SEARN regulatory updates

S.M. Sabrina Yesmin

SEARN Members' representative

Directorate General of Drug Administration, Bangladesh

South-East Asia Regulatory Network

South-East Asia Regulatory Network

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 (RCOEs)** 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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30th IMDRF 2026

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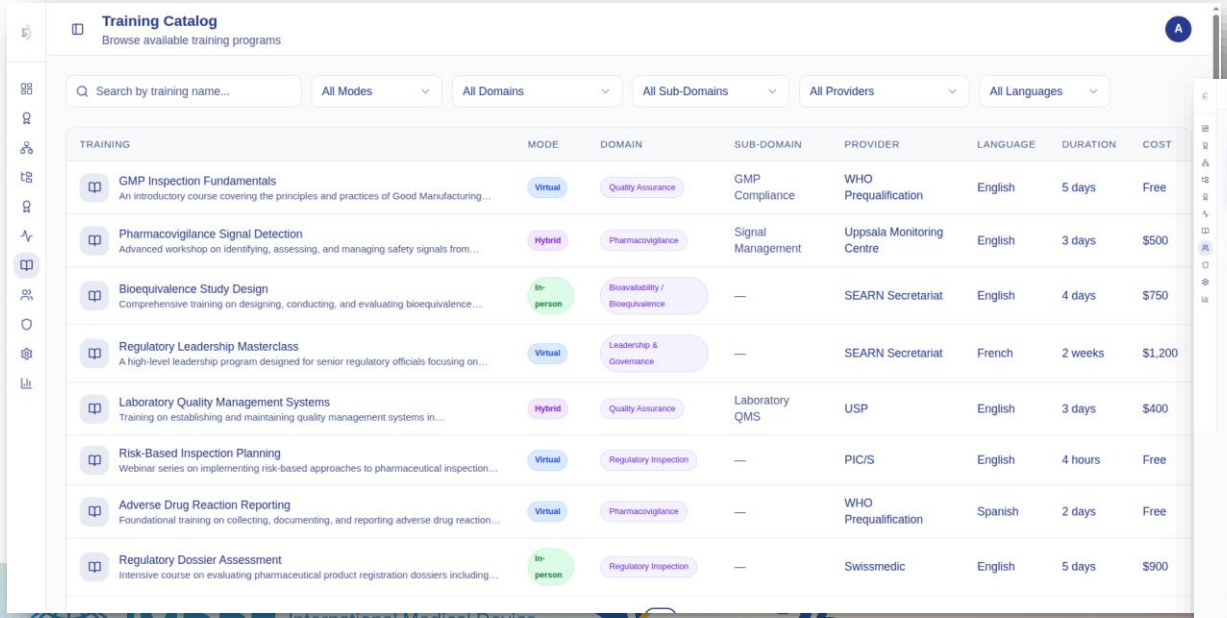
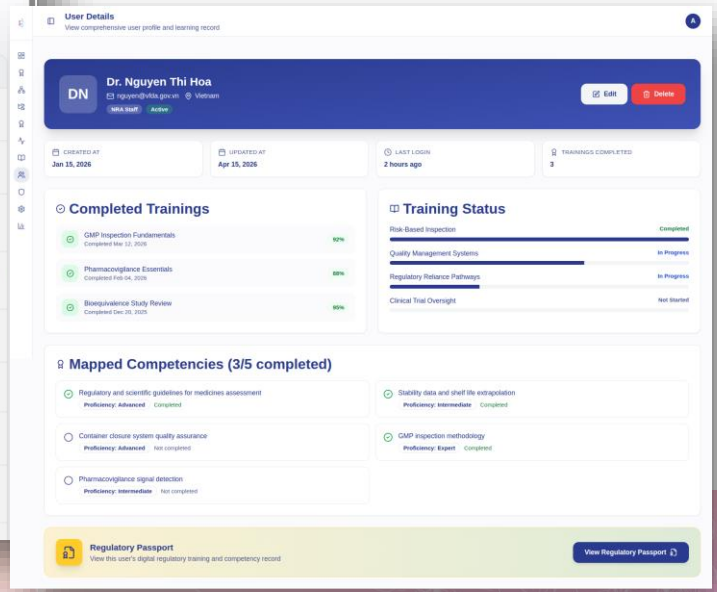
SEARN capacity building platform





IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority

25 YEARS AND BEYOND

South-East Asia Regulatory Network

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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

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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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