Overview of Conformity Assessment for Medical Devices and IVDs

GHTF/SG1/N78 & GHTF N046

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Useful definitions

Conformity Assessment: The **systematic examination** of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices*.

Conformity Assessment Body (CAB): A body, other than a Regulatory Authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.

Recognised Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Technical Documentation: The documented evidence, normally an output of the quality management system, that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*.

Principles of Conformity Assessment

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Conformity Assessment: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority (RA), to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices*.

IMDRF/GRRP WG/N47

Conformity assessment is a demonstration that a MD or IVD conforms to the essential principles as an assurance it is safe and performs as intended. Can include….. evaluation activities including examination of records and procedures undertaken by the manufacturer, under requirements established by the RA. In assessing the conformity of a MD with the essential principles, standards or parts of several standards may be utilized and combined in a way that is appropriate for the specific MD. In some cases, the use of parts of standards and/or combinations of standards should be acceptable for conformity assessment purposes. *(simplified)*

Rationale

GHTF/SG1/N78 & GHTF N046

1. Conformity assessment (CA) provides objective evidence of safety, performance, and benefits and risks to maintain public confidence

2. Complementary elements of a global regulatory model – CA conducted over product life-cycle (before and after device placed on market, and post-market surveillance)

3. CA is the device manufacturer's responsibility, ensures supplied device continues to conform to EP, required by the Regulatory Authority or the regulatory framework.

4. Risk-Based Approach - rigour of conformity assessment and regulatory oversight commensurate with the degree of potential hazards presented by device

Conformity Assessment Elements

GHTF/SG1/N78 & GHTF N046

1. A quality management system (QMS),
2. A system for post-market surveillance (PMS),
3. Technical documentation,
4. A declaration of conformity (DoC), and
5. Registration of manufacturers and their medical devices

Conformity Assessment Elements

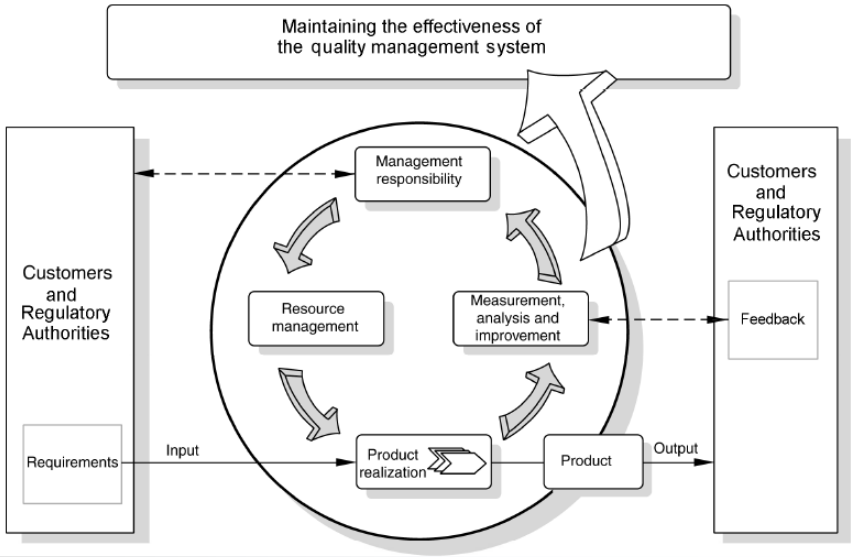
A quality management system (QMS), *example ISO 13485*

What is a QMS - a formalised system that documents processes, procedures, outputs and responsibilities for achieving quality policies and objectives.

Manufacturer should implement, document and maintain a QMS that ensures the medical devices it designs, manufactures and supplies to the market are safe, perform as intended and comply with the relevant provisions of the regulations.

Key components of system/procedure:

- Product Life-cycle Documentation
- Management Responsibility
- Design development
- Product V&V, Clinical evaluation
- Monitoring, measurement, analysis and improvement, e.g. Complaint handling, analysis, CAPA



Conformity Assessment Elements

A system for post-market surveillance (PMS)

Continued conformity to EP: such as complaint handling, vigilance reporting, and corrective and preventive action

Technical documentation

- Objective evidence that manufacturers must have to ensure device *(all risk classes)* conforms to EP (developed, designed and manufactured, etc).
- Updated as necessary to reflect the current status, specification and configuration of the device.
- RA (or CAB) determines the adequacy evidence and other regulatory requirements through a review.

Conformity Assessment Elements

A Declaration of Conformity (DoC)

Regulatory declaration/attestation device conforming to EP.

Registration of manufacturers and their medical devices

Record & information on dealers & products

DECLARATION OF CONFORMITY

[To be printed on Company Letterhead of Product Owner]

Name and Address of Product Owner:

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:
< Physical manufacturing site(s) including sterilisation site(s) >

Medical Device(s):
< e.g. product name and model number>

Risk Classification: e.g. Class B, rule
< Risk Classification of medical device(s) according to the classification rule, and the rule(s) used to determine the classification>

Quality Management System Certificate:
< Certification Body and Certificate Number, issue date, expiry date>

Standards Applied:
< International standards; OR Regional Standard; OR See Attached Schedule for multiple standards >
/

This declaration of conformity is valid from *<Day Month Year>*

Authorised Signatory:

Name, Position

Date

PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Medical Device | Device Category | Registrant | Product Owner | Importer | Wholesaler | Local Manufacturer | Advance Search

Medical Device

0-9 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

APM GLOBAL FACE RECOGNITION TERMINAL WITH THERMAL SCANNER [APM GLOBAL PTE LTD], APM Face recognitio...

0-9

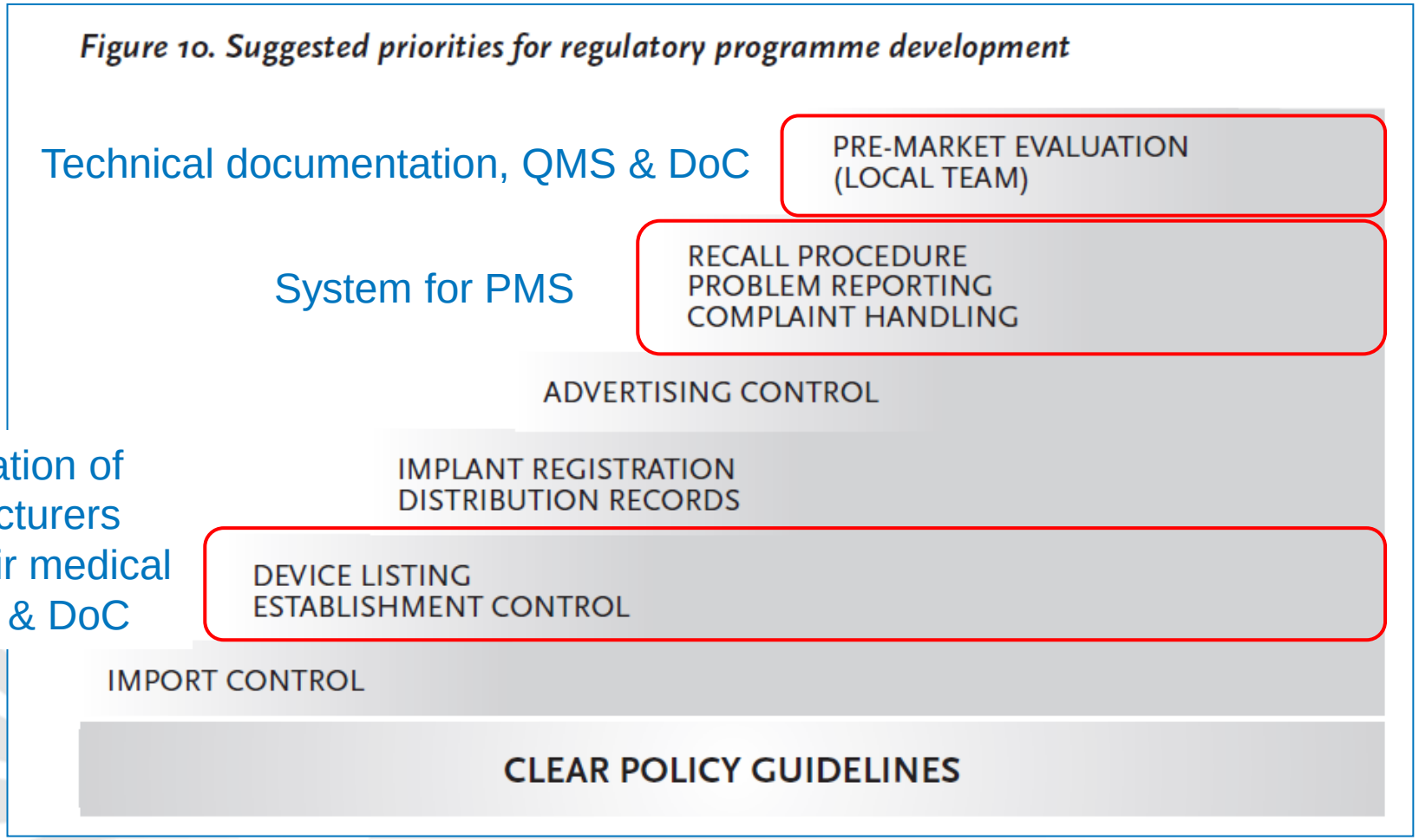
1ST SURGICONCEPT SPRING THREAD® ELASTIC SUTURE WITH COGS [1st SurgiConcept], Mild to moderate ptosis...
1stQ AddOn Intraocular Lens (Spherical) [1stQ GmbH], 1stQ AddOn IOLs are intended for implantation i...
1stQ AddOn Intraocular Lens (Toric) [1stQ GmbH], All 1stQ AddOn IOLs are indicated for implantation ...
3-D Matrix PuraStat®Absorbable Haemostat [3-D Matrix Europe SAS], PuraStat is indicated for haemosta...
3A Health Care OMRON Compressor Nebulizer with Nasal Aspirator [3A HEALTH CARE S.r.l.], The intended...
3C-Medical Intelligence BodyFIX® System [3C-Medical Intelligence GmbH], The BodyFIX System is intend...
3C-Medical Intelligence Fraxion™ [3C-Medical Intelligence GmbH], Is intended to be used for immobili...
3C-Medical Intelligence HexaPOD™ evo RT System [3C-Medical Intelligence GmbH], is intended use of th...
3D-Shaper Medical 3D-SHAPER [3D-Shaper Medical S.L], 3D-SHAPER® is a stand-alone medical software th...

Total 19920 matching record(s) Page 1 of 1992 Go [first] | [previous] | [next] | [last]

Note: All device listings on the Singapore Medical Device Register (SMDR) are active. Class A medical devices are not registered in the SMDR. To retrieve Class A medical devices, please visit Class A Medical Device Database.

Key Takeaways

WHO: Setting Priorities for Regulatory Programme Development



Source: World Health Organisation, Medical Device Regulations: Global overview and guiding principles

Utilization of Conformity Assessment by Regulatory Authorities - HSA's Experience

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HSA's Role in Health Products Regulation

Our Role *(Medical Devices)*

- Ensure **medical devices** in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy throughout the product life cycle
- Ensure timely access to good quality & safe health products
- Support the health and biomedical sciences industry and facilitating its development

Our Regulatory Philosophy

1. Benefits outweigh foreseeable risks
2. Risk-based approach
3. Confidence-based approach
4. Adoption and judicious adaption of international standards & best practices
5. Forging strategic partnership both regionally in ASEAN and internationally

Regulatory Convergence

Opportunities

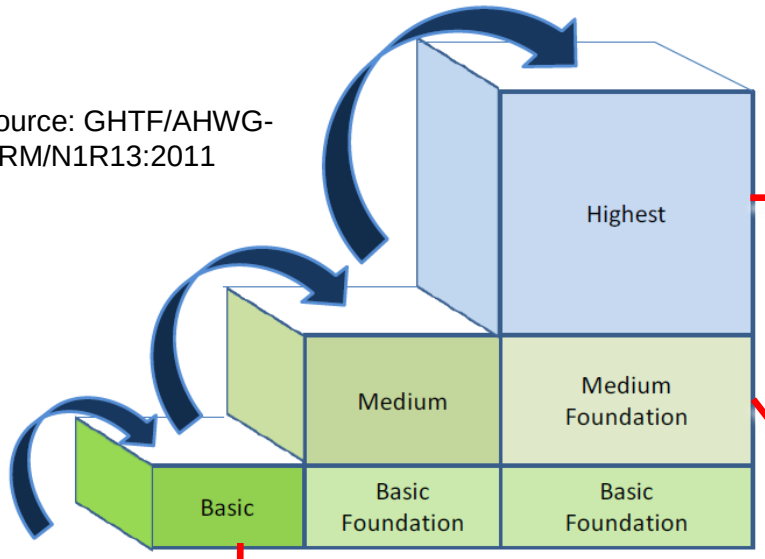
IMDRF/GRRP WG/N47 - EP

The worldwide adoption of a common set of fundamental design and manufacturing requirements for medical devices that, when met, provide assurance the device is safe and performs as intended, offers significant benefits to, among others, manufacturers, users, patients/consumers, and to Regulatory Authorities. Reducing differences between jurisdictions decreases the cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.

IMDRF/GRRP WG/N47

Developing Framework in accordance with GHTF Recommendations

Source: GHTF/AHWG-GRM/N1R13:2011

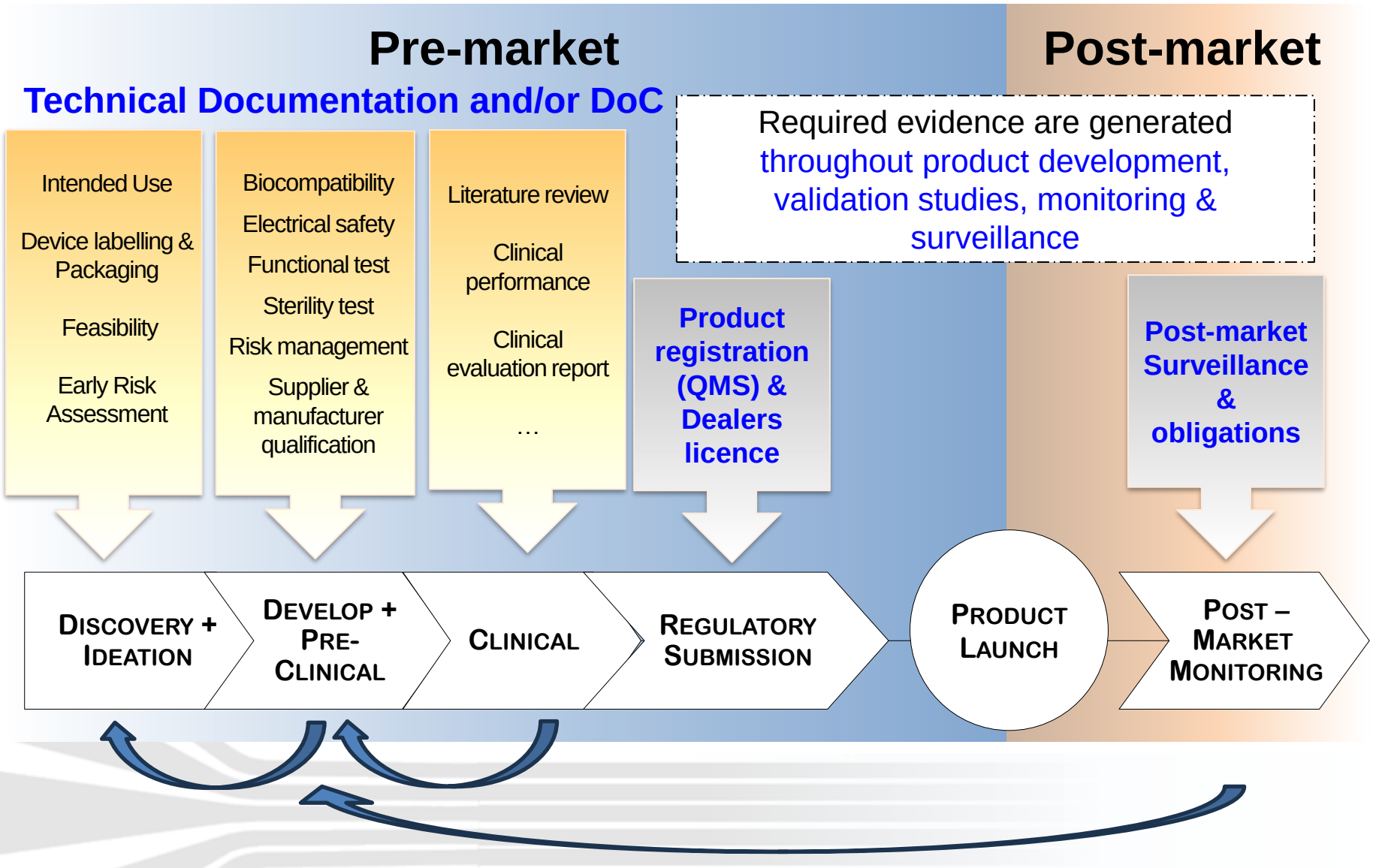


- Technical Information Review
- Robust clinical trial applications review
- Oversight of conformity assessment of the manufacturer's QMS
- Robust Post-market Surveillance system with Inspection system
- Post-market testing ability

- Risk classification
- Definitions –
  Manufacturer/importer/ distributor/medical device
- Registry for listing/dealers
- Post-market Surveillance system
- QMS
- Record keeping
- Labeling

- Compliance with essential principles of safety and performance
- Recognition of International standards
- Clinical trials - oversight
- Special access program
- Advertisement control

Medical Device Product Lifecycle

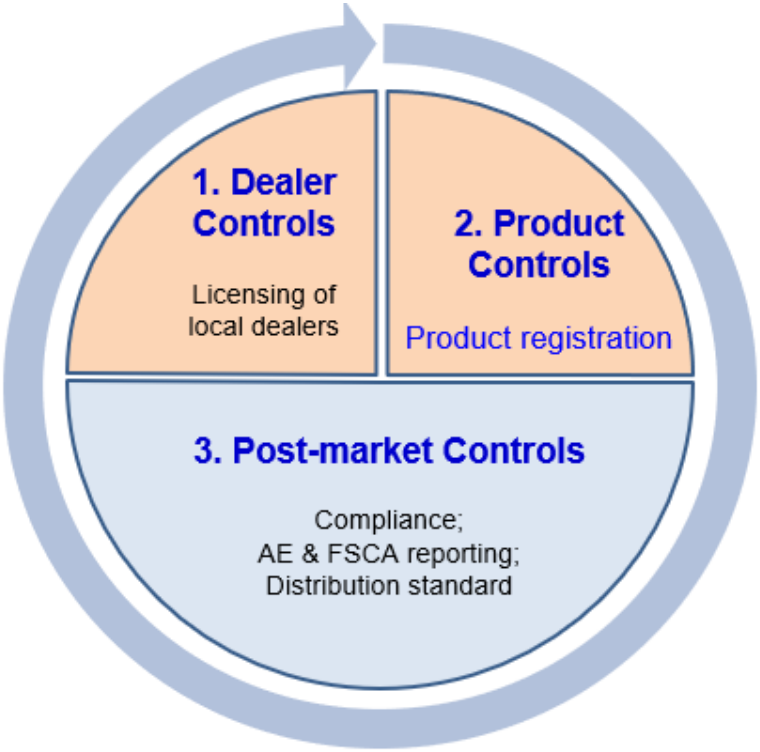


Device Life-cycle & Risk-based Approach

Review requirements on evidence stratified in accordance with device's **Risk Classification**

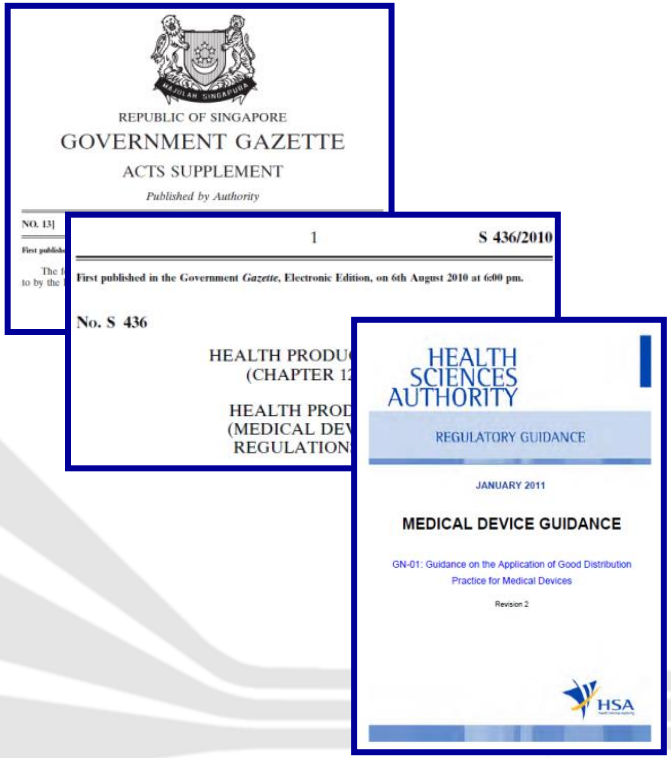
Risk class	Risk level	Product registration requirements
D	High Risk	**Requires** registration. More thorough review of documentary evidence with increased device risk.
C	Medium – High Risk	
B	Low – Medium Risk	
A	Low Risk	**Not required** to register

Key regulatory controls/ CA Elements



Legal Framework

- *Health Products Act (2007)*
- *Health Products (Medical Devices) Regulations 2010*
- Hierarchy of regulatory framework



- ***Act (Health Products Act)***
- **Regulations** *(Health Products (Medical Devices) Regulations 2010)*
- **Guidance Documents** *(Public information available on website)*

Technical documentation

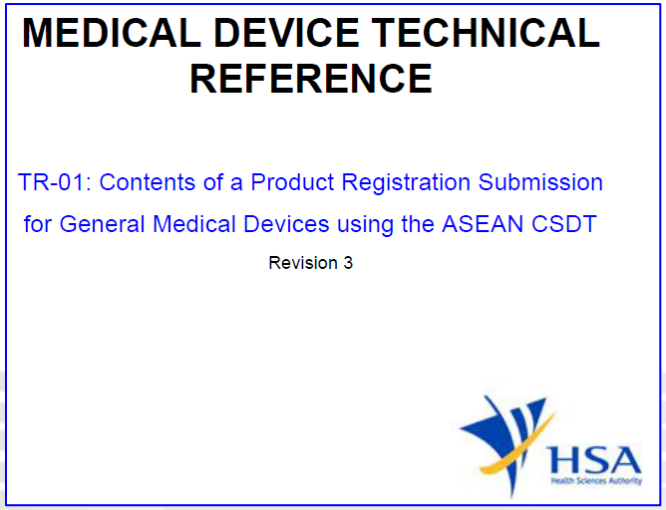
IMDRF ToC dossier

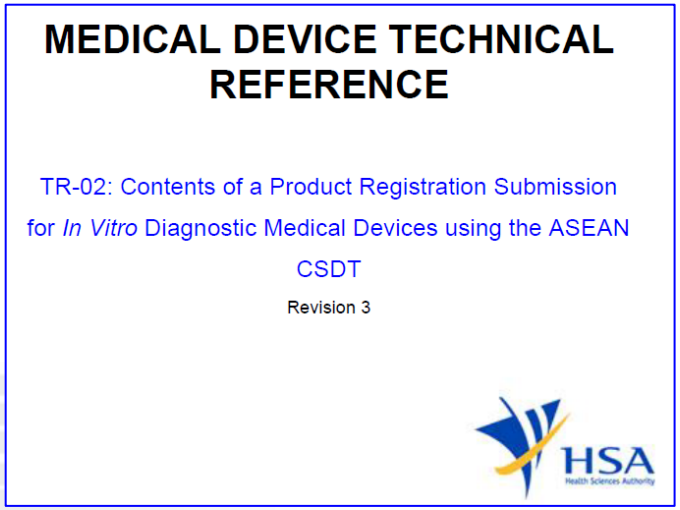
Provides an internationally harmonized, modular, format for use when filing medical device submissions to regulatory authorities for market authorization.

IMDRF/RPS WG/N9 - Non-In Vitro Diagnostic Device Market Authorization Table of Contents

IMDRF/RPS WG/N13 - In Vitro Diagnostic Medical Device Market Authorization Table of Contents
(IVD MA ToC)

Guidance on Submission for Product Registration





Technical documentation

IMDRF ToC dossier

CHAPTER 3 – NON-CLINICAL EVIDENCE	
CH3.1	Chapter Table of Contents
CH3.2	Risk Management
CH3.3	Essential Principles (EP) Checklist
CH3.4	Standards
CH3.4.1	List of Standards
CH3.4.2	Declaration and/or Certification of Conformity
CH3.5	Non-clinical Studies
CH3.5.01	Physical and Mechanical Characterization
CH3.5.01.1	[Study description, study identifier, date of initiation]
CH3.5.01.1.1	Summary
CH3.5.01.1.2	Full Report
CH3.5.01.1.3	Statistical Data

CHAPTER 4 – CLINICAL EVIDENCE	
CH4.1	Chapter Table of Contents
CH4.2	Overall Clinical Evidence Summary
CH4.2.1	Clinical Evaluation Report
CH4.2.2	Device Specific Clinical Trials
CH4.2.2.1	[Trial description, protocol #, date of initiation]
CH4.2.2.1.1	Clinical Trial Synopsis
CH4.2.2.1.2	Clinical Trial Report
CH4.2.2.1.3	Clinical Trial Data
CH4.2.3	Clinical Literature Review and Other Reasonable Known Information

Technical documentation

IMDRF ToC dossier sections comparison - PMS

	MEDICS Application Form - Dossier & Supporting Document(s)	Reference technical documents	
		IMDRF nIVD ToC	CSDT TR-01
6	**Executive Summary**		
	▪ Introductory descriptive information on the medical device, the intended use and indications for use of the device.	CH2.6 Global Market History CH2.2 General Summary of Submission	3. Executive Summary
	▪ Information on the use of the device, if any, such as targeted patient population, user profile (e.g. specific trained users), specific disease status or clinical condition (e.g. continuous monitoring in critically ill patients), mode of action (e.g. absorption profile) etc.		
	▪ To include a summary of reportable adverse events (AEs) and field safety corrective actions (FSCAs) for the medical device since its first introduction on the global market, in a tabular format as per TR-01.		
	▪ For FSCAs that are 'open', provide a description of any analysis and/or corrective and preventive actions undertaken by the product owner.		
	▪ If there have been no adverse events or FSCAs to date, provide an attestation from product owner on company letterhead, that there have been no adverse events or FSCAs since commercial introduction of the device globally. R1.3 ►This attestation is not restricted to usage only as intended by the product owner. ◄		

Technical documentation

IMDRF ToC dossier sections comparison - DoC

	MEDICS Application Form - Dossier & Supporting Document(s)	Reference technical documents	
		IMDRF nIVD ToC	CSDT TR-01
7	**Essential Principles Checklist and Declaration of conformity**		
	▪ Essential Principles conformity checklist (EP checklist). The checklist of conformity to the Singapore Essential Principles is to be submitted. Alternatively, the checklist to EU or Australian Essential Requirements can be submitted. ▪ GN-11 Declaration of Conformity (DOC). Alternatively, the EC or AU DOC can be submitted. ▪ List the standards that have been complied with in the design and manufacture (including sterilisation) of the device, if this has not been provided in the EP checklist or DOC.	CH1.11.6 Declaration of Conformity CH3.3 Essential Principles (EP) Checklist CH3.4 Standards	4.1. Relevant Essential Principles and Method Used to Demonstrate Conformity ***NOTE:*** *Refer to GN-16 Guidance on Essential Principles for Safety and Performance of Medical Devices for more details.*

Conformance to EP: methods that may be used include compliance with consensus or other standards, state of the art or internal industry methods, comparisons to other similar marketed devices, etc.

Technical documentation

IMDRF ToC dossier sections comparison - Standards

	MEDICS Application Form - Dossier & Supporting Document(s)	Reference technical documents	
		IMDRF nIVD ToC	CSDT TR-01
9	**Design verification and validation documents including** • **Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software** • **Metrological requirements** • **Sterilisation validation (if applicable)** **Shelf-life studies and projected useful life**		
	▪ Evidence supporting the physical or mechanical properties of the subject device	CH3.5 Non-clinical Studies CH3.6 Non-clinical Bibliography CH3.7 Expiration Period and Package Validation CH3.8 Other non-clinical Evidence	4.3 Summary of Design Verification and Validation Documents
	▪ Evidence supporting electrical safety and electromagnetic compatibility. For example, if a device is claimed to meet the requirements of IEC 60601-1 and IEC 60601-1-2, summary ▪ test reports and/or certificates are to be submitted for verification of conformance to these standards.		
	▪ Specify the version of the software to be supplied. R1.1 ►***NOTE:*** *The exact software version that represents all software changes/iteration (e.g. graphic interface, functionality, bug fixes and etc.) should be provided. Software version numbering that is solely for testing or internal use are not required.*◄		

Technical documentation

IMDRF ToC dossier sections comparison - QMS

	MEDICS Application Form - Dossier & Supporting Document(s)	Reference technical documents	
		IMDRF nIVD ToC	CSDT TR-01
11	**Clinical evidence**		
	▪ A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. Clinical evidence may include clinical literature review, clinical experience (e.g. registries and post market surveillance reports), and clinical investigation.	CH4.2 Overall Clinical Evidence Summary CH4.5 Other Clinical Evidence	4.3.2. Clinical Evidence ***NOTE:*** *Refer to GN-20 Guidance on Clinical Evaluation for more details*
14	**Proof of QMS - E.g.: ISO13485 Certificate, R2 ► MDSAP Certificate, ◄ Conformity to US FDA Quality Syst**		
	▪ ISO 13485 R2 ► or MDSAP ◄ certificates are to be provided for manufacturing and sterilisation sites of finished devices. ○ R2 ► For refurbished devices, refurbishment process must be covered within the scope of the QMS certificate of the manufacturer. ◄	CH1.06 Quality Management System, Full Quality System or Other Regulatory Certificates	4.6. Manufacturer Information
	▪ For sites without ISO 13485 R2 ► or MDSAP ◄ certification, comparable audit reports for the actual site e.g. US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 can be submitted.		

Relevant Essential Principles and Method Used to Demonstrate Conformity

No.	Essential Principles – General Requirements	Applicable to the Device?	Method of Conformity	Identity of Specific Documents
1	Medical Devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	Yes	Quality System Standard: - ISO 13485: 2016 Risk Management Standard: - ISO 14971:2019 Design Control Procedures: -S83782	Mfg A Ltd Corporate Quality Manual ISO 13485 certificate No. 135 Risk Management Report Design Specifications 322/2005/08

Relevant Essential Principles and Method Used to Demonstrate Conformity

IMDRF/GRRP WG/N47
Annex

Essential Principle	Guidances	Relevant Standards
5.1	GHTF/SG3/N18:2010 *Quality Management System –Medical Devices – Guidance on Corrective Action and Preventive Action and related QMS Processes* GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers* GHTF/SG3/N99-10:2004 *Quality Management Systems - Process Validation Guidance* GHTF/SG3/N15R8 *Implementation of Risk Management Principles and Activities within a Quality Management System* ISO 13485:2016 Handbook	ISO 13485 ISO 14971 ISO 23640 ISO 24971 CLSI EP25

Pre-clinical studies

Biocompatibility Studies

Table 1: *In vitro* and *In vivo* Toxicity Data for 15/85% by volume β-TCP/Poly(lactide co-glycolide) Biocomposite Material

Study	GLP	Methods	Results	Study Number
In vitro Cytotoxicity ISO Elution Test (MEM Extract)	Yes	2ml of extraction media were placed in 10 cm^2 wells containing mouse L-929 fibroblasts. Incubation time: 48 hours	Non-cytotoxic by USP standards. Toxicity of positive control: Moderate (grade 3) - 24 hours; Severely toxic -48 hours (grade 4)	Y3D111G
Pyrogenicity in Rabbits ISO	Yes	Single injection of 10 ml/kg saline extract into marginal ear vein in 3 rabbits. Rectal temperatures measured 0-3 hours at 30-minute intervals.	Non-pyrogenic	X3D342G
Intracutaneous (Intradermal) Reactivity Test ISO	Yes	3 rabbits were treated with 0.2 ml saline or cottonseed oil extracts. Five 0.2ml intracutaneous injections of extracts /vehicle controls were administered on either side of the cranial or caudal portion of the back.	There was no evidence of irritation for any of the materials tested resulting in a primary irritation score of 0.0. Response classified as negligible	X3D339G
Systemic Injection Test USP/ISO	Yes	5 mice/group were injected with 50 ml/kg of saline (IV) or cottonseed oil (IP) extracts or vehicle controls	No mortality, clinical signs or weight loss occurred in any of the groups over the 72 hour observation period.	X3D341G

Pre-clinical Studies

- **Physical Tests/ Performance Testing**
  - ✓ Physical testing is conducted, for example to predict the adequacy of device response to physiological stresses, undesirable conditions, long-term use and all possible failure modes
  - ✓ To include the finished device and its components
  - ✓ Physical tests to be performed - as appropriate for the Device in question and its intended use.

Intragastric Balloon System

- Balloon deflation puncture test
- Acid Exposure and Elasticity test
- Elongation and tensile strength of the fill tube
- Tensile strength and percent elongation of the balloon shell
- Bond strength between fill tube and sheath.....

(Non exhaustive list)

Pre-clinical Studies

Cardiovascular Guidewires

- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating adherence/integrity
- Catheter Compatibility.....

(Non exhaustive list)

Resorbable Bone Void Filler Device

- pH testing
- Dissolution/ Solubility testing
- Working time
- Setting time
- Dimensional stability
- Setting reaction temperature
- Chemical analysis of the final device.....

(Non exhaustive list)

Pre-clinical studies

Animal studies

- ✓ Rationale and limitations of selecting the particular animal model
- ✓ To address the interactions of the device with body fluids and tissues and the functional effectiveness of the device

Study	GLP	Methods	Results	Study Number
Tissue Reaction/ Systemic Absorption	Yes	Female Beagle dogs were implanted with 15/85% by volume β-TCP/Poly(lactide co-glycolide) biocomposite rods in each femur for 3, a total of 3, 9.8, 15, 18 and 24 months. Clinical, hematological, clinical chemistry and histopathological parameters were examined.	Minimal tissue reactions were observed at 3 and 10 months. The magnitude of the response dissipated to minimal to 0 from 15 to 18-24 months. Minor absorption was noted as early as 3-10 months, which progressed to marked by 18 months post-implantation. Absorption was almost complete by 24 months for both cortical and cancellous bone. 15/85% by volume β-TCP/Poly(lactide co-glycolide) biocomposite rods were found to be biocompatible with cortical and cancellous bone into which they were implanted.	00-0112

Pre-clinical studies - IVD

- Analytical Sensitivity
- Analytical Specificity
- Interfering Substances
- Precision (Repeatability/ Reproducibility)
- Linearity (Reportable Range)
- Trueness
- Recovery
- Stability of reagent
- Specimen type and storage recommendations
- Potential Carryover
- Traceability & Expected Values (Controls, Calibrators, Methods)

Clinical Evidence

Clinical evaluation report

- Data from Literature Search
  - ✓ Literature Search Protocol
  - ✓ Literature Search Report
  - ✓ Published articles and other references identified as relevant to the medical device

- Data generated through clinical experience
  - ✓ Post-market surveillance reports, registries or cohort studies
  - ✓ Adverse events databases
  - ✓ Details of clinically relevant field corrective actions

- Data from Clinical Investigations
  - ✓ To include design, ethical and regulatory approvals, conduct, results and conclusions of the Clinical Investigation

Clinical Evidence - IVD

Performance evaluation studies using human specimens

- Clinical Sensitivity
- Clinical Specificity
- Performance evaluation studies in comparison to a predicate/ well-established device
- Clinical Cut-off
- Reference Interval
- For self-testing and point-of-care IVD, performance evaluation when used by the target users e.g. lay person in case of self-testing IVD

Technical documentation

Review Routes *(turn-around time working days)*

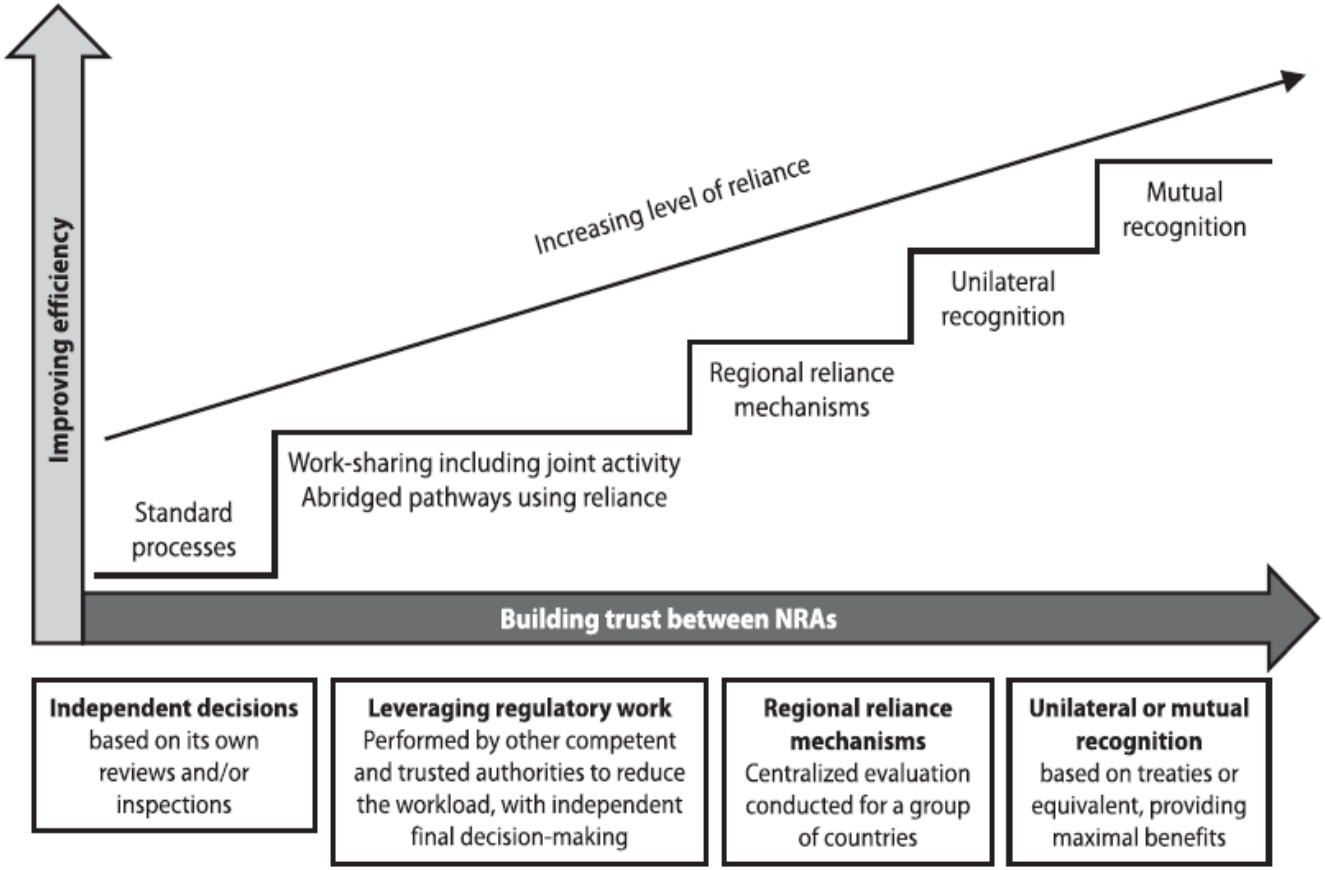
Risk Class	Full
Class B	160
Class C	220
Class D	310
Class D (devices incorporating medicinal products)	310

GN-15: Guidance on Medical Device Product Registration

Regulatory Reliance

Regulatory Reliance

The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to (i.e., totally or partially rely on work products by) another regulatory authority or trusted institution in reaching its own decision.



Source:
WHO - *Good Reliance Practices in the Regulation of Medical Products: High Level Principles and Considerations*

Regulatory Reliance

- Promotes regulatory efficiency by leveraging the work done by other trusted agency/institution

- Enhances accessibility to safe, effective and good quality medical devices

- Allows the relying regulatory authority to retain its jurisdictional independence
  - Relies on the assessments or decisions from others
  - Retains sovereignty of decision making
  - Remains responsible and accountable for regulatory decisions taken

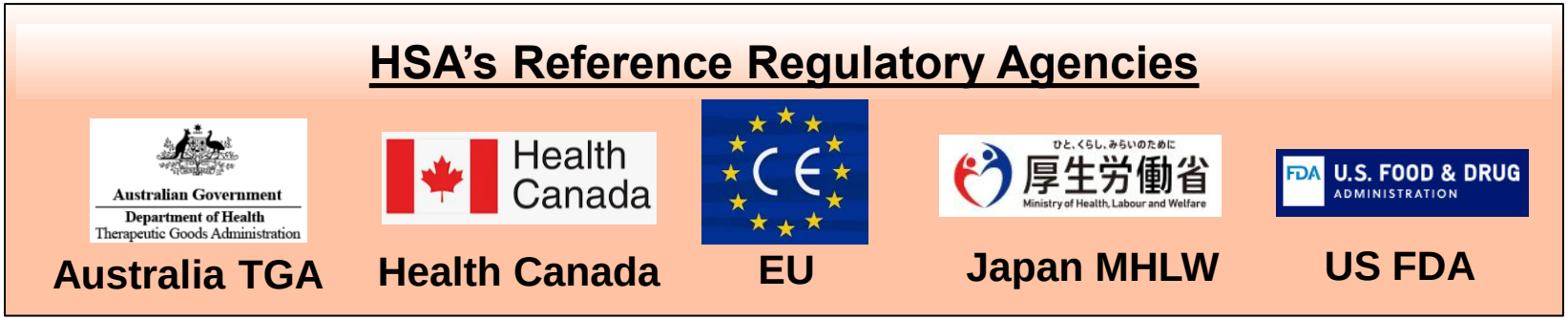
- Establishing an effective reliance approach requires:
  - Relying agency: Build **confidence** in the evaluations and assessments conducted by the other trusted agency *(e.g. Thailand)*
  - Other trusted agency: Be **transparent** on the evaluation and assessment criteria and practices including the decision making processes

- Sustaining the reliance approach requires on-going engagement and collaboration between the agencies to build trust and confidence

Regulatory Reliance

Confidence-based evaluation route of Class B, C, D MDs:

1. CA approach - Prior **approval** from HSA's reference agencies (RAs), with identical labelled intended use.



**Global Harmonization Task Force (GHTF) founding members*

**Type of recognised approvals can be found in *GN-15: Guidance on Medical Device Product Registration*

2. Safe marketing history in the respective RAs.

→ Devices may go through an evaluation route with Shorter timeline + Lower cost + Less dossier requirements.

Technical documentation

Review Routes *(turn-around time working days)*

Risk Class	TAT for Registration Routes (in working days)			
	Immediate	**Expedited**	**Abridged**	**Full**
Class B	Immediate Registration upon Submission		100	160
Class C	Immediate registration upon submission (for Class C standalone medical mobile application only)	120	160	220
Class D		180	220	310
Class D (devices incorporating medicinal products)			220	310

GN-15: Guidance on Medical Device Product Registration

Technical documentation

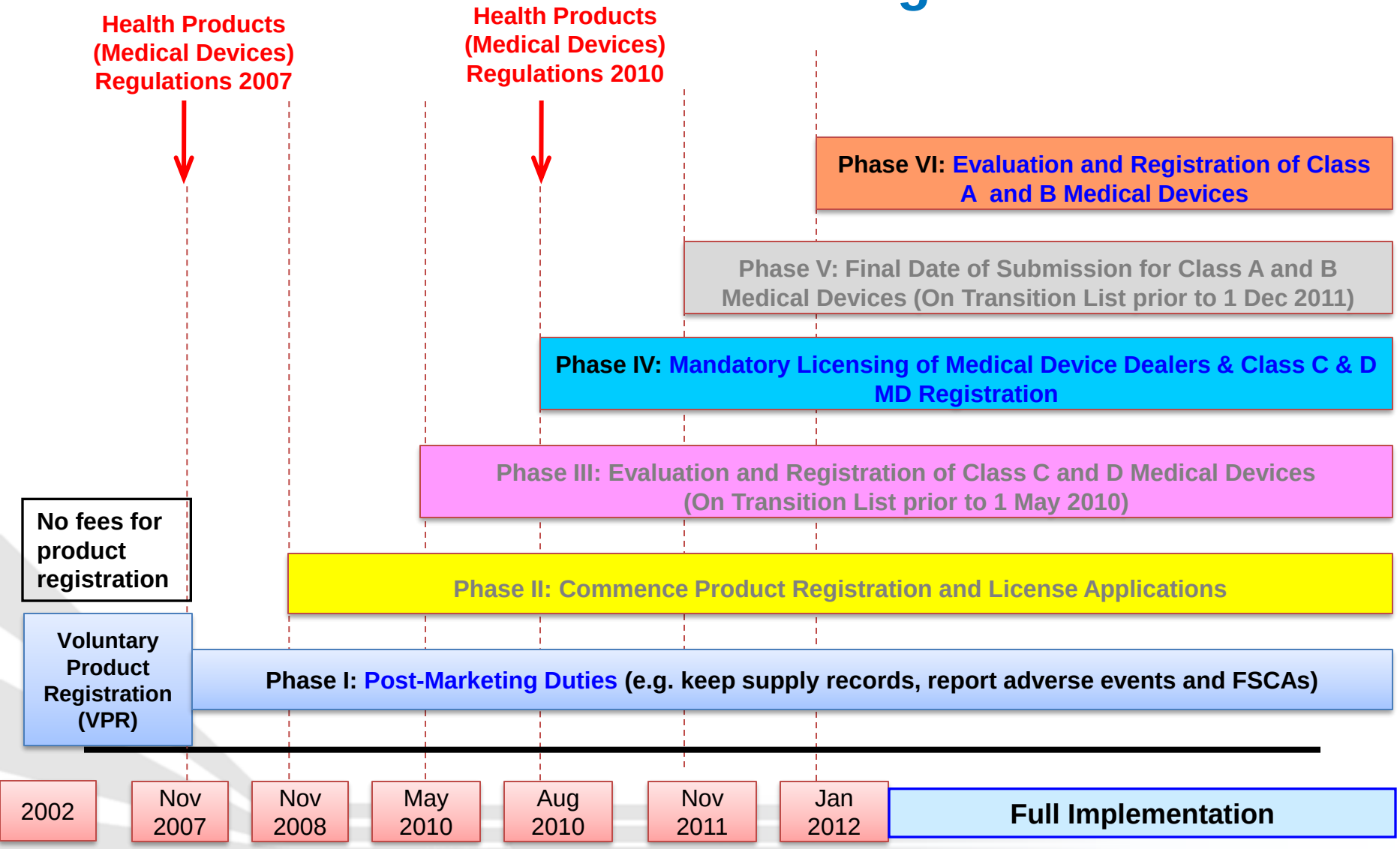
Summary of Submission Requirements (Class B)

	Documentary Requirements	Full	Abridged	IBR
1	Letter of Authorisation **(Annex 1)**	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓
3	Proof of reference agency's approval(s)		✓	✓
4	Proof of marketing history in the reference agencies' jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history **(Annex 2)**			✓ Only required for Condition 1
5	Declaration of no safety issues globally **(Annex 3)**			✓
6	Justification for an unmet clinical need	✓ Only required for Priority Review Scheme Route 1		
7	Executive Summary	✓	✓	✓
8	Essential Principles Checklist and Declaration of Conformity	✓	✓	
9	Device Description	✓	✓	✓

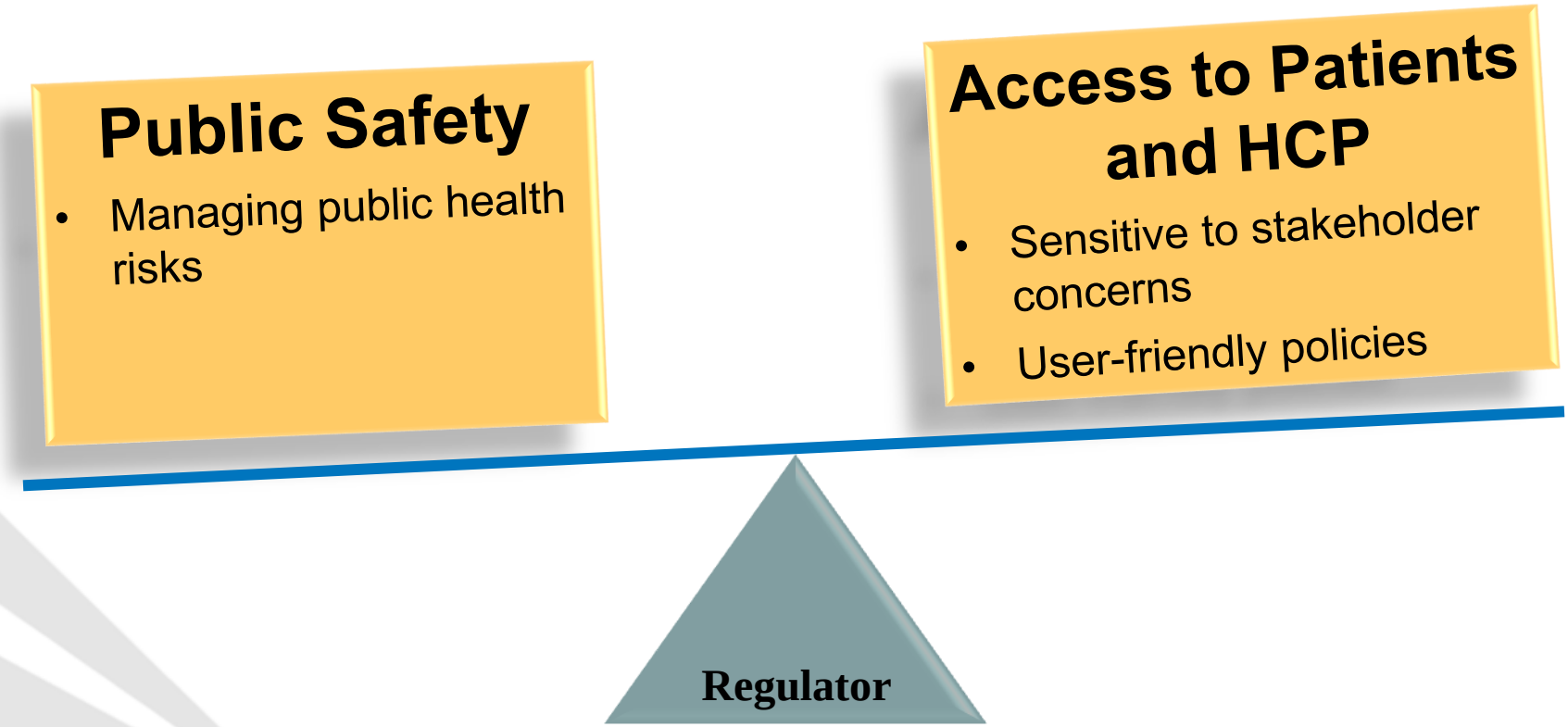
Technical documentation

10	Design verification and validation documents including: • Preclinical studies e.g. physical test data, biocompatibility studies, animal studies, software verification and validation studies, R11► traceability analysis (only for Full evaluation route) ◄ and R7.5► evidence to support the cybersecurity of connected medical devices ◄ • Metrological requirements • Sterilisation validation (if applicable) • Shelf-life studies and projected useful life	✓ Detailed reports[1]	✓ Summary[2]	✓ Sterilisation validation for Sterile devices only[3] Software verification and validation studies for standalone medical mobile applications only[4] R7.5► Evidence to support the cybersecurity of connected medical devices◄
11	Clinical Evidence[5, 6]	If applicable		
12	Proposed Device Labelling[5]	✓	✓	✓
13	Risk Analysis	✓	✓	
14	Manufacturer Information (site's name and address)	✓	✓	✓
15	Proof of QMS – Eg: ISO13485 R9 ► or MDSAP certificate ◄, conformity to US FDA Quality System Regulations, or Japan MHLW Ordinance 169	✓	✓	✓
16	Manufacturing Process – Flow Chart	✓		

Phased Approach : Medical Device Regulations Roll-Out



Regulatory Paradigm

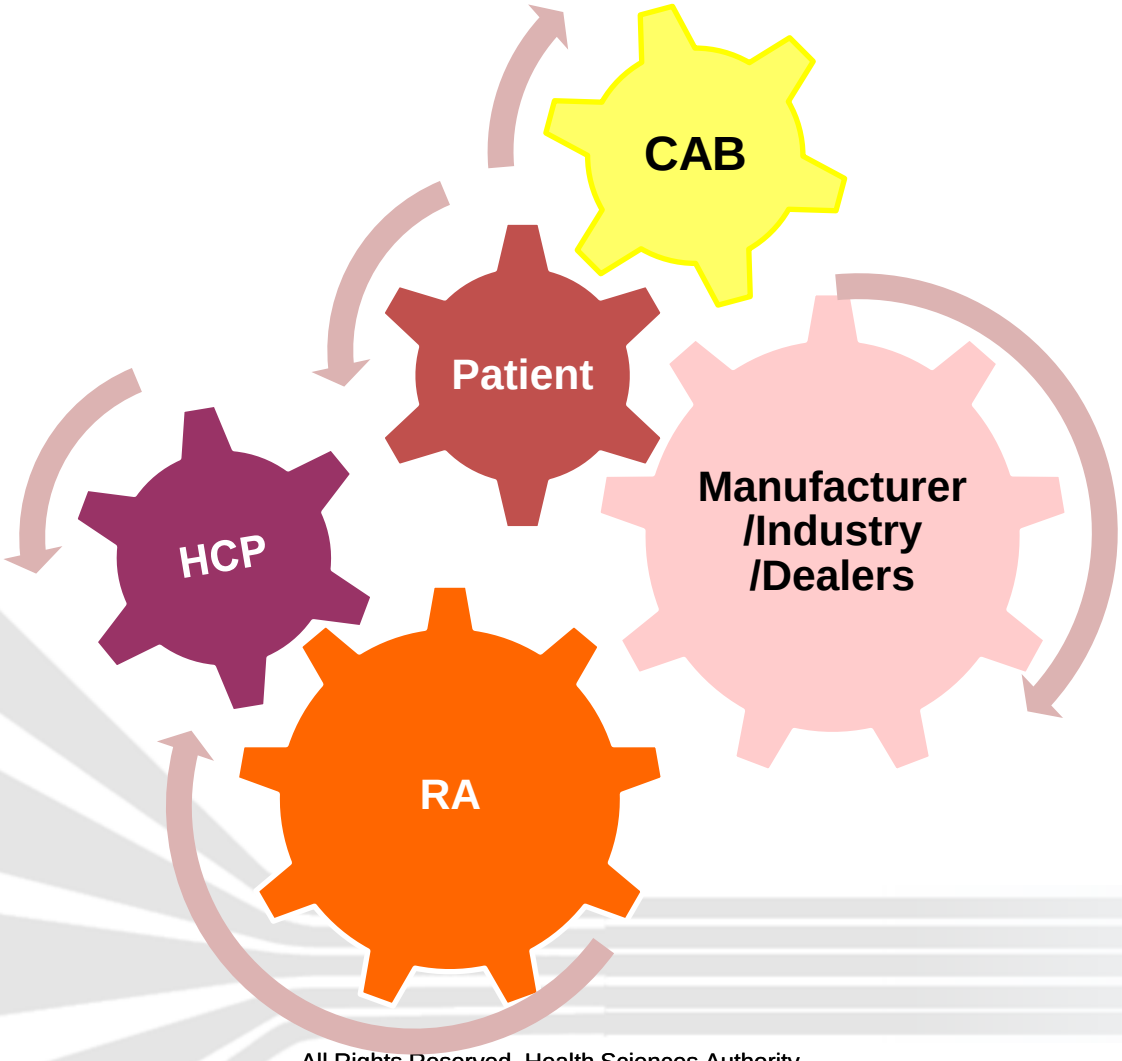


Relevant, Responsive & Ready

TECH
ENABLING REGULATORY COMPLIANCE
An Initiative by HSA

Managing Medical Device Risk Collaboratively

Many participants in the Medical Device life-cycle:

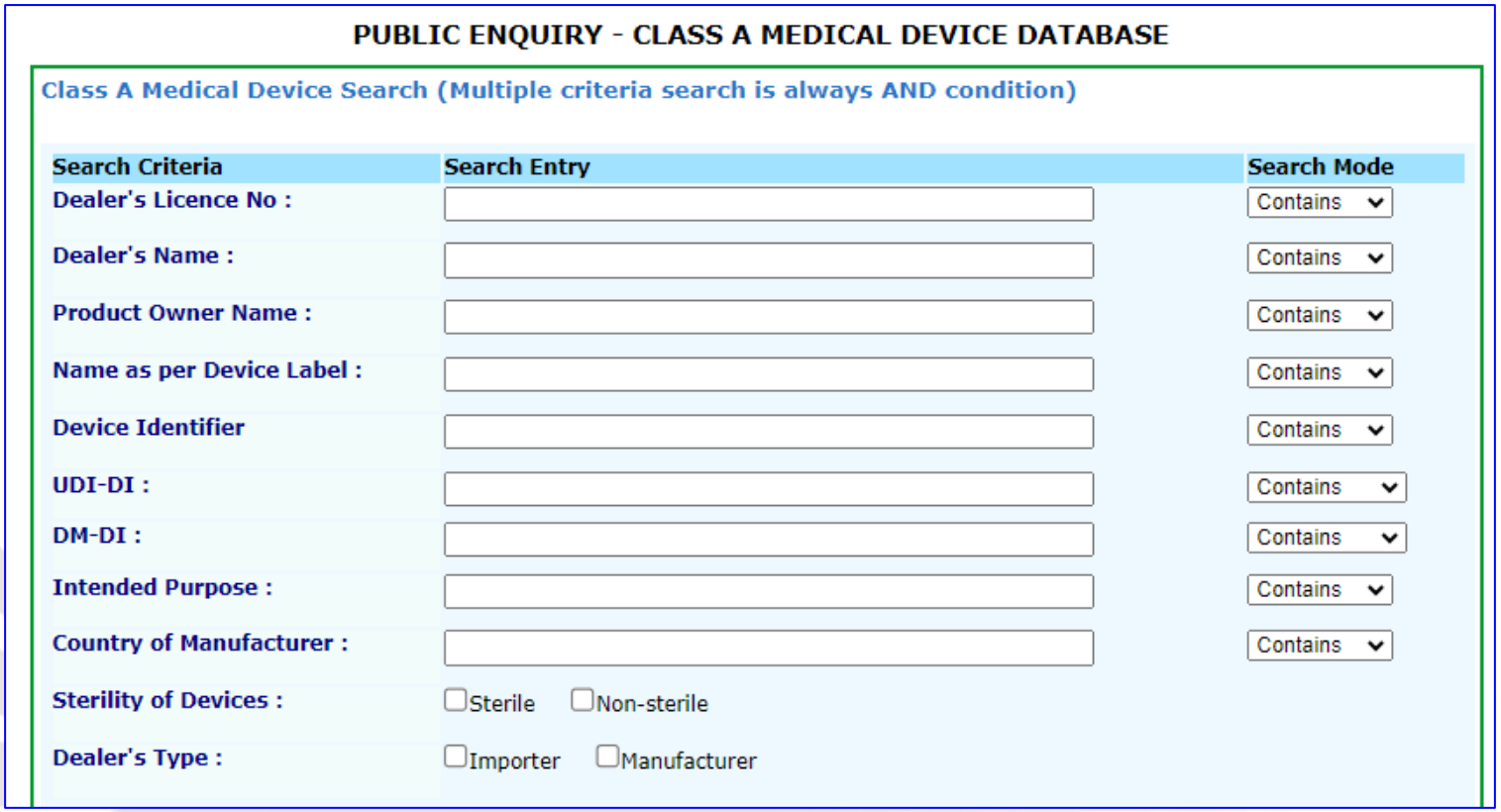


All stakeholders in this ecosystem contributes to management of risks and towards achieving positive health outcomes.

Listing of Class A devices & QMS

“Registration of manufacturers and their medical devices” - collection and retention of these information are fundamental elements of regulatory control.

?Remember? Phased Implementation (VI) 2012 : Evaluation and Registration of Class A and B Medical Devices



PUBLIC ENQUIRY - CLASS A MEDICAL DEVICE DATABASE

Class A Medical Device Search (Multiple criteria search is always AND condition)

Search Criteria	Search Entry	Search Mode
Dealer's Licence No :		Contains
Dealer's Name :		Contains
Product Owner Name :		Contains
Name as per Device Label :		Contains
Device Identifier		Contains
UDI-DI :		Contains
DM-DI :		Contains
Intended Purpose :		Contains
Country of Manufacturer :		Contains
Sterility of Devices :	☐ Sterile ☐ Non-sterile	
Dealer's Type :	☐ Importer ☐ Manufacturer	

Good Distribution Practice for Medical Devices (GDPMDS)

- Certification performed by **3rd party certification bodies** accredited by the Singapore Accreditation Council (SAC).
- SS 620 will be replacing GDPMDS, implemented on 9 November 2017 with a 3 year transition period.

Purpose

- Ensure that companies dealing with medical devices have a quality distribution system in place in maintaining devices' QUALITY & INTEGRITY throughout the process.

SCOPE

1. Product (Medical Devices)
   - Storage & Stock Handling
   - Delivery
   - Installation & Servicing
2. Facilities
3. Services provided by External Parties (3PL)
4. Post market Activities

QMS

Accreditation of Certification Bodies assessing conformance to QMS standards as pre-requisite for HSA Dealer's Licenses.

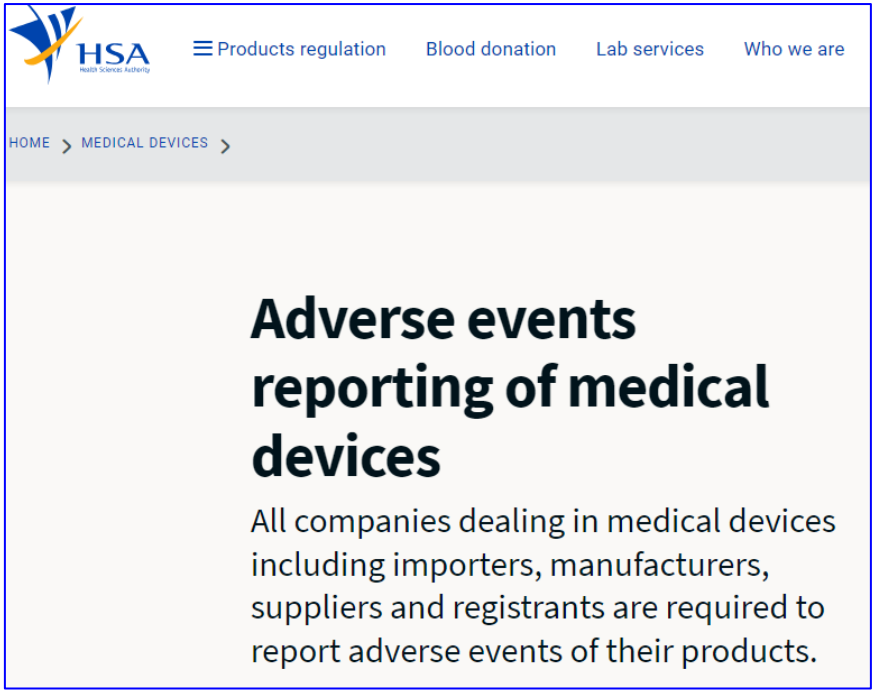
License / QMS requirements	Manufacturer's	Importer's	Wholesaler's
Type of QMS certification	ISO 13485 / MDSAP	GDPMDS* or ISO 13485 / MDSAP	
Class A Only - QMS certification	Declaration of conformity to a QMS		

*QMS for importers & wholesalers → SS 620: Singapore Standard for Good Distribution Practice for Medical Devices – Requirements (GDPMDS)

Prior to 2010 – Accredited certification bodies issuing SS620/GDPMDS QMS certificates.

From 2025 - Accredited certification bodies issuing ISO 13485 QMS certificates.

PMS



Global Regulatory Regimes

Control	USA	EU	Canada	Australia	Japan	Singapore (2007, 2010)
Product Classification	Risk stratification system					
- Review process (High to low risk)	- PMA (full evaluation) - 510K Notification (predicate equivalence) - 510k (3rd Party Review) -Exempted from product review	EU NB system - Full Quality System Audit - Design Examination (i.e. full evaluation) - Type testing - Self declaration	- Full evaluation - Product review - Notification - Self declaration	- Full Quality System Audit - Design Examination (i.e. full evaluation) - Type testing - Self declaration	- Full evaluation - Product review - Product review (CAB) - Notification - Self declaration	- Full evaluation (~ <1%) - Abridged review - Immediate/ Expedited review - Exempted/ Declared
Dealers Control	✓	✓	✓	✓	✓	✓
Manufacturer (QMS)	MDSAP ISO13485 / (QSR)	MDSAP/ ISO13485	MDSAP/ ISO13485	MDSAP/ ISO13485	MDSAP/ ISO13485; MO 169	MDSAP/ ISO13485
Post-market	Post-market Control - PMS					

Take-home Message…

1. Medical devices are regulated under the Health Products Act and the Health Products (Medical Devices) Regulations
2. The primary objective of regulation is to safeguard public health and establish traceability via Conformity Assessment elements.
3. HSA adopts a product life-cycle approach (change management) and applies risk-based controls.
4. Regulatory controls are constantly evolving. We should strive for continuous improvement.
5. Stakeholders form the fabric of a comprehensive regulatory landscape.

THANK YOU

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