

SEARN regulatory updates

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IMDRF

International Medical Device
Regulators Forum



HSA
Health Sciences Authority

25
YEARS AND BEYOND



Highlights from the August 2026 meeting the SEARN Assembly

4-5 August, Kathmandu, Nepal

General

- SEARN finalized its **overarching capacity building strategy**:
 - A SEARN **competency framework** has been established based on the WHO Global competency framework
 - A **network of Regional Centers of Excellence (RCOE)** has been created to develop and implement capacity building activities in a sustainable and impactful manner
 - The **SEARN capacity building platform** linking the competency framework and training catalogues has been finalized and is ready for deployment
- SEARN concluded a series of meetings with **public procurement agencies**
 - Recommended the creation of a **regional forum to facilitate access to quality medical products**
 - Coordination group with procurement agencies on **shortages**



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SEARN capacity building platform

Training Catalog								
Browse available training programs								
Search by training name... All Modes All Domains All Sub-Domains All Providers All Languages								
TRAINING	MODE	DOMAIN	SUB-DOMAIN	PROVIDER	LANGUAGE	DURATION	COST	
GMP Inspection Fundamentals An introductory course covering the principles and practices of Good Manufacturing...	Virtual	Quality Assurance	GMP Compliance	WHO Prequalification	English	5 days	Free	
Pharmacovigilance Signal Detection Advanced workshop on identifying, assessing, and managing safety signals from...	Hybrid	Pharmacovigilance	Signal Management	Uppsala Monitoring Centre	English	3 days	\$500	
Bioequivalence Study Design Comprehensive training on designing, conducting, and evaluating bioequivalence...	In-person	Bioavailability / Bioequivalence	—	SEARN Secretariat	English	4 days	\$750	
Regulatory Leadership Masterclass A high-level leadership program designed for senior regulatory officials focusing on...	Virtual	Leadership & Governance	—	SEARN Secretariat	French	2 weeks	\$1,200	
Laboratory Quality Management Systems Training on establishing and maintaining quality management systems in...	Hybrid	Quality Assurance	Laboratory QMS	USP	English	3 days	\$400	
Risk-Based Inspection Planning Webinar series on implementing risk-based approaches to pharmaceutical inspection...	Virtual	Regulatory Inspection	—	PIC/S	English	4 hours	Free	
Adverse Drug Reaction Reporting Foundational training on collecting, documenting, and reporting adverse drug reaction...	Virtual	Pharmacovigilance	—	WHO Prequalification	Spanish	2 days	Free	
Regulatory Dossier Assessment Intensive course on evaluating pharmaceutical product registration dossiers including...	In-person	Regulatory Inspection	—	Swissmedic	English	5 days	\$900	

User Details

View comprehensive user profile and learning record

DN

Dr. Nguyen Thi Hoa

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CREATED AT

Jan 15, 2026

UPDATED AT

Apr 15, 2026

LAST LOGIN

2 hours ago

TRAININGS COMPLETED

3

Completed Trainings

GMP Inspection Fundamentals
Completed Feb 12, 2026 90%

Pharmacovigilance Essentials
Completed Feb 16, 2026 88%

Bioequivalence Study Review
Completed Dec 28, 2025 95%

Training Status

Risk-Based Inspection

Completed

Quality Management Systems

In Progress

Regulatory Reference Pathways

In Progress

Clinical Trial Oversight

Not Started

Mapped Competencies (3/5 completed)

Regulatory and scientific guidelines for medicines assessment
Proficiency: Advanced Completed

Container closure system quality assurance
Proficiency: Advanced Not completed

Pharmacovigilance signal detection
Proficiency: Intermediate Not completed

Stability data and shelf life extrapolation
Proficiency: Intermediate Completed

GMP inspection methodology
Proficiency: Expert Completed

Regulatory Passport

View this user's digital regulatory training and competency record

View Regulatory Passport

International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND



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Medical devices

- 3 training programmes were developed on
 - (1) the assessment of manufacturers' QMS,
 - (2) pre-marketing assessment and market surveillance of IVD has been developed, and
 - (3) Reviewing applications for medical devices and IVDs through reliance pathways
- The Assembly adapted a Convergence Mechanism for Medical devices including IVDs
 - Regional technical forum to discuss one particular product
- 2 Regional centers of excellence were designated and will lead training activities in their domain:

Domain	NRA	Academic/Other institutions
Medical devices (including IVDs)		
MA for MDs	CDSCO India	jointly with National Institute of Health and Family Welfare Delhi
MA for IVDs	Thai FDA	Faculty of Medical Technology, Mahidol University



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Medical devices – 2026-2027 Workplan

- AP18 Reliance for Medical Devices:
 - Organize a consultation meeting with industry on the concept of convergence workshops
 - Finalize the proposed concept and pilot it based on a call for expression of interest.
 - Continue the programme of presentations to WG5 from reference organizations on their regulatory systems and how to use their generated information for reliance
 - Address any emerging issue related to reliance for medical devices (including IVDs).
- Creation of 2 new action points relevant to medical devices:
 - AP24 Clinical Trials
 - AP25 Market control and surveillance





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Medical devices

2026-2027 MnE Framework

- One new indicator created

#	AP	Lead WG	Need	Indicators	Method	Time
69	17	5	Capacity building for medical devices, including IVD	Number of Members having implemented / Partially implemented / Not applicable / Not implemented*: - GHTF/SG1/N071:2012 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device - GHTF/SG1/N055: 2009 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer - GHTF/SG1/N77:2012 – Principles of Medical Devices Classification - IMDRF/GRRP WG/N64 FINAL:2021 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification If other than implemented, are you planning to implement it? If not, why? * Implemented: All relevant elements, concepts and principles of the IMDRF document are followed. Partly implemented: The IMDRF document has been implemented in a modified way that a) does not include all relevant elements, concepts and principles of the IMDRF document or b) requires application of the document for a smaller range of products than outlined in the IMDRF document. Not applicable: The implementation of a specific IMDRF document is not applicable in a country/region. Not implemented: The process for the implementation of the IMDRF document has not yet started or is not completed. (IMDRF/MC/N84 FINAL:2025 (Edition 2) – IMDRF Document Implementation Report)	Survey	Twice a year



Highlights from the August 2026 meeting the SEARN Assembly 4-5 August, Kathmandu, Nepal

Other updates

- IMDRF:
 - EOI to participate in IMDRF Medical Device Cybersecurity Working Group (Bangladesh)
- MDSAP
 - Bhutan, Sri Lanka and secretariat represented SEARN during the June 2026 MDSAP annual forum, invited by the Government of Japan
 - Bhutan and Sri Lanka shared their experience with WG5





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IMDRF International Medical Device
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IMDRF is a global forum of medical device regulators from 30 countries, established in 2012. The forum provides a platform for regulators to share information, experiences and best practices, and to develop common standards and guidelines. The forum is organized into several working groups, each focusing on a specific area of medical device regulation. The working groups are: Clinical, Regulatory, Quality, Safety, and Technical. The forum also organizes annual meetings, workshops, and other events to facilitate collaboration and knowledge sharing among its members.

