USAID
FROM THE AMERICAN PEOPLE

USAID TECHNICAL ASSISTANCE IN QUALITY ASSURANCE

The USAID Global Health Supply Chain – Quality Assurance Program (GHSC-QA) offers technical assistance to develop in-country quality assurance capacity.

GHSC-QA provides comprehensive product quality assurance (QA) and technical assistance to USAID procurement and distribution programs covering the different health elements in the USAID Global Health Bureau. FHI 360 is the prime contractor for GHSC-QA and the program is led by FHI 360's Product Quality and Compliance (PQC) Department, which has internationally accredited testing laboratories in Durham, North Carolina, and Bangkok, Thailand.[1] GHSC-QA works with multiple testing laboratories around the world, international sampling agents, and manages several sample retention stores.

JESSICA SCRANTON / FHI 360

TECHNICAL ASSISTANCE AND CAPACITY BUILDING

Technical assistance is an important tool that can be used to develop local infrastructure and strengthen capacity of existing country programs and systems focused on monitoring quality products in local markets. As a leader in QA with extensive knowledge and experience, GHSC-QA frequently provides guidance and training to support local capacity building and systems strengthening. GHSC-QA's technical assistance activities span the globe and locations have included Latin America and the Caribbean, Asia, and Africa. GHSC-QA provides these services for pharmaceuticals, medical devices (including in-vitro diagnostics), food by prescription, and vector control commodities.

TECHNICAL ASSISTANCE PARTNERS

GHSC-QA technical assistance supports partner country governments' efforts working with organizations in quality assurance and quality control (QC) to develop local supply chain capacity. GHSC-QA has worked with testing laboratories; academic institutions; regulatory authorities; wholesalers, suppliers, and manufacturers of health commodities; medical storage and distribution facilities; government agencies; and other QA stakeholders.

TECHNICAL ASSISTANCE APPROACH & ACTIVITIES

GHSC-QA's risk-based approach to QA and QC can serve as a mechanism for developing capacity of local supply chains in resource constrained settings. GHSC-QA provides both short-term and longer-term technical assistance which may be tailored to meet specific program or country needs. Areas of technical assistance may include:

TRAININGS AND WORKSHOPS

GHSC-QA delivers in-country trainings and workshops and hosts trainings at either of our state-of-the-art testing laboratories to share knowledge and develop competency. Attendees generally are comprised of laboratory or regulatory staff with roles in QA and QC. Training agenda and scope will be developed to address specific needs but can cover topics such as laboratory management; equipment maintenance and calibration; risk-based sampling and testing of health commodities; development of standard operating procedures (SOPs); implementation of quality management systems to comply with ISO 9001, ISO 17025 and WHO QC lab standards (pharmaceutical, including microbiological); and regulatory product assessment activities.

SUPPLIER AND DISTRIBUTOR ASSESSMENTS

Supplier and distributor assessment activities build capacity of local vendors and distributors to offer in-country partners the option to purchase product locally. GHSC-QA has experience convening in-country meetings on the requirements and process for becoming an approved USAID vendor. Customized prescreening questionnaires, on-site audits and guidance from GHSC-QA experts provide an opportunity for suppliers and distributors to identify gaps in compliance with WHO standards (cGMP, GDP, GSP) and improve the quality of health commodities offered in the local market products.

SUSTAINABLE APPROACHES

GHSC-QA implements technical assistance in-line with host country health goals and priorities. Activities are developed with a health systems perspective that allows for impact across multiple health elements. For example, GHSC-QA technical assistance to a national testing laboratory includes proficiency testing on antiretroviral (ARV) drugs and support with new testing equipment purchases. This type of activity provides essential technical knowledge to laboratory staff and empowers in-country laboratories to meet anticipated demand for in-country product and testing needs. GHSC-QA also leverages technical expertise to develop innovative QC strategies for countries with limited resources. GHSC-QA experts are experienced in implementing alternative techniques and testing strategies to use fewer resources, generate less waste, and provide faster analysis.

ADDITIONAL AREAS OF ASSISTANCE

Other technical assistance activities not noted above may be provided, such as on-site assessments to identify areas of potential improvement. GHSC-QA experts can oversee or assist in conducting investigations around product quality concerns, compliance with international quality standards, and other regulatory issues related to health commodities. GHSC-QA also manages interlaboratory proficiency trials for medical devices (including condoms) and pharmaceuticals to ensure that participating laboratories provide quality testing.

TECHNICAL ASSISTANCE

- In-country laboratory training on product testing
- On-site technical assessments
- Regulatory, compliance, and accreditation trainings
- Assessment, revision, and development of quality management systems
- Investigations and assistance around product quality concerns
- Support for technical development and capacity building
- Proficiency studies
- Supplier and distributor assessments/audits

CONTACT US

To learn more, contact Christine Malati (cmalati@usaid.gov) and Adrian Barojas (abarojas@fhi360.org).

[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.