

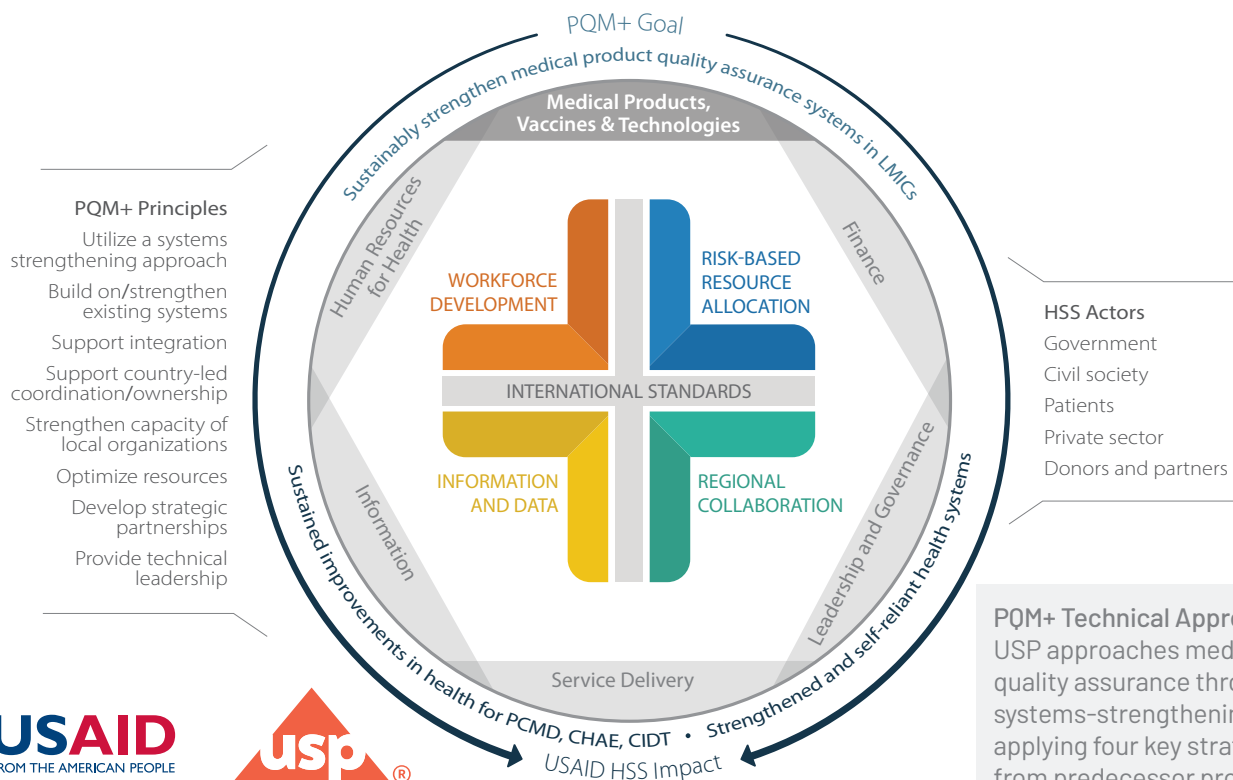
PQM+ TECHNICAL APPROACH



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.

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.



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.