IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

# IMDRF Foundational Regulatory Pathways

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# OVERVIEW

- History of the GHTF/IMDRF Global Regulatory Framework
- Overview of the model, past and current
- Where are we going from here?

# History of the IMDRF Global Regulatory Framework

- Builds on the foundation laid under the GHTF banner
- GHTF was founded in 1992 with the five founding members
- Model evolved over time to a structure of 5 Study Groups and a Steering Committee (with Ad Hoc Working Groups occasionally convened as needed for specific work items outside the scope of the SGs)

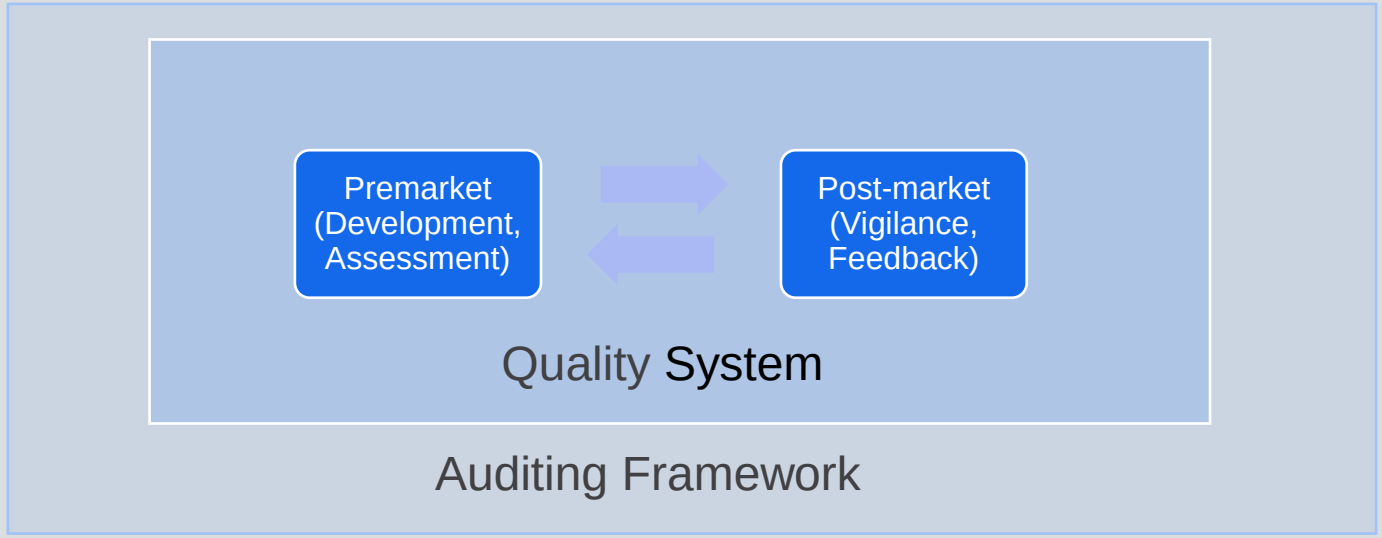
# History of the IMDRF Global Regulatory Framework

- Study groups were organized as follows:
  - SG1 – Pre-Market Evaluation
  - SG2 – Post-Market Surveillance/Vigilance
  - SG3 – Quality Systems
  - SG4 – Regulatory Auditing
  - SG5 – Clinical Safety/Performance

# History of the IMDRF Global Regulatory Framework

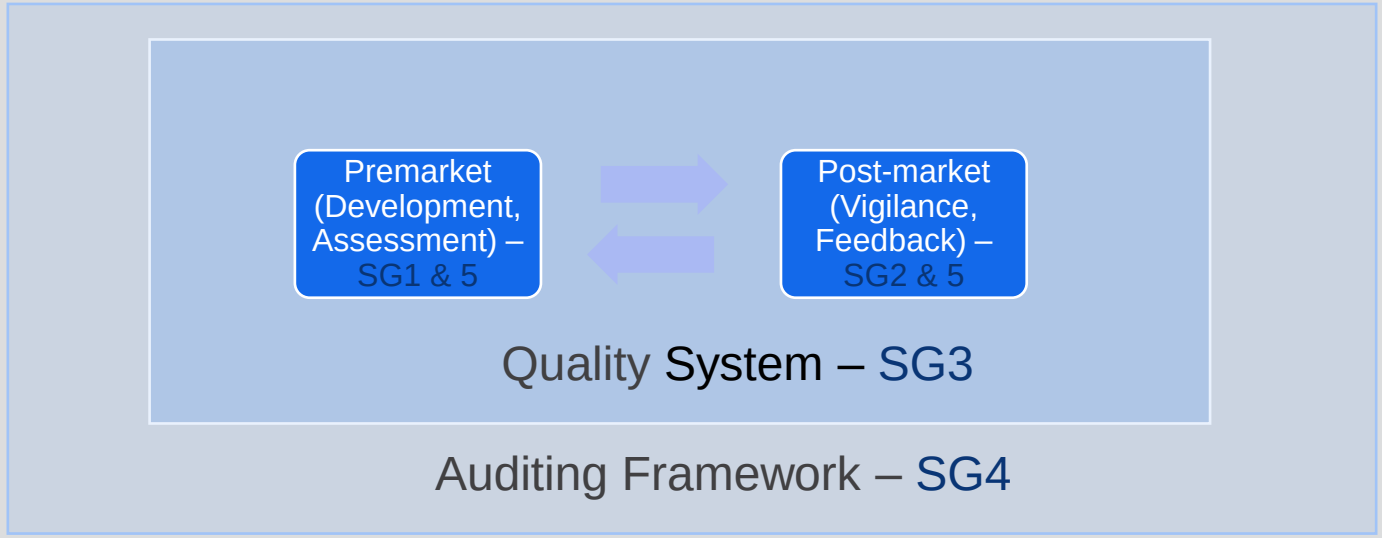
The work of each of these SGs combined to cover various aspects of the life cycle of a medical device, and collectively defined what became knowns as the GHTF Regulatory Model:

# History of the IMDRF Global Regulatory Framework



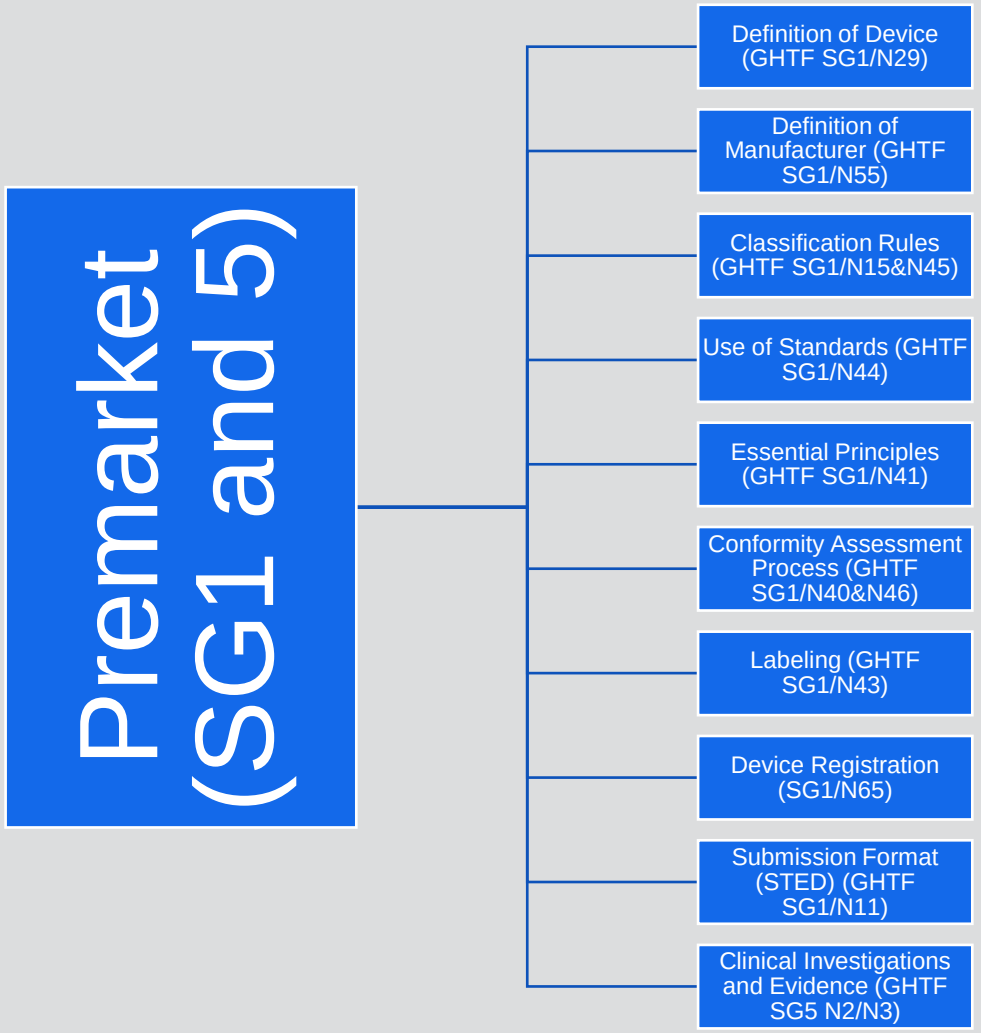

Schematic of the GHTF Regulatory Model

# History of the IMDRF Global Regulatory Framework




Schematic of the GHTF Regulatory Model

# Overview of the GHTF Model



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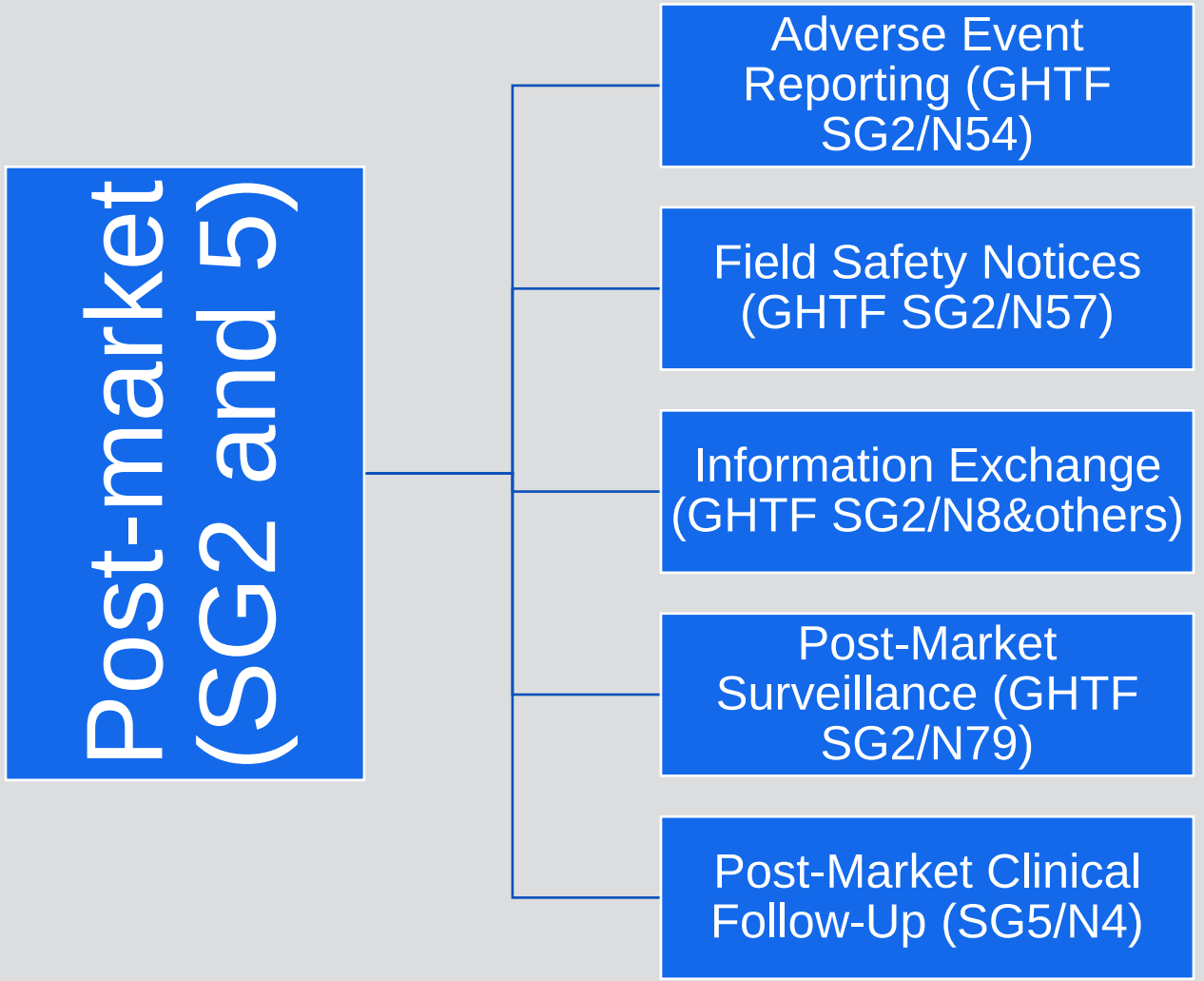

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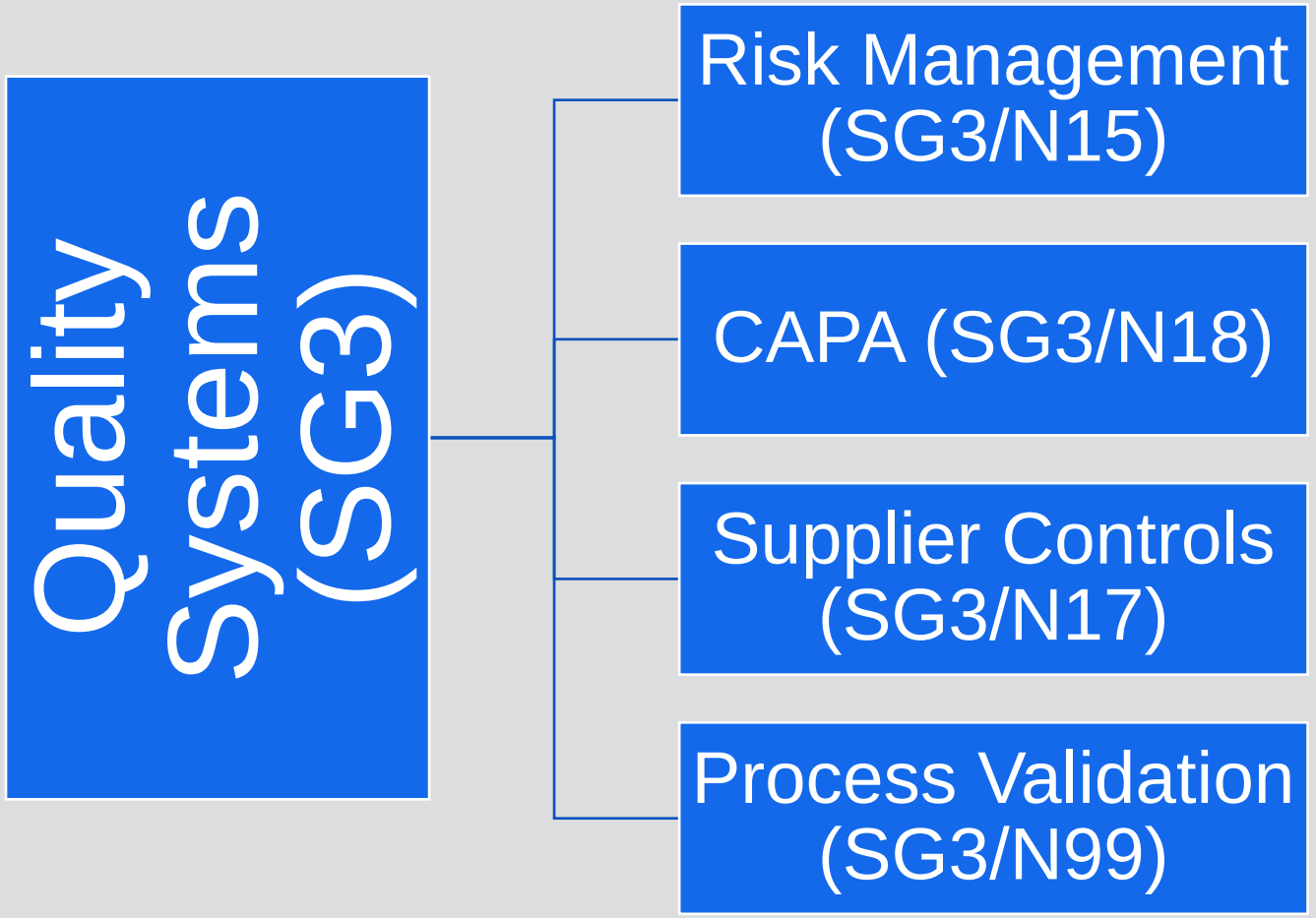

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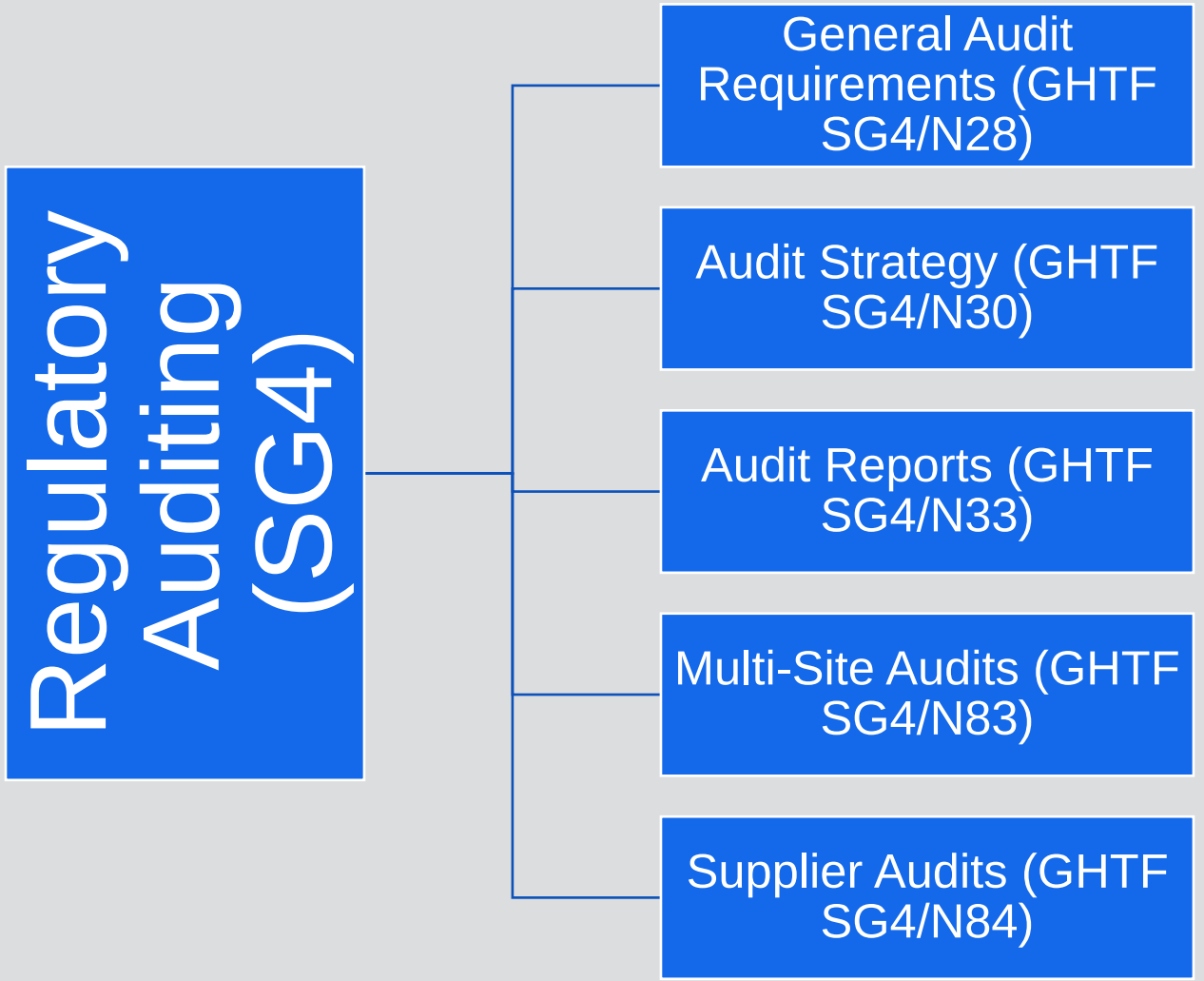
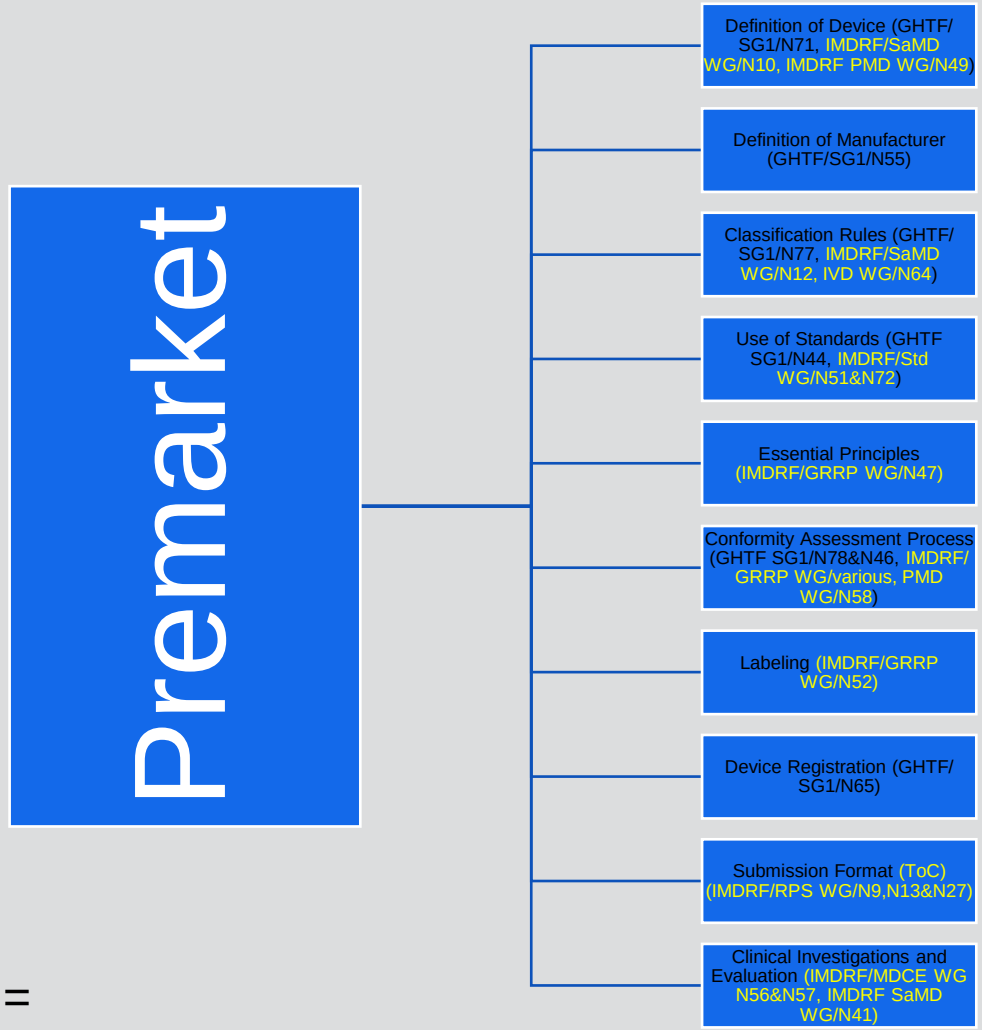


# History of the IMDRF Global Regulatory Framework

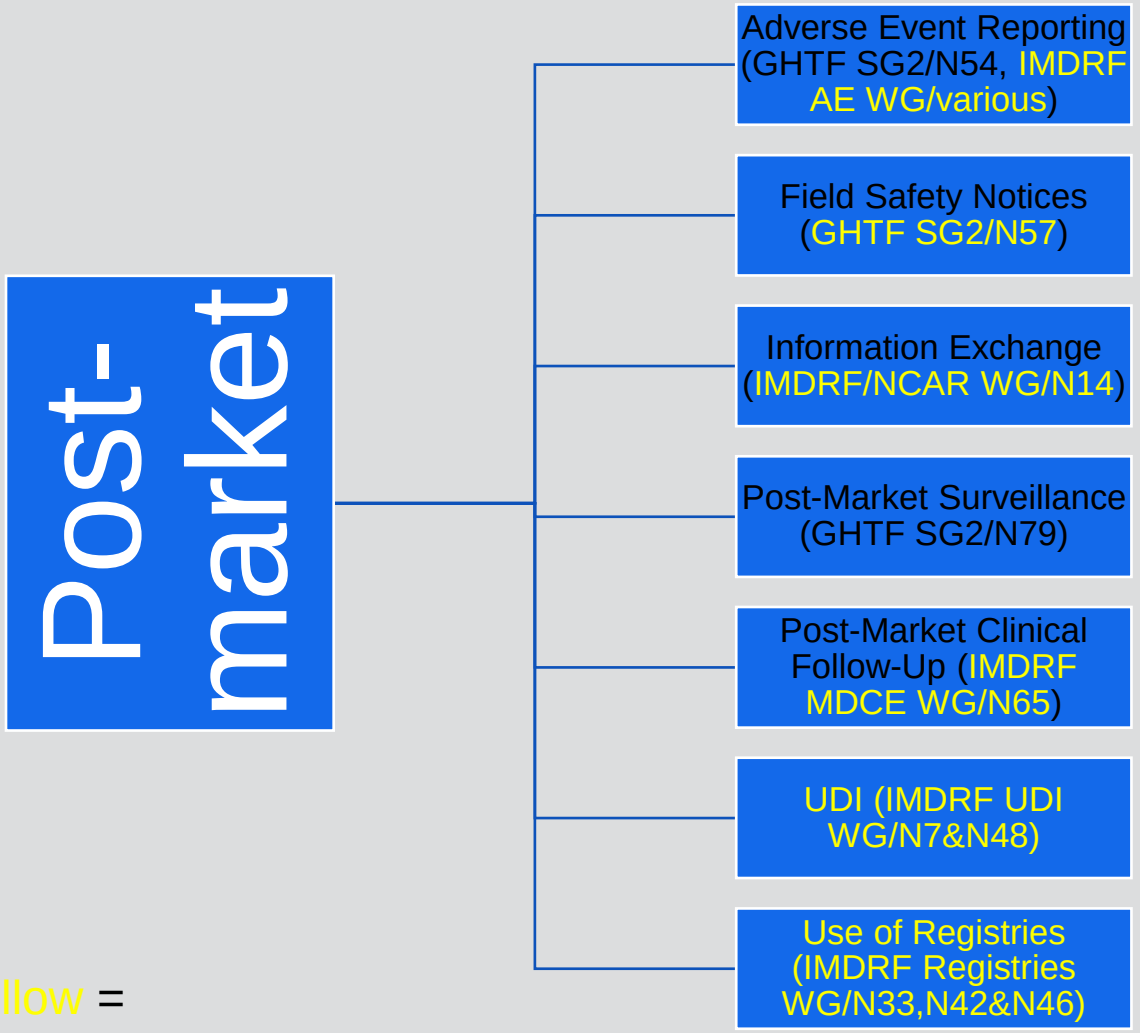
- Then, in October 2011, the IMDRF was established and the transition away from the GHTF approach began
- Instead of standing Study Groups, the IMDRF uses more task-oriented Working Groups (somewhat analogous to the AHWGs that were used occasionally in GHTF)
- Continues to build on the GHTF Regulatory Model, updating some of the previous work, and adding new pieces to the puzzle:

# Evolution to the IMDRF Model




Legend: Black = GHTF documents still active, Yellow = new IMDRF documents

# Evolution to the IMDRF Model

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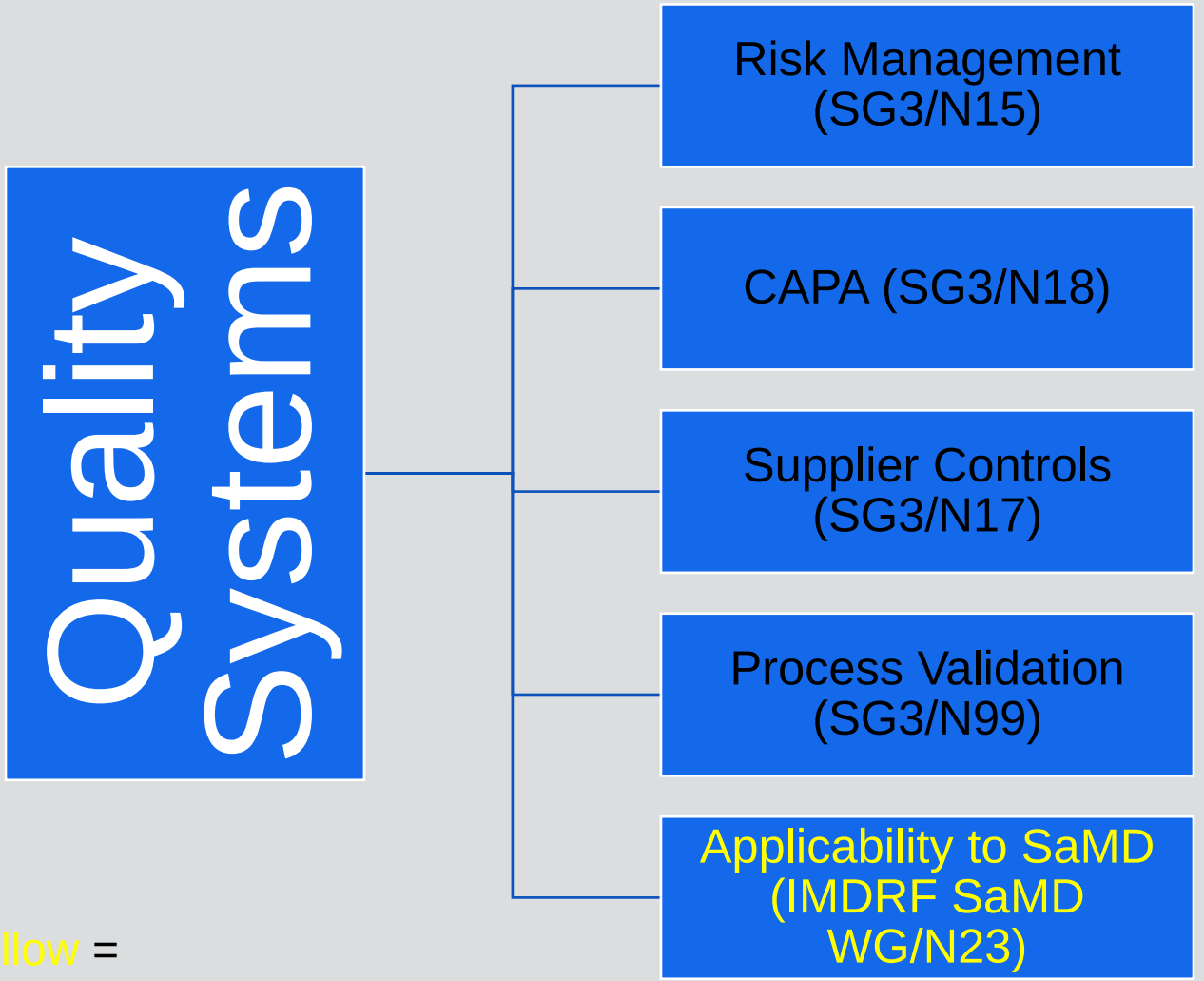


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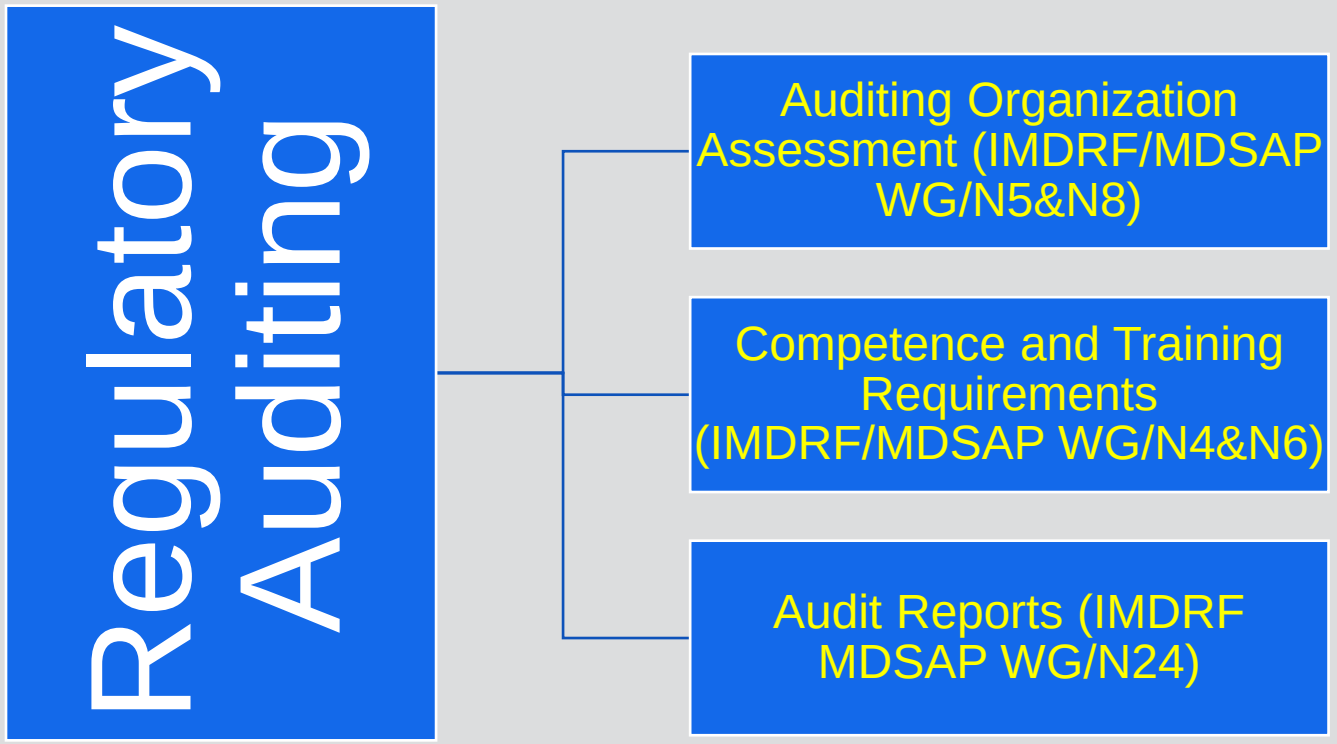


Legend: Black = GHTF documents still active, Yellow = new IMDRF documents

# Current IMDRF Global Regulatory Framework

- So, we can see that the basic building blocks continue to be updated and expanded upon
- Work is ongoing – current WGs include:
  - AE Terminology (Post-Market)
  - AI/ML Medical Devices (Pre-Market)
  - GRRP (Pre-Market)
  - Personalized Medical Devices (Pre-Market)
  - Quality Management Systems
  - RPS (Pre-Market)
  - SaMD (mainly Pre-Market)

# Current IMDRF Global Regulatory Framework

Up next:

- How are these documents and this framework used by regulatory authorities as part of their models?
- Looking beyond the basics – specialized regulatory pathways building upon this framework

# Foundational vs. specialised documents

| Foundational | Specialised |
|---|---|
| Definition of terms medical device and IVD<br>GHTF/SG1/N071:2012 | Definitions for personalised medical devices<br>IMDRF/PMD WG/N49 |
| Principles of medical device classification<br>GHTF/SG1/N77:2012 | Principles of IVD Medical Device Classification<br>IMDRF/IVD WG/N54 |
| Principles of conformity assessment for medical devices GHTF/SG1/N78:2012 | Assembly and technical guide for IMDRF Table of Contents Submissions IMDRF/RPS WG/N27 |
| Medical Device post-market surveillance<br>GHTF/SG2/N79R11:2009 | PMS: NCAR Exchange Criteria and Report Form<br>IMDRF/NCAR WG/N14 |
| Principles of labelling for medical devices and IVDs<br>IMDRF GRRP WG/N52 | Unique Device Identification (UDI) Application Guide<br>IMDRF UDI WG/N48 |
| Clinical Evaluation<br>IMDRF MDCE WG/N56 | Software as a Medical Device (SaMD): Clinical evaluation IMDRF/SAMD WG/N41 |
| Post-market clinical follow up studies<br>IMDRF/MDCE WG/N65 | Methodological principles in the use of international medical device registry data IMDRF/Registry WG/N42 |

# Regulatory authority/regional use of IMDRF documents

- Can be used to inform regulatory models and best practices across member authorities
- Promotes regulatory harmonisation & convergence of regulatory principles, methodologies & requirements
- Improves clarity, enhances information and hopefully increases awareness and understanding of regulatory requirements
- Level of implementation/adoption by regulatory authorities/regions will be dependent on applicable legislative framework and associated policies
- Nature of document will also have a bearing on extent of implementation

# Use case – adverse event reporting

GHTF/SG2/N54R8:2006

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices

Authoring Group: Study Group 2

Date: 30 November 2006

Georgette Lalis, GHTF Chair

The document herein was produced by the Global Harmonization Task Force, which is comprised of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide *non-binding* guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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GHTF/SG2/N57R8:2006

GHTF

FINAL DOCUMENT

Medical Devices Post Market Surveillance: Content of Field Safety Notices

ing Group: Study Group 2

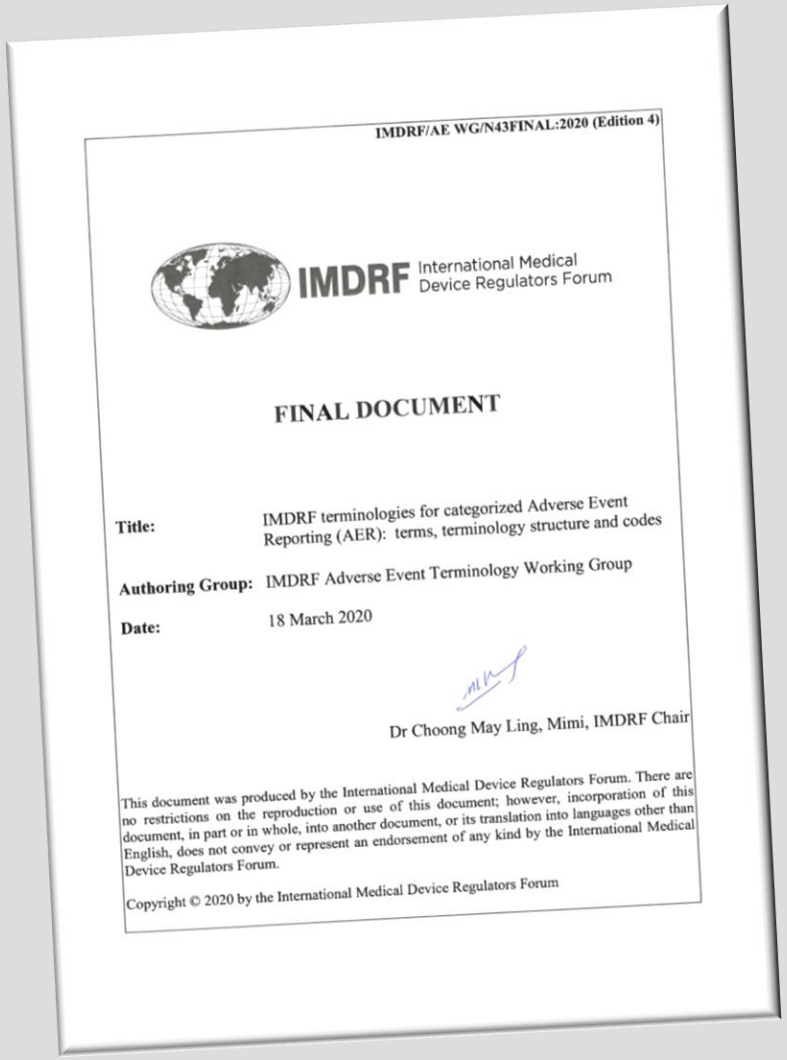
ed by: The Global Harmonization Task Force

7 June 2006

Georgette Lalis, GHTF Chair

- Aim to ensure consistent, accurate and timely adverse incidents globally
- Describe good practice without inhibiting potential for regional variance
- Used in EU to develop MEDDEV guidance under Directives – informed legal text in MDR and IVDR
- Variances in definitions, reporting timelines etc.

# Use case – adverse event nomenclature



IMDRF/AE WG/N43FINAL:2020 (Edition 4)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

**Title:** IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes

**Authoring Group:** IMDRF Adverse Event Terminology Working Group

**Date:** 18 March 2020

Dr Choong May Ling, Mimi, IMDRF Chair



- Improve accuracy and consistency of AE reporting and facilitate analysis for trends and signals
- Common language for AE reporting and could be used by regulators, manufacturers and potentially health care providers
- EU adopted in EUDAMED and EU manufacturer incident report (MIR) form
- Adopted by multiple NCA at EU level and multiple regulators at international level

# Use case – Drafting IVD Regulation in EU

GHTF/SG1/N045:2008

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

**Title:** Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Date:** 19 February 2008

Larry Kessler, GHTF Chair

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GHTF/SG5/N6:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

**Clinical Evidence for IVD medical devices** – Key Definitions and pts

**ring Group:** Study Group 5 of the Global Harmonization Task Force

November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

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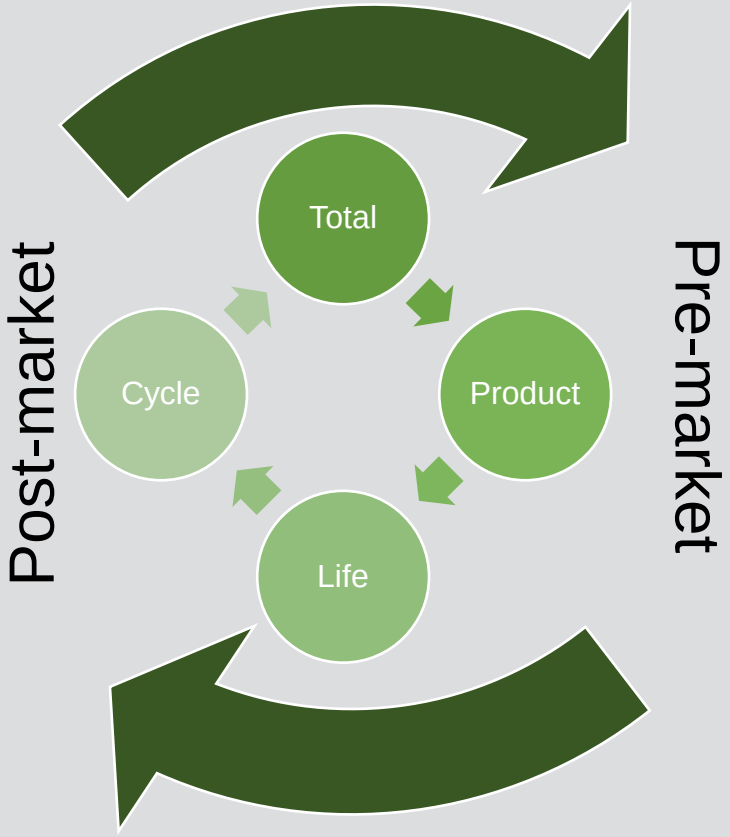
- Classification system for IVDs based on 2008 GHTF document
  - Principles on risk levels used for device classification
  - Differences in wording of rules – which could result in regional variances
- Clinical evidence for IVD medical devices
  - Used as a starting point for performance evaluation requirements

# Device lifecycle




- Foundational and specialised documents may cover some or all phases of lifecycle
- Trend towards increasing specialisation of documents from IMDRF
- Devices for discrete populations and specific technology types underline importance of lifecycle regulation
- Regulatory paradigm determines roles of regulatory authority at each phase

# Regulatory paradigm

Two main paradigms

- authorisation and market surveillance by regulatory authority (RA)
- certification by conformity assessment body (CAB), regulatory authority role in market surveillance and CAB oversight

| RA assessment | CAB assessment |
|---|---|
| Centralised | Decentralised |
| Expertise concentration | Expertise distributed |
| Government | Government oversight |

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# THANK YOU / QUESTIONS

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European Commission

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