HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

29th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 10 March 2026

APEC RHSC Update
Medical Device Priority Work Area (MD PWA)

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APEC Regulatory Harmonization Steering Committee (RHSC) - Overview

A multi-stakeholder cooperation mechanism for regulatory harmonization established in 2009, covering pharmaceuticals, biologics and **medical devices**

- Organized around **Priority Work Areas (PWAs)**
- Promotes regulatory alignment and reliance-based cooperation
- Delivers structured **training** through designated **Centers of Excellence (CoEs)**
- Enhances regulatory science **capacity** across the APEC region

- A regional platform for sustainable regulatory **capacity building**, open to global participation
- Bridging **global regulatory convergence** with practical **implementation and reliance**

Medical Device Priority Work Area (MD PWA) - Training Framework

- Roadmap-driven implementation
- Core Curriculum-based training
- Programme Committee and SC review
- Structured oversight of CoE activities

Implementation Platform: Center of Excellence (CoE) Host Institutions

1. Sichuan University (SCU), China
2. Pharmaceuticals and Medical Devices Agency (PMDA), Japan
3. Soonchunhyang University (SCH), Korea
4. Taiwan Food and Drug Administration (TFDA), Chinese Taipei
5. University of Southern California (USC), United States

Governance Support: MD PWA CoE Steering Committee (SC)

Co-Champions (Regulators)

- Japan (MHLW/PMDA)·
- United States (US FDA)
- Korea (MFDS)

Sub-Champions (Industry)

- AdvaMed
- JIRA

APEC SOM1 2026 RHSC Plenary Meeting (Guangzhou, China, 1-2 February 2026)

- SOM1 2026 RHSC Ongoing work and Emerging Projects
- Cross-fora updates to strengthen alignment and coordination with RHSC priorities (ICH/IPRP, IMDRF and GHWP)
- Update from MFDS Global Harmonization Centre (GHC): Recent activities & progress
- **Strategic Discussion** on maximizing the impact of RHSC, including stronger alignment across PWAs, CoEs and RHSC objectives
- Enhanced **Regulatory Dialogue** with topics identified through engagement with member economies to support problem-solving and regulatory harmonization
- **PWA and CoE progress and updates**:
  - Multi-regional Clinical Trials and Good Clinical Practices Inspection
  - Global Supply Chain Integrity
  - Advanced Therapies & Biotherapeutic Products
  - Good Registration Management
  - Pharmacovigilance
  - **Medical Devices** (+MDSAP)
  - Electronic Data Standards
  - Pharmaceutical Quality

MD PWA Roadmap

Roadmap guiding the implementation of internationally aligned guidance supporting regulatory **convergence** and **capacity building** across APEC

❖ Key Directions

- To be aligned with **IMDRF foundational documents**
- To be linked to **IMDRF Strategic Plan**
- Based on a Total Product Life Cycle (TPLC) approach

❖ Objectives

- Promote **consistent interpretation** of international regulatory principles
- Strengthen regulatory **implementation capacity**
- Support reduced duplication and enhance **reliance**

➢ Translating internationally agreed guidance into practical training and regulatory implementation

➢ Providing the foundation for the MD PWA Core Curriculum and CoE training programmes

MD PWA Roadmap – Core Curriculum: Training Content

- **Core Curriculum** (*Built on IMDRF / GHTF Documents*)
  - **Pre-market**
    - MD/IVD Definitions & Classification
    - Essential Principles of safety and performance
    - Optimizing standards for regulatory use
    - Conformity assessment principles
    - Requirements for regulatory reviewers
    - Clinical evaluation & investigation
    - Principles of labeling
    - QMS & risk management (ISO 13485/ISO 14971)
    - Overview of MDSAP
  - **Post-market**
    - IMDRF Adverse Event Reporting/Terminology (AER/AET)

MD PWA - Center of Excellence (CoE): Implementing Training

❖ Formal CoE Host Institutions

1. Sichuan University (**SCU**), China
2. Pharmaceuticals and Medical Devices Agency (**PMDA**), Japan
3. Soonchunhyang University (**SCH**), Korea
4. Taiwan Food and Drug Administration (**TFDA**), Chinese Taipei
5. University of Southern California (**USC**), United States

❖ Role of CoEs

- Deliver MD PWA training programs based on the **Core Curriculum**
- Organize courses, workshops and capacity building activities
- Facilitate practical understanding and implementation of IMDRF Guidance

❖ Operating Mechanism

- Training programs developed and delivered by CoEs
- Programs reviewed by the Programme Committee and PWA CoE Steering Committee
- Training activities aligned with the MD PWA Roadmap and Core Curriculum

MD PWA – 2025 Training Outcomes

- **SCH** (Online, 4 September–31 October)
  - 232 participants from 29 economies (18 non-APEC economies; ~72% regulators)
  - Satisfaction score: 4.7 / 5

- **USC** (Online, 3–4 November (US) / 4–5 November (Asia))
  - 149 participants from 25 economies (10 non-APEC economies)
  - 100% indicated willingness to attend again

- **SCU** (Hybrid, 21–23 October)
  - 96% positive satisfaction
  - Knowledge score improved from 3.36 to 4.05

- **TFDA** (Hybrid, 26–28 August)
  - 33 participants from 9 economies
  - Satisfaction score: 4.8 / 5

➢ Demonstrating **broad participation** and **learning outcomes** across APEC and beyond, supporting international regulatory **convergence**

MD PWA – 2026 Training Plans

❖ Training continues in 2026

- Open to both APEC and non-APEC economies
- Programs scheduled throughout the year

  ✓ SCH (Online, October-November)
  ✓ USC (Format TBC, Training planned in Q4)
  ✓ SCU (Hybrid, 24-26 June, 28-30 October)
  ✓ TFDA (Hybrid, Late August)

❖ Governance-Based Training Delivery Process

1. CoE develops agenda, flyer and training materials
2. Review by CoE Programme Committee
3. Review and endorsement by PWA Steering Committee
4. Official dissemination through RHSC communication channels

➢ Ensuring structured **capacity building** grounded in the MD PWA **Core Curriculum**

Thank You!

For any follow-up questions, please feel free to contact us at:

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