Week of Quality 2023

On the origin of specifications: Strengthening Quality for Manufacturing of Vaccines, Medicines, and In Vitro Diagnostics

12 to 16 June 2023 | 12:00-14:30 Geneva, Switzerland Time (UTC+2)

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World Health Organization

Local Production & Assistance Unit (LPA)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)

The COVID-19 pandemic has created challenges in maintaining the quality of medicines, vaccines, and IVDs due to the increased demand and pressure on manufacturers. The Week of Quality, organized by the **Local Production and Assistance (LPA) Unit**, serves as a yearly commemoration of the vital role that quality plays in the pharmaceutical and IVD industries.

The workshop aims to strengthen the capacity of low- and middle-income countries' (LMICs) manufacturers of medicines, vaccines, and IVDs to produce safe, effective, and high-quality products during a pandemic and beyond. The workshop will focus on enhancing manufacturers' knowledge on quality data requirements and expectations for vaccines, medicines and IVDs as described in the guidelines of WHO and regulatory authorities, for prequalification (PQ), emergency use listing (EUL) and licensing purposes.

The workshop is designed for technical personnel working in production, QC, QA, dossier preparation and regulatory affairs. Regulators and relevant government ministries/institutions are welcomed to participate.

Vaccines

12 June	**Setting the Standard: Achieving Quality Specification for Vaccine Manufacturing**	
	SESSION 1	Establishing patient-centric specifications
	SESSION 2	Clinical qualification of vaccines acceptable ranges
13 June	SESSION 3	Establishing harmonized specifications for new vaccines: lessons learned from the COVID vaccines
	SESSION 4	Replacement of in vivo potency testing by in vitro assay
	SESSION 5	Addressing the setting of specification in a CTD application

Medicines

14 June	**Ensuring Excellence of Medicines: Getting the Specification Right**	
	SESSION 6	API monographs
	SESSION 7	Control of API characteristics
	SESSION 8	Control of organic impurities
	SESSION 9	Control of other impurities
15 June	SESSION 10	Dosage form specific requirements
	SESSION 11	Setting requirements for dissolution
	SESSION 12	Control of impurities

In vitro diagnostics

16 June	**Bridging the gap between design validation and quality specifications for IVDs**	
	SESSION 13	Designing, implementing, and applying design controls
	SESSION 14	Design Control Challenges
	SESSION 15	Design Verification and Validation
	SESSION 16	Design transfer and changes