

# Quality Management System Training and Developing an Implementation Plan for ISO 17025 Accreditation & WHO Prequalification

Accra, Ghana  
March 8 – 11, 2011

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## *Trip Report*

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## Executive Summary

The trip had two primary objectives:

- Conduct working sessions with key Food and Drugs Board (FDB) staff to identify the primary scope of accreditation, establish priorities, and develop an ISO 17025 and WHO prequalification implementation plan.
- Deliver trainings to all staff regarding Quality Management System (QMS) issues (ex: ISO & WHO standards, external audit expectations, auditee behavior, internal audit procedures, etc.).

The ultimate goal for the FDB medicine quality control (QC) laboratory is to obtain ISO/IEC 17025:2005 accreditation and, at a later stage, be incorporated in the list of WHO Prequalified (PQ) medicine QC laboratories.

The following are the key findings and conclusions:

- PQM was pleased with the outcome of the trip as the ISO 17025 Accreditation and WHO Prequalification Implementation Plan was drafted and approved by upper management of FDB. The implementation plan has established a clear roadmap towards obtaining ISO 17025 accreditation and WHO prequalification, which will allow the FDB to comply with Global Fund (GF) Quality Assurance policies and therefore have the ability to test GF procured medicines.
- FDB lab staff have a better understanding of how to develop a stringent QMS that will comply with ISO & WHO standards.

The following are the next steps:

- FDB will begin to execute Stage 1 of the ISO & WHO Implementation Plan. Stage 1 should be completed by May 27, 2011.
- Monthly updates regarding the lab's progress on the ISO & WHO Implementation Plan will be delivered to the FDB CEO.
- PQM will sponsor selected FDB staff to attend a measurement uncertainty course at the Ethiopia MoH medicine QC lab in July 2011.
- FDB should communicate with PQM regarding any requests for technical assistance in improving their QMS.

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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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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice.

## ACRONYMS

CAPA	Corrective Action Preventative Action
CDC	U.S. Centers for Disease Control and Prevention
FDB	Food and Drug Board
GF	Global Fund
GLP	Good Laboratory Practices
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HPLC	High Performance Liquid Chromatography
ISO	International Organization for Standardization
KF	Karl Fisher Titration
LOD	Loss on Drying
MOH	Ministry of Health
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQ	Prequalification
PQM	The Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
TAP	Technical Assistance Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
UV-Vis	Ultraviolet – Visible Spectrophotometry
WHO	World Health Organization

## **Background**

The Promoting the Quality of Medicines (PQM) Program first began supporting the Ghana Food and Drugs Board (FDB) in 2005, and continued their support in 2008 with funding from the President's Malaria Initiative (PMI). PQM has focused on providing technical assistance to the FDB to establish a functional medicine post-marketing surveillance program throughout the country. For these activities, the FDB medicine quality control (QC) lab has been conducting tests of medicines procured by Global Fund (GF). However, the GF quality assurance (QA) policy (July 2009) stipulates that testing for GF-procured products must occur at WHO prequalified or ISO/IEC 17025:2005 accredited labs. Currently, the FDB medicine QC lab does not meet these standards, and GF procured medicines are shipped abroad to a laboratory that is compliant with GF requirements.

In 2010, PQM received funding to strengthen the FDB medicine QC lab's quality management system (QMS) with the ultimate goal of obtaining ISO/IEC 17025:2005 accreditation and subsequently WHO prequalification. Achieving accreditation and prequalification will allow the FDB to test medicines procured by the GF and would result in FDB generating needed revenue to support other quality assurance activities.

## **Purpose of Trip**

The trip had two primary objectives:

- Conduct working sessions with key FDB staff to identify the primary scope of accreditation, establish priorities, and develop an ISO 17025 and WHO prequalification implementation plan.
- Deliver trainings to all staff regarding QMS issues (ex: ISO & WHO standards, external audit expectations, auditee behavior, internal audit procedures, etc.).

## **Source of Funding**

These activities were funded by USAID/Ghana through PMI.

## **Overview of Activities**

The full agenda for the trip is included in *Annex 1*.

### QMS Training Sessions

Thirty-five FDB technical staff participated in the trainings (see *Annex 2* for a list of participants).

The training sessions were intended to enhance the staff's knowledge of the international quality standards and how to implement a stringent QMS that complies with both ISO/IEC 17025:2005 and WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL). The topics covered during this training were:

- International Quality Standards: ISO/IEC 17025:2005 & WHO GPPQCL
- Stringent Quality Management Systems
- Introduction to the Principles of Traceability and Uncertainty of Measurement
- Proficiency Testing and Inter-laboratory Testing Schemes

- Expectations of External Audits & Recommended Auditee Behavior
- Simulated Method Audit

The staff was engaged and asked many questions during each of the training sessions. Due to the level of interest, a separate Q&A session was added to the schedule on the last day. The session allowed the PQM team to share their experience with the staff on a variety of topics covering analytical techniques and QMS.

Each trainee was provided with a CD containing the entire presentation and relevant QMS documents covered during these training sessions. The staff was asked to provide their feedback on the training, and a summary of these evaluations is provided as *Annex 3*.

### QMS Working Sessions

FDB gathered a small working group of key staff for three activities—

#### 1. Determine the initial ISO/IEC 17025:2005 Scope of Accreditation:

The group identified techniques to include in the primary and secondary scopes of accreditation. The following techniques will be included in the primary scope of accreditation:

- pH measurement
- Weighing/Balance
- Loss on Drying (LOD)
- Water Determination by Karl Fisher Titration (KF)
- High Pressure Liquid Chromatography (HPLC)

It is important to note that, based on the lab's progress, the lab may amend the primary scope of accreditation and may potentially add three additional tests (Dissolution, UV-Vis spectrophotometry, and FT-IR).

#### 2. Develop an ISO 17025 and WHO prequalification implementation plan:

PQM presented the working group with a draft of an implementation plan, which provides guidance from the current status until the ultimate objective of obtaining ISO/IEC 17025:2005 Accreditation and WHO Prequalification for all tests performed at the FDB medicine QC lab. The implementation plan is structured in five different stages with individual tasks and objectives for each stage.

The working group accepted the proposed plan and established fixed dates for each stage. If the lab successfully executes the plan, PQM believes the lab can successfully obtain the primary scope of accreditation within three to six months of moving to the new lab.

Please see *Annex 4* for the entire ISO 17025 and WHO Prequalification Implementation Plan.

#### 3. Identify gaps in QMS documentation and prioritize the documents needed for Primary Scope of Accreditation:

For the FDB to obtain the primary scope of accreditation, it is of utmost importance to identify the gaps in the current QMS documents and review, update, and create documents that are

outdated or missing. To accomplish this, the working group identified all QMS documents (both technical and general) required to perform HPLC according to ISO 17025 & WHO GPPQCL standards. The group reviewed the status of each of these documents, identified required revisions, prioritized in order of importance and assigned lead staff for each document.

HPLC was chosen as it is one of the more complex techniques in the primary scope of accreditation. If the lab successfully develops and complies with all the QMS documents for HPLC analysis the remainder of the techniques in the primary scope of accreditation will be easily obtained.

Please refer to *Annex 5* for the relevant documents for this activity.

#### Meetings with FDB Chief Executive Officer (CEO)

PQM met with Dr. Stephen Opuni, the FDB CEO, to present the trip objectives and outcome of the QMS visit, obtain the FDB CEO's approval for the ISO 17025 and WHO Prequalification Implementation Plan, and introduce Kwasi Boateng, PQM's recently hired in-country consultant. The following are the main outcomes of the meeting:

- The FDB CEO approved the ISO 17025 and WHO Prequalification Implementation Plan. He reiterated his commitment to providing the human and financial resources that are necessary for FDB to effectively comply with each stage of the Implementation Plan.
- The FDB was pleased to see PQM will have an in-country presence to assist the lab in executing the ISO 17025 and WHO Prequalification Implementation Plan.
- PQM reiterated that if the lab successfully executes the plan, PQM believes the lab can successfully obtain the primary scope of accreditation within three to six months of moving to the new lab.
- The FDB CEO asked Dr. Eric Karikari (Director of the FDB Lab Services Department) and Kwasi Boateng to provide monthly updates regarding the lab's compliance with the implementation plan.

#### Debrief Meeting with USAID/Ghana

PQM staff met with Dr. Paul Psychas, CDC resident advisor, to debrief USAID staff on the outcomes of the visit. The discussions are summarized below:

PQM presented the trip objectives and outcomes and shared the next steps towards strengthening the QMS of the FDB medicine QC lab:

- The group discussed the obstacles in obtaining ISO 17025 accreditation and WHO prequalification and the current status, including a brief overview of the ISO 17025 and WHO Prequalification Implementation Plan.
- PQM shared two activities that will complement the efforts of USAID/Ghana towards strengthening the QMS of the FDB medicine QC lab:
  - USP has selected FDB to participate in a new technical assistance program (TAP). This is a donation program that will provide FDB with \$25,000 worth of reference standards in addition to reference books and three pharmacopeial training courses at no cost to FDB. The first training is scheduled to be delivered in Ghana during the week of April 18, 2011 with participants from the MoH

medicine QC labs of Ethiopia, Ghana, Kenya, Senegal and Sierra Leone. This program is solely financed by USP and will complement PMI-supported activities.

- PQM has scheduled a training at the Ethiopia MoH medicine QC lab on measurement uncertainty (tentatively scheduled for the week of July 18, 2011). The training will be delivered by ACLASS, an internationally recognized accrediting body, and will include a planning visit (pre-audit) of the Ethiopian lab's QMS. This activity is being sponsored by the USAID/Ethiopia PEPFAR Program and will complement USAID/Ghana PMI activities.
- Kwasi Boateng, PQM's recently hired in-country consultant, was presented to USAID:
  - Mr. Baoteng will be providing follow-up to PQM's activities in Ghana.
  - USAID was pleased to see that PQM was able to establish an in-country presence.
  - USAID discussed with Mr. Boateng their expectations for him as PQM's in-country representative.
- USAID asked PQM to provide updates on the progress of the ISO 17025 and WHO Prequalification Implementation Plan.

## **Conclusions**

PQM was pleased with the outcome of the trip as the ISO 17025 Accreditation and WHO Prequalification Implementation Plan was drafted and approved by upper management of FDB. This Implementation Plan has established a clear roadmap towards obtaining ISO 17025 accreditation and WHO prequalification, as well as allowing the FDB to comply with GF QA policies and have the ability to tests GF procured medicines.

## **Next Steps**

- FDB will share and discuss the outcomes of the working sessions (ISO & WHO Implementation Plan and HPLC Prioritization Exercise) with all staff.
- FDB will begin to execute Stage 1 of the ISO & WHO Implementation Plan. Stage 1 should be completed by May 27, 2011.
- Management at FDB should continue to train staff on QMS issues, particularly compliance with internal SOPs.
- Monthly updates regarding the lab's progress on the ISO & WHO Implementation Plan will be delivered to the FDB CEO.
- PQM will sponsor selected FDB staff to attend a measurement uncertainty course at the Ethiopia MoH medicine QC lab in July, 2011.
- FDB should communicate with PQM regarding any requests for technical assistance in improving their QMS.

**Agenda for PQM QMS Visit to Food and Drugs Board:**

Accra, Ghana  
March 8 – 11, 2011

<b>Day</b>	<b>Activities</b>
Tuesday	<ul style="list-style-type: none"> <li>• Meeting with FDB Lab Director and senior staff</li> <li>• Opening meeting (Lectures for all or only relevant staff):               <ul style="list-style-type: none"> <li>○ Introductions</li> <li>○ Discuss objectives and expectations of visit</li> </ul> </li> <li>• Theoretical Presentations (Lectures for all or only relevant staff):               <ul style="list-style-type: none"> <li>○ International Quality Standards: ISO 17025 &amp; WHO GLPs</li> <li>○ Stringent Quality Management Systems</li> </ul> </li> <li>• Working session with relevant FDB staff:               <ul style="list-style-type: none"> <li>○ Update on current QMS</li> </ul> </li> </ul>
Wednesday	<ul style="list-style-type: none"> <li>• Continue working session with relevant FDB staff:               <ul style="list-style-type: none"> <li>○ Discuss FDB goals and define initial ISO 17025 Scope of Accreditation</li> <li>○ Identification of all QMS documents required for 1 test from initial ISO 17025 Scope of Accreditation</li> <li>○ Begin developing implementation plan</li> </ul> </li> <li>• Facility inspection (time dependent)</li> </ul>
Thursday	<ul style="list-style-type: none"> <li>• Finish facility inspection (if necessary)</li> <li>• Continue working session with relevant FDB staff:               <ul style="list-style-type: none"> <li>○ Continue working on implementation plan</li> <li>○ Define next steps</li> <li>○ Address other issues as necessary</li> </ul> </li> <li>• PQM Meeting with USAID</li> </ul>
Friday	<ul style="list-style-type: none"> <li>• Theoretical Presentations (Lectures for all or only relevant staff):               <ul style="list-style-type: none"> <li>○ Principles of Traceability &amp; Uncertainty of Measurement</li> <li>○ Proficiency Testing Schemes</li> <li>○ Expectations of External Audits &amp; Recommended Auditee Behavior</li> <li>○ Simulated Method Audit (time dependent)</li> </ul> </li> <li>• Presentation: Trip Findings, Recommendations and Next Steps</li> <li>• Q &amp; A session regarding QMS and USP-NF topics</li> <li>• Other pending activities</li> <li>• Closing meeting</li> </ul>

**PQM Trip: Lists of Participants**

Accra, Ghana  
March 8 – 11, 2011

**March 8 & 11, 2011 – QMS Training Sessions**

<b>Participant</b>	<b>Institution</b>
Eric Karikari	FDB
Joseph Ofosu	FDB
Akwasi Fredua	FDB
Araba Esiaa	FDB
Victor Ofori	FDB
Bridget Tawiah	FDB
Beatrice Mensah	FDB
Priscilla Adjei	FDB
Joseph Eml	FDB
Alberta Adams	FDB
Jane Bahh	FDB
Dina Dzifa	FDB
Asante Agyekumwah	FDB
Jerome Soglo	FDB
Mohammed Awal	FDB
Curtis Twumasi	FDB
Jemima Odonkor	FDB
Isaac Adom	FDB
Clement Yawson	FDB
Setsoafia Danial Dadzi Yaw	FDB
Badu Nana	FDB
Evelyn Agyei	FDB
Jessica Addotey	FDB
Eno Buruwaa	FDB
Delali Abra	FDB
Ishmael Larkai	FDB
Sefakor Rowland	FDB
Daniel Kally	FDB
Cheetham Mingle	FDB
Ernest Afesey	FDB
Jeff Aboyer	FDB
Sandra Amponsah	FDB
Samuel Kwakye	FDB
James Aboagye	FDB
Coffy Dzifa	FDB
Adrian Barojas	PQM
Kwasi Boateng	PQM consultant

**March 9 - 10, 2011 – QMS Working Sessions**

<b>Participant</b>	<b>Institution</b>
Delali Abra	FDB
Ernest Afesey	FDB

Eric Karikari	FDB
Samuel Kwakye	FDB
Cheetham Mingle	FDB
Jemima Odonkor	FDB
Victor Ofori	FDB
Joseph Ofosu	FDB
Araba Thompson	FDB
Adrian Barojas	PQM
Kwasi Boateng	PQM consultant

**March 10, 2011 – Meeting with USAID/Ghana**

<b>Participant</b>	<b>Institution</b>
Paul Psychas	USAID
Adrian Barojas	PQM
Kwasi Boateng	PQM consultant

**March 10 & 11, 2011 –Meetings with FDB CEO**

<b>Participant</b>	<b>Institution</b>
Stephen Opuni	FDB CEO
Eric Karikari	FDB
Adrian Barojas	PQM
Kwasi Boateng	PQM consultant

### Evaluation by Participants

Location of QMS Visit: FDB, Accra, Ghana | Date of QMS Visit: March 8 – 11, 2011

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Trip objectives were relevant to my needs	18 (82%)	4 (18%)	
2. I was able to understand the content of the materials presented	13 (59%)	9 (41%)	
3. Overall the materials presented were useful and will help me do my job better	12 (55%)	10 (45%)	
4. There were enough practical exercises to facilitate understanding of the materials presented	5 (23%)	13 (59%)	4 (18%)
5. The pacing of sessions was appropriate for my understanding of materials presented	14 (64%)	7 (32%)	1 (5%)
6. The instructor were knowledgeable on the subject	21 (95%)	1 (5%)	
7. The instructor allowed an appropriate level of participation during the presentation of materials	20 (91%)	2 (9%)	

1. Which topic(s) or aspects of the visit should not be included in future trips?
  - The majority of participants indicated satisfaction with the topics of the QMS visit and did not request for material to be excluded in future trips.
  
2. What are your recommendations/suggestions for improvement of the visit?
  - Increase the amount of practical exercises (hands-on session) where the facilitator evaluates/observes staff perform tests & testing areas (ex: method audit & facility inspections) (8)
  - Increase time of training/activities (4)
  - Ensure there is frequent follow-up with all staff to ensure the objectives and advantages of accreditation/prequalification are understood by all staff (4)
  - Ensure all of the week's activities incorporate all of the lab staff (2)
  - Deliver certificates at the end of the educational component (1)
  - Expand scope of activities to other testing areas (ex: medical devices) and not limit the examples to pharmaceuticals (1)
  - Provide more definitions of terms (1)
  - Perform a measurement of uncertainty calculation for a test performed at the lab (1)
  
3. What did you like most from the QMS visit?
  - Explanation of all of the components of a stringent QMS & international QMS standards (13)
  - The dedication, objectivity and knowledge of the instructor (6)
  - The simulated method audit (1)
  - PQM assistance in developing a road map from the current situation to accreditation & prequalification (1)
  
4. Please describe other QMS activities that you would like to receive assistance from PQM
  - A course focusing on Good Laboratory Practices and compliance with internal QMS, particularly SOPs (4)
  - Course on traceability & uncertainty of measurement (3)
  - QMS courses/activities for testing areas other than pharmaceuticals (ex: medical devices) (2)
  - Assistance in resource management (1)
  - Procurement of safety goggles (1)

**FDB IMPLEMENTATION PLAN FOR ISO ACCREDITATION & WHO  
PREQUALIFICATION**

March 11, 2011

I. Objective:

Obtain ISO/IEC 17025:2005 Accreditation and WHO Prequalification for all tests performed at the FDB medicine QC lab.

II. General Recommendations to FDB Upper Management:

It is evident upper management at FDB supports the labs pursuit of obtaining ISO/IEC 17025:2005 Accreditation and WHO Prequalification. It is highly recommended for management to continue displaying this support with a focus in the following areas:

- Formally authorize the new Lab Services Division Organizational chart, which includes an independent Quality Assurance Unit.
- Formally authorize the new Lab Services Division Quality Assurance Manager.
- To the extent possible ensure the construction of the new facility progresses accordingly and allows the medicine QC lab to move in August/September 2011.
- Provide support in procurement of equipment, reagents, chemicals and glassware of appropriate quality.
- Explore possibility of including a quantitative metric associated with the quality of work in the staff performance procedure. The ultimate objective of this activity would be to provide incentives for staff to perform good quality analysis.

III. Overview of Implementation Plan:

The following overview provides a high level review of the proposed implementation plan. Below (see Section V) is an overview of the detailed technical activities involved in each stage and implementation will begin upon management approval of this document.

STAGE	TIMELINE	PRIORITY RECOMMENDATIONS TO BE IMPLEMENTED
1	March 21 – May 27, 2011	<ul style="list-style-type: none"> <li>• Management Approval of implementation plan</li> <li>• Formalize a Quality Assurance (QA) Unit</li> <li>• Primary Scope of Accreditation identified</li> <li>• Clean and Organize lab</li> <li>• Review, approve &amp; train staff on Quality Manual</li> <li>• Write, approve &amp; train staff on SOPs/WIs identified in Priorities # 1 – 2 of Prioritization Activity during PQM visit in March 2011               <ul style="list-style-type: none"> <li>○ Total 18 documents</li> </ul> </li> <li>• Update safety procedures and train staff</li> <li>• Begin creating adequate Staff Training &amp; Equipment records</li> </ul>
2	May 30 – August 5, 2011	<ul style="list-style-type: none"> <li>• If necessary amend Primary Scope of Accreditation</li> <li>• Perform a compliance audit the SOPs/WIs developed during Stage # 1</li> <li>• Write, approve &amp; train staff on SOPs/WIs identified in Priorities # 3 – 4 of Prioritization Activity during PQM visit in March 2011               <ul style="list-style-type: none"> <li>○ Total 13 documents</li> </ul> </li> <li>• Selected staff will participate in the PQM sponsored training on Uncertainty of Measurement held at the lab in Ethiopia (tentatively scheduled for week of July 18, 2011)</li> </ul>

		<ul style="list-style-type: none"> <li>• Continue to implement robust procedures for lab cleaning, safety, staff training and equipment (qualification, calibration, and maintenance) schedule</li> <li>• Participate in Proficiency Testing activities as necessary</li> </ul>
3	August 8 – November 4, 2011	<ul style="list-style-type: none"> <li>• Move medicine QC lab to new facility <ul style="list-style-type: none"> <li>○ Qualify Equipment</li> <li>○ Review &amp; adjust documentation, specifically SOPs as needed</li> </ul> </li> <li>• Develop uncertainty of measurement calculations (budget) for the Primary Scope of Accreditation</li> <li>• Conduct QMS evaluation (mock audit)</li> <li>• PQM and USP QA staff will perform QMS evaluation (mock audit) according to ISO/IEC 17025:2005 &amp; WHO GPPQCL standards</li> </ul>
4	November 7, 2011 – April 27, 2012	<ul style="list-style-type: none"> <li>• Submit application to ACLASS (internationally recognized accrediting body - AB)</li> <li>• Undergo ACLASS Planning Visit <ul style="list-style-type: none"> <li>○ According to results prepare for ACLASS assessment of Primary Scope of Accreditation</li> </ul> </li> <li>• Undergo ACLASS Assessment for Primary Scope of Accreditation</li> <li>• Obtain ISO/IEC 17025:2005 Accreditation for Priority Tests</li> </ul>
5	April 30 2012- April 26, 2013	<ul style="list-style-type: none"> <li>• Identify expanded ISO/IEC 17025:2005 Accreditation Scope <ul style="list-style-type: none"> <li>○ Update QMS accordingly</li> <li>○ Schedule &amp; undergo assessment of expanded scope with ACLASS</li> </ul> </li> <li>• Obtain ISO/IEC 17025:2005 Accreditation of Expanded Scope</li> <li>• Submit Expression of Interest to participate in WHO Medicine QC lab Prequalification Programme <ul style="list-style-type: none"> <li>○ Undergo WHO Inspection</li> </ul> </li> <li>• Obtain WHO Prequalification for all tests performed at medicine QC lab</li> </ul>

#### IV. Outcomes and Conclusions:

When the FDB medicine QC lab obtains WHO prequalification and ISO/IEC 17025:2005 accreditation, it will not only play the major role of protecting the public health in Ghana, but could also play major role in quality control at the international level. The lab could engage in activities such as:

- Participate in collaborative studies with international Pharmacopeias and other drug regulatory authorities
- Test medicines for international organization (ex: Global Fund) and generate additional revenues
- Collaborate closely and participate in studies with WHO and other UN agencies
- Act as a center of excellence in West Africa
- The laboratory could easily generate enough revenues to be self funded if it is WHO Prequalified and ISO/IEC 17025:2005 accredited

With FDB management commitment and support of the laboratory and with USP PQM technical support, the set targets could easily be achieved within the timelines set forth in this implementation plan.

#### V. FDB Implementation Plan for ISO Accreditation & WHO Prequalification Stage Details:

##### **Stage 1 (March 21 – May 27):**

1. Management sensitization
  - Share implementation plan with management

- Ensure support is available for dedicating staff to plan, improve procurement procedures to ensure compliance with quality of materials/reagents/equipment, propose staff evaluation modification with an inclusion of a quantitative metric for quality tests with ultimate objective of providing incentives for staff to perform good quality analysis
- 2. Formalizing a Quality Assurance (QA) Unit:
  - Assign staff member as QA officer, whose sole responsibility is implementing a QMS
    - Position description & official appointment of QA officer
  - Update organigram & Quality Manual (QM)
    - Ensure QA unit is clearly defined in organizational structure
- 3. QMS Documents:
  - Update Quality Manual (QM): By the end of this stage the QM should be finalized and comply with all of the ISO/IEC 17025:2005 requirements
  - Write/revise. Approve & train staff on SOPs/WIs identified in Priorities # 1 – 2 of Prioritization Activity during PQM visit in March 2011
    - Writer (review), approve & train staff according to agreed upon schedule
- 4. Cleaning and basic organization of FDB:
  - Management commitment to maintaining a clean and well organized lab
  - Bi-weekly lab clean-up
  - Train support staff adequately
  - Prevent environmental contamination/impact
- 5. Safety
  - Update safety procedures to comply with WHO GPPQCL standards (section 4)
- 6. Equipment
  - Records
    - Daily use (logbooks & notebooks)
    - Equipment History File (EHF)
      - Matrix of all equipment necessary for Primary Scope of Accreditation
  - Categorize equipment into groups
    - Annual calibration (external or internal)
    - Annual qualification (external or internal)
    - Annual maintenance (external or internal)
    - Daily verification/calibration for balances/pH meter
    - No special treatment
  - Develop schedule to qualify/calibrate/maintain equipment according to category and need for Primary Scope of Accreditation
  - Daily verification/calibration for balances/pH meter
- 7. Staff training
  - Records
    - Matrix of all staff performing tests associated with Primary Scope of Accreditation
    - Create individual record for each analyst
    - Identify gaps
    - Train analysts on new/revise SOPs per agreed upon dates established during Prioritization Activity during PQM visit in March 2011

## **Stage 2 (May 30 – August 5):**

If necessary amend Primary Scope of Accreditation

- Based on the lab's progress in implementing Stage 1 the lab should decide if it will include 3 additional tests (Dissolution, UV-Vis spectrophotometry & FT-IR) in its Primary Scope of Accreditation
1. Management sensitization
    - Provide update of status with management
  2. Internal audit
    - Perform a compliance audit (ensure adequate implementation by staff) on the SOPs developed during Priorities # 1 – 2 of the Prioritization Activity during PQM visit in March 2011
    - Discuss findings with management & staff
    - Develop CAPAs as necessary
  3. QMS Documents
    - Write/revise. Approve & train staff on SOPs identified in Priorities # 3 - 4 of Prioritization Activity during PQM visit in March 2011
      - Writer (review), approve & train staff according to agreed upon schedule
    - Select staff will participate in the PQM sponsored training on Uncertainty of Measurement held at the lab in Ethiopia (tentatively scheduled for week of July 18, 2011)
  4. Cleaning and basic organization of FDB:
    - Continue Bi-weekly lab cleanups
  5. Safety
    - Monitor compliance of staff
  6. Equipment
    - Continue implementing schedule to qualify/calibrate/maintain equipment according to category and need for Primary Scope of Accreditation
  7. Proficiency Testing (PT)
    - Identify PT activities if needed for Primary Accreditation Scope

## **Stage 3 (August 8 – November 4):**

1. Move to New Lab Facility
  - Qualify Equipment
  - Review & adjust documentation, specifically SOPs as needed
2. Using the knowledge gained at the training received in Ethiopia develop uncertainty of measurement calculations (budget) for the Primary Scope of Accreditation
3. Conduct QMS evaluation (mock audit)
  - PQM and USP QA staff will review documentation and perform onsite mock audit according to ISO/IEC 17025:2005 & WHO GPPQCL standards
  - Develop CAPA plan according to audit results
  - Provide TA as needed

## **Stage 4 (November 7, 2011 – April 27, 2012):**

Prepare FDB lab for ISO/IEC 17025:2005 accreditation assessment (audit)

- Submit application to ACLASS (internationally recognized accrediting body - AB)
- Program ACLASS Planning Visit

- Provide TA in preparation
  - Program according to AB Planning Visit Results
- 1. Undergo AB assessment for Primary Scope of Accreditation
  - Provide TA in preparation
  - Remediate any non-conformities identified by AB
- 2. Celebrate Accreditation

**Stage 5 (April 30 2012 - April 26, 2013):**

1. Expand scope of ISO/IEC 17025:2005 accreditation and obtain WHO prequalification
  - ISO/IEC 17025:2005
    - Identify expanded scope
    - Develop, train & implement missing SOPs
    - Schedule & undergo assessment of expanded scope with AB
    - Remediate any non-conformities identified by AB
    - Celebrate Expanded Accreditation
  - WHO
    - Implement more rigorous method verification program
    - Submit Expression of Interest to WHO
      - Letter of interest
      - Laboratory Information File
      - Evidence of participation in proficiency testing scheme
    - WHO Inspection
      - Remediate any non-conformities identified by WHO
      - Celebrate WHO Prequalification

## Summary of SOPs Needed to Ensure HPLC Tests comply w/ Standard

Revised: 11 Mar 11

No	Title	Category	Status	Priority	Responsibility
1	HPLC Use	WI	Review	1	Araba
2	Workflow (ensure all steps from receiving request to emission & retention of CoA)	SOP	Review	1	Victor
3	RS & RM Use	SOP	Review	1	Samuel
4	Notebook use & revision	SOP	Review	1	Victor
5	Control, protection & back-up of electronic data	SOP	Draft	1	Victor
6	Document control	SOP	Review	1	Victor
7	Record control	SOP	Draft	1	Victor
8	Quality Manual	QM	Review	1	Eric
9	Balance Use & daily/weekly calibration/verification	WI	Review	1	Jemima
10	HPLC Qualification	WI	Draft	2	Kwasi/Adrian
11	Waste management	SOP	Review	2	Victor
12	Column treatment	SOP	Draft	2	Cheetam
13	Maintenance/Calibration/Qualification/Repair of Equipment	SOP	Review	2	Joseph
14	Staff Training	SOP	Review	2	Victor
15	Sol/Sample Prep	SOP	Review	2	Jemima
16	Ensuring Quality of Reagents/H <sub>2</sub> O/Solvents	SOP	Review	2	Joseph
17	Glassware Use & cleaning	SOP	Review	2	Joseph
18	pH use & daily calibration/verification	SOP	Review	2	Araba
19	Internal Audit	SOP	Review	2	Victor
20	KF use & daily calibration/verification	SOP	Draft	3	Samuel
21	Deviations	SOP	Draft	3	Victor
22	Environmental conditions of storage	SOP	Draft	3	Araba
23	Environmental conditions of testing areas	SOP	Draft	3	Araba
24	LOD	SOP	Draft	3	Jemima
25	Oven & pressure gauge operation	WI	Review	3	Jemima
26	CAPA	SOP	Draft	3	Victor
27	Management review	SOP	Review	3	Victor
28	Measurement Uncertainty	SOP	Draft	4	Eric
29	Method verification/validation	SOP	Review	4	Samuel
30	Evaluation of services & subcontractors used for testing	SOP	Review	4	Victor
31	Handling complaints	SOP	Review	4	Victor
32	Out of Specification (OOS) results	SOP	Review	4	Victor

**SOPs Needed to Ensure HPLC Tests comply w/ Standard**

Revised: 11 Mar 11

No	Title	Code	Category	Draft	Under Review	Appr.	Train.	Impl	Comments	Priority	Responsibility given to
1	Balance Use & daily/weekly calibration/verification	Multiple Wis (ex: FDB/LSD/PC/WI009 & FDB/LSD/PC/WI018)	WI		X				1) Have multiple WI (specific for each balance). Many are exactly the same and can be merged into one WI. Suggested to add a scope section into the format of WIs. In the scope section the balances that should be used with the WI should be explicitly stated. 2) Ensure the WI includes the weekly/daily calibration/verification of balances before use (PQM recommends to do this check daily before beginning use of balances).	1	Jemima
2	Workflow (ensure all steps from receiving request to emission & retention of CoA)	Separate SOPs (sample rec, store, distro, test, & re-test)	SOP		X				1) Ensure QM (section 4.4) has workflow chart encompassing entire workflow and make reference to respective SOP. 2) WG to decide if need to merge SOPs or maintain as separate. 3) Ensure one of the SOPs (current or new) states how test results are reviewed and reported.	1	Victor
3	Notebook use & revision	FDB/LSD/SOP-009 & SOP for Product testing	SOP		X				1) Ensure SOP Titled "Procedure for Laboratory Notebook Management" incorporates all components of Notebook use (issue, control, analyst use, reviewer use & archiving). 2) Explore possibility of removing NB use instructions in Product Testing SOP (recommend to make a reference to NB SOP in the Product Testing SOP).	1	Victor
4	Control, protection & back-up of electronic data	NA	SOP	X					Ensure SOP complies with ISO clause 4.13.1.4	1	Victor
5	Document control	Separate SOPs (writing SOP, withdrawal of SOPs, Approval & Issue of Documents SOP)	SOP		X				Update SOP per group discussion to capture Doc approval/review/control procedure for unit specific and general SOPs/WI. Look at possibility of merging current SOPs titled "Procedure for Approval and Issue of Documents" & "Procedure for writing laboratory SOP" & "Procedure for Withdrawal of Documents". Make sure the SOP includes reference to Master Doc List for all cont. docs (QM, SOPs, WI, Forms, etc...)	1	Victor
6	Quality Manual	FDB/LSD/MN -001	QM		X				1) Update to include new org chart. 2) Ensure Document hierarchy is stated. 3) Include workflow process map (probably section 4.4). 4) Ensure all high level policies are clearly stated in document (see WHO clause 2.2)	1	Eric
7	Record control	NA	SOP	X					Ensure SOP complies with ISO clause 4.13	1	Victor

**SOPs Needed to Ensure HPLC Tests comply w/ Standard**

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No	Title	Code	Category	Draft	Under Review	Appr.	Train.	Impl	Comments	Priority	Responsibility given to
8	RS & RM Use	FDB/LSD/SOP-028	SOP		X				1) Ensure that SOP titled "Procedure for Management of Chemical reference Standards " adequately addressed RS/RM storage conditions. 2) Ensure this SOP includes management of RM (ex: calibrated weights).	1	Samuel
9	HPLC Use	Multiple WIs	WI		X				1) Have multiple WI (specific for each HPLC). Many are exactly the same and can be merged into one WI. Suggested to add a scope section into the format of WIs. In the scope section the HPLCs that should be used with the WI should be explicitly stated.	1	Araba
10	Maintenance/Calibration/Qualification/Repair of Equipment	Separate SOPs (qualify , calib, maint & repair)	SOP		X				WG to decide if the 4 SOPs shall be merged into one SOP (dictated by repetition of content in each respective SOP).	2	Joseph
11	Column treatment	NA	SOP	X					Make simple straightforward (short) SOP	2	Cheetam
12	Waste management	FDB/LSD/SOP-011	SOP		X				Ensure SOP titled "Procedure for Disposal of Laboratory Waste" adequately addresses WHO requirements (section 4)	2	Victor
13	HPLC Qualification	NA	WI	X					PQM will assist in drafting of document	2	Kwasi/Adrian
14	Staff Training	Separate SOPs (training of staff & identifying needs)	SOP		X				WG to decide if the 2 SOPs shall be merged into one SOP (dictated by repetition of content in each respective SOP).	2	Victor
15	Ensuring Quality of Reagents/H2O/Solvents	FDB/LSD/SOP-008	SOP		X				Ensure SOP Titled "Procedure for Stocking of chemicals, Reagents, Reference standards and Media" incorporates entire cycle of reagents/solvents. The SOP should have a procedure for ensuring the quality of materials before they enter the lab for use. If necessary make reference to SOP on handling of RS/RM	2	Joseph
16	Internal Audit	FDB/LSD/SOP-020	SOP		X				1) Ensure SOP titled "Procedure for Internal Quality Audit" is: a) not too restrictive and allows flexibility accordingly (refer to audit plan and audit schedule); b) explicitly states all clauses of standard will be audited internally at least once a year; c) internal audit results are communicated to management and when appropriate, results in impact (ex: CAPAs). 2) Ensure SOP complies with ISO clause 4.14	2	Victor

### SOPs Needed to Ensure HPLC Tests comply w/ Standard

Revised: 11 Mar 11

No	Title	Code	Category	Draft	Under Review	Appr.	Train.	Impl	Comments	Priority	Responsibility given to
17	Glassware Use & cleaning	FDB/LSD/SOP-012	SOP		X				1) Ensure SOP titled" Procedure for cleaning of Laboratory Glassware" includes a procedure for reviewing glassware specifications before placed in use inside the lab. 2) Ensure tender specifications for glassware meet lab needs to comply with compendial requirements for volumetric solutions.	2	Joseph
18	pH use & daily calibration/verification	Multiple WIs	WI		X				1) Explore possibility of merging WIs of multiple pH meters	2	Araba
19	Sol/Sample Prep	FDB/LSD/SOP-005	SOP		X				Ensure SOP titled "Procedure for Preparation and Standardisation of Solutions and Reagents" incorporates all types of solutions (sample prep, volumetric, test, etc....)	2	Jemima
20	KF use & daily calibration/verification	NA	WI	X					1) Ensure WI captures both the daily calibration of titrant and use.	3	Samuel
21	Deviations	NA	SOP	X					PQM will assist in developing deviation program SOP	3	Victor
22	Environmental conditions of storage areas	NA	SOP	X					Ensure SOP complies with ISO clause 5.3	3	Araba
23	Environmental conditions of testing areas	NA	SOP	X					Ensure SOP complies with ISO clause 5.3	3	Araba
24	CAPA	FDB/LSD/SOP-015 & FDB/LSD/SOP-016	SOP		X				Ensure SOPs titled "Procedure for taking Corrective Action" & "Procedure for taking Preventive Action" comply with ISO requirements in clauses 4.11 & 4.12	3	Victor
25	LOD	NA	SOP	X					1) Create an SOP that describes the process of performing LODs and develop WI on how to use oves/pressure gauges.	3	Jemima
26	Oven & pressure gauge operation	Multiple WIs	WI		X				2) Explore possibility of merging WIs of multiple ovens/gauges	3	Jemima
27	Management review	FDB/LSD/SOP-033	SOP		X				Ensure SOP titled "Procedure for Management Review Meeting" ensures compliance with ISO clause 4.15.	3	Victor
28	Out of Specification (OOS) results	FDB/LSD/SOP-006	SOP		X				1) Create individual SOP for OOS. 2) Remove the OOS information in SOP titled "Procedure for Product Testing" and make reference to OOS SOP. 3) Follow WHO clause 18	4	Victor
29	Measurment Uncertainty	NA	SOP	X					PQM will assist in drafting of document & ACLASS course in Ethiopia will be attended by Ghana staff.	4	Staff to attend Ethiopia Training (Eric)

**SOPs Needed to Ensure HPLC Tests comply w/ Standard**

Revised: 11 Mar 11

No	Title	Code	Category	Draft	Under Review	Appr.	Train.	Impl	Comments	Priority	Responsibility given to
30	Evaluation of services & subcontractors used for testing	FDB/LSD/SOP-013	SOP		X				1) Update SOP titled "Procedure for Subcontracting" and ensure it incorporates procedure for evaluating services (ex: external calibrations) used for testing. 2) Clearly define the scope of the subcontracting for the units that subcontract tests (ex: Medical devices). 3) Ensure SOP complies with ISO requirements 4.4 & 4.5	4	Victor
31	Handeling complaints	FDB/LSD/SOP-025	SOP		X				Ensure SOP titled "Procedure for receiving Customer Complaints" complies with ISO requirements of clause 4.8.	4	Victor
32	Method verification/validation	FDB/LSD/SOP-014	SOP		X				1) Ensure SOP titled "Procedure for development and implementation of New Test Methods" complies with WHO requirements (section 16.3). 2) Ensure this SOP does not confuse between method validation & verification.	4	Samuel & PQM