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

APEC RHSC Update to IMDRF: Key Outcomes from SOM3 2026

Medical Device Priority Work Area Focus

Ministry of Food and Drug Safety · Republic of Korea

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: Key Outcomes from SOM3 2026

Medical Device Priority Work Area Focus

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APEC RHSC SOM3 2026 UPDATE

SOM3 2026: What advanced since our last IMDRF update

APEC RHSC SOM3 2026 | 17–18 August 2026 | Dalian, China

RHSC-wide priorities

Phase 2 KPIs to measure regulatory convergence

PWA/CoE reporting tools, certificate discussion and training strategy improvements

Medical Device PWA

Revised roadmap and curriculum change

Transition from one broad curriculum to two complementary curricula

Cross-cutting dialogues

Rare disease evidence and RWD

Risk-based pharmaceutical quality control, reliance and alignment

Main message for IMDRF: RHSC is strengthening the implementation pathway for internationally agreed medical device principles.

APEC RHSC SOM3 2026 UPDATE

Medical Device PWA: revised roadmap and curriculum structure

From one broad lifecycle curriculum to two complementary curricula

Curriculum Restructuring

Single Core Curriculum

Broad coverage across the total product lifecycle

01 General Medical Device Lifecycle

Broad, high-level training across pre-market / conformity assessment and post-market activities

02 Medical Device Auditing

Specialized, in-depth training on manufacturer auditing and QMS assessment

WHY Clearer learning depth • More focused CoE delivery • Targeted KPIs • No new topics or documents

APEC RHSC SOM3 2026 UPDATE

A bridge from IMDRF/GHTF work to regional implementation

Implementation Pathway

Principles & Foundational Documents
IMDRF / GHTF

Core Curricula
MD PWA

Training & Capacity building
APEC CoEs

Regulatory implementation
APEC economies

Lifecycle topics 01

Definitions, classification, Essential Principles, conformity assessment, clinical evidence, PMS and AER/AET

Auditing topics 02

ISO 13485, ISO 14971, QMS, CAPA, supplier control, process validation and audit principles

IMDRF Relevance

The revised curricula operationalize IMDRF/GHTF principles through structured regional training, while encouraging reliance on existing assessments and programs such as MDSAP.

APEC RHSC SOM3 2026 UPDATE

CoE implementation: transition and re-evaluation

Transition Plan

1 **AUG 2026**

Roadmap & curriculum proposal endorsed

2 **SEP 2026**

Confirm existing CoE intentions

3 **OCT–DEC 2026**

CoE re-evaluation by MD PWA leadership

4 **EARLY 2027**

Report progress at **RHSC SOM1**

Pilot CoE Expansion

Malaysia MDA pilot application; 2027 pre-market training planned subject to RHSC endorsement.

Upcoming CoE Activities

USC, SCH and SCU in late 2026; PMDA in 2027, with continued IMDRF/GHTF and MDSAP emphasis.

APEC RHSC SOM3 2026 UPDATE

CoE activities: key takeaways from recent workshops

Feedback across CoEs shows strong demand for practical, case-based and emerging-topic training.

TFDA · Chinese Taipei

Practical case-based learning valued; interest in reliance, expedited pathways, UDI, SaMD and cybersecurity.

SCH · Korea

High participation and satisfaction; demand increasing for SaMD, AI/ML, cybersecurity and adverse-event reporting.

SCU · China

Lifecycle-based training with case analysis and group discussion; hybrid delivery needs stronger online engagement.

USC · United States

Strong relevance for clinical evidence, risk management, IVDs and PMS; demand for more hands-on examples.

PMDA · Japan

QMS inspections, low-risk products and SaMD identified as areas of continued training interest.

MDA · Malaysia (pilot)

Pilot CoE application stage; work plan designed to reflect diverse regulatory maturity and APEC training needs.

Common message: CoE activities are moving toward more applied training that supports implementation of IMDRF/GHTF principles in regulatory practice.

APEC RHSC SOM3 2026 UPDATE

CoE training workshops: recent and upcoming activities

The CoE network continues to deliver lifecycle, IVD, auditing and implementation-focused training.

TFDA	**26–28 Aug 2026** Taipei City / hybrid	Recently completed: key IMDRF documents across pre-market, QMS and post-market.
SCH	**7 Oct–18 Nov 2026** Online	TPLC training: harmonized principles, IVD classification and AET codes.
SCU	**28–30 Oct 2026** Chengdu / primarily online + in-person	Medical Device Regulation: common terms, principles and cross-border cooperation.
USC	**2–3 Nov 2026 (U.S.)** **3–4 Nov 2026 (Asia)** Online	IVD regulation and risk management: clinical evidence and risk management across the lifecycle.
PMDA	**2027** In-person or online	Medical Devices Workshop: implementation of IMDRF/GHTF documents and MDSAP report utilization.
MDA (pilot)	**30 Jun–2 Jul 2027** Cyberjaya, Malaysia	Pilot CoE pre-market training: MD/IVD definitions, classification and lifecycle requirements.

Note: MDA training remains subject to RHSC endorsement and final consultation with the MD PWA Steering Committee.

APEC RHSC SOM3 2026 UPDATE

Measuring progress: linking CoE training to implementation

MD PWA KPI direction

Proposed MD PWA KPIs focus on implementation of internationally recognized guidance, participation in harmonization activities, and auditing/MDSAP-related capacity.

General MD Lifecycle

Implementation of IMDRF/GHTF documents and consensus standards covered in the curriculum

Harmonization participation

Economies/RAs participating in IMDRF, MDSAP and APEC RHSC as active members or observers

Medical Device Auditing

Completed manufacturer audits, certified auditors and participation in MDSAP

Auditing implementation

Implementation of relevant IMDRF/MDSAP/GHTF documents covered in the auditing curriculum

Next step for MD PWA: refine outcome-oriented KPIs so CoE training can be linked more directly to measurable regulatory implementation.

APEC RHSC SOM3 2026 UPDATE

Other SOM3 discussions relevant to regulatory convergence

RHSC Regulatory Dialogue Sessions

RHSC Regulatory Dialogues provide a structured forum for regulators, industry and technical experts to examine cross-cutting regulatory challenges, share practical approaches and identify opportunities for greater convergence and follow-up action

Rare disease therapies

Dialogue examined small-population evidence, non-traditional evidence, RWD, reliance and lifecycle evidence generation.

Risk-based quality control

Dialogue considered duplicate testing, reliance on trusted assessments and science- and risk-based approaches to product quality testing.

Operational improvement

RHSC discussed more standardized processes, PWA reporting templates, regulatory dialogue procedures and CoE training strategies.

These discussions reinforce RHSC's broader role: turning convergence principles into operational tools, training and practical capacity-building.

Thank You!