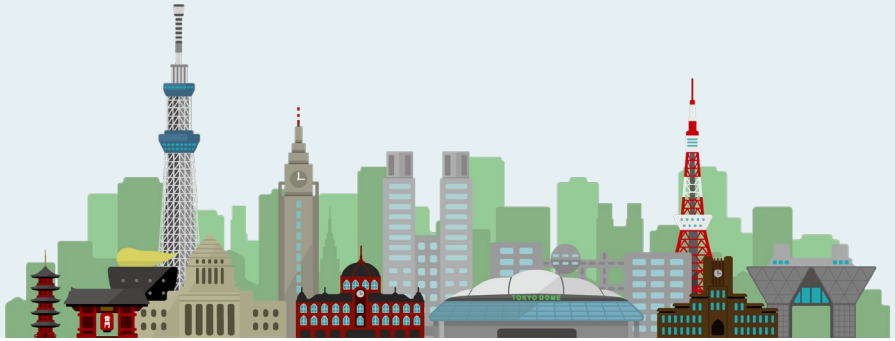
IMDRF International Medical Device Regulators Forum



Implementation of IMDRF document in China

Based on IMDRF/MC/N84 FINAL:2024

IMDRF International Medical Device Regulators Forum

Contents

- Introduction on IMDRF/MC/N84 FINAL:2024
- Implementation of IMDRF documents in China

◆ Overview on IMDRF/MC/N84 FINAL:2024

Title: IMDRF Document Implementation Report

Release Date: 30 August,2024

Contents: Introduction, Report

Introduction

- IMDRF activities and initiatives may fall into several categories, one of which being technical documents created to address technical matters relating to the regulation of medical devices.
- The process for developing technical documents is described in the IMDRF Standard Operating Procedure (SOP) and includes seven stages.
- The last stage of development is implementation, which is at the discretion of each regulatory authority responsible for medical devices in the area.
- Each regulatory authority may need at least one year to implement a document after publication in final.

Implementation levels

- The implementation levels are defined in the IMDRF SOP.

Implementation levels	Meaning
Implemented	All relevant elements, concepts and principles of the IMDRF document are followed.
Partly implemented	The IMDRF document has been implemented in a modified way that a) does not include all relevant elements, concepts and principles of the IMDRF document or b) requires application of the document for a smaller range of products than outlined in the IMDRF document.
Not applicable	The implementation of a specific IMDRF document is not applicable in a country/region.
Not implemented	The process for the implementation of the IMDRF document has not yet started or is not completed.

◆ Purpose

- Provide a report on the status of implementation of IMDRF technical documents as self-identified by IMDRF members as of the date of publication.
- GHTF documents and documents relevant to Medical Devices Single Audit Program(MDSAP) are not included in this report.

◆ Overview of included technical documents

31 IMDRF technical documents from 11 working groups

Working group	Number	Document No.
Software as a Medical Device (SaMD)	4	N10,N12,N23,N41
Unique Device Identification (UDI)	2	N7,N48
Regulated Products Submission (RPS)	3	N9,N13,N19
Standards(Standards)	1	N51
Good Regulatory Review Practices (GRRP)	8	N40,N47,N52,N59,N61,N63,N66,N71
Personalized Medical Device (PMD)	3	N49,N58,N74
Adverse Event Terminology (AET)	1	N43
Medical Device Clinical Evaluation (MDCE)	4	N55,N56,N57,N65
Medical Device Cybersecurity (Cyber)	3	N60,N70,N73
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IVD)	1	N64
Artificial Intelligence (AIMD)	1	N67

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- **Implementation of IMDRF documents in China**

◆ Overview of implementation in China

- All of the 31 documents have been implemented or partly implemented in China.

Implementation levels	Number
Implemented	16
Partly implemented	15

◆ Good Regulatory Review Practices (GRRP):8 documents

Document	Implementation in China
IMDRF/GRRP WG/N40 FINAL:2024 (Edition 2)Competence, Training, and Conduct Requirements for Regulatory Reviewers	PI
IMDRF/GRRP WG/N47 FINAL:2024 (Edition 2)Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices	FI
IMDRF/GRRP WG/N52 FINAL:2024 (Edition 2)Principles of Labelling for Medical Devices and IVD Medical Devices	FI
IMDRF/GRRP WG/N59 FINAL:2024 (Edition 2)Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	PI
IMDRF/GRRP WG/N61 FINAL:2024 (Edition 2)Regulatory Authority Assessment Method for Recognition and Surveillance of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	PI
IMDRF/GRRP WG/N63 FINAL:2024 (Edition 2)Competence and Training Requirements for Regulatory Authority Assessors of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	PI
IMDRF/GRRP WG/N66 FINAL:2024 (Edition 2)Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews	PI
IMDRF/GRRP WG/N71 FINAL:2024 (Edition 2)Medical Device Regulatory Review Report: Guidance Regarding Information to be Included	PI

◆ Personalized Medical Device (PMD):3 documents

Document	Implementation in China
IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices	FI
IMDRF/PMD WG/N58:2023 (Edition 2)Personalized Medical Devices - Regulatory Pathways	PI
IMDRF/PMD WG/N74 FINAL:2023 (Edition 1)Personalized Medical Devices – Production Verification and Validation	PI

◆ Regulated Products Submission (RPS):3 documents

Document	Implementation in China
IMDRF/RPS WG/N9 Final:2024 (Edition 4)Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)	FI
IMDRF/RPS WG/N13 Final:2024 (Edition 4)In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC)	FI
IMDRF/RPS WG/N19 FINAL:2016Common Data Elements for Medical Device Identification	PI

◆ Software as a Medical Device (SaMD):4 documents

Document	Implementation in China
IMDRF/SaMD WG/N10 FINAL:2013 Software as a Medical Device (SaMD): Key Definitions	FI
IMDRF/SaMD WG/N12 FINAL:2014 Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations	FI
IMDRF/SaMD WG/N23 FINAL:2015 Software as a Medical Device (SaMD): Application of Quality Management System	FI
IMDRF/SaMD WG/N41FINAL:2017 Software as a Medical Device (SaMD): Clinical Evaluation	FI

◆ Unique Device Identification (UDI):2 documents

Document	Implementation in China
IMDRF/UDI WG/N7 FINAL:2013 UDI Guidance: Unique Device Identification (UDI) of Medical Devices	FI
IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification System (UDI system) Application Guide	FI

◆ Medical Device Clinical Evaluation (MDCE):4 documents

Document	Implementation in China
IMDRF MDCE WG/N55 FINAL:2019 Clinical Evidence - Key Definitions and Concepts (formerly GHTF/SG5/N1R8:2007)	FI
IMDRF MDCE WG/N56FINAL:2019 Clinical Evaluation (formerly GHTF/SG5/N2R8:2007)	FI
IMDRF MDCE WG/N57FINAL:2019 Clinical Investigation (formerly GHTF/SG5/N3:2010)	FI
IMDRF MDCE WG/N65FINAL:2021 Post-Market Clinical Follow-Up Studies (formerly GHTF/SG5/N4:2010)	PI

◆ Medical Device Cybersecurity (Cyber):3 documents

Document	Implementation in China
IMDRF/CYBER WG/N60 FINAL:2020 Principles and Practices for Medical Device Cybersecurity	PI
IMDRF/CYBER WG/N70 FINAL:2023 (Edition1)Principles and Practices for the Cybersecurity of Legacy Medical Devices	PI
IMDRF/CYBER WG/N73 FINAL:2023 (Edition 1)Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity	PI

◆ Adverse Event Terminology (AET):1 document

Document title	Implementation in China
IMDRF/AE WG/N43 FINAL:2020 (Edition 4)Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes	PI

◆ Standard:1 documents

Document	Implementation in China
IMDRF/Standards WG/N51 FINAL:2018 Optimizing Standards for Regulatory Use	FI

◆ Principles of In Vitro Diagnostic Medical Devices Classification (IVD):1 document

Document	Implementation in China
IMDRF/IVD WG/N64 FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	PI

◆ Artificial Intelligence (AIMD):1 documents

Document	Implementation in China
IMDRF/AIMD WG/N67 (Edition 1)Machine Learning-enabled Medical Devices: Key Terms and Definitions	FI

Thank you/Questions