The Promoting the Quality of Medicines Plus (PQM+) program anchors its efforts in USP’s decades of experience implementing quality assurance programs, builds on lessons learned, and drives value-added practices that best utilize available resources and information.

Program goal: To sustainably strengthen medical product quality assurance systems in low- and middle-income countries.

Because PQM+ recognizes that systems support is not sustainable on its own, our efforts are implemented through a systems-strengthening lens which reflects an understanding of the wider pharmaceutical landscape, system levers, interactions, and externalities that affect medical product quality. PQM+ guiding principles are reflected in our approach and will guide implementation, connecting our strategies to health system functions and key actors.

PQM+ Technical Approach: USP approaches medical product quality assurance through a systems-strengthening lens and by applying four key strategies honed from predecessor programs.
PQM+ TECHNICAL APPROACH

At the heart of our systems-strengthening approach (see figure on previous page) is the application of international standards to lay the groundwork for consistent quality and facilitate regulatory reliance. Four complementary and synergistic strategies are used to support the adoption of international standards and promote a culture of quality in the pharmaceutical sector:

+ **Using risk-based resource allocation** to align human and financial resources proportionally to public health risks and to adapt to a complex and evolving regulatory landscape while protecting the public from poor-quality medical products.

+ **Strengthening local and regional workforce capacity** to ensure regulatory authorities are staffed with an appropriate number of professionals with the right skill mix and competencies to make evidence-based regulatory decisions.

+ **Using information and data** to improve evidence-based decision-making, collaboration, engagement, and advocacy across key sectors, and expand access to technical and market information to support the supply of essential, quality-assured medical products.

+ **Enhancing regional collaboration** to strengthen medical product quality assurance systems through work-sharing platforms and information exchange, as well as identifying opportunities for and advancing reliance, convergence, and harmonization, where feasible.

PQM+ PRINCIPLES

**Use a systems-strengthening approach**: Consider the influence and interaction of health systems functions on medical product quality assurance.

**Build on and strengthen existing systems**: Understand current capabilities and systems and develop locally relevant strategies to further strengthen existing tools and approaches.

**Support integration**: Institutionalize medical product quality functions, where feasible and appropriate, while addressing fragmentation.

**Support country-led coordination and ownership**: Engage local stakeholders effectively to coalesce around a common agenda for advancing medical product quality assurance.

**Strengthen capacity of local organizations**: Work with local entities for improved south-to-south capacity-building and locally driven leadership and sustainability.

**Prioritize and optimize resources**: Reduce waste and increase efficiency in the allocation and use of resources.

**Develop strategic partnerships**: Enhance engagement with partners, including those in the private sector, to advance coordinated approaches to assure the quality of medical products.

**Provide technical leadership**: Move the science of medical product quality assurance forward through proven tools, research, collaboration, and advocacy.

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