Promoting the Quality of Medicines

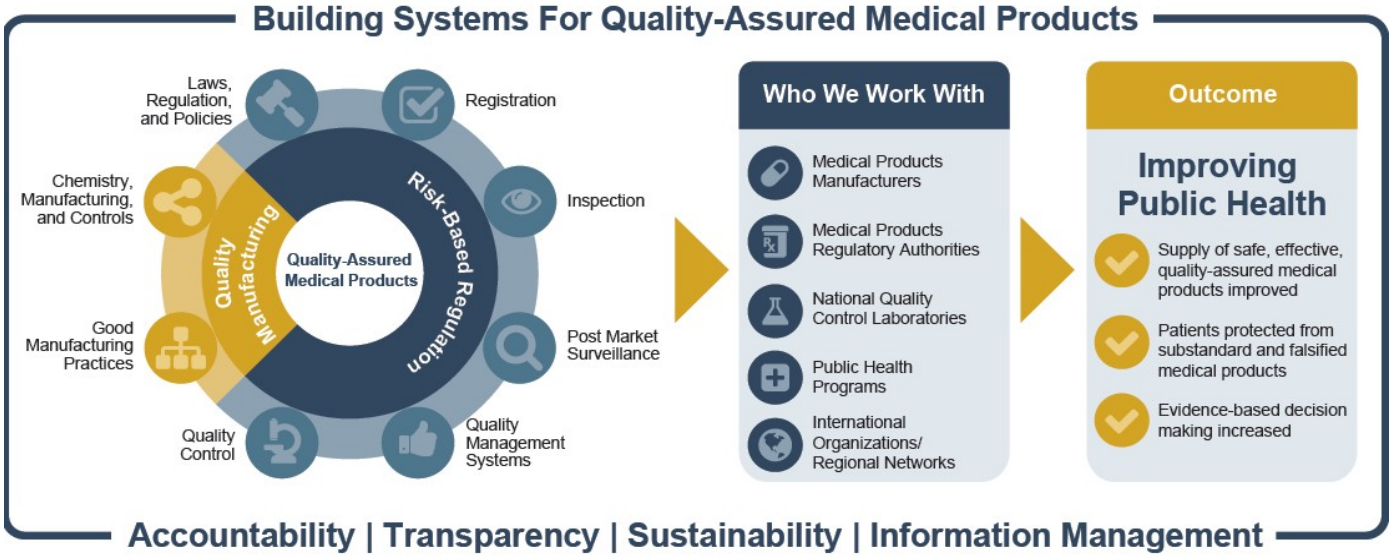
Promoting the Quality of Medicines
Program Approach and Technical Areas

What We Do

> *Improve the quality of essential medicines in low- and middle-income countries by strengthening regulatory systems and building capacity for quality assurance across the supply chain.*

Our Approach

The Promoting the Quality of Medicines (PQM) approach reflects a holistic view of medicines quality assurance—seeking to address quality-related aspects of medicine production, patient use, and everything in between—to strengthen and improve the systems, structures, and processes that promote product quality. This approach recognizes the dynamic and cross-cutting relationships among different components of the health system, and therefore seeks to address product quality issues in a sustainable manner using systems-based thinking and solutions. The framework below serves as a visual guide for how we build quality assurance systems for medicines by working with key stakeholders in the areas of quality manufacturing and risk-based regulation to achieve critical public health outcomes.



Strengthening Regulatory Systems

To improve the availability of safe, effective, and quality-assured medicines in low- and middle-income countries, PQM partners with regional and national regulatory authorities, national quality control laboratories, academic institutions, and other international organizations to strengthen local capacity to carry out key quality assurance functions, including product registration, inspections of medicine producers and distributors, and post-marketing surveillance. Spanning multiple aspects of the health system, we work to support the adoption of effective and enforceable policies and legislation, bolster human resource capacity to effectively manage product quality, and harness information to facilitate transparent, accountable, and evidence-based decision making at all levels.

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An important component of our work is collaborating with regulatory authorities to design and implement technically sound and sustainable risk-based medicines surveillance programs that are responsive to unique country contexts and needs. Moving from intermittent medicines quality monitoring to risk-based post-marketing surveillance programs is critical to ensure the quality of medicines. This risk-based approach optimizes the use of resources and enables countries to transition from donor-supported sampling and testing activities to locally funded and sustainable post-marketing surveillance programs.

As part of these efforts, we work with national quality control laboratories to strengthen systems that enable laboratories to accurately and reliably test the quality of medicines. Through this support, the laboratories we work with pursue and achieve compliance with international standards, such as ISO/IEC 17025:2005 and the World Health Organization (WHO) prequalification program.

Increasing the Supply of Quality-Assured Medicines

To increase the supply of quality-assured essential medicines, PQM works to identify and support local and international manufacturers in producing priority medicines that meet internationally recognized good manufacturing practices and standards set by the WHO prequalification program and/or regulatory authorities from countries with stringent standards. These efforts have helped avert shortages of essential medicines and in some cases resulted in a substantial reduction in price.

Technical Areas of Expertise

Regulatory	Quality Control Laboratories	Manufacturing
• Laws, policies, regulation • Quality assurance guidelines • Dossier evaluation • Product registration • Inspections • Integrated information management • Post-marketing surveillance • Bioequivalence studies	• Quality management systems • Analytical instrumentation support • Support for WHO/ISO accreditation • Analytical testing • Self-inspection	• Good manufacturing practices • Chemistry, manufacturing, and controls • Product and process development • Support for WHO/ISO accreditation • Common Technical Document (CTD) dossier compilation

Workforce development • Information management • Decision-making tools • Curriculum development

PQM Principles

- **Risk-based and pragmatic solutions:** Assessing local risks to public health helps prioritize interventions and direct human and financial resources where they are most needed.
- **Internationally recognized standards and best practices:** PQM assists countries to build on existing systems to achieve international standards such as WHO prequalification and ISO 17025:2005.
- **Regional harmonization**: Harmonization at the regional level helps leverage resources to address regulatory needs across multiple countries and encourages South-to-South collaboration.
- **Complementarity and partnership**: PQM works with other implementing partners, multilateral organizations, government agencies, and academic institutions to coordinate efforts and maximize results.
- **Resilience and sustainability**: We seek to improve the quality of medicines by addressing cross-cutting quality assurance issues that influence quality through systems-based approaches and solutions.

PQM is funded by the U.S. Agency for International Development (USAID) and led by the U.S. Pharmacopeial Convention (USP). USP has worked with USAID for 25 years to support low- and middle-income countries in addressing critical pharmaceutical challenges. **LEARN MORE** about PQM at www.usp-pqm.org.

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