

Product Quality and Compliance (PQC)

QUALITY ASSURANCE FOR HEALTH COMMODITIES

- Antimalarial medicines
- Antiretrovirals (ARVs)
- Food by prescription
- Instrument-based diagnostics
- Intrauterine devices (IUDs)
- Laboratory supplies
- Long-lasting insecticidal nets (LLINs)
- Male and female condoms
- Microbicides
- Oral and injectable contraceptives
- Other essential and strategic medicines
- Personal protective equipment (PPE)
- Rapid diagnostic test kits (RDTs)
- Tuberculosis preventive treatment products
- Voluntary medical male circumcision (VMMC) and other procedural kits



Jessica Scranton/FHI 360

Product quality and compliance at FHI 360 is dedicated to ensuring that global health commodities comply with international standards for quality, safety, and efficacy, and perform per manufacturer claims. Established in 1989, the product quality and compliance (PQC) department provides comprehensive quality assurance and quality control services for a wide range of global health products. With laboratories in Durham, North Carolina and Bangkok, Thailand that are both accredited to International Organization for Standardization (ISO) 17025¹ and more than 45 staff, we work for government agencies, multilateral organizations, nongovernmental and development organizations, and the private industry.

COMPREHENSIVE PRODUCT RISK MANAGEMENT

We provide holistic risk management that includes risk-based quality assurance services to provide the best value to clients and lowest risk to patients and end users.

Product and Supplier Qualification

Our robust product regulatory compliance services help to ensure the quality and suitability of health commodities available for our clients. We accomplish this by:

- Establishing quality specifications for procurement
- Reviewing quality components of procurement tenders
- Managing product eligibility lists for procurement
- Performing risk-based technical evaluations

Supplier Audits and Inspections

PQC monitors suppliers through audits, site visits, and desk reviews to determine compliance with international quality standards, including the World Health

About FHI 360: FHI 360 is a nonprofit human development organization dedicated to improving lives in lasting ways by advancing integrated, locally driven solutions. Our staff includes experts in health, education, nutrition, environment, economic development, civil society, gender, youth, research, technology, communication and social marketing — creating a unique mix of capabilities to address today's interrelated development challenges. FHI 360 serves more than 70 countries and all U.S. states and territories.

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Organization (WHO), current good manufacturing practice (cGMP), ISO, the WHO Model Quality Assurance System for Procurement Agencies, and the American Society for Testing and Materials (ASTM) International.

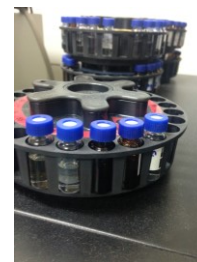
Product Quality Incident and Recall Management

PQC implements an incident management system to detect and rapidly respond to potential product quality, safety, and/or efficacy issues that may arise and to provide clients with recommendations for product disposition, remediation, and closure.

Quality Control

Our risk-based quality control strategy includes:

- Product performance evaluation through sampling, inspection, testing, and evaluation of products
- Establishing sampling and testing schemes
- Developing standardized testing protocols
- Coordinating interlaboratory proficiency trials, including an annual male condom interlaboratory trial with participating laboratories in government, commercial, manufacturing, and regulatory sectors



Product Analytical Research and Innovation

Our technical experts identify and develop innovative quality control methods and technologies that are more accurate, more efficient, and lower cost. These may be laboratory-based or for use in the field to identify substandard and falsified products.

Technical Assistance

As a leader in quality assurance, we offer technical assistance to donors, collaborating agencies, commercial clients, and other relevant stakeholders around the world to strengthen regulatory functions of health systems and increase access to quality-assured medical products in low- and middle-income countries.

TECHNICAL LEADERSHIP

PQC has been a trusted QA provider for **USAID** for more than 30 years and we have a long history of collaborative relationships with global QA stakeholders such as the **WHO, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the United Nations Population Fund** to ensure and improve product quality for all beneficiaries. We regularly participate in standards and industry meetings, global conferences, and multilateral meetings with international agencies, regulatory bodies, and standard-setting organizations. We are a member of **ISO** and **ASTM International** and we work with industry leaders to continue to develop internationally recognized product and test standards. PQC is also a member of the **African Medicines Regulatory Harmonization Partnership Platform** to support regulatory harmonization with Africa and the global QA community.

ⁱ FHI 360's North Carolina laboratory is American Association for Laboratory Accreditation (A2LA) accredited to ISO/IEC 17025 per certificate number 0367.01. The Bangkok laboratory is accredited to ISO/IEC 17025 by the Thailand Bureau of Laboratory Quality Standards per certificate MOPH 0621/04/0980.

PRODUCT QUALITY AND COMPLIANCE

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