PQM+ Program

Background

Everyone should have access to safe and effective medicines. Still, manufacturers and regulators in some low- and middle-income countries (LMICs) do not always have access to the infrastructure to make that possible. Shortages in quality-assured medicines impede efforts to reduce the prevalence of life-threatening diseases and threaten the length and quality of people's lives.

Opportunity to strengthen quality

Healthcare systems in LMICs face manufacturing and regulatory challenges that limit access to quality medicines and increase the risk of patients being exposed to substandard and falsified medicines. USP addresses these challenges through the Promoting the Quality of Medicines Plus (PQM+) program.

USP solutions

PQM+, funded by USAID and implemented by USP, strengthens medical product quality assurance systems in LMICs. Our technical assistance and capability building in quality management systems, good laboratory practices, and quality control procedures develops manufacturers and regulators capacity and effectiveness using international quality assurance standards and builds stronger quality assurance systems.

USP technical support to national quality control laboratories includes training in how tests are performed and documented, maintaining data integrity and lab equipment, and monitoring laboratory environmental conditions.

Additional areas of technical support and training for manufacturers and laboratories include:

Facility design and planning	**Technology transfer**
Human resource and business planning	**Active pharmaceutical ingredient and product development**
Workforce development	**Process scale-up**
Equipment specifications, calibration, and maintenance	**Good manufacturing practices**
Quality management systems	**Dossier compilation**
Provision of public standards	**WHO prequalification and Stringent Regulatory Authority (SRA) approval**
Testing and documentation	

Areas of technical support and training for regulatory authorities include:

Policy, legislation, and regulation	**Medicines registration, marketing authorization and licensing**
Guidelines, procedures, and specifications	**Data standards and regulatory information management**
Pharmaceutical sector inspection, including cGMP inspection	**Dossier review and evaluation**
	Post marketing surveillance

Why it's important

USP collaborates with USAID, WHO, and other donor organizations to help regulators, manufacturers and healthcare providers in LMICs deliver quality treatments that protect and promote public health.

Through PQM+, USP builds the capacity of local manufacturers to produce medicines according to quality standards. We strengthen regulatory systems so they can verify medicines meet those standards, increasing the availability of quality essential medicines for patients.

Our support helps national quality control laboratories earn and retain the WHO prequalification accreditation, certifying the reliability of the lab's analyses and technical competence of its staff and allowing international recognition of the services it performs.

Web resources

- https://www.usp.org/our-impact/promoting-quality-of-medicines
- https://www.usp.org/global-public-health
- https://www.usp.org/global-public-health/assuring-the-quality-of-medical-products
- https://www.usp.org/global-public-health/strengthening-regulatory-systems
- https://www.usp.org/global-public-health/building-manufacturing-capacity