



Promoting the Quality of Medicines in Developing Countries

The effects of poor quality medicines are devastating. In developing countries where resources to combat them are limited, their impact is hardest felt. The detrimental effects on health caused by substandard and counterfeit medicines include treatment failure, increased morbidity and mortality, and continued development of drug resistance—effects which, in turn, result in wasted human and financial resources.

Since 1992, USP has worked cooperatively with the United States Agency for International Development (USAID) to help developing countries address critical issues related to poor quality medicines. This partnership operated as the Drug Quality and Information (DQI) program until 2009 when, to better meet growing global needs, USAID awarded USP a five-year, \$35 million cooperative agreement to establish a new, expanded program—Promoting the Quality of Medicines (PQM). In 2013, USAID extended the PQM program for five additional years (through September 2019), increasing its funding from \$35 million to \$110 million and allowing further expansion of the geographical reach of the program. PQM serves as a primary mechanism to help USAID-supported countries strengthen their quality assurance and quality control systems to better ensure the quality of medicines that reach patients.

GLOBAL IMPACT

USP–USAID collaborative efforts have assisted more than 35 countries.

Current PQM activities are under way in

Africa	Angola • Benin • Burkina Faso • Ethiopia Ghana • Guinea • Kenya • Liberia • Mali Mozambique • Nigeria • Senegal
Asia	Bangladesh • Burma • Cambodia • China India • Indonesia • Kazakhstan • Laos • Nepal Pakistan • Philippines • South Korea • Thailand Ukraine • Uzbekistan
Latin America and the Caribbean	Brazil • Colombia • Ecuador • Guatemala Guyana • Peru • Suriname
Middle East	West Bank and Gaza

LEARN MORE about PQM at <http://uspgo.to/qualitymeds>, or contact our staff at pqm@usp.org or +1-301-881-0666.

PQM Program Objectives and Core Activities

Supported by knowledgeable staff and state-of-the-art facilities around the world, PQM strives to accomplish four key objectives:

- Strengthening regulatory and quality assurance (QA) systems**
 PQM helps countries ensure the quality of the medicines in the national market by (1) supporting reforms toward comprehensive medicines legislation and regulation; (2) enhancing the capacity of national regulatory systems to enforce regulations and strengthen QA/quality control (QC) systems; (3) providing technical assistance in medicines registration and evaluation; (4) establishing medicines quality monitoring programs; (5) enhancing countries' QC capabilities by training field personnel in screening methodologies and national QC laboratories (NQCLs) in compendial test methods; (6) supporting NQCLs to attain compliance with internationally accepted standards, such as ISO/IEC 17025:2005 accreditation and World Health Organization (WHO) prequalification; and (7) working with manufacturers to reach WHO prequalification status.
- Increasing the supply of essential quality-assured medicines**
 PQM works with WHO and United Nations agencies to prepare selected manufacturers to meet internationally accepted standards to increase the supply of locally produced, quality-assured medicines, particularly targeting those that support USAID priority health programs.
- Combating the availability of falsified, substandard, and unapproved medicines**
 PQM promotes medicines QA and effective implementation of corrective action by developing monographs for priority medicines, collecting evidence-based data on product quality through collaborative research, providing technical resources and training, and building expertise at national and regional levels.
- Providing technical leadership and global advocacy**
 PQM leverages its technical expertise to educate the global community on the dangers of falsified, substandard, and unapproved medicines and advocates the value of medicines QA. Strategies include public service campaigns, journal articles and technical reports, and presentations at international forums. PQM has also launched a free, publicly available Internet-based Medicines Quality Database that provides results of quality testing and other relevant information from medicines sampled in participating countries around the world.