# SUPPORTING INNOVATION AND FASTER ACCESS TO SAFE MEDICAL DEVICES

**1 AUGUST 2018**

**Medical Devices Branch**
**Medical Devices Cluster**
**Health Products Regulation Group**
**Health Sciences Authority**

# Health Sciences Authority

# HSA's Role in Health Products Regulation

## Our Role

- Ensure that pharmaceuticals, biologics, medical devices and health-related products 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

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# Regulatory Scope - Diverse Range of Products

Medical Devices

Therapeutic Products

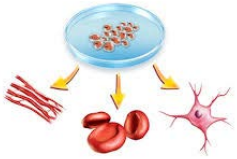
**Range of Products under HSA's Oversight**

Investigational Drugs

Tobacco Products

Cosmetics

Complementary Health Products



Cell, Tissue and Gene Therapy Products

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# Overview of Singapore Medical Devices Regulatory Framework

# What is regulated as a Medical Device?

***Definition per First Schedule of the Health Products Act 2007***

Any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article that is **intended by its manufacturer** to be used, whether alone or in combination, for **humans** for one or more of the specific purposes of: —

I. diagnosis, prevention, monitoring, treatment or alleviation of any disease;
II. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
III. investigation, replacement, modification, or support of the anatomy or of a physiological process;
IV. supporting or sustaining life;
V. control of conception;
VI. disinfection of medical devices; or
VII. providing information for medical or diagnostic purposes 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; and (b) Includes the following articles:

(i) any implant for the modification or fixation of any body part;

(ii) any injectable dermal filler or mucous membrane filler;

(iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

# What is regulated as a Medical Device?

## Definition in abridged and simpler terms


An instrument, appliance, implant, software etc

And Intended to be used on humans

And Not a drug

And Diagnose, treat, prevent or monitor a clinical condition

Or Is for contraception

Or Sustains life

Or Disinfects Medical Devices

# What is NOT a Medical Device


Research Use Only (RUO) products

Whereas *In-Vitro* Diagnostic (IVD) devices are Medical Devices

Whereas devices meant for both human and animal use are Medical Devices

Devices for animal use only

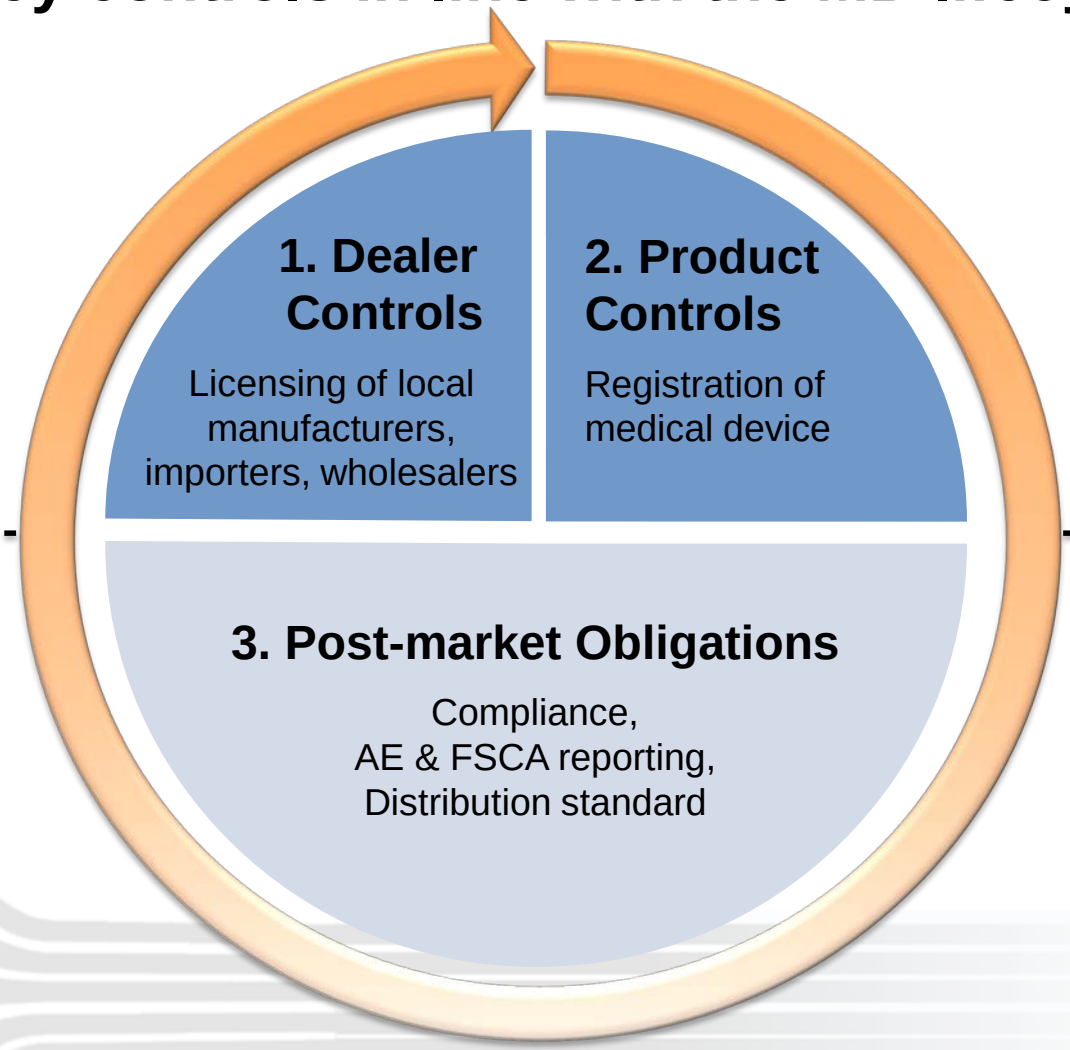
Drug pre-loaded syringes

Regulated as a Drug

Whereas dermal filler pre-loaded syringes, for physical augmentation of soft tissues are Medical Devices

# Entering the Singapore Market

## Three key controls in line with the MD lifecycle:

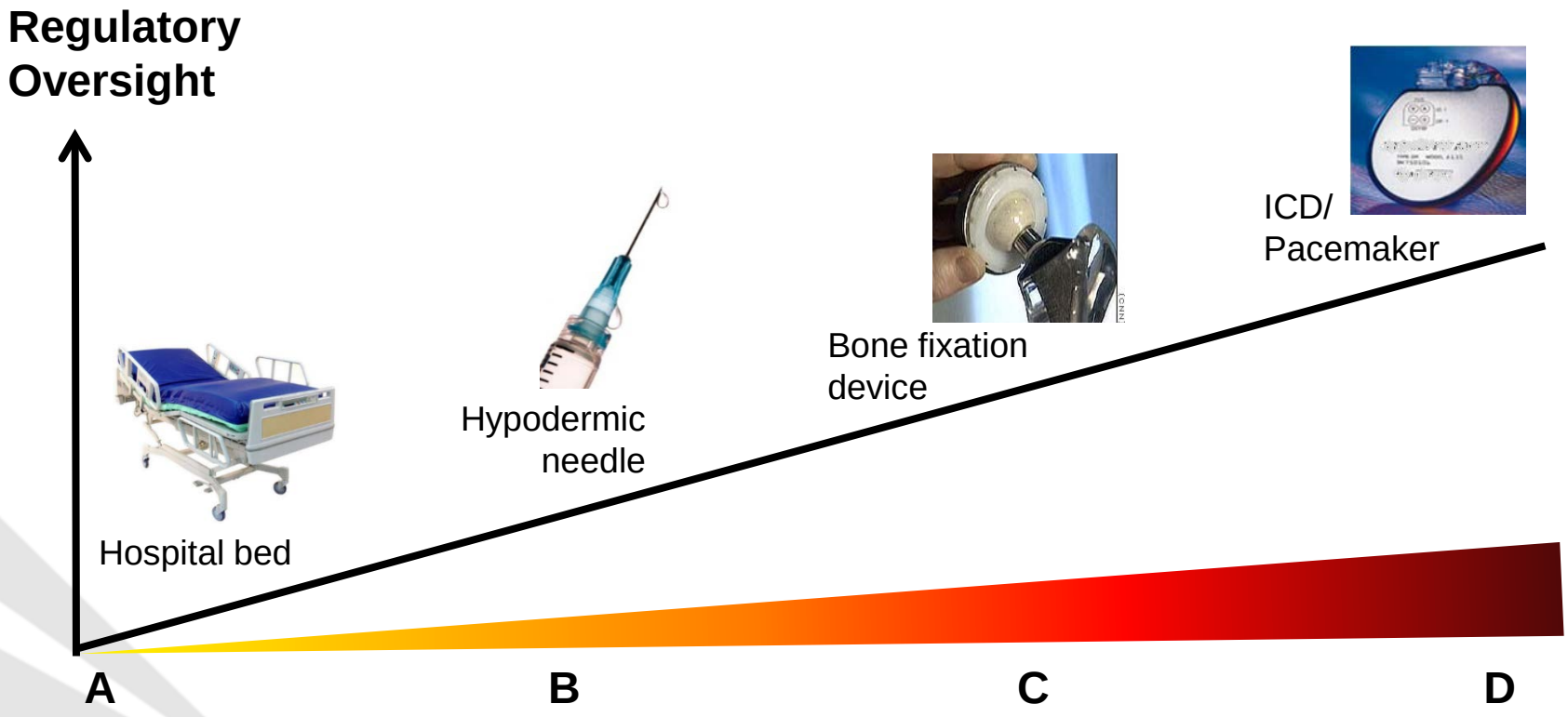



**Pre-market**

**Post-market**

# Risk-based Approach

Medical Devices were categorized into 4 risk classes, aligned with the international rule-based classification system



# Risk-based Approach

## Risk Classification

**Defined by intended use assigned by the product owner, NOT the class assigned to other similar products**

| | General Medical Devices | In-Vitro Diagnostics (IVDs) |
|---|---|---|
| Factors | • Contact duration<br>• Invasiveness<br>• site of use, etc… | Impact of result on individual and/or public health |
| References | ***GN-13*** *Guidance on the Risk Classification of General Medical Devices* | ***GN-14*** *Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices* |
| | ***Risk Classification Tool*** | |

# Risk-based Approach

## Controls stratified according to device's Risk Class

| Risk Class | Dealers license | Product registration | Post-market obligations |
|---|---|---|---|
| D | ✓ GDPMDS* / ISO 13485 | ✓ Require registration using CSDT** format | ✓ |
| C | | | |
| B | | | |
| A | ✓ Declaration of conformity to a QMS | ✗ Declared under Class A Medical Device Register | |

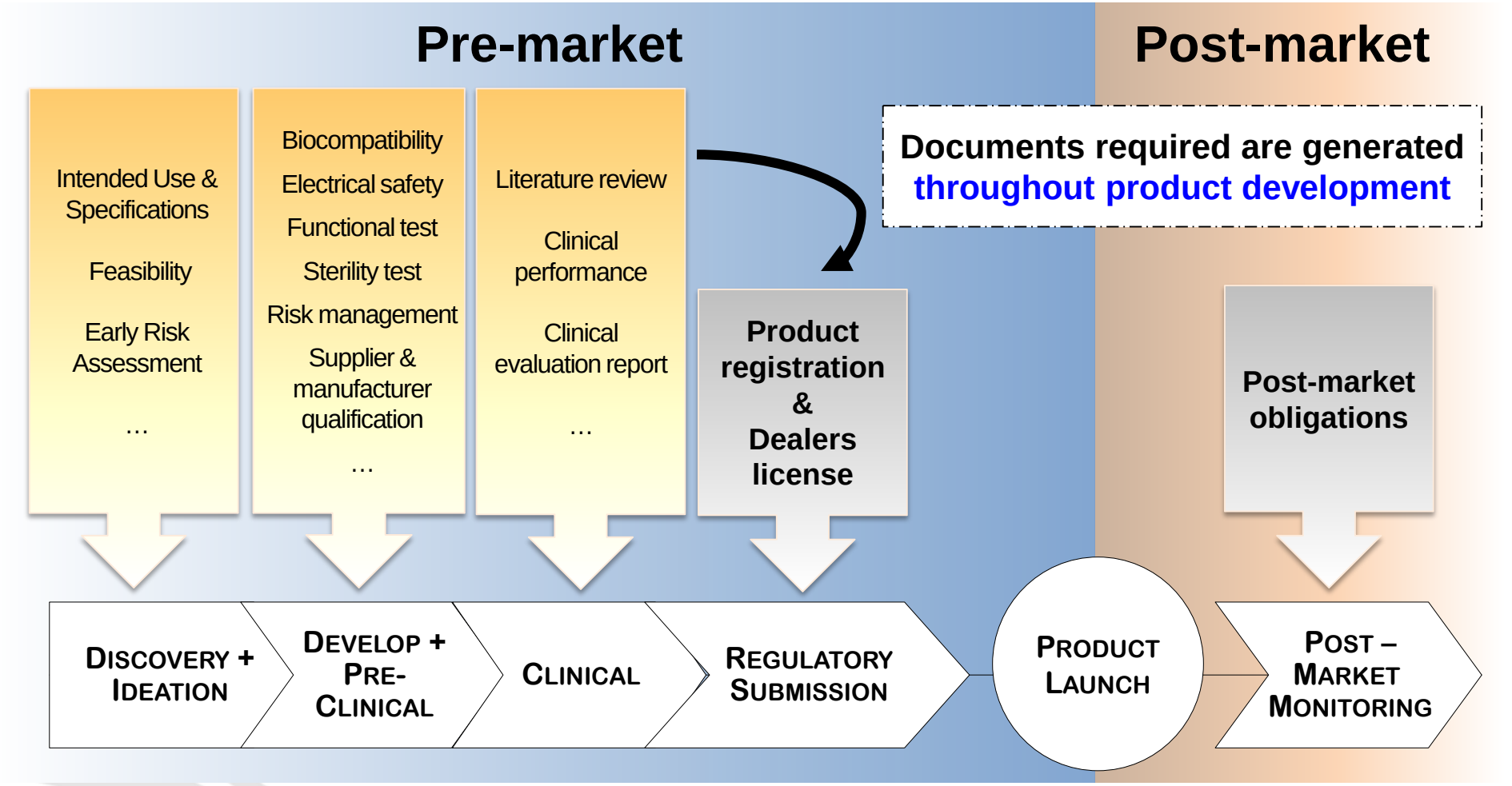
** Good Distribution Practice for Medical Devices*
*** ASEAN Common Submission Dossier Template*

# Dossier Requirements

| | Documentary Requirements | A | B | C | D |
|---|---|---|---|---|---|
| 1 | Letter of authorization | Not applicable<br><br>Essential safety & performance requirements shall be met | ✓ | ✓ | ✓ |
| 2 | Annex 2 List of Configurations | | ✓ | ✓ | ✓ |
| 3 | Executive Summary | | ✓ | ✓ | ✓ |
| 4 | Essential Principles Checklist & Declaration of conformity | | ✓ | ✓ | ✓ |
| 5 | Device description | | ✓ | ✓ | ✓ |
| 6 | Design verification and validation, e.g.<br>• Functional test<br>• Biocompatibility studies<br>• Software V&V<br>• Sterilisation validation<br>• Shelf-life studies | | ✓ | ✓ | ✓ |
| 7 | Clinical evidence | | If applicable | ✓ | ✓ |
| 8 | Proposed device labelling | | ✓ | ✓ | ✓ |
| 9 | Risk analysis | | ✓ | ✓ | ✓ |
| 10 | Manufacturing information<br>• Site's name & address<br>• Proof of QMS | | ✓ | ✓ | ✓ |

***Reference:*** *GN-15 Guidance on Medical Device Registration*

# Medical Device Product Lifecycle



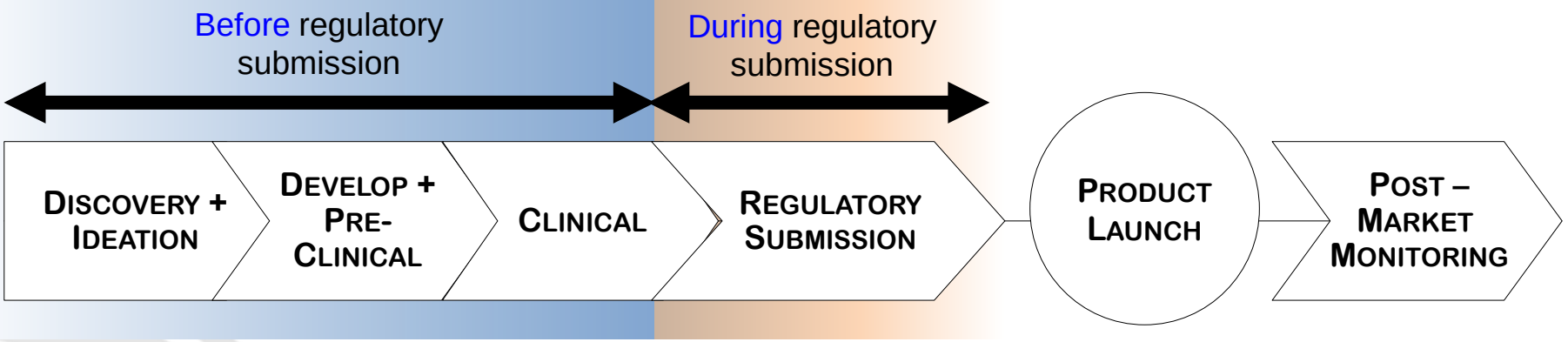
# HSA's Initiatives in Supporting Innovation & Device Development

# HSA's Initiatives

## To provide support through the device development lifecycle

**Pre-Market Consultation (PMC) Scheme**

Support innovation and device development by ensuring devices are in line with regulatory requirements

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# Pre-Market Consultation (PMC) Scheme

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

## 1 Medical Device Development Consultation

**SCOPE:** Clarification on regulatory requirements applicable to the device in development, which may include

- Regulatory strategy
- Regulatory requirements
  - Device claims
  - Safety / Performance studies
  - Sterility
  - Biocompatibility
  - Risk management
  - Clinical trials

# Pre-Market Consultation (PMC) Scheme

**SCOPE:** Seek feedback on the device dossier, in accordance to prescribed Common Submission Dossier Template (CSDT) guidance template, which may include

- Risk Classification
- Registration Route
- Grouping
- Technical & administrative documents

## 2 Medical Device Pre-submission Consultation

Channel for stakeholders to **seek feedback on device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

# Pre-Market Consultation (PMC) Scheme

| | WHO | WHEN | WHAT |
|---|---|---|---|
| **Medical Device Development Consultation** | MD developers, researchers | Any time during device development | 1 specific device / a group of MDs intended to be used together |
| **Medical Device Pre-Submission Consultation** | Stakeholders submitting MDs for registration | Before submission of pre-market application to HSA | Devices to be registered in 1 single pre-market application |

## What it is not

- Endorsement of any validation plans, test protocols and/or results that were discussed
- Not a scientific evaluation of the device
- Does not guarantee approval / marketing clearance

# Pre-Market Consultation (PMC) Scheme

Following are examples of queries which do not require PMC :

- General questions regarding registration procedures or documentary requirements for product registration
- Clarification on the guidance documents on the website
- To seek advice on the risk classification or grouping
- During the review process of a product registration
- To appeal a decision made during pre-market submission

etc…

These enquiries can be sent as general enquiries / using dedicated enquiry form(s) to HSA_MD_Info@hsa.gov.sg, or to contact officer in charge for application specific queries.

# Session Duration & Fees

| Consultation Category | Fees | Duration per session* |
|---|---|---|
| **Medical Device Development Consultation** | **$500** per **device** per consultation | Up to 2 hours |
| **Medical Device Pre-submission Consultation** | **$200** per **device application** per consultation | Up to 1 hour |

** Refers to only face-to-face meet-up consultation session.*

# Process & Timeline

| 5 Months before | ≥ 30 Days before | ●●● | Appointment Date |
|---|---|---|---|
| **1. Appointment booking** | **2. Document Submission** | **Request for Information** | |
| Slots are available for booking on the online Appointment Booking System **5 months before** the appointment date.<br><br>*E.g. on 1 August 2018, applicants will be able to book appointments till 31 December 2018.* | **ALL** required documents **30 days** before appointment date via email.<br><br>**Failure to submit** required documents by the due date may result in **rescheduling/ cancellation** of the appointment. | Upon submission, HSA will review the documents and may request for further information/ clarification before the appointment, where necessary.<br><br>**Failure to respond** or address deficiencies **by the stipulated period** may result in **rescheduling/ cancellation** of the appointment. | |

**No extension** of due date is permitted.
Only **ONE** rescheduling is allowed per booking reference.
Fees paid are non-refundable.

# 1. Appointment Booking

Appointment can be made via the **online Appointment Booking System** at the following url:

*http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html*

Application Guides with step-by-step guidance are available on website.

***Note:***

- *No CRIS / SingPass / CorpPass login is required.*
- *Ensure contact details are keyed in accurately as that will be the only form of verification upon payment and booking confirmation.*
- *Ensure you are able to provide with relevant information required for the consultation 30 days before the selected date as fees paid are non-refundable.*

# 2. Document Submission

- Submit the following information at least 30 days before the scheduled date:
  **(a) Completed consultation form**
  **(b) Relevant information described in the form**

- Information to be provided by replying to the confirmation email, or email to HSA_MD_Tech@hsa.gov.sg and quote the appointment booking reference number.

- The respective consultation form(s) can be downloaded from HSA website. Instructions will be provided in the confirmation email and forms.

***Reminder:***

- *Incomplete/insufficient information may result in rescheduling or cancellation of the appointment.*

# 2. Document Submission

(a) **Medical Device Development Consultation Form**

- ✓ Proposed agenda
- ✓ Brief device information
- ✓ Overview of device development status

**+**

(b) **Supporting documents*** in relation to the areas to be discussed. Information can be provided in **preferred format**, e.g. PowerPoint slides, summary copies etc.

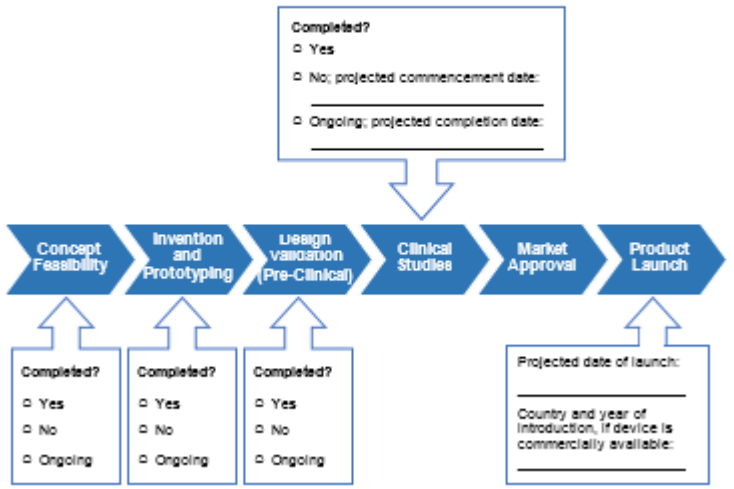
** Please ensure that the supporting information is appropriate and relevant to the questions on hand. Please avoid submission of extraneous information.*

**SECTON C: BASIC MEDICAL DEVICE INFORMATION**
*(please provide sufficient information for better understanding of the device to be discussed)*

| | |
|---|---|
| **PRODUCT NAME** | |
| **PROPOSED INTENDED USE/ INDICATIONS FOR USE**<br>*This may include:*<br>• *Disease/ condition the device is indicated to prevent, mitigate, screen, monitor, treat, or diagnose.*<br>• *For IVDs, the analyte/condition to detect and the assay methodology*<br>• *Targeted population*<br>• *Part of the body or type of tissue to which applied or with which the device is interacting* | |
| **DEVICE/ TECHNOLOGY DESCRIPTION**<br>*To include sufficient information to understand what the proposed device is and how it works, such as:*<br>• *Brief device description in text, pictures and/or diagrams (as applicable)*<br>• *Brief explanation of the mechanism of action, technology basis, and/or, if applicable, how the device output is used*<br>• *An explanation of the scientific basis for the device and/or the expected clinical utility*<br>• *Description of the materials used in the device (where necessary)*<br>• *For an IVD, detailed technical description of the device including instruments, reagents, components, software, principles of operation, and accessories* | |

**OVERVIEW OF DEVICE DEVELOPMENT**

*(please select accordingly based on current development progress of the device)*



# 2. Document Submission

(a) **Medical Device Pre-Submission Consultation Form**

- ✓ Device information
- ✓ Application information

**+**

(b) **Complete CSDT dossier*** based on selected **risk class** and **evaluation route**

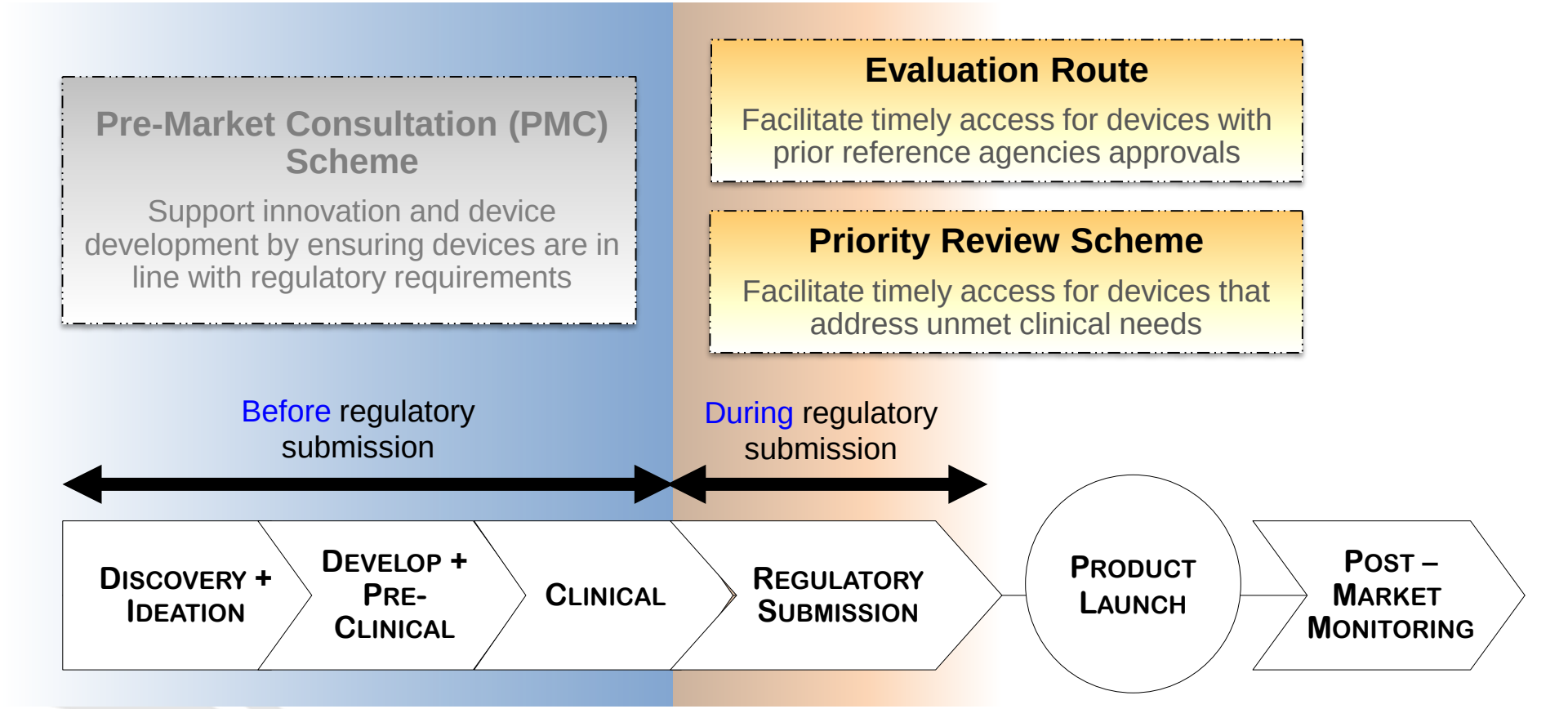
** Reference guidance documents:*

- *GN-15: Guidance on Medical Device Product Registration*
- *GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT*
- *GN-18: Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT*

| SECTION B: MEDICAL DEVICE DETAILS | |
|---|---|
| Name of Product Owner | |
| Name of Medical Device | |
| Medical Device Type | *Please select one:*<br>○ General Medical Device<br>○ In-Vitro Diagnostic Medical Device |
| Proposed Risk Classification | *Please select one:*<br>○ Class B (Low moderate risk)<br>Based on Rule _____<br>○ Class C (Moderate high risk)<br>Based on Rule _____<br>○ Class D (High risk)<br>Based on Rule _____<br>*Reference documents:*<br>• *GN-13: Guidance on the Risk Classification of General Medical Devices*<br>• *GN-14: Guidance on the Risk Classification of In-Vitro Diagnostic Medical Devices* |
| Proposed Evaluation Route | *Please select one:*<br>○ Full<br>○ Abridged<br>○ Expedited<br>○ Immediate<br>*Reference documents:*<br>• *GN-15: Guidance on Medical Device Product Registration* |
| Proposed Grouping Type | *Please select one:*<br>○ SINGLE<br>○ FAMILY<br>○ SYSTEM<br>○ TEST KIT<br>○ CLUSTER<br>○ DEVICE SPECIFIC (GN-12-2):_____<br>*Reference documents:*<br>• *GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria*<br>• *GN-12-2: Guidance on Grouping of Medical devices for Product Registration – Device Specific Grouping Criteria* |

# HSA's Initiatives

## To provide support through the device development lifecycle



# Evaluation Route

## HSA's Reference Agencies (RAs)

US FDA, EU, Australia TGA, Health Canada, Japan MHLW

<table>
<tr><th rowspan="2">Evaluation Route</th><th colspan="3">Qualifying Criteria</th></tr>
<tr><th>Class B</th><th>Class C</th><th>Class D</th></tr>
<tr><td>FULL</td><td colspan="3">Not approved in any RA</td></tr>
<tr><td>ABRIDGED</td><td colspan="3">1 RA approval</td></tr>
<tr><td rowspan="2">EXPEDITED*<br>(Class C, D)<br><br>&<br><br>IMMEDIATE<br>(Class B)</td><td>• 2 RAs approval<br>• No rejection/withdrawal by RA/HSA<br>• No safety issues globally</td><td colspan="2">• 2 RAs approval<br>• No rejection/withdrawal by RA/HSA</td></tr>
<tr><td colspan="2">• 1 RA approval<br>• 3 years marketing in RA/SG<br>• No rejection/withdrawal by RA/HSA<br>• No safety issues globally</td><td></td></tr>
<tr><td>IMMEDIATE<br>(Standalone Mobile App)</td><td colspan="2">• 1 RA approval<br>• No rejection/withdrawal by RA/HSA<br>• No safety issues globally</td><td></td></tr>
</table>

** Not within device group in exclusion list.*

*EU & TGA approval via Mutual Recognition Agreement (MRA) considered as 1 RA approval.*

***Reference:*** *GN-15 Guidance on Medical Device Registration*

# Priority Review Scheme

**Medical devices* to be registered via FULL Evaluation Route** → **Route 2**

**1 Falls under 1 of the 5 healthcare focus area**

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

**2 Designed & validated to meet unmet clinical needs**

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

**OR**

Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

**Route 1**

** Exclude devices incorporating registrable medicinal products*

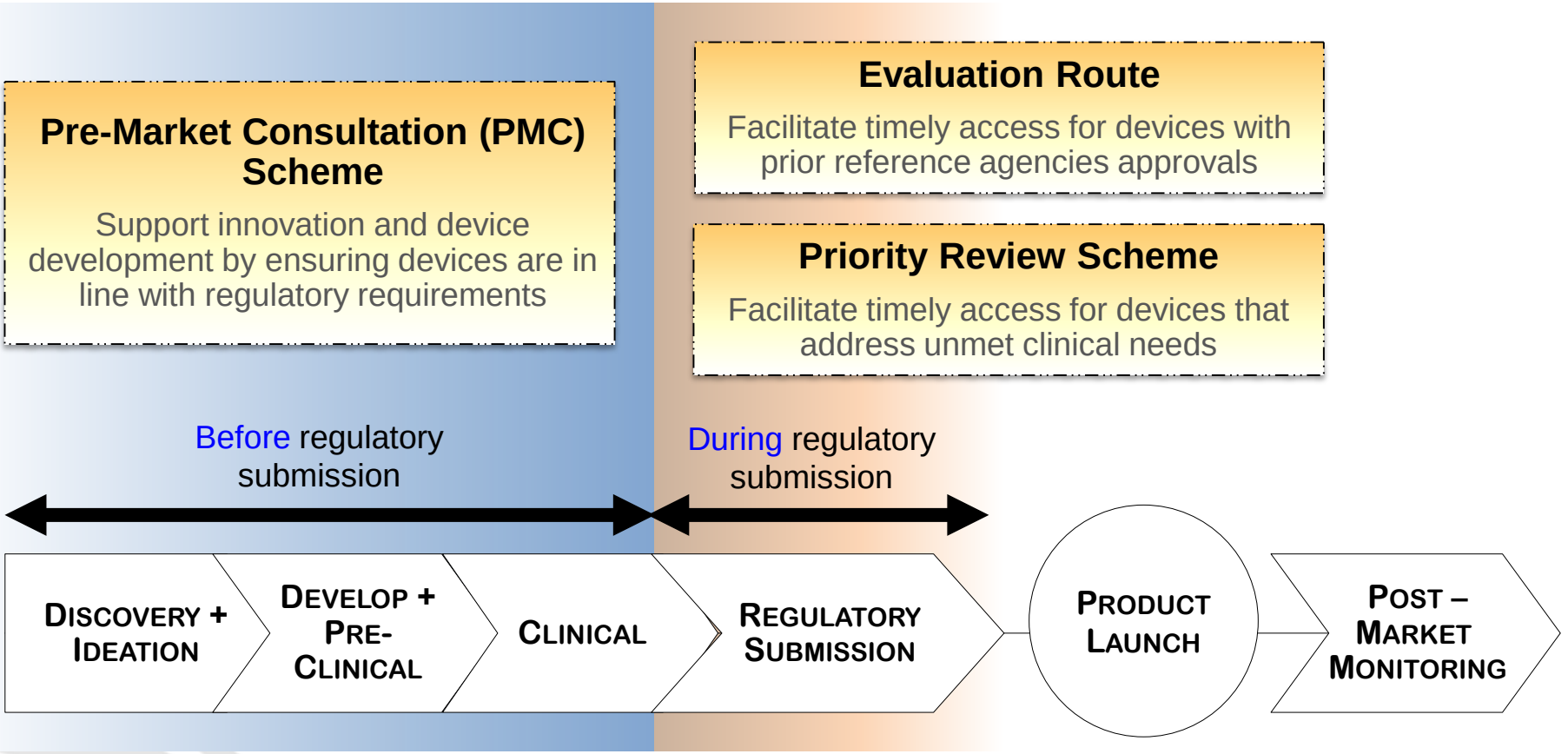
# Turn-Around-Time (TAT) & Fees

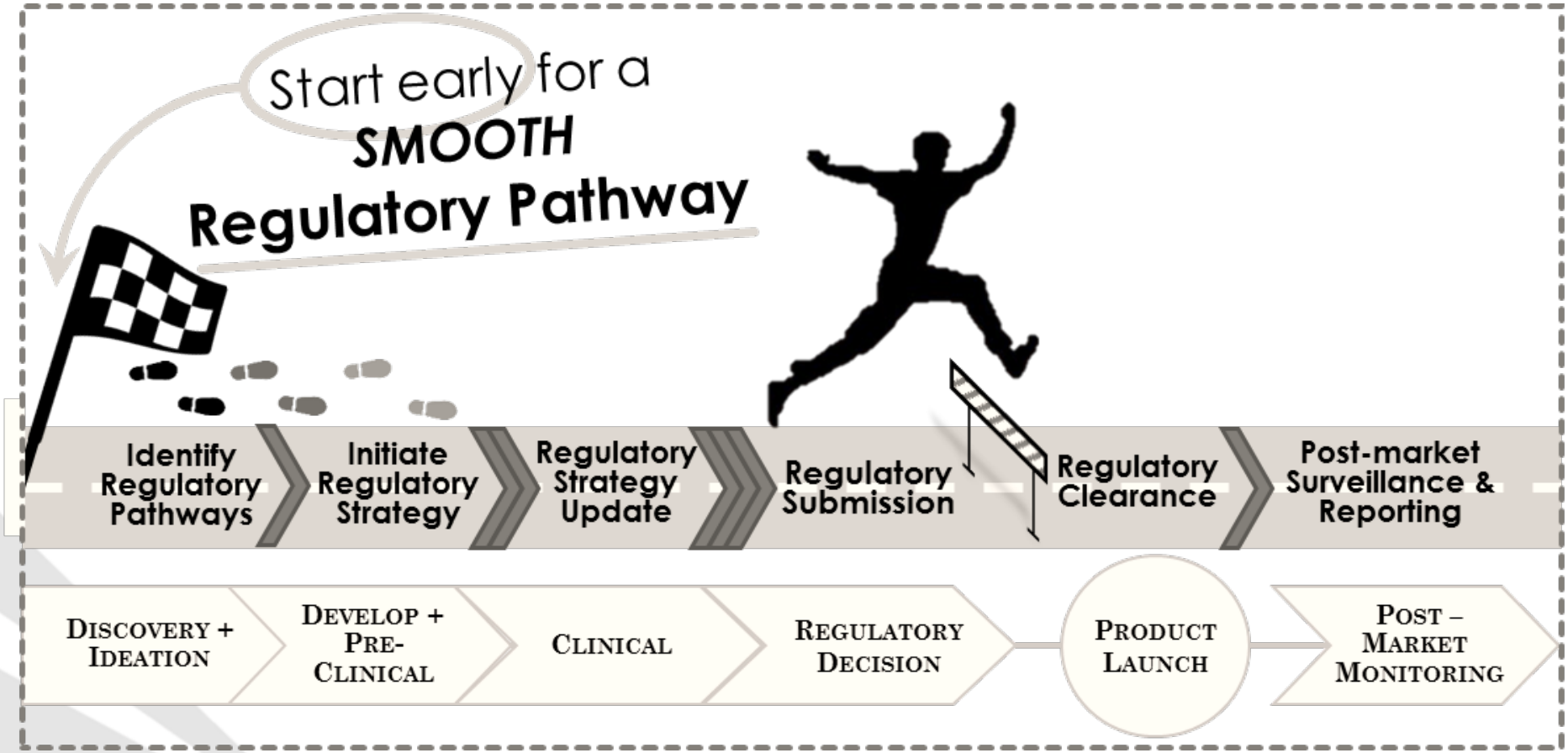
| Risk Class | TAT (working days)* | | | Fee (S$) | | |
|---|---|---|---|---|---|---|
| | Standard | Route 1 & 2 | | Standard | Route 1 | Route 2 |
| | | 25% ↓ | 35% ↓ (by end 2019) | | 15% ↑ | 50% ↑ |
| Class B (FULL) | 160 | 120 | 105 | 4,000 | 4,600 | 5,800 |
| Class C (FULL) | 220 | 165 | 145 | 6,200 | 7,100 | 9,100 |
| Class D (FULL) | 310 | 235 | 205 | 11,900 | 13,700 | 17,600 |

* *Excluding stop-clock*

# HSA's Initiatives

## To provide support through the device development lifecycle





# THANK YOU

Scan to know more about the schemes !

For enquiries relating to the schemes, please contact us at HSA_MD_Tech@hsa.gov.sg

# Online Resources

## Relevant Guidances for Product Registration

- **GN-15** Guidance on Medical Device Registration
- **GN-12** Guidance on Grouping of Medical Devices for Product Registration

### General Medical Devices

- **GN-13** Guidance on the Risk Classification of General Medical Devices
- **GN-17** Guidance on Preparation of a Product Registration Submission for General Medical Device using the ASEAN CSDT

### In-Vitro Diagnostic Devices (IVDs)

- **GN-14** Guidance on the Risk Classification of In-Vitro Diagnostic Medical Devices
- **GN-18** Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT

Access to all published guidances
*http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html*

# Online Resources

## Relevant Guidances for Dealer's Licenses

- **GN-02** Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices

### GDPMDS

- **TS-01** Good Distribution Practice for Medical Devices - Requirements
- **GN-01** Guidance on the Application of Good Distribution Practice for Medical Devices in Singapore
- **GN-03** Guidance on Preparation of a Site Master File for Licensing

### Quick Guide

http://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Overview_Framework_Policies/Regulatory_Framework/QUICK%20GUIDE%20TO%20MD%20REGISTRATION%20AND%20LICENSING_Jun%202018-pub.pdf

Access to all published guidances
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Overview/Guidances_for_Medical_Device_Registration.html