IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

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Regulatory Updates
Health Sciences Authority (HSA), Singapore

Ms Annie Tan

Director, MD Quality System, Adverse Event and Compliance Branch

HSA, Singapore

Overview

Two updates today:

- **Regulatory Guidance Updates**
  - GL-04: Software Medical Device Guidelines
  - AIHGle 2.0: AI in Healthcare Guidelines

- **AI Innovation in Regulatory Operations**
  - AI-Assisted Adverse Event Code Classification

GL-04 Updated Software Medical Devices Guidelines

What's New

- ✓ One-stop reference covering the full software lifecycle
- ✓ Clearer requirements for AI/ML-enabled medical devices
- ✓ Strengthened cybersecurity guidance (threat modelling, vulnerability management)
- ✓ *Change Management Program (CMP)*: manufacturers can implement pre-approved software changes through their own QMS — HSA shifts to post-market monitoring instead of upfront review

Alignment to International Standards

- ✓ Harmonised definitions with international standards and IMDRF guidance
- ✓ MLMD requirements aligned with IMDRF AIML WG/N88 FINAL: 2025 (Good Machine Learning Practice)

Why It Matters

- ✓ Reduces regulatory burden while maintaining oversight — aligned with IMDRF AIML WG/N88 FINAL: 2025

GL-04: A Closer Look at Key Updates

- **Cybersecurity**
  - Maintain cybersecurity plan across full product lifecycle
  - Plans required for OS end-of-support scenarios
  - Covers threat modelling, vulnerability assessment & timely response to emerging threats

- **Machine Learning-Enabled Medical Devices (MLMD)**
  - Clearer premarket submission requirements (model description, datasets, performance validation)
  - ML-specific risk management: overfitting, model drift, model degradation
  - Change notification aligned with GN-21 guidance

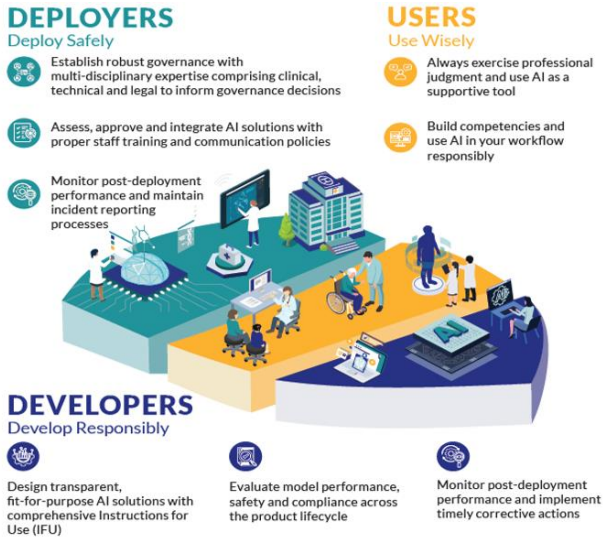
AIHGle 2.0: AI in Healthcare Guidelines *(published 10 Mar 2026)*

Key Updates from 2021 Version

- ✓ Clearer accountability for developers, deployers & users
- ✓ Stronger transparency & explainability requirements
- ✓ Enhanced risk tools for validation, monitoring & model drift
- ✓ New guidance on generative AI
- ✓ New Deployers' Toolkit & infographic

Bottom Line

- ✓ Practical, living guidance to support safe and responsible AI adoption in healthcare — complements HSA's existing regulatory framework



AI Innovation : The Problem

Manual adverse event (AE) coding is time-consuming and cognitively demanding

- ⏱️ 30–45 min per report
- 📋 ~1,000 reports per year
- 🦛 7 IMDRF annexes and multiple hierarchy to cross-reference manually
- ⚠️ Risk of variability across officers

Rising volumes made the current process unsustainable

AI Innovation : The Solution

AI-Assisted IMDRF Code Classification

✓ A human-in-the-loop tool that supports — not replaces — officer judgement

- AE report ingested
- AI extracts key entities
- Ranked code recommendations generated with confidence scores & reasoning
- Officer reviews, challenges or overrides
- Validated codes stored; feedback loop improves model

✓ Guardrail: outputs constrained strictly to official IMDRF taxonomy

Required Solution & Goals

Core Product Features

- Free-text AE ingestion
- Entity extraction• Ranked recommendations with confidence, rationale and auditability
- Officer challenge / override
- Feedback loop

Solution Flow

1. AE Report received
2. LLM extracts key entities
3. AI generates IMDRF code recommendations
4. Confidence scores + reasoning
5. Officer reviews recommendations
6. Validated codes stored

Key Goals

Efficiency
Reduce manual taxonomy lookup effort and improve triage efficiency.

Consistency
Improve consistency and defensibility of IMDRF coding decisions.

Accountability
Preserve human review and constrain outputs to official IMDRF taxonomy.

AI Innovation : The Results

What We Measured	Target	Outcome
Reduction in triage time	≥40%	~50% ✅
AI-officer code agreement	≥80%	≥80% ✅
Invalid codes generated	0	0 ✅

Projected Year 1 Value: ~S$12,900 in manpower savings *(based on 1,200 cases/year, validated on >220 historical cases)*

Thank You!