



INVESTING IN WORKFORCE DEVELOPMENT

Assuring the quality of medical products and achieving the goal of Universal Health Coverage (UHC) require highly skilled staff in many health-related fields, including regulatory, manufacturing, customs, education, and law enforcement. While investments have been made to build quality assurance capacity in these fields, chronic shortages of qualified staff and the absence of approaches which take a whole-of-market view impede the ability of low- and middle-income countries to meet pharmaceutical sector objectives related to access to quality-assured medical products.

The Promoting the Quality of Medicines Plus (PQM+) program is a global program funded by the U.S. Agency for International Development and led by USP that works to increase access to quality-assured medical products by supporting the development of a qualified and capable workforce and addressing other critical areas that help sustainably strengthen medical product quality assurance systems in low- and middle-income countries.

PQM+ takes a whole-of-labor-market approach to understand the forces behind supply and demand trends of the regulatory and quality assurance workforce in the public and private sectors and at regional and national levels. PQM+ considers regional and domestic labor force production capacity, compensation, career pathways, and competency profiles. Through PQM+, USP and IntraHealth International will lead regulatory and quality assurance workforce strengthening, tailoring the following strategies to country context.

KEY PQM+ STRATEGIES

Gather data and use existing frameworks to inform country-specific workforce development plans

- + Adapt existing models from WHO, HRH2030, and the People that Deliver Human Resources for Supply Chain Management Theory of Change to develop strategies to manage the workload, quantity, type, and capacity of human resources.
- + Support regional initiatives and national regulatory authorities to devise data-driven regulatory and quality assurance workforce policies and plans.



Increase competencies in quality assurance across sectors

- + Engage with academic institutions to reform and revise pre- and in-service training curricula to incorporate regulatory science and quality assurance topics such as bioequivalence, formulation science, unit operations, stability studies, and pharmaceutical analysis to respond to emerging needs in the pharmaceutical sector.
- + Introduce and support scale up of innovations in regulatory and quality assurance in-service training, such as context-based learning, adaptive teaching, and computational learning, combined with the appropriate use of eLearning and mobile technologies.
- + Support the integration of demonstrated new approaches with current standards and practices of regulatory education and professional development programs.
- + Support implementation of global pharmaceutical and health workforce development initiatives including the FIPEd Transforming Workforce, WHO Global Regulatory Competency Framework and Curriculum, and WHO Competency Framework for Antimicrobial Resistance.

- + Document and disseminate best practices and effective approaches to regulatory workforce development through rigorous evaluation of efficiency, effectiveness, and sustainability.

Increase access to and strengthen use of available workforce data to support evidence-based decision-making in medical product quality assurance

- + Facilitate and support the introduction, use, and maintenance of human resource management information systems for regulatory authorities, moving to active analysis and use of data to support human resource decisions.
- + Support human resource departments of regulatory agencies to develop human resource policies, procedures, and guidelines.

Address gender-based disparities in workforce representation

- + Analyze and address gender barriers for women entering the fields related to medical product quality assurance as part of a labor force market analysis.
- + Support the creation of working groups/forums for female regulatory leaders to share their experiences and advocate for necessary support mechanisms, to increase women's participation in regulatory and quality assurance systems.