IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
Singapore

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Medical Device Pre-market Registration

- Review and Redesign of our guidance documents on General medical device and IVD medical device registration
  - Clarification on specific requirements based on common queries or feedback
  - Reader-friendly format

Key changes: GN-17 and GN-18 Guidance Documents

Simple layout

Simple

Reader friendly

Interactive

Improve accessibility to information e.g. guidance documents and templates

Submission requirements

Salient and succinct to provide greater clarity and reduce input request queries

Facilitate preparation and review of CSDT dossier

CSDT – Common Submission Dossier Template

Medical Device Pre-market Registration

- In Singapore, the pre-market submission, review and registration processes are performed on an online system called MEDICS
- Applicants submit their pre-market applications via this MEDICS portal
- The section in MEDICS where the various documents and reports from the dossier are to be uploaded, is designed as few modules.
- A submission guide that maps the various modules in our MEDICS system to the ASEAN CSDT dossier and to the IMDRF ToC has been developed to assist applicants with their online submission

Mapping the MEDIC modules to Dossiers

E-Submission Guide for **General Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS

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E-Submission Guide for **In Vitro Diagnostic Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS

- Specifies the appropriate modules in MEDICS for uploading of the corresponding sections of the CSDT or IMDRF ToC dossier
- Includes guidance on submitting responses to input request queries
  - To provide a written response to each input request query
  - To indicate the relevant file name(s) in the response if these are used to support the response

Mapping the MEDICS modules to Dossiers

ASEAN CSDT

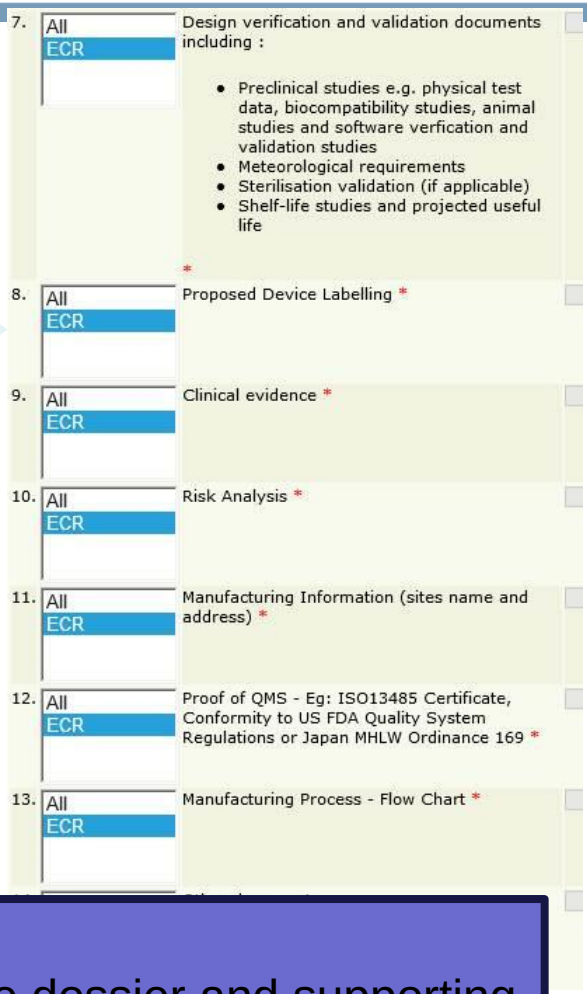
SECTIONS

- Executive summary
- Essential Principles & Evidence of Conformity
- Device Description
- Design Verification & Validation
- Clinical Evidence
- Device Labelling
- Risk Analysis
- Manufacturer Information

IMDRF ToC

SECTIONS

- Chapter 1 Regional Administrative
- Chapter 2 Submission Context
- Chapter 3 Non-Clinical Evidence
- Chapter 4 Clinical Evidence
- Chapter 5 Labelling and Promotional Material
- Chapter 6A Quality Management System Procedures
- Chapter 6B Quality Management System Device Specific Information



7.	All / ECR	Design verification and validation documents including : • Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verfication and validation studies • Meteorological requirements • Sterilisation validation (if applicable) • Shelf-life studies and projected useful life *
8.	All / ECR	Proposed Device Labelling *
9.	All / ECR	Clinical evidence *
10.	All / ECR	Risk Analysis *
11.	All / ECR	Manufacturing Information (sites name and address) *
12.	All / ECR	Proof of QMS - Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169 *
13.	All / ECR	Manufacturing Process - Flow Chart *

To facilitate review of the pre-market application

- Applicants shall ensure that the relevant section of the dossier and supporting documents are uploaded correctly under each MEDICS module
- Document file names should also be **meaningful** and provide some indication of their content.

E-Submission Guides

	MEDICS Application Form - Dossier & Supporting Document(s)	Reference technical documents		Class B			Class C & D			
		IMDRF nIVD ToC	CSDT TR-01	F	A	I	F	A	E	I
1	**Letter of authorization**									
	▪ Letter of Authorisation of Registrant by the Product Owner for all the products to be registered, using the latest template as per GN-15 Annex 1 Letter of Authorisation template	CH1.13 Letter of Authorization	NA	✓	✓	✓	✓	✓	✓	✓
2	**Annex 2 List of Configurations**									
	▪ A copy of Annex 2 for GN17 and GN18 List of Configurations, including the complete list of configurations of medical devices subject to the submission. This is to be submitted in a Microsoft Excel file.	CH1.05 Listing of Device(s)	4.2 Device Description	✓	✓	✓	✓	✓	✓	✓
3	**Proof of reference agency's approval(s)**									
	▪ Copies of approval letter(s) from each reference agency. For CE marked devices, the EU declaration of conformity by the product owner must be submitted, in addition to the EC certificate issued by the notified bodies.	CH1.07 Free Sale Certificate/ Certificate of Marketing authorization	3. Executive Summary		✓	✓		✓	✓	✓

Modules as per the 'Dossier & Supporting Document(s)' section of the MEDICS application form

Brief description of the expected contents to be uploaded under each of the modules

Sections of the CSDT or ToC to be uploaded under the respective module in MEDICS.

Data requirements for the respective evaluation routes (as per GN-15)

Published online in December 2018

Online Reporting System for Recalls and Field Safety Corrective Actions

- A new online system for submission of recalls and field safety corrective actions (FSCA) for medical devices has been developed
  - Enhance ease of reporting and efficiency of follow-ups
- Development of training videos and final usability tests in progress

- To be launched in June 2019

Guidance Documents – New Documents in 2019

- Guidance on the regulatory requirements for medical device software – a lifecycle approach

- Guidance on Next Generation Sequencing (NGS) based IVD medical devices

Thank you!