

## Product Quality and Assessment Directorate: ISO 17025 Reassessment Workshop

Addis Ababa, Ethiopia  
July 29 - August 2, 2013

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### *Trip Report*

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

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## **Executive Summary**

As a component of assisting the Product Quality and Assessment Directorate (PQAD) in obtaining ISO 17025 accreditation,, PQM traveled to Ethiopia prior to the reassessment visit by ACLASS in October, for the following reasons:

- Ensure ACLASS findings (from 2012 surveillance visit) have been adequately resolved
- Ensure adequate follow-up has been performed regarding PQM recommendations on the corrective actions (from November 2012 ACLASS surveillance audit)
- Deliver training for selected tests from the scope of accreditation to new PQAD staff
- Ensure the new Karl Fischer was installed correctly and staff trained on the use of the equipment
- Ensure that PQAD's physic-chemical lab will be ready and meets all ISO 17025 Standard environmental condition requirements before the ACLASS reassessment in October 2013
- Evaluate PQAD QMS since the move to the new site

ACLASS provided PQM and PQAD with details of the findings from the surveillance audit in November 2012. Since PQAD successfully corrected all the findings from the surveillance audit, PQM would like to ensure that any opportunity for improvement (OFI) findings were appropriately addressed and corrected based on PQM's recommendation. Additionally, PQM will work with PQAD on implementing effective corrective actions to mitigate these findings and ensure that the lab is ready for the upcoming reassessment. As a secondary objective PQM will conduct a training workshop pertinent to the scope of accreditation for junior and new staff in preparation of the reassessment visit from ACLASS

The next step for PQAD will be to prepare for the reassessment audit by ACLASS in October 2013.

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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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- Yehulu Alamneh, FMHACA Director General, Mengistab Aregay, FMHACA Deputy Director General, and Bikila Bayissa, Director of PQAD, for their support and assistance during this visit.
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.
- Anthony Boni and Maria Miralles at USAID/Washington for their support and advice.

## ACRONYMS

CAPA	Corrective and Preventative Action
DQI	Drug Quality and Information Program
FMHACA	Food, Medicine, Health Administration and Control Authority
GDP	Good Documentation practices
GLP	Good Laboratory Practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HPLC	High Pressure Liquid Chromatography
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KF	Karl Fisher Titration
LOD	Loss on Drying
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQAD	Product Quality Assessment Directorate
PQ	Prequalification
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
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) program through USAID/Ethiopia to strengthen the 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. The ultimate goal for PQAD is to obtain ISO/IEC 17025:2005 accreditation and subsequently be incorporated in the list of World Health Organization (WHO) Prequalified (PQ) medicine quality control (QC) laboratories. In November 2011 PQAD obtained ISO 17025 accreditation for seven tests and has maintained the accreditation status on those seven tests. PQM continues to work with PQAD to subsequently expand its scope of accreditation by adding additional tests and to be included on the list of WHO PQ medicine quality control labs.

## Purpose of Trip

The primary objective of the trip was for PQM to evaluate the new PQAD physic-chemical laboratory in preparation for ACLASS reassessment that will take place in October 2013. PQM wanted to ensure that adequate follow-up has been performed on any QMS-related corrective actions stemming from the surveillance audit in November 2012 and subsequent corrective actions. Additionally, PQM wanted to ensure that the new staff of PQAD was trained properly, especially in relation to the tests involved in their scope of accreditation.

## Source of Funding

These activities were funded by USAID/Ethiopia, PEPFAR program.

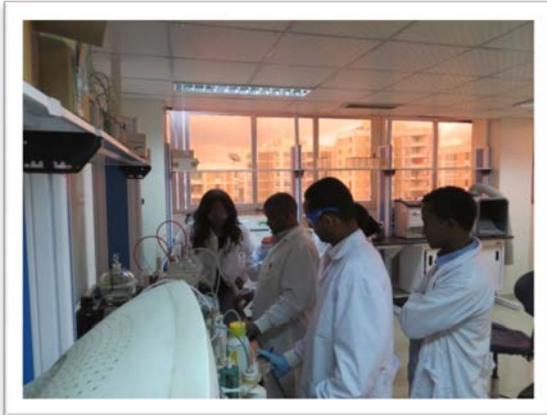
## Overview of Activities

The goal for PQAD is to maintain ISO/IEC 17025:2005 accreditation and, at a later stage, be incorporated in the list of WHO PQ medicine QC laboratories. Maintaining good working conditions that conform to these stringent standards will assure that the administrative and technical operations of the laboratory continue to function at the highest internationally recognized standards and will provide Ethiopia’s Ministry of Health with a QC laboratory capable of producing accurate and valid results.

For details of other meetings with partners during this time, see *Annex 1*.

Item	Description
Institution Evaluated	Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine, Health Administration and Control Authority (FMHACA)
Specific Objectives	<ul style="list-style-type: none"><li>• Ensure ACLASS findings/observations have been adequately resolved</li><li>• Ensure the environmental conditions at the new site meet standard requirements and that all applicable standard operating procedures (SOPs), records, and corrective actions are in place</li><li>• Deliver training for selected tests from the scope of accreditation</li><li>• PQM will help PQAD address all pending issues before the ACLASS reassessment</li></ul>
Key Personnel	<ul style="list-style-type: none"><li>• See <i>Annex 2</i> for the list of participants</li></ul>
Agenda	<ul style="list-style-type: none"><li>• See <i>Annex 3</i> for the agenda</li></ul>

<p>Conclusions</p>	<ul style="list-style-type: none"> <li>• PQM was pleased that PQAD finally moved to its new location because the new space accommodates the staff and equipment much better, and some of the environmental conditions that violated ISO requirements in the old lab seem to be corrected in the new lab.</li> <li>• It is worth mentioning that PQAD has maintained its ISO 17025 accreditation with the assistance of PQM. However, PQM would like to see the Quality Manager become more proactive in auditing the lab against ISO standards and ensuring that PQAD's QMS system continuously improves and staff abides by the lab's SOPs and policies.</li> <li>• PQM will assist PQAD in addressing any open corrective actions and opportunities for improvement stemming from the November ACLASS surveillance audit.</li> <li>• PQM recommends strengthening the proficiency of about 10 new PQAD staff by providing identified training to PQAD on techniques for the scope of accreditation, especially UV, Karl Fischer, Loss on Drying, and HPLC. This PQM activity will happen after the ACLASS assessment visit since the new staff will not be demonstrating any tests within the scope of accreditation during the audit. Nonetheless, based on this visit, it is pertinent that the new staff be brought up to speed accordingly.</li> </ul>
<p>Next Steps</p>	<ul style="list-style-type: none"> <li>• PQM will assist PQAD in completing any pending issues before the ACLASS assessment audit during the first week of October 2013.</li> <li>• ACLASS will conduct the reassessment audit.</li> </ul>



**Regina Okafor conducts Karl Fischer training at PQAD (left)**



**The new PQAD laboratory is more spacious for staff and equipment (right and below)**



**PQM Visit: Additional Meetings**

Addis Ababa, Ethiopia  
July 29 – August 2, 2013

**Opening Meeting with PQAD Management:**

July 29, 2013

Participants: See *Annex 2* for a list of participants. The full agenda for the trip is included in *Annex 3*.

PQM met with the PQAD management team to discuss the following:

- The agenda for the visit and what techniques will be trained on for the new staff in preparation for the assessment audit.
- PQAD director selected 9 new analysts and one junior staff to be trained on the selected techniques.
- PQM asked about the status of calibration of equipment that was to be performed by the Ethiopian National Metrological Institute (NMI) and informed PQAD that PQM will enlist the help of an accredited Egyptian calibration body (PQM used this organization in 2011 to calibrate PQAD's equipment before the accreditation audit).
- The Ethiopian NMI performed the calibrations; however, the calibration certificates have not yet been provided by the company and some of the certificates are without an accreditation logo. Mr. Zelalem Mamo informed all participants that it was discovered that when the Ethiopian NMI travels to perform calibrations, they are not accredited to do so. However, when equipment is taken to them and calibration is done internally, they are accredited to do so. Thus, there will be an accreditation logo.
- PQM reiterated the importance of obtaining the calibration certificates before the ACLASS assessment audit.
- PQM also provided supplies and equipment and a certificate of accreditation for equipment procured for PQAD
- The group discussed the proficiency test (PT) progress and PQM emphasized the importance of PQAD participating in all tests within their scope of accreditation before the ACLASS visit in October 2013.

**Training on Five Techniques**

July 29 –August 2, 2013

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

Training was conducted on the following techniques:

- Karl Fischer
- Good Documentation Practices in the Laboratory
- Good weighing techniques
- Volumetric techniques
- Following QMS rules, the analysts' responsibility

## **Meeting with USAID/Ethiopia**

August 1, 2013

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

PQM discussed the objectives and main findings of the current trip. The following are the main outcomes of the meeting:

- PQM provided details about the objectives of the trip and training conducted
  - ACLASS reassessment will take place in October 2013 and PQM wants to ensure that PQAD is ready for the audit
  - PQM wanted to evaluate the new lab to ensure there will not be any pending building or aesthetic issues relating to incompleteness of construction before the audit
  - Training of the new staff and the evaluation of the QMS status of PQAD
- PQM shared the next steps, particularly regarding the ACLASS formal assessment visit that will occur in October 2013 and ensure that PQM will arrive a few days earlier than ACLASS to make sure there are no pending issues that could negatively impact the audit.
- PQM summarized all the pending issues that FMHACA and PQAD will have to complete and PQM's role in assisting from Rockville to mitigate any issues relating to QMS that are pending.
- Mr. Tesfaye was very interested in the status of the lab and wanted to make sure that all pending construction issues remaining on the 4<sup>th</sup> and 5<sup>th</sup> floor (which is the location of the physico-chemical lab) would be completed by FMHACA and PQAD. He enquired about the possibility of moving the audit date as a result of any delays. He mentioned that September is a busy month in Ethiopia and questions if FMHACA will be able to complete all tasks. PQM informed him that we will be in constant communication with PQAD on the progress of completing pending issues and that ACLASS was the one who set the date due to their tight schedule and availability. Mr. Tesfaye also mentioned that he would talk to the director of the lab to ensure that PQAD makes this a priority.
- Mr. Tesfaye also encouraged collaboration between PQM, PQAD, and the local pharmacy school in utilizing the pharmacy/university staff to train some lab staff. He emphasized how this will help with capacity building of PQAD and also demonstrate their knowledge; for example, to show their skills in the lab and demonstrations on how to use the Minilab<sup>®</sup>. PQAD staff can train regionally as well, as a means to save money. PQM mentioned the staff of PQAD traveling to the Center for Pharmaceutical Advancement and Training (CePAT) in Ghana to train on some of the activities instead of PQM Rockville staff traveling to conduct the training. Mr. Tesfaye also mentioned that, to be successful in improving the quality of medicine in Ethiopia, the mindset of the people has to change; to invigorate people about the way they think of the quality of medicine.

## **Closing meeting with PQAD Management**

August 2, 2013

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

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

- PQM thanks PQAD management staff for their participation in the preparation for PQM visit, for completing the move to the new location, and all the work that was completed to date.

- PQAD management informed PQM they believe that all construction will be complete before the audit.
- PQM discussed how proficient the senior chemists of PQAD are becoming, especially in assisting with the training of the selected junior chemists that underwent training by PQM. PQM is confident that these senior analysts are competent to carry out demonstrations of the seven techniques during the assessment audit and also in continuing to train the new PQAD staff. PQM informed PQAD management that in order for this training to be effective, all staff will have to undergo refresher training of important tasks/topics like GDP, safety, GLP, etc. Some of the topics for the refresher training may result from the internal auditing if it is performed correctly and objectively. The lab is supposed to continuously improve.
- PQM also reiterated the importance of closing all CAPAs that had not been closed since the last ACLASS visit. Particularly important are the CAPAs relating to issues identified by ACLASS and recommendations given by PQM. During this meeting PQM especially emphasized some of the key things that could impede a successful outcome of the audit which are:
  - Quality department needs to be more diligent and proactive in resolving quality issues: internal audits, opening corrective actions, be more functional and not wait until the last minute to complete tasks, management review, and additional staff is needed for the quality department, making sure all staff has authorization letters, etc.
  - Backing up of all data electronically especially since the move to the new site
  - Proficiency testing is not complete
  - Equipment calibration - a lot of equipments are not calibrated that cover tests that are within the scope of accreditation
  - SOP revisions - a lot of SOPs have exceeded the revision due dates
  - New certificate of analysis (COA) approved but not used by the lab
  - Management review and internal audit not done according to SOP
  - Falsification of data by analysts in the lab
  - QC trending still not done
  - All new staff training records have to be updated
  - Environmental monitoring is not performed as specified in the SOP and in a timely manner
- PQM also identified areas where technical assistance can be provided:
  - Helping to procure standards that can be used for QC trending
  - Facilitating the Egyptian calibration body to travel to Ethiopia to calibrate equipments
  - Procuring Lab X software for the Karl Fischer
  - Helping coordinate internal auditing for staff that assists QA manager
- PQM reaffirmed to PQAD management its dedication in assisting PQAD to obtaining accreditation and assisting to resolve any issues before the reassessment visit.

**PQM observations that could impact the reassessment visit from ACLASS**

1. The construction on the 4<sup>th</sup> and 5<sup>th</sup> floor of the facility needs to be completed no later than the third week of September.
2. Proficiency testing needs to be completed by the third week of September.
3. The building and laboratory access control is not maintained, allowing anyone access to their floors.
4. The Quality Manager must be proactive in maintaining the QMS. The following issues were observed in QA:

- a. ACLASS findings not fully completed after one year
    - i. Trending of QC have not been conducted
    - ii. PTs have not been conducted at current site
  - b. CAPA and OFI not opened at all times
    - i. CAPA program appear to be ineffective due to repeating issues.
    - ii. Nonconforming work not document at all times
    - iii. No survey has been submitted to customer by PQAD
  - c. Management Review and Internal audits have been delayed
  - d. Staff falsifying data in some areas must be documented and CAPA opened
    - i. Missing temp reading
    - ii. Data out of range
  - e. Deputy Quality Manager not being trained
  - f. Internal Auditors without documented training
  - g. Electronic data generated related to the scope of accreditation needs to be backed-up on a scheduled basis and confirmed
  - h. All equipment related the scope of accreditation is not ready (Ovens and Dissolution equipment)
  - i. SOPs have not been generated or are obsolete related the scope of accreditation
  - j. The use of obsolete forms for final customer certificate must be eliminated
  - k. Sample receipt area has novice staff (hired 22 JUL 2013) that requires more training as they may be audited by ACLASS
5. All equipment that will be serviced by CCG of Egypt must be available, functioning, and in proper location by 09 AUG 2013
  6. Reuse of HPLC vials must be stopped
  7. Staffs need to be authorized in their current positions by the Lab Director
  8. Internal Auditor training needs to be documented prior to AB visit
  9. Director needs to submit WHO PQ documentation after accreditation

### **Recommendations**

- FMHACA management should make it a priority that any pending construction on the 4th and 5th floor is completed by the third week of September 2013
- PQAD should complete management review and internal audit before the end of September. All resulting findings should be accompanied by corrective and/or preventative actions accordingly.
- QA manager should introduce all findings during this PQM visit into the CAPA system and be proactive in responding to PQM requests and offered assistance
- PQM recommends that PQAD complete all issues that PQM has provided to PQAD as follow-up items before the ACLASS reassessment visit

### **Next Steps**

- PQM will assist PQAD in completing any issues that have been identified before the ACLASS audit. Therefore, PQM will arrive at PQAD two days before the assessment audit to finalize and help resolve any pending issues before the audit
- ACLASS will conduct the reassessment audit during the first week of October 2013
- PQM will assist PQAD to resolve and respond to any issues identified during the ACLASS reassessment audit

**PQM Trip: Lists of Participants**

Addis Ababa, Ethiopia

July 29 – August 2, 2013

**July 29 – August 2, 2013 Participants in Training Workshop**

<b>Participant</b>	<b>Institution</b>
Merkebu Aytenfisu	PQAD
Wakshum Toli	PQAD
Mintewab Zeleke	PQAD
Yisihak Abreham	PQAD
Jundurehman Mohammed	PQAD
Tsion Tikimachew	PQAD
Assefa Takele	PQAD
Addisu Ashargie	PQAD
Yoftahe Teshome	PQAD

**July 29, 2013 – Opening Meeting with PQAD Management**

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

**August 1, 2013 – Meeting with USAID/Ethiopia**

<b>Participant</b>	<b>Institution</b>
Dessalegn Tesfaye	USAID/Ethiopia
Donnell Charles	PQM Rockville
Eshetu Wondemagegnehu	PQM Ethiopia
Regina Okafor	PQM Rockville

**August 2, 2013 Closing meeting with PQAD Management**

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

**PQAD Reassessment Training Workshop**

Addis Ababa, Ethiopia

July 29 – August 2, 2013

**Agenda**

**MONDAY**

Opening meeting with PQAD Management Team  
Adjustment of agenda as necessary  
Review of QMS of PQAD  
Review of ACLASS findings from surveillance audit in November 2012  
Start review of major ISO requirements  
Tour of the new lab  
Determine new staff to participate in PQM training

**TUESDAY**

Review CAPAs from ACLASS findings  
Proper weighing in the laboratory training  
Volumetric analysis training  
Good documentation training  
Begin review of CAPAs from PQM evaluation and open CAPAs  
Observe Dissolution demonstration  
Observe HPLC demonstration  
Evaluate key QMS findings with QA  
Evaluate Karl Fischer (KF) installation with senior staff

**WEDNESDAY**

Continue CAPA review from PQM Evaluation  
Evaluate key QMS findings with QA  
Address any training issues  
Complete HPLC demonstration  
Observe UV demonstration  
Observe pH demonstration  
Theory training on Karl Fischer to new staff

**THURSDAY**

Review pending CAPAs – handling of complaints SOP  
Check gap on training records of staff  
Review equipment calibration status and equipment history files  
KF hands-on training with new staff – 2 different groups  
Review data from all training and check proficiency  
Debrief USAID

**FRIDAY**

Closing meeting (PQAD management team and all PQAD staff)  
Complete all training pending  
Summarize all training topics/Question and answer session  
Discuss next step for PQAD – reassessment audit

**Annex 4**  
**Summary of Course Evaluation Form**

**Course Name: PQAD Reassessment training workshop: GDP, Karl Fisher, Weighing practices, Volumetric analysis**  
**July 29 – August 2, 2013, Addis Ababa Ethiopia**

**1. Overall Evaluation of the Course**

Using a scale from **1** through **5**, where **1 = Disagree Strongly** and **5 = Agree Strongly**, please circle one number to indicate the extent to which you agree or disagree with each statement below.

STATEMENT	DISAGREE STRONGLY			AGREE STRONGLY		NOT APPLICABLE
	1	2	3	4	5	
My expectations/personal objectives have been met. <sup>1</sup>	1	2	3	4	5	0
The training material helped me understand the course better. <sup>2</sup>	1	2	3	4	5	0
There were enough practical exercises to facilitate understanding of the course. <sup>3</sup>	1	2	3	4	5	0
The instructor(s) was effective in presenting the material. <sup>4</sup>	1	2	3	4	5	0
The instructor(s) allowed an appropriate level of participation. <sup>5</sup>	1	2	3	4	5	0
I am satisfied with the overall content and topics covered. <sup>6</sup>	1	2	3	4	5	0
The training will make a difference in the way I do my work. <sup>7</sup>	1	2	3	4	5	0
Support for logistics (accommodations, registration, etc.) was adequate. <sup>8</sup>	1	2	3	4	5	0

- 1 = 5 trainees = (5) strongly agree; 2 trainees = (4); 1 trainee = (3)**
- 2 = 6 trainees = (5) strongly agree; 2 trainees = (4)**
- 3 = 2 trainees = (5) strongly agree; 3 trainees = (4); 3 trainee = (3)**
- 4 = 6 trainees = (5) strongly agree; 2 trainees = (4); 0 trainee = (3)**
- 5 = 7 trainees = (5) strongly agree; 1 trainees = (4); 0 trainee = (3)**

6 = 5 trainees = (5) strongly agree; 2 trainees = (4); 1 trainee = (3)  
 7 = 5 trainees = (5) strongly agree; 3 trainees = (4); 0 trainee = (3)  
 8 = 5 trainees = (1) strongly agree; 2 trainees = (4); 1 trainee = (2); 5 trainees = (0) Not applicable

**Self-Assessment of Impact of Training**

Rating scale 1 through 5 where 1 = Low Skills and 5 = High Skills

BEFORE TRAINING					KNOWLEDGE AND SKILLS RELATED TO:	AFTER TRAINING				
1	2	3	4	5	Proper weighing in the lab	1	2	3	4	5
1	2	3	4	5	Volumetric techniques in the lab	1	2	3	4	5
1	2	3	4	5	GDP in the lab	1	2	3	4	5
1	2	3	4	5	Karl Fischer	1	2	3	4	5

**2. Other Comments/Suggestions:**

- I. What did you like best about the course?  
**Practical training on the Karl Fischer was helpful**  
**All courses especially Karl Fischer**  
**Lab techniques; the presentation and the practical part**
- II. What did you like least about the course?  
**Weighing techniques**
- III. What are your recommendations/suggestions for improvement of the course?  
**Provide refreshments, water, etc.**  
**More time for practical exercises**
- IV. What additional topics would you like to see covered in the course?  
**HPLC, UV, GC, GC-MS, GMP, GLP, Infrared Identification, Dissolution, Loss on Drying**