



Quality Management Systems and External Quality Control

The Quality Management System (QMS) is a framework used to build the knowledge, skills and activities required to ensure a laboratory's culture of quality. By integrating operations, services and infrastructure, QMS facilitates the creation of systems that help laboratories meet applicable regulatory guidelines and customer requirements and promotes the continual improvement of laboratory services. ISO 15189 and 17025 accreditation require all laboratories have a designated quality officers, who must be trained and deemed competent in QMS, but it is important that all personnel are competent in their laboratory's QMS implementation.

External quality assessment (EQA) or proficiency testing (PT) panels ensure the quality and accuracy of laboratory testing by providing an external assessment of a laboratory's performance. External quality controls ensure that the laboratory is producing reliable and accurate results. Laboratories can enroll in commercially available EQA programs, though these can be limited and become expensive over time—especially as the number of tests offered increases.

The Association of Public Health Laboratories (APHL) supports public health laboratories to build and maintain their QMS. APHL also supports laboratory procurement, analysis of EQA results and provision of technical assistance to help laboratories build their own EQA programs. QMS should be implemented in any laboratory that conducts diagnostic testing and is working toward accreditation.

APHL's mission is to shape national and global health outcomes by promoting the value and contributions of public health laboratories and continuously improving the public health laboratory system and practice. A key to meeting this goal is supporting ISO15189 accreditation or other standards such as national standards in international laboratories.

SUCCESS STORY: GHANA ESTABLISHES SARS-COV-2 EQA

In an effort to manage expenditures and enhance the accessibility of EQA molecular panels in Africa, the Ghana Health Service wanted to build in-country capacity to create EQA/PT panels for SARS-CoV-2 molecular testing. The National Public Health and Reference Laboratory (NPHRL) collaborated with APHL to build SARS-CoV-2 molecular diagnostic EQA panels.

APHL technical expertise assisted in establishing the laboratory space, procuring reagents and equipment, EQA training creation, validation and distribution, and the QMS surrounding PT Panels.

APHL worked with the Noguchi National Influenza Center to procure the heat-inactivated SARS-CoV-2 virus and human cell line, establishing an in-country source for these essential components.

NPHRL received hands-on training from an APHL consultant to build the molecular SARS-CoV-2 PT panels and successfully piloted them in twenty laboratories in September 2023. NPHRL also collaborated with the African Society of Laboratory Medicine, US Centers for Disease Control and Prevention, and Ghana Health Service's Policy, Planning, Monitoring and Evaluation Division to implement an electronic PT (ePT) data management system to digitally capture all EQA data for molecular SARS-CoV-2 diagnostic testing and future diagnostic tests in Ghana.

Photo at right: Training participant builds a PT panel.

APHL Supports Building Quality Laboratory Systems

APHL offers a comprehensive set of tools to facilitate laboratory accreditation and maintenance of quality systems.

QMS Training

It is a requirement of ISO 15189 and 17025 that all laboratories have designated quality officers who are trained and deemed competent in QMS. APHL has created a QMS course to support laboratories in reaching ISO 15189 or 17025 accreditation. This course focuses on the 12 essential elements of an effective and sustainable QMS and provides resources for implementation. The course is a five-day, in-person training with a follow-up at three months.

QMS Training of Trainers

Quality officers must proficiently train colleagues to ensure a successful laboratory quality program, so having a robust grasp of QMS and adept teaching tools and skills are vital. The QMS Training of Trainers (ToT) course ensures that quality officers master QMS basics, acquire effective teaching skills and practice in a secure environment receiving, real-time feedback from facilitators and peers. The course builds local trainers' capacity to educate laboratory personnel.

QMS Mentorship Program

APHL's QMS Mentorship Program is an essential tool for laboratories to build successful quality programs. APHL QMS Mentors collaborate with laboratories to identify issues, gaps and training requirements, and create and implement action plans to address these needs. These mentors work with the laboratory and help implement requirements and provide guidance and accountability to enable the laboratory to build a quality program.

EQA Panel Development and Distribution

APHL expertly facilitates EQA through tailored testing schemes, panel procurement and implementation of electronic databases for the result submission. APHL provides training to enable in-country laboratories to develop, standardize, validate, verify and implement EQA panels and support accreditation for ISO 17043.

