

# Product Quality and Compliance (PQC)



## Commodity Groups

- In vitro diagnostics
- Medical devices
- Pharmaceuticals
- Vector control commodities

## Health Areas

- HIV
- Malaria
- Maternal and child health
- Nutrition
- Other infectious diseases and emerging pandemic threats
- Tuberculosis

*Please contact us to learn more about the specific commodities that we can support.*

## 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 (QA) and quality control (QC) 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

PQC's holistic quality risk management (QRM) provides the best value to clients and lowest risk to patients and end users. We use a lifecycle approach to balance the probability and severity of potential risks against the resources needed to ensure product quality. Supported by our custom database, we integrate data to inform QRM strategies and resource allocation. The database features real-time dashboards and reports with customized statistical programming and lot traceability, which is essential during critical product quality incidents.

PQC's risk-based QA program is scalable, allowing us to implement our entire program or a selection of services for clients.

### Product and Supplier Qualification

We perform preventive risk-based activities to qualify suppliers for procurement and then place eligible products in risk categories that drive risk mitigation activities to continually ensure products and suppliers meet established QA criteria. Our product and supplier qualification work includes:

- 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 evaluates and monitors manufacturers and suppliers through audits and desk reviews to determine compliance with international quality standards, including World Health Organization (WHO) good manufacturing practices, good storage and distribution practices, and Model Quality Assurance System for Procurement Agencies (MQAS); ISO; ASTM International; and the U.S. Food and Drug Administration. PQC also audits procurement service agents and other procurement entities to assess their level of compliance with MQAS.

### 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 before they impact the supply chain. We provide clients with risk-based recommendations for product disposition to avoid adverse impact to patient safety, unnecessary destruction of products, and wasted resources.

### Quality Control

We conduct independent sampling and testing of health commodities to provide objective evidence of compliance with international standards and specifications. This reduces the risk of costly product recalls, destruction of product, or stockouts. PQC also manages purchase orders to ensure procured products appear on applicable eligibility lists (and comply with the required characteristics such as approved specifications, manufacturing site, and shelf life) and provides a centralized repository for real-time order and lot traceability.

## TECHNICAL LEADERSHIP

PQC has been a trusted QA provider for the U.S. Government for more than 30 years and has a long history of collaborative relationships with global QA stakeholders such as the WHO, the Global Fund, and United Nations agencies to ensure and improve product quality. We 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 provides training or technical assistance to strengthen regulatory functions of health systems. We can also develop organizational capacity to independently perform QA and QC functions. In addition, PQC provides technical guidance to stakeholders on risk-based strategies and QA and QC activities.

## Product Quality and Compliance

2810 Meridian Parkway,  
Suite 160  
Durham, NC 27713 USA  
T 919.544.7040  
E [abarojas@fhi360.org](mailto:abarojas@fhi360.org)

<https://www.fhi360.org/expertise/product-quality-and-compliance>

<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.

