IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Session 3: IMDRF Working Group (WG) Updates

Adverse Event Terminology Working Group Update

Working Group Chair(s):
Andrea Hanson, Health Products Regulatory Authority, Ireland
Evan Jacobs, Food and Drug Administration, USA

About the Working Group

The aim of the working group is to:

- Establish IMDRF adverse event terminology including terms for medical device malfunction, evaluation result/conclusion, patient/user outcome, and part/component of a medical device
- Support the implementation and the use of the terminology through the provision of guidance documents and training materials
- Improve, harmonize and where necessary expand the terminology and systems being used to code information relating to medical device adverse events

Focus of Work

a) The continued development and improvement of the Adverse Event Terminology and coding system to ensure that it is accurate, agile and moving with innovation. **Annual maintenance cycle** for 2026 has commenced.

b) Projects examining specific codes
   - Primary and secondary locations
   - Cracks and Breaks

c) The working group is conducting a review of the ***N43 Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*** and ***N44 Maintenance of IMDRF AE Terminologies*** with the intention of combining them into a single guidance document that is consistent with the content of the newly-published considerations for selection (N86) guidance document. Work continues on this item.

d) IMDRF NCAR Exchange review

Artificial Intelligence/ Machine Learning Working Group Update

Working Group Chair(s):
Danielle Faruq, Food and Drug Administration, USA
Gabriela Commatteo, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Updates from AI/ML Working Group

- Public consultation on N93 Technical Framework for Artificial Intelligence Life Cycle Management (Draft) closed on 10 July 2026
- Over 500 individual comments received from 26 organizations
- Comment resolution in progress; targeting Spring 2027 for N93 Final submission to Management Committee

Clinical Evidence for In Vitro Diagnostic Medical Devices Working Group Update

Working Group Chair(s):
Annie Truong, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
Joseph Burt, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
Nada Alkhayat, European Commission, European Union
Olga Tkachenko, European Commission, European Union
Orla Daly, European Commission, European Union

About the Working Group

Objective: To update and streamline existing GHTF documents on Clinical evidence for IVD medical devices, including:

- GHTF/SG5/N6 (Clinical Evidence for IVD Medical Devices-Key Definitions and Concepts)
- GHTF/SG5/N7 (Clinical Evidence for IVD Medical Devices-Scientific validity determination and Performance Evaluation)
- GHTF/SG5/N8 (Clinical Evidence for IVD Medical Devices-Clinical Performance studies for IVDs)

Our progress

Draft IMDRF document IMDRF/CEIVD WG/N91 DRAFT: 2026 “Clinical Evidence for IVD Medical Devices – Definitions and Principles of Performance”:

- Public consultation closed on 5 May 2026. A total of 151 pages of comments were received, with input from regulators, medical device manufacturers and trade associations.
- The co-chairs completed an initial review of the comments received and proposed approaches for their resolution.
- The proposed resolutions were circulated to WG members for comment over July-August.
- Co-chairs will review WG members’ feedback and prioritise comments for meetings starting in September.

GHTF document N8 “Clinical Performance Studies for IVD Medical Devices”:

- Plans to commence review of the document following completion of IMDRF/CEIVD WG/N91 DRAFT due to limited capacity.

Foundational Documents Working Group Update

Working Group Chair(s):
Wil Vargas, Food and Drug Administration, USA
Tan Yuhua, Health Sciences Authority (HSA) Singapore

About the Working Group

Co-chairs: US FDA & HSA | Kick-off: 30 June 2026

Objective

Review the set of foundational GHTF/IMDRF documents to support regulators in establishing harmonised medical device regulatory frameworks.

Scope

- From the list of foundational documents — determine whether to convert, update before conversion, or archive
- Identify gaps in foundational regulatory guidance collection
- Develop training assets for foundational collection

Progress to date

- Reviewing Appendix A, document categories of legacy GHTF documents for direct conversion, conversion after revision, or archiving

- Identifying order of documents to begin revision effort

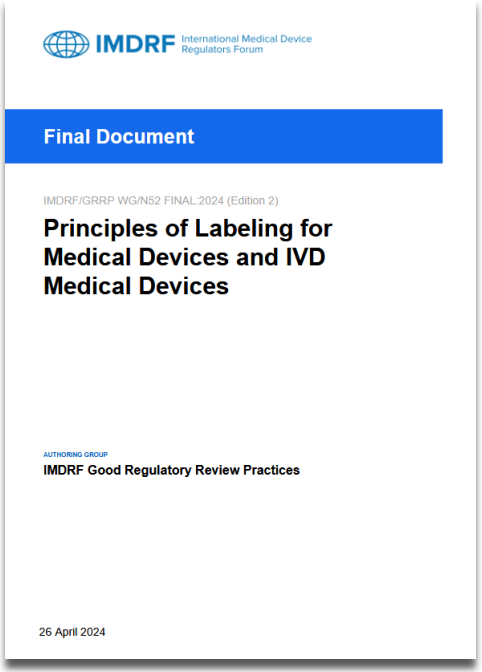
Good Regulatory Review Practices (GRRP) Working Group Update

Working Group Chair(s):
Lai Peng Low, Health Sciences Authority (HSA) Singapore
Kenneth Cavanaugh, Food and Drug Administration, USA

Updates to IMDRF/GRRP WG/N52: Principles of Labeling for Medical Devices and IVD Medical Devices

- Work item approved in **September 2025** to update N52 with additional guidance on electronic labeling practices and terminology
  - Clarify selection of appropriate use cases for e-labeling within the IMDRF labeling framework
  - Promote timely availability of updated labeling
  - Maintain equitable access for users and patients

- Draft document expected within next several months
  - Final document expected for publication in mid/late 2027



Quality Management Systems Working Group Update

Working Group Chair(s):
Benefran JS Bezerra, Brazilian Health Regulatory Agency (ANVISA) Brazil
Ana Margarida Teixeira, National Authority of Medicines and Health Products, I.P. (INFARMED) European Union

Quality Management Systems Working Group

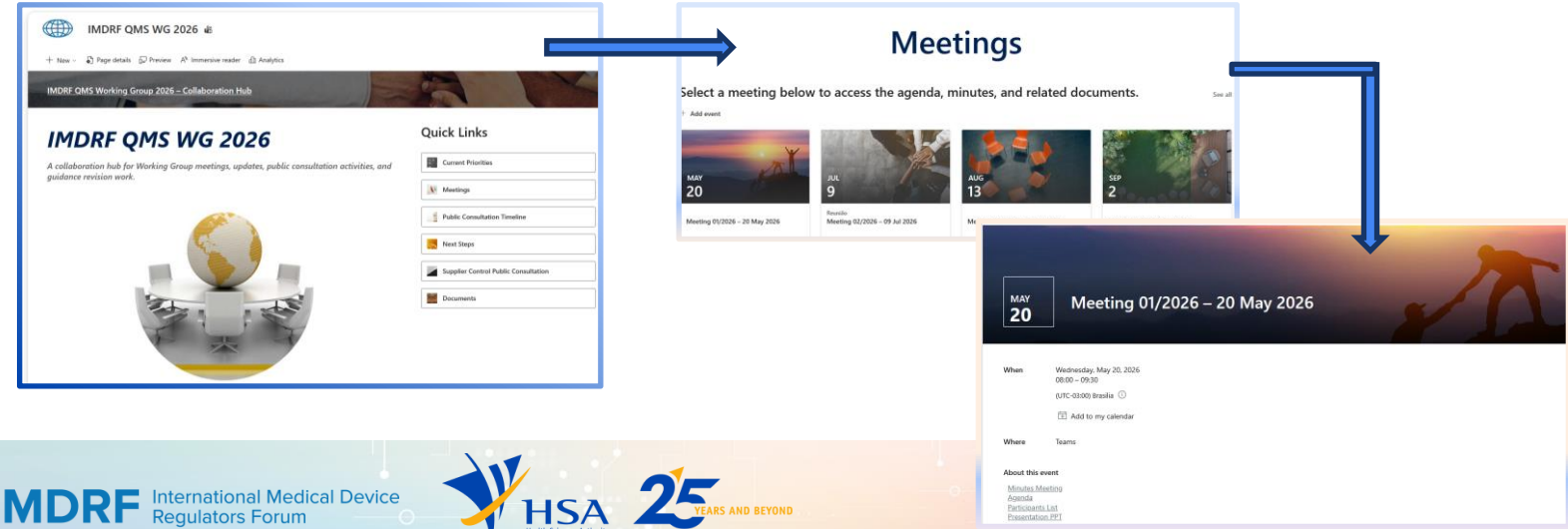
- Change of co-chairs

FDA (USA)
EuropeanCommission (EU)

ANVISA (Brazil)
INFARMED, I.P. (Portugal, EU)

- 3 WG meetings held: May, July and August 2026

- Development of an internal WG collaboration hub



Quality Management Systems Working Group

Guidance-related activities

- Guidance on the Control of Products and Services Obtained from Suppliers
  - Public consultation from 6 May 2026 to 6 July 2026
    - 413 comments received
  - From July on: compilation of comments, initial screening and analysis >> Foreseen to be concluded by November / December 2026

- Internal WG survey to define remaining QMS WG guidance documents revision priorities (Jun/Jul 2026)

- Current plan on next document for revision (but still to be confirmed):
  - Guidance on corrective action and preventive action and related QMS processes - November 2010
  - To be started on December 2026 / January 2027

Software as a Medical Device Working Group Update

Working Group Chair:
Ambreen Athar, Food and Drug Administration, USA

About the SaMD Working Group

Co-chair: US FDA

Members: Argentina, Australia, Brazil, Canada, EU, Japan, Singapore, South Korea, Switzerland, UK, US, DITTA, GMTA

Published six documents

- N10: Software as a Medical Device (SaMD): Key Definitions (2013)
- N12: SaMD: Possible Framework for Risk Categorization and Corresponding Considerations (2014)
- N23: SaMD: Application of Quality Management System (2015)
- N41: SaMD: Clinical Evaluation (2017)
- N81: Characterization Considerations for Medical Device Software and Software-Specific Risk (2025)
- **N90: Essential Principles and Content of Predetermined Change Control Plans (2026)**

Publication – N90: Essential Principles and Content of Predetermined Change Control Plans

Published: 06 August 2026

Document Purpose: The purpose of this document is to provide internationally harmonized high-level guidelines on what should be included in a PCCP and best practices for developing and documenting a PCCP while allowing each jurisdiction to apply the concepts within the scope of regulations applicable to their jurisdiction.

Next Steps: The working group has drafted a corresponding **training slide deck** for N90 with planned completion expected in September 2026.

Thank You!