

## **ACCLASS Surveillance Audit: Product Quality and Assessment Directorate**

Addis Ababa, Ethiopia  
November 12-15, 2012

---

### ***Trip Report***

**Regina Okafor, MBA**  
**Program Manager, Africa**

**Donnell Charles, Ph.D.**  
**Manager/, Laboratory Quality Management Services**

### **Promoting the Quality of Medicines**

Implemented by U.S. Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852 USA  
Tel: (+1) 301-230-3240  
Email: [pqm@usp.org](mailto:pqm@usp.org) and [dxc@usp.org](mailto:dxc@usp.org)

**Cooperative Agreement #** GHS-A-00-09-00003-00  
**Funding Source:** USAID/Ethiopia – PEPFAR Program  
**Grantee:** Promoting the Quality of Medicines (PQM) Program  
**Author(s) Name:** Regina Okafor and Donnell Charles  
**Language:** English  
**Date of Publication:** January 3, 2013



This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00. The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID or the United States Government.

## **Executive Summary**

The objective of this trip was for ACLASS, an internationally recognized accrediting body, to conduct a surveillance assessment of the Quality Management System (QMS) of the Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, Health Administration and Control Authority (FMHACA). The purpose of the surveillance assessment by ACLASS is to sample PQAD's organizational management and technical system to ensure it is maintained and remains effective following initial accreditation that occurred in 2011.

PQM arrived before the ACLASS assessment to review PQAD's QMS and evaluate the corrective actions and preventative actions initiated as a result of last year's ACLASS accreditation assessment. PQM provided assistance with the nonconformities identified during the visit, including suggested corrective action(s) and how to remediate any nonconformity observed.

Upon completion of the ACLASS surveillance audit, there were three findings and four opportunities for improvement. ACLASS recommended PQAD for maintaining its ISO 17025 accreditation, provided that the findings are corrected to ACLASS' satisfaction within thirty days. PQM will work with PQAD on implementing effective corrective actions to remediate the findings.

## TABLE OF CONTENTS

<b><u>Acknowledgements</u></b> .....	4
<b><u>Acronyms</u></b> .....	5
<b><u>Background</u></b> .....	6
<b><u>Purpose of Trip</u></b> .....	6
<b><u>Source of Funding</u></b> .....	6
<b><u>Overview of Activities</u></b> .....	6
<b><u>Annex 1: Agenda</u></b> .....	8
<b><u>Annex 2: Lists of Participants</u></b> .....	10
<b><u>Annex 3: ACLASS Assessment Report</u></b> .....	12
<b><u>Annex 4: Details of Other Meetings</u></b> .....	14

### **About PQM**

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

## **ACKNOWLEDGEMENTS**

The authors would like to thank:

- PQAD staff for their high level of interest and feedback
- Ms. Elina Sverdlova, USAID/Ethiopia, for her support of this program
- Mr. Yehulu Alamneh, FMHACA Director General, and Mr. Bikila Bayissa, Director of PQAD, for their support and assistance during this evaluation
- Mrs. Tessie Gamber, QMS Assessor from ACLASS, for her support and assistance during this reassessment
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

## ACRONYMS

ACCLASS	ANSI-ASQ National Accreditation Board
CAPA	Corrective and Preventative Action
DQI	Drug Quality and Information Program
FMHACA	Food, Medicine, Health Administration and Control Authority
FY	Fiscal Year
GDP	Good Documentation Practices
GLP	Good Laboratory Practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HPLC	High Performance Liquid Chromatography
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KF	Karl Fischer
LOD	Loss on Drying
OFI	Opportunity for Improvements
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malarial Initiative
PQAD	Product Quality Assessment Directorate
PQM	The Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
TA	Technical Assistance
UDU	Uniformity of Dosage Unit
USAID	United States Agency for International Development
USP	United States Pharmacopeia
UV	Ultraviolet Absorption
WHO	World Health Organization

## Background

In 2010, PQM received funding from the President's Emergency Plan for AIDS Relief (PEPFAR) through USAID/Ethiopia to strengthen the Ethiopian Food, Medicine, Health Administration and Control Authority (FMHACA)'s capacity. A critical component of PQM's technical assistance (TA) has been to strengthen the Product Quality Assessment Directorate (PQAD) lab's compliance with international quality management system (QMS) standards. PQAD's ultimate goal is to obtain ISO/IEC 17025:2005 accreditation and subsequently be incorporated into the list of World Health Organization (WHO) Prequalified (PQ) medicine quality control (QC) laboratories.

In November 2011, PQAD obtained ISO/IEC 17025:2005 accreditation on seven tests in the physic-chemical department, which includes about 70-80% of their testing. These tests include High Performance Liquid Chromatography (HPLC), pH, Ultraviolet Absorption (UV), Dissolution, Karl Fischer (KF) titration, Loss on Drying (LOD), and Uniformity of Dosage Unit (UDU). PQM continues to work with PQAD in maintaining its accreditation status, expanding their scope of accreditation to include other tests, and obtaining WHO PQ.

## Purpose of Trip

The primary objective of the trip was to accompany ACLASS to conduct a surveillance assessment. PQM arrived a few days before ACLASS to help PQAD prepare for the assessment. Secondary objectives include discussing the progress of PQAD's move from the old facility to the new facility and discussing the future expansion of the scope of accreditation to include additional tests or possibly other departments.

## Source of Funding

These activities were funded by PEPFAR through USAID/Ethiopia.

## Overview of Activities

The goal for PQAD is to maintain their ISO/IEC 17025:2005 accreditation status as a testing QC laboratory, and in the future, expand its scope of accreditation to include additional tests and departments like microbiology, toxicology, and condom testing. Maintaining its accreditation status ensures that PQAD continues to demonstrate proficiency in the accredited tests and maintains its competitive edge and recognition internationally.

Item	Description
Institution Evaluated	Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, Health Administration and Control Authority (FMHACA)
Specific Objectives	ACLASS will perform surveillance ISO 17025 assessment of PQAD to sample PQAD's organizational management and technical system to ensure it is maintained and remains effective following initial accreditation that occurred in 2011.
ACLASS Assessor	Tessie Gamber
Agenda	See <i>Annex 1</i> for a detailed agenda
Key Personnel	See <i>Annex 2</i> for list of participants
Areas Evaluated	See <i>Annex 3</i> for the ACLASS report of the assessment

Key Findings	<ul style="list-style-type: none"> <li>• PQAD has made significant progress in implementing and maintaining a QMS that is compliant with ISO/IEC 17025:2005. Nonetheless, the evaluation did identify nonconformities with ISO/IEC 17025:2005</li> <li>• ACLASS assessment identified 3 nonconformities and four opportunities for improvement (OFIs): <ul style="list-style-type: none"> <li>○ 1 Major finding</li> <li>○ 2 Minor findings</li> <li>○ 4 OFIs</li> </ul> </li> </ul>
Conclusion	<ul style="list-style-type: none"> <li>• There were 3 nonconformities and 4 OFIs identified during the ACLASS surveillance audit. ACLASS has recommended PQAD for maintenance of its ISO 17025 accreditation provided that the 3 major and minor findings are corrected to ACLASS' satisfaction within 30 days.</li> </ul>
Next Steps	<ul style="list-style-type: none"> <li>• PQM will assist PQAD in completing any issues that have been identified during the ACLASS audit</li> <li>• PQAD will complete all Corrective Action Responses (CARs) and maintain its ISO 17025 accreditation from ACLASS (by December 2012)</li> <li>• PQM will assist PQAD to plan for scope expansion to include additional tests in the physic-chemical department and to evaluate the toxicology, microbiology, and condom testing for ISO 17025 accreditation and also WHO prequalification</li> </ul>

**PQM Recommendations**

- To comply with ISO standards, upper management at FMHACA and PQAD should place top priority on lab staff training and compliance with internal QMS documents.
- PQAD should undergo a reassessment visit (full scope audit) by ACLASS for the new building in November 2013.
  - PQM strongly recommends activities impacting the new building be completed prior to July 2013. This requires full commitment from FMHACA.



Mrs. Tess of ACLASS observes demonstration sample of PQAD scope of accreditation

For details of additional meetings with partners see *Annex 4*.

**PQM Quality Management System (QMS) Evaluation Overview & Agenda:**

Product Quality Assessment Directorate (PQAD) of the Ethiopian  
Food, Medicine, Health Administration and Control Authority (FMHACA)

Addis Ababa, Ethiopia

November 12 – November 15, 2012

<b>Date 12 NOV 12</b>	<b>DAY 1-Morning Activity</b>	<b>Responsible</b>
<b>08:30-10:00</b>	<ul style="list-style-type: none"> <li>● Introduction of Participants</li> <li>● Presentation of the agenda/objective of the visit</li> </ul>	PQAD representative USP/PQM representative
<b>10:00-12:00</b>	<ul style="list-style-type: none"> <li>● PQM pre-reassessment activities               <ul style="list-style-type: none"> <li>● Status of Quality Manual and System                   <ul style="list-style-type: none"> <li>○ Discuss any changes since the last visit. Present a copy of your quality manual if there have been any changes.</li> </ul> </li> <li>● Review of any changes to the accreditation scope including uncertainty budgets.</li> <li>● Review of closure/implementation of prior non-conformities.                   <ul style="list-style-type: none"> <li>○ Please present each finding, its solution, and evidence of closure. Solutions will be verified.</li> <li>○ Review of prior OFI</li> </ul> </li> <li>● Use of ACLASS logo                   <ul style="list-style-type: none"> <li>○ Present representative samples of your use of the logo.</li> </ul> </li> <li>● Management &amp; Organization (4.1)</li> </ul> </li> </ul>	PQAD representative USP/PQM representative
<b>12:00-13:00</b>	<b>Lunch &amp; Break</b>	<b>All</b>
<b>13:00-17:00</b>	<ul style="list-style-type: none"> <li>● PQM pre-reassessment activities               <ul style="list-style-type: none"> <li>● Document Control (4.3)                   <ul style="list-style-type: none"> <li>○ <u>Master List (External Document Control)</u></li> <li>○ <u>Distribution location</u></li> </ul> </li> <li>● Complaints (4.8)</li> <li>● Corrective and Preventative Action (4.11)</li> <li>● Internal Audits (4.14)</li> <li>● Management Review (4.15)</li> <li>● Accommodation &amp; Environment (5.3)</li> </ul> </li> </ul>	PQAD representative USP/PQM representative
<b>Date 13 NOV 12</b>	<b>DAY 2-Morning Activity</b>	<b>Responsible</b>

08:30-12:00	<ul style="list-style-type: none"> <li>• PQM pre-reassessment activities</li> <li>• Accommodation &amp; Environment (5.3)</li> <li>• Calibration and test methods &amp; method validation (5.4)</li> <li>• Equipment (5.5) <ul style="list-style-type: none"> <li>○ <u>Software Master ( List of all software used pertaining to your ISO accreditation)</u></li> </ul> </li> <li>• Handling of calibration and test items (5.8)</li> </ul>	PQAD representative USP/PQM representative
12:00-13:00	<b>Lunch &amp; Break</b>	<b>All</b>
13:00-15:00	<ul style="list-style-type: none"> <li>• PQM pre-reassessment activities</li> <li>• Assuring quality of calibration and test results (5.9)</li> <li>• Reporting the results (5.10) <ul style="list-style-type: none"> <li>○ <u>Trending Controls</u></li> </ul> </li> <li>• Review of scope</li> <li>• Review of all Proficiency Testing Activities and four-year plan</li> </ul>	PQAD representative USP/PQM representative
15:00-18:00	<ul style="list-style-type: none"> <li>• Laboratory Inspection/Walkthrough</li> <li>• On-site Equipment Review</li> <li>• Accommodation &amp; Environment (5.3)</li> </ul>	PQAD representative USP/PQM representative
<b>Date 14NOV 12</b>	<b>DAY 3-Morning Activity</b>	<b>Responsible</b>
08:30-12:00	<ul style="list-style-type: none"> <li>• ACLASS Assessor Audit</li> </ul>	ACCLASS USP/PQM representative PQAD representative
12:00-13:00	<b>Lunch &amp; Break</b>	<b>All</b>
13:00-18:00	<ul style="list-style-type: none"> <li>• ACLASS Assessor Audit</li> <li>• New Facility Walkthrough (TBD)</li> </ul>	ACCLASS USP/PQM representative PQAD representative
<b>Date 15NOV 12</b>	<b>DAY 4-Morning Activity</b>	<b>Responsible</b>
08:30-10:00	<p>Wrap up and closing meeting</p> <ul style="list-style-type: none"> <li>• ACLASS discussion of all Deficiencies and OFI's found during Reassessment</li> <li>• Review of all Deficiencies and OFI's found during Reassessment</li> </ul>	ACCLASS USP/PQM representative PQAD representative
10:00-12:00	<ul style="list-style-type: none"> <li>• Meeting with FMHACA</li> </ul>	PQM representative PQAD representative FMHACA representative (if applicable)
12:00-13:00	<b>Lunch &amp; Break</b>	<b>All</b>

**PQM Trip: Lists of Participants**

Addis Ababa, Ethiopia

November 12 – November 15, 2012

**November 12, 2012 – Opening Meeting with PQAD Management and PQM Review**

<b>Participant</b>	<b>Institution</b>
Regina Okafor	PQM
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Bikila Bayissa	PQAD

**November 13, 2012 – PQAD QMS Document Review**

<b>Participant</b>	<b>Institution</b>
Regina Okafor	PQM
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Bikila Bayissa	PQAD
Getachew Genete Gebeyeh	PQAD

**November 14, 2012 – ACLASS Assessment Opening Meeting**

<b>Participant</b>	<b>Institution</b>
Tessie A. Gamber	ACLASS
Regina Okafor	PQM
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Bikila Bayissa	PQAD
Dintineh Abeb	PQAD
Getachew Genete Gebeyeh	PQAD
Seyoum Wolde	PQAD

**November 14, 2012 – PQAD Staff conducting Demonstration**

<b>Participant</b>	<b>Institution</b>	<b>Method</b>
Lanitider Kessaye	PQAD	pH
Lanitider Kessaye	PQAD	HPLC
Getachew Genete Gebeyeh	PQAD	HPLC
Kemal Hussein	PQAD	KF

**November 15, 2012 – Closing Meeting with ACLASS and PQAD**

<b>Participant</b>	<b>Institution</b>
Tessie A. Gamber	ACLASS
Regina Okafor	PQM
Donnell Charles	PQM
Zelalem Mamo	PQM

Awot Gebre-Egziabher	PQAD
Bikila Bayissa	PQAD
Dintineh Abeb	PQAD
Getachew Genete Gebeyeh	PQAD
Seyoum Wolde	PQAD

**November 15, 2012 – PQM and FMHACA Meeting**

Yehulu Alamneh	FMHACA
Mengistab Woldearegay	FMHACA
Sefanit Gebreab	FMHACA
Bikila Bayissa	PQAD
Regina Okafor	PQM
Eshetu Wondemagegnehu	PQM
Zelalem Mamo	PQM
Teferi Bedane	PQM

**ACLASS Assessment Report:**  
Addis Ababa, Ethiopia  
November 12 – November 15, 2012

**NC # 1 Detail**

NCR #	Type of Finding	NCR Status	Customer	City	Standard	Standard Clause	Assessment Type	Assessor
TAG-SA-12-1	Minor	Issued	Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, & Health Care Administration and Control Authority (FMHACA)	Addis Ababa	ISO/IEC 17025	4.3.2.1Q2	<b>SA</b>	Tessie A Gamber

**Statement of Nonconformance (Description of Finding)**

The standard requires the master list to contain all of the documents in the laboratory's management system. The master list of documents reviewed at the time of the assessment does not include external documents such as ISO 17025, ACLASS related documents and references.

**NC #2 Detail**

NCR #	Type of Finding	NCR Status	Customer	City	Standard	Standard Clause	Assessment Type	Assessor
TAG-SA-12-2	Minor	Issued	Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, & Health Care Administration and Control Authority (FMHACA)	Addis Ababa	ISO/IEC 17025	5.5.2Q3	<b>SA</b>	Tessie A Gamber

**Statement of Nonconformance (Description of Finding)**

The standard requires before being placed into service, the equipment is calibrated to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. While records of pH meter verification were available, the laboratory was not able to provide records of calibration of the pH meter including the slope and acceptable limits.

**NC #3 Detail**

NCR #	Type of Finding	NCR Status	Customer	City	Standard	Standard Clause	Assessment Type	Assessor
TAG-SA-12-3	Major	Issued	Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, & Health Care Administration and Control Authority (FMHACA)	Addis Ababa	ISO/IEC 17025	5.6.3.2Q1	<b>SA</b>	Tessie A Gamber

Statement of Nonconformance (Description of Finding)
The standard requires reference materials, where possible, traceable to SI units of measurement, or to certified reference materials. No certificate or uncertainties were available for the current pH standard solutions used by the laboratory. (Repeat deficiency). Note: Per discussion with laboratory staff, the laboratory placed an order for pH standards from a Guide 34 accredited provider about a year ago but has not received the standards.

**Opportunities for Improvements – OFI**

Clause	Section Name	OFI Comments	Assessor Comments
4.3.2.2d	Obsolete retention	Ensure that obsolete SOPs (old revisions) are promptly removed from all points of issue or use.	
5.9.1Q1	Procedure	Clearly include in the quality control procedures the laboratory's requirement for QC samples for quantitative test methods including frequency and acceptable limits.	
5.10.2f	Item description	Clearly include on the test report the condition of the sample being tested.	
5.11 A.17Q2	Within scope only	Clearly include in the QAM the ACLASS requirement when ACLASS symbol is being used on test report to ensure the ACLASS symbol is not used in misleading manner.	

**Opening Meeting and Review with PQAD Management:**

November 12-13, 2012

Participants: See *Annex 2* for a complete list of participants

PQM met with the director and QA manager of PQAD to discuss the status of QMS compliance and the objectives and expectations of the surveillance audit. The following are the main outcomes of the meeting:

- PQM evaluated PQAD's QMS status by first reviewing the corrective and preventive actions (CAPAs) relating to all the findings from the ACLASS accreditation audit from September 2011
- In conducting document review, PQM was able to identify some nonconformities that required opening corrective actions to remediate before the ACLASS audit.
- PQM and PQAD worked together to close any open CAPAs relating to findings from ACLASS and that could potentially result in additional findings



**Closing Meeting with ACLASS Management**

November 15, 2012

Participants: See *Annex 2* for a complete list of participants.

ACLASS met with the PQM team and PQAD management to discuss the trip findings, recommendations, and next steps. The following are the main outcomes of the meeting:

- ACLASS stated that the assessment audit was successful.
- ACLASS recommends that PQAD maintain its ISO 17025 accreditation of the seven tests, provided that the following are completed within thirty days:
  - Respond to findings on Enterprise Quality Manager (EQM) database and create Corrective Action Responses (CARs) by submitting evidence and providing good root cause analysis
- ACLASS also notified PQM and PQAD that the assessment audit report will officially be posted on the EQM database.

PQM met with PQAD management to discuss the following:

- PQM noted the progress made by the lab since accreditation in November 2011 in maintaining a good QMS; however, significant nonconformities exist and there are many opportunities for improvement.
- PQM also reiterated that staff training and development is important for future staff retention and maintaining accreditation.
- PQM noted that there is a need to have the following due to the amount of new staff observed since the last visit in September 2011:
  - CAPA Training
  - ISO 17025 Element Training
  - QMS Auditor Training
  - Root Cause Analysis Training
    - 5 Why Development
    - Follow-up Actions



### **Next Steps**

- PQM will assist PQAD in completing and submitting the corrective actions and objective evidence in response to the ACLASS findings by December 2012
- PQM will continue to work with FMHACA to ensure all repairs and upgrades to the new building are completed by May-June 2013
- PQM will continue to work with PQAD in new staff training to close any gaps noticed between new (untrained) staff and current (trained) staff
- PQM will assist PQAD management to determine additional tests for scope expansion for the next ACLASS assessment
- PQM will help prepare PQAD for scope expansion based on tests identified (writing Standard Operating Procedures and staff training in proficiency of tests identified)