

# Product Quality and Compliance (PQC)



## Quality Assurance for Health Commodities

- Antimalarial medicines
- Antiretroviral drugs
- COVID-19 vaccines
- Food by prescription
- Instrument-based diagnostics
- Intrauterine devices
- Laboratory supplies
- Long-lasting insecticidal nets
- Male and female condoms
- Microbicides
- Oral and injectable contraceptives
- Other essential and strategic medicines
- Personal protective equipment
- Rapid diagnostic test kits
- Tuberculosis preventive treatment products
- Voluntary medical male circumcision and other procedural kits

## PQC OVERVIEW

Product quality and compliance at FHI 360 ensures 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. The PQC department is certified to International Organization for Standardization (ISO) 9001 and FHI 360's laboratory in Durham, North Carolina, is accredited to ISO 17025.<sup>1</sup> We work for government agencies, multilateral organizations, nongovernmental and development organizations, and 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 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 Evaluations

PQC monitors suppliers through audits, site visits, and desk reviews to determine compliance with international quality standards, including the World Health Organization (WHO) good manufacturing practices, good storage and distribution practices, and Model Quality Assurance System for Procurement Agencies; ISO; ASTM International; and the U.S. Code of Federal Regulations.



## 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

## 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, 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.

FHI 360 is a global organization that mobilizes research, resources and relationships so people everywhere have access to the opportunities they need to lead full and healthy lives. With collaborations in over 60 countries, we work directly with local leaders to advance social and economic equity, improve health and well-being, respond to humanitarian crises and strengthen community resilience. We share data-driven insights and scalable tools that expand access and equity so communities can effectively address complex challenges, respond to shocks and achieve thriving futures.

<sup>1</sup> The product quality and compliance department is certified to ISO 9001 by BSI per certificate number FM 732783. FHI 360's North Carolina laboratory is American Association for Laboratory Accreditation (A2LA) accredited to ISO/IEC 17025 certificate number 0367.01..



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