

**PQM Compendia training for the Liberian Medicines and Health Products Regulatory Authority Quality Control Laboratory**

**Monrovia, Liberia  
February 25 - March 1, 2013**

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***Trip Report***

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## **Executive Summary**

Dr. El Hadri and Ms. Regina Okafor travelled to Liberia to train Liberian Medicines and Health Products Regulatory Authority Quality Control Laboratory staff on compendia testing and USP General Chapters and General Notices.

The training objectives were accomplished despite challenges. PQM observed that the participants were receptive to the training and showed interest and dedication in learning the new techniques.

PQM staff also conducted meetings to lay the groundwork for implementing workplan activities for this fiscal year and discussed with LMHRA ways of addressing the challenges that impede the lab from becoming fully operational.

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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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## ACRONYMS

DQI	Drug Quality and Information Program
GDP	Good Documentation Practices
HPLC	High Pressure Liquid Chromatography
LMHRA	Liberia Medicines and Health Products Regulatory Authority
LOD	Loss on Drying
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
USAID	United States Agency for International Development
USP	United States Pharmacopeia
USP NF	United States Pharmacopeia National Formulary
UV-Vis	Ultraviolet–visible spectroscopy
WHO	World Health Organization

## **Background**

The United States Agency for International Development (USAID) and the United States Pharmacopeia (USP) have been providing technical assistance to Liberia in the areas of quality assurance and quality control (QA/QC) of medicines since 2008. Recently, Promoting the Quality of Medicines (PQM) has begun helping the Liberia Medicines and Health Products Regulatory Authority (LMHRA) develop their capacity to undertake effective medicine regulatory inspections, as well as supporting other key regulatory strategies to strengthen the Authority's operations.

PQM has provided several analytical trainings to LMHRA's National Quality Control Laboratory (NQCL). Using the techniques learned in the trainings, the lab staff has been able to provide evidence-based data to LMHRA. Using these data, the head of LMHRA was able to take regulatory actions on non-conforming medicine samples. To continue building the lab's capacity, PQM has planned to provide additional training to the lab staff and to train personnel who have joined the lab in the last year.

## **Purpose of Trip**

The trip had the following goals:

- Provide compendia testing training to LMHRA lab staff
- Install lab equipment at LMHRA lab
- Discuss lab maintenance contract with LMHRA
- Meet with USAID/Liberia and discuss workplan activities
- Discuss workplan activities with relevant partners

## **Overview of Activities**

### ***Briefing USAID/Liberia***

Mr. Augustin Randolph, Dr. Soukeynatou Traore, and Mrs. Sophie Parwon of USAID/Liberia met with the PQM team, Dr. Latifa El Hadri and Ms. Regina Okafor.

The PQM team provided an overview of the training agenda and the planned activities for the visit. The main outcomes of this meeting include:

- Dr. Soukeynatou Traore advised PQM to update the workplan with the suggestions provided and integrate monitoring the quality of other essential medicines (in addition to antimalarials)
- After discussing the recurring issues the lab is having with water quality and power outages, Mr. Augustin Randolph asked PQM to inquire if LMHRA has funds allocated to solve these issues. The Mission recommended combining solar energy with the generator and adding another filtration system and an additional barrel for more water storage.
- USAID staff requested more information on the processes involved in achieving ISO 17025 and/or World Health Organization (WHO) prequalification. PQM mentioned that the lab is still in early stages of conducting routine lab activities. There is a need for more funds to cover intensive training, provide continuous technical support, and hire more technical staff. PQM proposed having a Quality Management System (QMS) audit and lab equipment inspection in order to provide a proposal with timelines and an itemized budget to help the lab achieve these milestones.

At the end of the meeting, PQM invited the group to visit the lab during the training.

### **LMHRA Laboratory Training**

The training activities conducted during this visit are summarized in the table below. Acronyms used in the chart are explained in the Acronyms list included on page 5.

<b>Item</b>	<b>Description</b>
Specific Objectives	Provide step-by-step training on the following lab techniques: <ul style="list-style-type: none"> <li>• LOD – theory and hands-on</li> <li>• pH – theory and hands-on</li> <li>• HPLC – follow-up on progress – perform hands-on</li> <li>• HPLC – demonstrate how to run gradient runs</li> <li>• UV-Vis – follow-up on progress – perform hands-on</li> <li>• How to effectively use USP NF and understand USP</li> </ul>
Venue/Location	LMHRA NQCL
Organizers	PQM, USAID/Liberia
Sponsors	USAID/Liberia
Trainers	Regina Okafor and Latifa El-Hadri
Agenda	See Agenda in <i>Annex 1</i> for detailed information
Trainees	Five staff from LMHRA NQCL attended the whole training
Opening Ceremony	<ul style="list-style-type: none"> <li>• Latifa El-Hadri, Program Manager, PQM</li> <li>• Regina Okafor, Program Manager, PQM</li> <li>• David Sumo, Managing Director, LMHRA</li> </ul>
Modules	<ul style="list-style-type: none"> <li>• HPLC (theory and hands-on)</li> <li>• LOD (theory and hands-on)</li> <li>• pH (theory and hands-on)</li> <li>• HPLC follow-up (hands-on practice)</li> <li>• How to read and understand USP (practical)</li> <li>• UV-Vis (hands-on practice)</li> </ul>
Closing Ceremony	<ul style="list-style-type: none"> <li>• Latifa El-Hadri, PQM</li> <li>• Regina Okafor, PQM</li> <li>• David Sumo, Managing Director, LMHRA</li> <li>• Soukeynatou Traoré, PMI Advisor, USAID/Liberia</li> <li>• Clavenda Bright Parker, Chairperson, LMHRA</li> </ul>
Outcomes/Conclusion	<ul style="list-style-type: none"> <li>• Trained LMHRA staff on HPLC, LOD, UV-Vis, pH</li> <li>• Trained LMHRA staff on how to read and understand USP General Chapters and General Notices               <ul style="list-style-type: none"> <li>○ Although this training was not in the scope of work, it was discovered that the training was necessary in order for the participants to fully understand and apply the analytical technique according to USP monograph</li> </ul> </li> <li>• Trainees stated that the course was useful and will help them do their jobs better (see <i>Annex 2</i> for trainee evaluations)</li> <li>• As a follow-up, LMHRA staff were given practice assignments to complete and forward to PQM for evaluation</li> </ul>
Next Steps	LMHRA staff should complete the practice assignments by April 30, 2013 and forward the results to PQM for evaluation and feedback

Notes from the training:

- The planned training was implemented according to the agenda. However, some issues were encountered during the training, including the quality of the water and frequent power outages. After cleaning, sanitizing, and installing new filters, the problems persisted.
- The 10KV generator procured by LMHRA was not adequate to support running the air conditioners in the lab and running all lab equipment.
- The lab staff are being proactive by trying to solve some technical issues and by seeking advice from PQM and lab equipment vendors when necessary.
- The lab staff are keeping good records in their laboratory notebooks according to Good Documentation Practices (GDP) requirements. PQM noted that applying GDP is one of the requirements for a lab to become ISO 17025 accredited or WHO prequalified. The dedication shown by a newly established lab demonstrates that the staff are interested in becoming ISO accredited and/or WHO prequalified.

### ***Meetings with LMHRA***

During the course of the training, Mr. David Sumo made several visits to the lab to attend the opening and the closing of the training and to discuss various lab issues. These include: power outages, water shortages, lack of continuous supply of consumables, the need for a maintenance contractor, and the need to hire additional qualified lab technicians. Dr. El Hadri shared with him USAID's suggestions of installing a solar energy system (that can be combined with the existing generator), an additional barrel for water storage on the roof of the lab, and another filtration system to clean the water before it enters the purification system in the lab. She also informed him that the Union Strong Group, a local vendor specializing in renewable energy, was contacted. Mr. Sumo welcomed the ideas and said that he will follow up with the vendor to get an estimate.

PQM also pointed out the need for buying lab supplies from reliable sources. The team showed Mr. Sumo the case of chlorine tablets that clogged the water purification system. To assist the lab in procuring lab supplies, PQM will provide technical assistance in identifying reliable vendors. In addition, to maintain the lab equipment, PQM will facilitate hiring a maintenance contractor who will come to the lab with Dr. El Hadri during the next visit.

The PQM team met with Mr. Sumo and Mrs. Bright Parker, along with Mr. Oliver Opratt and Mr. Levi Hinneh (of the national malaria control program) and Mr. Moses Badio (of the national AIDS control program) to discuss workplans. During the meeting, Mr. Sumo shared the Minilab<sup>®</sup> report on the third round of medicine quality monitoring (MQM) for antimalarials, antiretrovirals, and medicines to treat opportunistic infections. He pointed out action taken by the LMHRA on samples that failed both Minilab<sup>®</sup> and confirmatory testing. Dr. El Hadri then shared the planned activities for this fiscal year and underlined the need to have an integrated post-marketing surveillance program. PQM will organize another meeting with partners with the aim of establishing an MQM protocol and to select sentinel sites.



**Clogged filtration system**

### ***Debriefing USAID/Liberia***

This meeting took place at the LMHRA lab. Mrs. Parker and Mr. Sumo thanked USAID/Liberia for their support, and assured Dr. Traoré that they will work jointly with PQM to find the best solutions for solving the lab's main issues. Mr Sumo also informed Dr. Traoré that a portion of the funding allocated by the Ministry of Health for the lab will be used to improve water and issues.

Dr. Traore then took a tour of the lab, and Dr. El Hadri showed her herbal medicines that were confiscated by LMHRA. Mrs. Parker informed her about the existence of an illegal market of these types of medicines and the need for having a microbiology lab to conduct toxin tests that can help LMHRA enforce regulations of the market and prosecute unscrupulous sellers.



**Herbal medicines confiscated by LMHRA**

### **Conclusion**

The training objectives were accomplished during the visit despite the challenges faced. PQM was able to provide necessary additional training that was not originally in the scope of work. PQM observed that the participants were receptive to the training and showed interest and dedication in learning the new techniques.

Besides the training, PQM staff conducted meetings to lay the groundwork for implementing workplan activities for this fiscal year and discussed with LMHRA ways of addressing the challenges that impede the lab from becoming fully operational.

### **Next steps**

PQM will:

- Provide a list of qualified lab supply vendors to the lab (by March 2013)
- Follow up with partners to organize the MQM meeting (by April 2013)
- Follow up with lab staff on the post-training assignment and provide feedback (by April 2013)
- Facilitate hiring a maintenance contractor for the lab (by April 2013)

LMHRA will:

- Share with PQM the estimates for installing the solar energy system and the options for solving the water issues
- Coordinate with other health programs to implement the fourth round of MQM activities

## TRIPAGENDA

Day 1: Feb 25, 2013		
	Morning	Introductions Discussion of objectives Discuss status of lab Install parts for Water purification system
	Afternoon	Clean and sanitize water purification system Theory Training on LOD
Day 2: Feb 26, 2013		
	Morning	Hands-on training on LOD Uv-Vis hands-on Theory training on HPLC follow-up
	Afternoon	How to read and understand USP Complete LOD and perform calculation Evaluate result of LOD, discuss mistakes and errors
Day 3: Feb 27, 2013		
	Morning	Repeat LOD hands-on (another analyst) USAID Briefing
	Afternoon	Complete How to read and understand USP HPLC hands-preparation of solutions Run HPLC and evaluate chromatogram and system suitability
Day 4: Feb 28, 2013		
	Morning	Complete HPLC
	Afternoon	Discuss HPLC result Discuss outcomes of all training pH theory
Day 5: Mar 1, 2013		
	Morning	pH hands-on Training on HPLC gradient setup HPLC creation of new method Summarize HPLC trouble shooting
	Afternoon	Discuss results of pH Assign homework Review Monograph for Ciprofloxacin Tablet (to be used for NOMCOL participation)

**PQM PARTICIPANT TRAINING EVALUATION ♦ February 25 – March 1, 2013**

In order for PQM to evaluate the efficacy of each training module and improve the level of the courses, we as asked all participants to kindly provide their feedback by filling out evaluation sheets. The responses of the participants to the various questions asked are tabulated below.

A. Evaluation of the Specific Aspects of the Training Workshop

TRAINING	EXTENT TO WHICH THE TRAINING MET YOUR OVERALL EXPECTAIONS			
	Exceeded Expectations	Met Expectations	Met Some Expectations	Unsatisfactory
Loss on Drying		5		
HPLC			4	
How to read and Understand USP		4	1	

B. Overall Evaluation of the Training

	Strongly Agree	Agree	Somewhat Disagree
Course objectives were relevant to my needs	1	4	
The training materials helped me understand and better organize my activities	1	4	
I was able to understand the content of the materials presented		5	
Overall, the course was useful and helped me do my job better	3	2	
There were enough practical exercises to facilitate understanding of the course		3	2
The pacing of the various sessions was appropriate for my understanding of course materials		5	
The sequence in which the sessions were presented was appropriate for my understanding	1	4	
The Instructor was knowledgeable on the subject matter	3	2	
The instructor allowed an appropriate level of participation	1	4	

C. Other Comments/Suggestions

- Training should be more than one week
- Reagents and materials should be available before the start of training
- The course allowed for proper organization and planning of work and proper documentation