World Health Organization

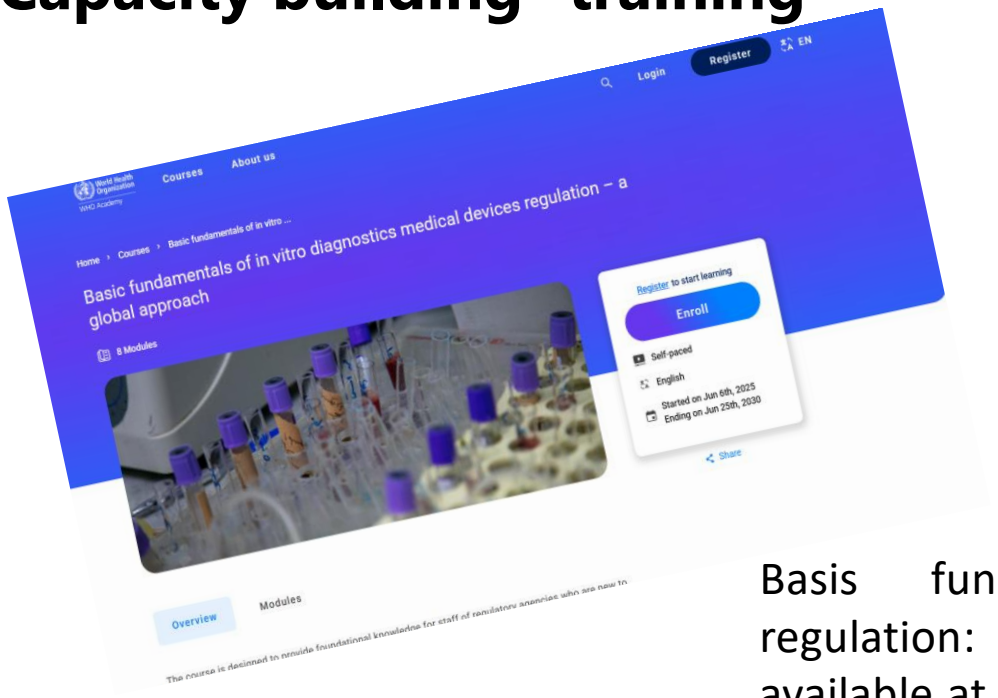
# Updates from WHO

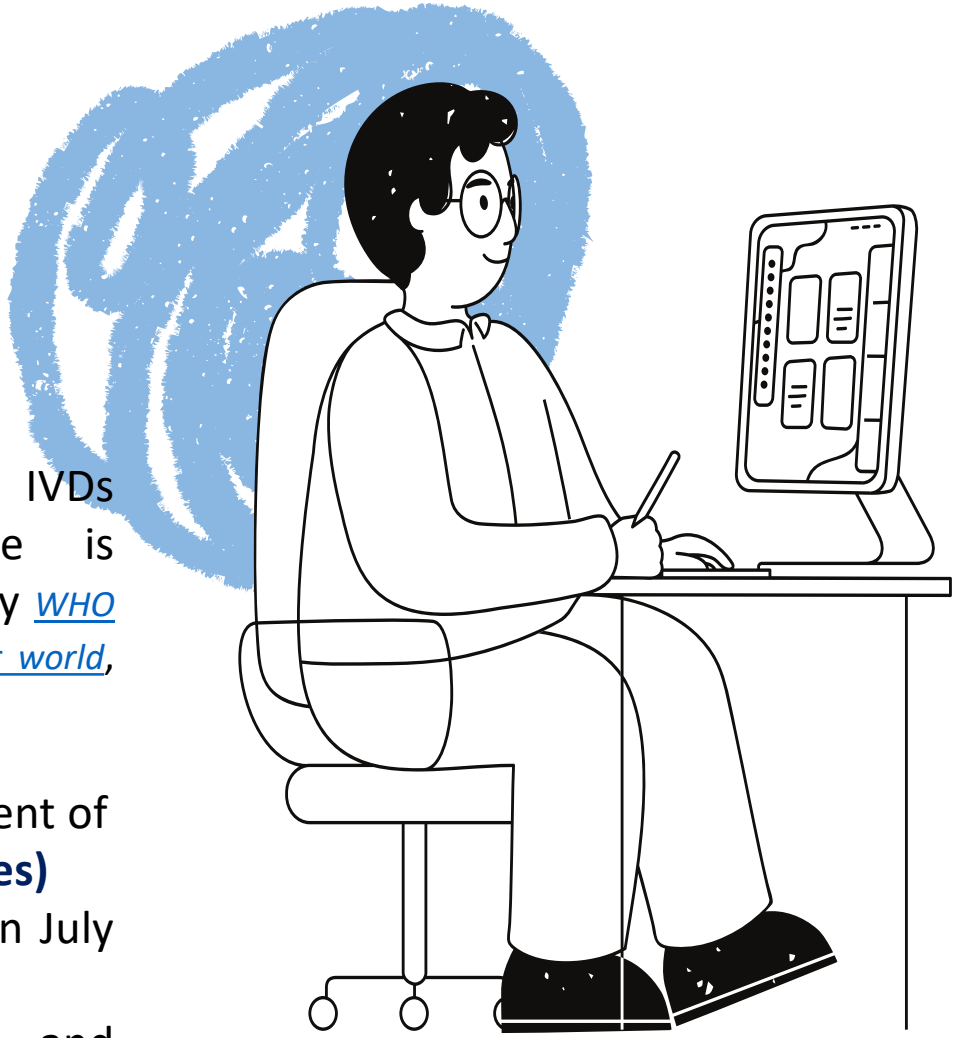
**29th Annual meeting of the Global Harmonization Working Party**
**Bangkok -Thailand**
**1 – 4 December 2025**

Agnes Sitta Kijo
Technical Officer, Special Access Program (SAP)
Email: kijoa@who.int, crp@who.int

Website: Special Access Program

# Capacity building- training



Basis fundamentals in IVDs regulation: Training course is available at the WHO Academy *WHO Academy | Learn to build a healthier world*, more than 200 trained.

Training materials on assessment of IVDs technical files **(17 modules)**
Validation workshop in Lyon in July 2025

- ✓ Review of feedback and finalization ongoing
- ✓ Expected to finalize in January 2025.

# Global benchmarking tool (GBT)+ and GMRF


*Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)*

- ✓ IDP follow up sessions with NAFDAC (August & October 2025). Formal benchmarking, November 2024.
- ✓ Regional workshop for selected countries in AFRO - September 2025
- ✓ Assistive self assessment : Senegal in September & Bhutan in November 2025
- ✓ Discussions on expansion of WLA policy to include medical devices
- ✓ Support to EMRO webinar on UDI – November 2025


- ✓ Presented in several platforms including; Regional meeting of MDs Regulators in WPRO , GHWP Regulatory training course in Guangzhou, Academy, and Swiss Medics training for Regulators to mention few.
- ✓ Publication on WHO website Q1 2026

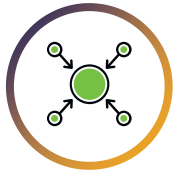
World Health Organization



*https://cdn.who.int/media/docs/default-source/biologicals/ecbs/annex3-gmrf-who_trs_1045.pdf?sfvrsn=88867b3a_3&download=true*

# Promoting regulatory reliance for medical devices regulation

## WHO Collaborative registration procedure for IVDs



- ✓ 6 additional national regulatory authorities signed agreement to participate CRP – IVDs, total of 41.
- ✓ 38 products registered in countries through CRP with average time of 71 days (within 90 days, making a total of 105 registrations.

## Support NRAs

- ✓ CRP 13th Annual meeting is planned in March 2025 in Addis Ababa, Ethiopia.
- ✓ Continue supporting the NRAs with technical sessions.
- ✓ Expanding CRP to include medical devices assessed by mature NRAs.

## Revision of the WHO Good Practices of NRAs in implementing CRP for medical products

- ✓ Guidance reviewed to include aspects of CRP for IVDs.
- ✓ Document is approved in the 58th ECSPP meeting in October 2024.
- ✓ Dissemination webinar was conducted on 10 July, 205 participants

World Health Organization

# Supporting manufacturers and regulators for post-market and market surveillance

## Regulators

- Renewed focus to strengthen national capacities using WHO global benchmarking tool for medical devices
- In September, WHO will support 7 African countries to self-benchmark themselves against these regulatory functions
  - ✓ National Regulatory System (RS);
  - ✓ Post-market surveillance, market surveillance and control (PS)
  - ✓ Licensing establishments (LI)
- Link to Evaluation of national regulatory systems of medical devices (GBT+ Medical devices)

## Industry

- From October 2025, WHO Global Surveillance and Monitoring System for substandard/falsified medical products (GSMS) will allow manufacturers to directly report incidents and FSCA through the GSMS portal.

World Health Organization

For more information, please contact:
Name: Agnes Sitta Kijo
Title: Technical Officer, Special Access Program (SAP)
Email: kijoa@who.int, crp@who.int

Website: Special Access Program


World Health Organization