

Promoting the Quality of Medicines Plus Program (PQM+) 2019-2024

Strong health systems to ensure access to
quality medical products



Around the world, millions of people face avoidable illness or death due to poor-quality medical products and lack of access to quality-assured essential medicines. Poor-quality medical products can also:



Undermine global health progress in preventing maternal and child deaths, controlling the HIV/AIDS epidemic, and combating infectious disease threats.



Result in wasteful spending by health systems and patients alike.



Contribute to antimicrobial resistance.



Erode trust in health systems and governments.

\$30.5 billion

WHO estimates that poor-quality medicines cost low- and middle-income countries \$30.5 billion every year. Global estimates range as high as \$200 billion per year.

3 of 10

The use of poor-quality medical products, underuse of affordable generics, and inappropriate use of medicines account for 3 of the 10 leading sources of inefficiencies in health systems.

2 billion

Nearly 2 billion people lack access to essential medicines, a major challenge to achieving global health objectives and universal health coverage.

PQM+ improves access to quality-assured priority medicines and addresses the proliferation of poor-quality medical products in low- and middle-income countries.

Made possible by the generous support of the American People through the U.S. Agency for International Development (USAID) and implemented by a consortium of partners led by USP, PQM+ sustainably strengthens medical product quality assurance systems in low- and middle-income countries through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system.

By sharing scientific expertise and providing technical support and leadership, we help create resilient and robust local health systems that address diseases like HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as improve maternal, newborn, and child health.



PQM+

Strengthening health systems to take on complex challenges

Medical product quality assurance is fundamental for strong health systems

Quality-related challenges occur not only within the health system but across sectors and disciplines. PQM+ takes a holistic view and considers quality-related issues that occur across a complex, globalized supply chain; variability of regulatory capacity across country and regional contexts; and market-based factors that affect the availability of quality-assured medical products.

Using a health systems-strengthening lens for lasting change

Our approach is informed by decades of experience responding to a complex and evolving pharmaceutical landscape and emerging health systems. Using a health systems-strengthening lens to guide our efforts, our work is rooted in the application of international standards across the pharmaceutical system. We implement risk-based approaches to optimize resources for maximum public health benefit, strengthen local and regional workforce capacity, enhance regional collaboration, and improve the use of information and data to achieve the objectives of PQM+.

PQM+ Principles



Use a systems-strengthening approach



Support integration



Build on and strengthen existing systems



Support country-led coordination and ownership



Strengthen capacity of local organizations



Develop strategic partnerships



Prioritize and optimize resources



Provide technical leadership



Program Goal

Sustainably strengthen medical product quality assurance systems in low- and middle-income countries.

PQM+ Objectives

1 Improve **governance** for medical product quality assurance systems

- » Developing, updating, and supporting implementation of evidence-based medical product quality assurance legislation, policies, and regulations
- » Promoting systems that facilitate transparency and accountability
- » Addressing fragmentation and promoting coordination across entities (public and private) with medical product quality assurance responsibilities
- » Developing and fortifying links among medical product quality assurance systems and other sectors

2 Improve country and regional **regulatory systems** to assure the quality of medical products in the public and private sectors

- » Improving sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies
- » Strengthening sustainable post-marketing surveillance systems and medical product quality control laboratory capacity
- » Supporting regional harmonization to strengthen medical product quality assurance regulatory capacity and networks
- » Supporting adoption of international data standards and integrated information systems to support regulatory medical product quality assurance functions
- » Improving the competence, efficiency, and expansion of the medical product quality assurance workforce

3 Optimize and increase **financial resources** for medical product quality assurance

- » Optimizing the allocation and use of investments for medical product quality assurance systems strengthening
- » Mobilizing sustainable resources for medical product quality assurance

4 Increase **supply** of quality-assured essential medical products of public health importance

- » Supporting pharmaceutical manufacturers for good manufacturing practices and medical product regulatory submissions/dossiers
- » Strengthening capacity to conduct bioequivalence studies for dossier submissions
- » Increasing capacity for market intelligence and analytics of public health pharmaceutical markets
- » Supporting incorporation of medical product quality requirements into health coverage schemes
- » Developing and supporting the use of monographs

5 Advance the **global learning and operational agenda** for medical product quality assurance

- » Developing and applying evidence-based approaches and tools
- » Conducting research and analysis to support medical product quality assurance systems strengthening
- » Supporting advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and antimicrobial resistance

Global expertise, local leadership

USP has assembled a consortium of internationally recognized leaders to address the most critical quality assurance challenges. Led by USP, each core partner brings specialized expertise to bear on achieving PQM+ objectives.

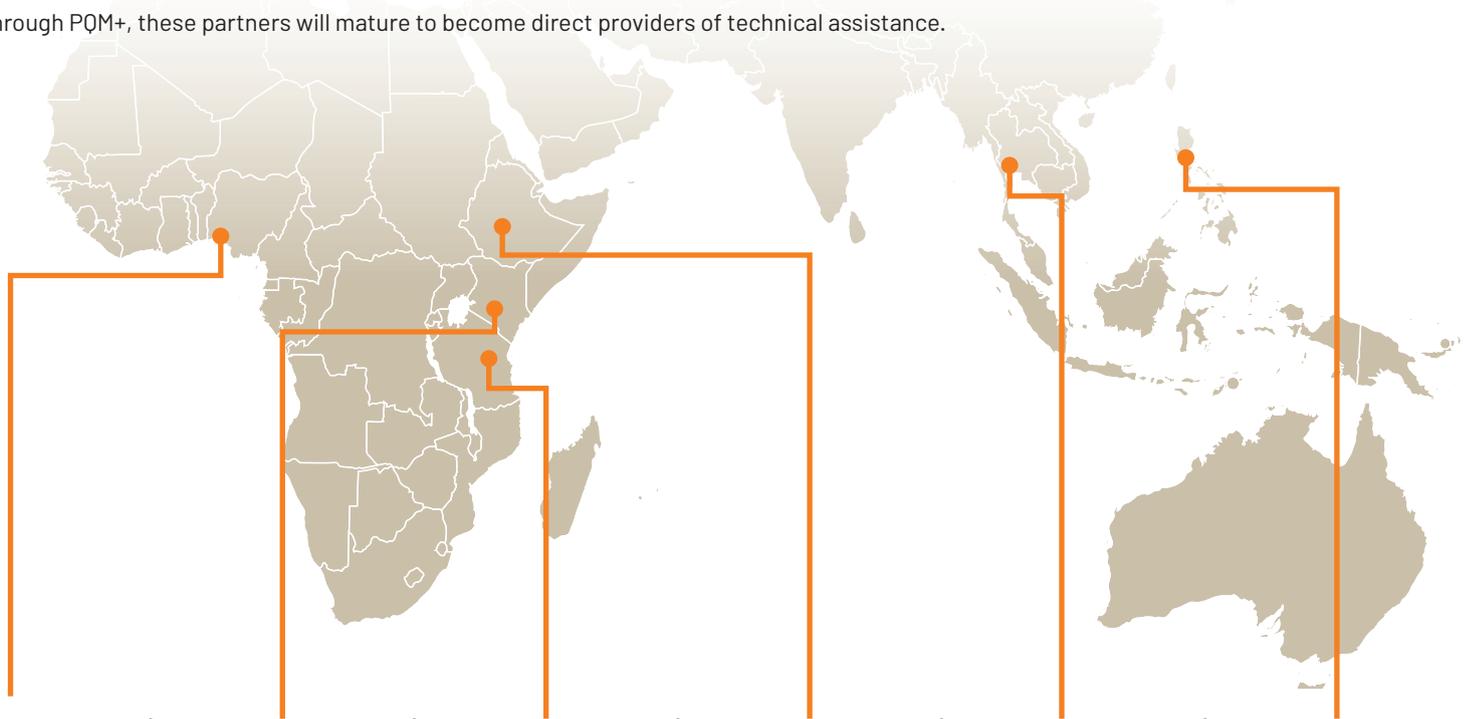
Core partners:

Core partners bring a wealth of knowledge and experience complementary to USP and their work will build on those capabilities to support all of the PQM+ objectives.

- » African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD)
- » IntraHealth International
- » IQVIA Government Solutions, Inc.
- » Panagora Group

Core-FLEX partners:

Core field-led extension (FLEX) partners are regional organizations that bring on-the-ground specialized expertise where it is needed most. Through PQM+, these partners will mature to become direct providers of technical assistance.



Center for Drug Discovery, Development and Production
Ibadan, Nigeria

Ecumenical Pharmaceutical Network
Nairobi, Kenya

Muhimbili University of Health and Allied Sciences
Dar es Salaam, Tanzania

Addis Ababa University School of Pharmacy Regional Bioequivalence Center
Addis Ababa, Ethiopia

Mahidol University Center for Analysis of Product Quality
Bangkok, Thailand

Association of Southeast Asian Nations Network for Drugs, Diagnostics and Vaccines Innovation
Taguig City, Philippines

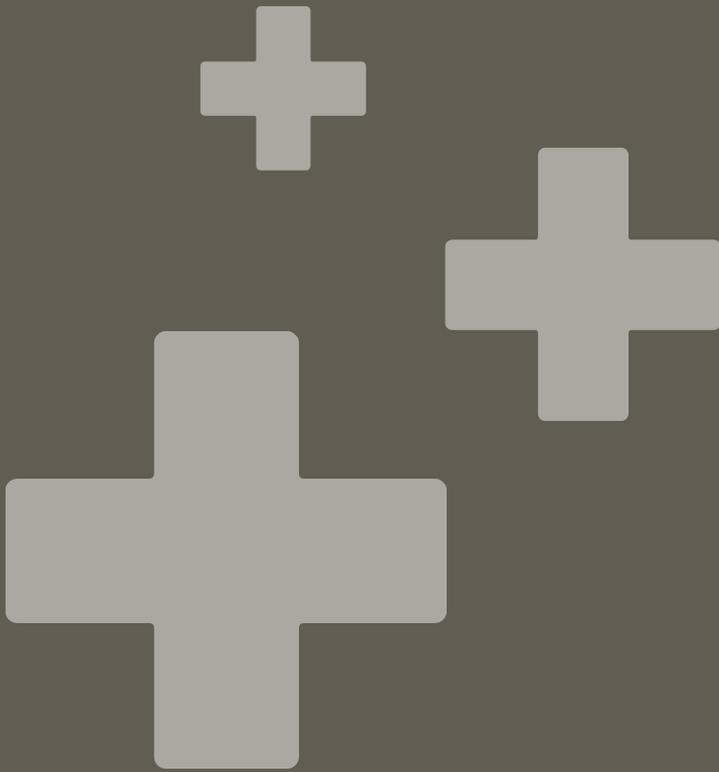
Technical Resource partners:

Technical resource partners will support specific, targeted areas such as quality of medical devices, risk-based approaches, advocacy, civil society engagement, research and data analysis, and continuous quality improvement. Technical resource partners include the following organizations: Asia Pacific Leaders Malaria Alliance, Boston Consulting Group, BroadReach Consulting Group, Centre for Innovation in Regulatory Science, Harvard Pilgrim Health Care, Howard University, the International Diagnostics Centre at the London School of Hygiene and Tropical Medicine, Purdue University, University of Washington.



**Access to medicines
alone, without quality
assurance, is not enough.**

Dr. Matshidiso Moeti,
WHO Regional Director for Africa



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USP is an independent scientific organization whose mission is to improve public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. Through our standards, advocacy, and capability-building, USP helps increase the availability of quality medicines, supplements and food in the United States and for billions of people worldwide. USP has offices in the United States, Asia, Africa, Latin America, and Europe, including five state-of-the-art laboratories, full-scale training facilities in Ghana and India, an online training system, and partnerships with national quality control laboratories around the world.