Week of Quality

2024

Optimising IVD product development: principles of design, quality and compliance

In Vitro Diagnostics

15-18 April 2024

12:00-14:30 Geneva time (UTC+2)

Virtually by Zoom

Register here

Registration of interest to participate is required. All registrations of interest will be reviewed and only selected registrants will receive a link for participation. Priority afforded to those from LMICs. The deadline for registration is 9 April 2024.

For more information please email:
localproduction@who.int

World Health Organization

Local Production & Assistance Unit (LPA)

Access to Medicines and Health Products Division

Week of Quality
IN VITRO DIAGNOSTICS

2024

The Local Production and Assistance (LPA) Unit, WHO is organizing the second Week of Quality in 2024, and offering an expanded list of topics for each product stream: April 15th to 18th for IVDs, May 13th to 16th for medicines, and June 10th to 13th (tentative) for vaccines & biotherapeutics. The Week of Quality for IVDs 2024 is a training intended to provide manufacturers and regulators with guidance on the fundamental design, quality and compliance requirements for IVDs, with an aim to promote enhanced strategies for product design, development and production of quality-assured IVDs.

Target Participants

The workshop is specifically designed for and will be beneficial to manufacturers of IVDs and Member State authorities, such as Ministry of Health (MoH), National Regulatory Authorities (NRAs) that are in a low- and middle-income countries (LMICs).

April 15	Session 1	Core elements of compliant performance evaluation
	Session 2	Building ‘quality by design’ into clinical performance studies
April 16	Session 3	Usability: a critical step towards true quality
	Session 4	IVD software excellence: streamlining validation & verification
April 17	Session 5	Improving the quality of Instructions for Use: content, process and tools
	Session 6	Enhancing quality, safety, and efficacy in the production of IVD analyzers
April 18	Session 7	Leveraging post-market surveillance data for product quality improvement
	Session 8	Increasing the likelihood of attaining “quality-assured” status for IVDs

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