **summary**: the STED is the organised face of the technical documentation, not the whole of it, and the manufacturer must hold the underlying full data for audit or on request. Its regulatory significance is portability: a STED prepared for one STED adopting jurisdiction can be readdressed to another with the local administrative layer replaced, which is the practical cash value of harmonisation, and the MRA205P practical list of this branch accordingly sets a STED application for a Class III device as an exercise. The IMDRF's table of contents for regulated product submissions is the STED's designated successor, broader and chaptered for electronic submission, and Unit 5 closes with the guidance family to which both belong.

The STED: contents of the summary dossier



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Figure: The STED chapters of section 1.10: device description and intended purpose, the essential principles checklist, labelling, design and manufacturing summary, verification and validation evidence, clinical evidence and the risk summary, the summary face of the full technical documentation held behind it (Unit 1, section 1.10).

1.11 Global Medical Device Nomenclature: the GMDN

Regulators cannot compare experience with devices they cannot name consistently, and the **Global Medical Device Nomenclature (GMDN)** is the naming system built for that purpose: a structured, coded vocabulary of generic device groups, maintained by the GMDN Agency, in which every device type is assigned a term and code describing what it generically is, a cardiac catheter, a hip prosthesis, a blood glucose analyser, regardless of brand or maker. Its regulatory uses are fundamental: classification rules are administered against generic groups; adverse event reports aggregate experience by GMDN term, so a problem appearing across brands of one generic type is visible at all; registration and listing systems file devices under it; and traceability systems, including the UDI device identifiers of Unit 3, draw their generic layer from it. The professional habit it embodies: in device regulation, precise generic naming is not housekeeping but the precondition of surveillance, since a signal that cannot be grouped cannot be counted.

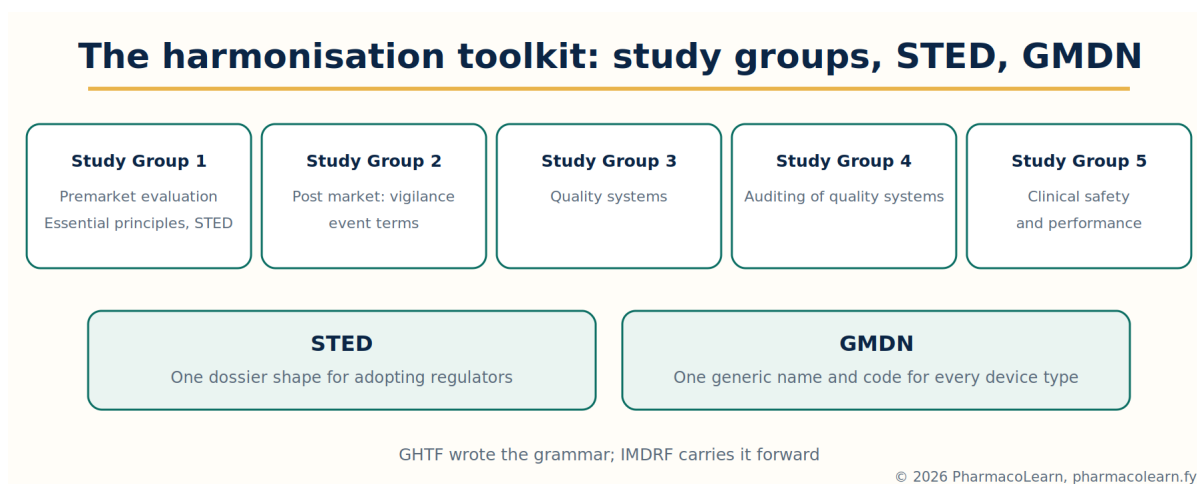


Figure: The GHTF and IMDRF toolkit of sections 1.9 to 1.11: essential principles and classification from Study Group 1, vigilance from Study Group 2, quality systems and auditing from Study Groups 3 and 4, clinical evidence from Study Group 5, carried by the two instruments every regulator reuses, the STED dossier and the GMDN nomenclature (Unit 1, sections 1.9 to 1.11).

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