

ACCLASS Reassessment Audit: Product Quality and Assessment Directorate

Addis Ababa, Ethiopia
September 30- October 4, 2013

Trip Report

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PROMOTING THE QUALITY OF MEDICINES

Executive Summary

The objective of this trip was for ACLASS, an internationally recognized accrediting body, to conduct a reassessment of the Quality Management System (QMS) of the Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, and Health Administration and Control Authority (FMHACA). The purpose of the reassessment by ACLASS is to sample PQAD's organizational management and technical system to ensure it is maintained and remains effective following initial accreditation (2011) and following the recent laboratory move (2013).

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

Upon completion of the ACLASS reaccreditation audit, there were eight minor findings and five opportunities for improvement. ACLASS recommended PQAD for maintaining its ISO 17025 accreditation provided the findings are corrected to ACLASS' satisfaction within thirty days. PQM will continue to work with PQAD on implementing effective corrective actions to remediate the findings. A detailed report of the audit has been sent to the PQAD management.

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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.

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- Mr. Yehulu Alamneh, FMHACA Director General; Mr. Dawit Dikaso, FMHACA Deputy Director General; Mr. Megistab Aregay, FMHACA Deputy Director; and Mr. Kemal Hussien, Acting Deputy Laboratory 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

AClass	ANSI-ASQ National Accreditation Board
CAPA	Corrective and Preventative Action
DQI	Drug Quality and Information Program
FMHACA	Food, Medicine, and 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
RA	Reaccreditation
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, and 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.

In November 2011, PQAD obtained ISO/IEC 17025:2005 accreditation for 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 and expanding their scope of accreditation to include other tests. PQAD would also like to be incorporated into the list of World Health Organization (WHO) Prequalified (PQ) medicine quality control (QC) laboratories.

In November 2012, ACLASS conducted a surveillance assessment of the Quality Management System (QMS) of PQAD. The purpose of the surveillance assessment by ACLASS was to sample PQAD’s organizational management and technical system to ensure it is maintained and remains effective following initial accreditation. In April 2013, PQAD moved to their new site. PQM traveled to Ethiopia in July 2013 to ensure that the lab would be ready for the reaccreditation assessment to be conducted by ACLASS.

Purpose of Trip

The primary objectives of the trip were to help PQAD prepare for the ACLASS reaccreditation assessment and accompany ACLASS during the assessment. Secondary objectives included 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, and Health Administration and Control Authority (FMHACA)
Specific Objectives	ACCLASS performed a reaccreditation ISO 17025 assessment of PQAD to sample PQAD’s organizational management and technical system to ensure it is maintained and remains effective following previous surveillance and the physical laboratory move that occurred in 2013.

ACLASS Assessor	Mrs. Tessie Gamber
Agenda	See Annex 1 for a detailed agenda
Key Personnel	See Annex 2 for list of participants
Areas Evaluated	The ACLASS report of the assessment will be sent to FMHACA.
Key Findings	<ul style="list-style-type: none"> • PQAD has made significant progress in moving, implementing and maintaining a QMS that is compliant with ISO 17025:2005. Nonetheless, the evaluation did identify nonconformities with ISO/IEC 17025:2005. • The ACLASS assessment identified eight minor nonconformities and five opportunities for improvement (OFIs).
Conclusion	<ul style="list-style-type: none"> • ACLASS has recommended PQAD for maintenance of its ISO 17025:2005 accreditation provided that the findings are corrected to ACLASS' satisfaction within 30 days.
Next Steps	<ul style="list-style-type: none"> • PQM will assist PQAD in remediating the issues that have been identified • PQAD will complete all Corrective Action Responses (CARs) and submit the responses to ACLASS. (by November 2013) • PQM will assist PQAD to plan for scope expansion to include additional tests in the physic-chemical department and to evaluate condom testing for ISO 17025:2005 accreditation.

PQM Recommendations

- To comply with ISO standards, upper management at FMHACA and PQAD should place top priority on quality training and compliance with internal QMS documents.
- PQAD should undergo a surveillance visit (scope audit and expansion) by ACLASS by November 2014.
 - PQM strongly recommends any additional activities impacting the new building be completed prior to August 2014. This requires full commitment from FMHACA.

For details of additional meetings with partners see [Annex 3](#).



Mrs. Gamber of ACLASS observes data and method demonstrations of PQAD scope of accreditation



ACLASS 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

Time/Date	Activity	Assessor
Tue/Oct 1	Day 1	
0830 am 0845	Arrival, Opening meeting; introductions, purpose of assessment, audit agenda reviewed, accuracy of application information confirmed	TAG
0845	Tour of Laboratory	TAG
0900	Review Management Requirements (ISO/IEC 17025, sec 4)	TAG
1230 pm	Lunch	
0100	Review Technical Requirements (ISO/IEC 17025 sec 5)	TAG
0430 pm	Daily Wrap Up	
Wed /Oct 2	Day 2	
0830 am 0845	Arrival Sample Login Observe/Review of methods: Chromatography HPLC, Dissolution, Uniformity of Dosage Units Staff Interviews/Records Review	TAG
1200	Lunch	
1230 pm	Observe/Review of methods: Spectrophotometry, pH, LOD, KF Staff Interviews/Records Review	TAG
0430 pm	Daily Wrap Up	
Thur/Oct 3	Day 3	
0830 am	Arrival	
0845	Complete observation of remaining test methods if necessary and wrap up any loose ends Review previous deficiency Review data packages and PT results /Complete Open Assessment Issues	TAG
1200	Lunch	
1230 pm	Completion of final reports Assemble, Review & Edit Report	TAG
4:00	Final exit briefing, copy and distribute reports	TAG
5:00 pm	Depart	



PQM Trip: Lists of Participants

Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, Health Administration and Control Authority (FMHACA)
Addis Ababa, Ethiopia — September 30-October 4, 2013

September 30, 2013–Meeting with PQAD Management and PQM Review

Participant	Institution
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Kemal Hussien	PQAD

September 30, 2013– PQAD QMS Document Review

Participant	Institution
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD

October 1, 2013 – ACLASS Assessment Opening Meeting

Participant(s)	Institution
Tessie A. Gamber	ACLASS
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Kemal Hussien	PQAD
Solomon Gethachew	PQAD
Dawit Dikaso	FMHACA

October 2, 2013 – PQAD Staff conducting Demonstration

Participant(s)	Institution	Method
Lanitider Kessaye	PQAD	KF
Lanitider Kessaye	PQAD	LOD
Terferi Mantegaftot	PQAD	HPLC
Terferi Mantegaftot	PQAD	Content Uniformity
Terferi Mantegaftot	PQAD	pH
Seyoum Wolde	PQAD	UV
Seyoum Wolde	PQAD	Dissolution
Merkebu Aytenfsu	PQAD	Sample Receipt

October 3, 2013 – Closing Meeting with ACLASS and PQAD

Participant(s)	Institution
Tessie A. Gamber	ACLASS
Donnell Charles	PQM
Zelalem Mamo	PQM
Awot Gebre-Egziabher	PQAD
Kemal Hussien	PQAD
Megistab Aregay	FMHACA

October 4, 2012 – PQM and FMHACA Meeting

Participant(s)	Institution
Yehulu Alamneh	FMHACA
Kemal Hussien	PQAD
Eshetu Wondemagegnehu	PQM
Zelalem Mamo	PQM
Donnell Charles	PQM

ACCLASS Reassessment Audit

Product Quality Assessment Directorate (PQAD) of the Ethiopian
Food, Medicine, Health Administration and Control Authority (FMHACA)
Addis Ababa, Ethiopia — September 30-October 4, 2013

Review with PQAD QMS Management:

September 30, 2013

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 actions and preventive actions (CAPAs) relating to all the findings from the ACLASS accreditation audit from September 2013.
- In conducting the 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 open additional CAPAs relating to findings.

Closing Meeting with ACLASS Management

October, 4, 2013

Participants: See [Annex 2](#) for a complete list of participants.

ACCLASS met with PQM 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.



Mrs. Gamber of ACLASS at the closing meeting of PQAD reaccreditation visit

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 conduct the following due to the number of observations since the previous surveillance:
 - CAPA Training
 - ISO 17025 Element Training

Closing Meeting with FMHACA Management

October, 4, 2013

Participants: See [Annex 2](#) for a complete list of participants

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

- FMHACA Director General Yehulu supported the accreditation program and ensured further support during the condom testing and microbiological expansion.
- FMHACA will be reviewing staff compensation and staff retention issues to reduce the loss of staff, especially in light of future laboratory expansion.
- A permanent Deputy QA Manager will be put in place by FMHACA before the end of the year.
- PQM will be providing a timeline and technical support for a seamless transition of the old accreditation to the new accreditation.

Next Steps

- PQM will assist PQAD in completing and submitting the corrective actions and objective evidence in response to the ACLASS findings by November 2013.
- The immediate assignment of a working Deputy Quality Assurance Manager to support the current manager is recommended.
- A Document Control Specialist to support the administrative area of Quality Assurance department should be assigned in the future.
- PQM will continue to support PQAD staff with training and identify any additional gaps.
- PQM will assist PQAD management to determine additional tests for scope expansion.
- PQM will help prepare PQAD for scope expansion based on tests identified (writing Standard Operating Procedures and staff training in proficiency of tests identified)
- FMHACA and PQAD should schedule the next surveillance audit at the new location for October of 2014.