Training on Minilab® at the National Quality Control Laboratory and Evaluation of the Laboratory Quality Management System

Nairobi, Kenya
April 22-26, 2013

Trip Report

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Executive Summary

PQM staff, Drs. Latifa El Hadri and Donnell Charles, traveled to Nairobi, Kenya in April to:

1. Conduct refresher Minilab® training and training on sampling, on-site testing, and data reporting for team leaders from the Pharmacy and Poisons Board (PPB) and National Quality Control Laboratory (NQCL)
2. Perform a quality management system (QMS) evaluation and lab inspection at NQCL

Following the training, the participants were able to test antimalarials and also other essential medicines to treat tuberculosis and HIV. The trainees will implement these skills during the upcoming rounds of MQM.

Dr. Charles completed the QMS evaluation and lab inspection at NQCL and submitted a full, confidential report directly to appropriate NQCL and USAID staff. The report contains details regarding the observations made during the assessment and a timeline for the next steps.

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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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- NQCL staff for their high level of interest and feedback, as well as for their efforts and logistical help, which helped make the trip successful
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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

ACRONYMS

DOMC	Division of Malaria Control
DQI	Drug Quality and Information Program
GMP	Good Manufacturing Practices
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
ISO	International Organization of Standardization
KF	Karl Fisher
MOH	Ministry of Health
NMCP	National Malaria Control Program
NQCL	National Quality Control Laboratory
OFI	Opportunity for Improvement
PMI	President's Malaria Initiative
PPB	Pharmacy and Poisons Board
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
SANAS	South African National Accreditation System
SOP	Standard Operating Procedure
TB	Tuberculosis
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
UV	UV Spectrophotometer
WHO	World Health Organization

Background

The U.S. Agency for International Development (USAID) and U.S. Pharmacopeia (USP) have been providing technical assistance to Kenya since 2009. The primary focus of PQM activities in Kenya is to strengthen medicines quality assurance by establishing a medicine quality monitoring (MQM) program in five sentinel sites. PQM provided Minilab® training in 2010 to fourteen staff from the Pharmacy and Poisons Board (PPB) and the National Quality Control Laboratory (NCQL) to begin MQM. Following monitoring and evaluation visits to the sentinel sites during three rounds of MQM, it was revealed that the sentinel site teams need refresher training on sampling and testing using Minilab® screening tests.

As part of improving the quality control (QC) of medicines in the country, PQM has also provided training on compendial testing and has begun assisting the lab with the process of becoming ISO 17025 accredited.

Purpose of Trip

PQM staff, Drs. Latifa El Hadri and Donnell Charles, traveled to Nairobi, Kenya to conduct the following activities:

- Conduct refresher Minilab® training for team leaders from PPB and NQCL
- Conduct training on sampling, on-site testing, and data reporting
- Perform a quality management system (QMS) evaluation and lab inspection at NQCL

Source of Funding

These activities were supported by USAID/Kenya.

Overview of Activities

Dr. Charles completed a QMS evaluation and lab inspection at NQCL and submitted a full, confidential report directly to appropriate NQCL and USAID staff. The report contains details regarding the observations made during the assessment and a timeline for the next steps. The QMS evaluation agenda is included in *Annex 1*. Please contact Dr. Charles at dxc@usp.org for more information.

NQCL management and PQM staff

The following chart contains details on the MQM training provided during the trip:

Item	Description
Training Objectives	Improve techniques for: • Sampling • Minilab® screening tests – focus on Thin Layer Chromatography (TLC) methods • Data reporting
Venue	NQCL, Nairobi, Kenya
Trainers	Dr. Latifa El Hadri, Dr. Donnell Charles, and Dr. Richard Jähnke (of Global Pharma Health Fund "GPHF")
Organizers	PPB, Division of Malaria Control (DOMC), NQCL, and PQM
Course Proceedings	Day 1: • Set up Minilab® training material and equipment • Improving sampling: How to target samples (suspicious samples, samples with enough units, use of mystery shoppers, and diversification source of sample collection) • Improving testing at sites: Staffs were trained on conducting preparatory session with sentinel site teams. The sentinel site team leaders were instructed to go over the list of samples to be tested and review TLC procedures, reporting forms, sample handling, and data reporting prior to sample collection. The preparatory session should take place one day before starting sampling in the field. Team leaders from the NQCL will supervise the testing using Minilabs®. . Day 2: • Introduction to basic tests and Minilabs® • Work group: visual inspection • Participants conducted visual inspection tests on several samples and filled out the forms for sample collection and visual and physical inspection • Work group: familiarization with TLC and how to do a proper spotting Day 3: • Work group: TLC testing of Artemether/ Lumefantrine • Work group: TLC testing of Dihydroartemisinin/Piperaquine, Day 4: • Work group: TLC testing of Rifampicin/Isoniazid/Ethambutol/Pyrazinamide and Lamivudine/Nevirapine/Zidovudine • Work group: review of sampling strategy, testing, and reporting for each sentinel site Day : 5 • Review of the training results • Wrap-up session • Evaluation of the workshop • Distribution of certificate
Participants	24 participants from PPB and NQCL attended the training, including representatives from the TB and HIV programs (see *Annex 2* for complete list of participants) Some trainees received this training in Jan 2010; this was a refresher for them. Others received the training for the first time.

Closing Ceremony	Following the closing remarks, certificates were awarded to all participants.
Course Outcomes	At the end of the course, participants were able to: • Test various medicines using the Minilab®, detect the quality of sample spotting, and draw conclusions on whether a sample failed or passed • Demonstrate good understanding on how to improve sample collection, handling, and testing • Report results with justifications on why a sample failed
Course Evaluation	Participants were asked to evaluate each of the course modules and sessions by filling out the Course Evaluation Form. A total of 14 participants returned their forms, and all agreed that the training met or exceeded their expectations. See *Annex 3* for the course evaluations.
Conclusion	The trainees benefited from the training and the sessions on improving sampling and testing at the sites and at the lab. The training was a good opportunity to discuss the upcoming MQM round and how the TB and HIV departments can join this activity. Photos from the training are included in *Annex 4*.
Next Steps	• The MQM focal point will ensure that each team leader conducts a preparatory session before sampling • PQM and the MQM focal point will communicate with the heads of the TB and HIV departments to check if they are going to participate in this coming round

Debrief USAID/Kenya

Dr. El Hadri debriefed Dr. Kaendi, Senior PMI advisor at USAID/Kenya, on the outcomes of the training, the lab inspection, and the QMS assessment. She underlined that the Minilab® training was extended to one participant from the TB division and one from the HIV division. The heads of these two divisions are interested in integrating their post-marketing surveillance programs under the MQM program.

Dr. El Hadri also updated Dr. Kaendi about the findings from the QMS assessment and lab inspection.

Annex 1

PQM QMS Evaluation Agenda

National Quality Control Laboratory
Nairobi, Kenya
April 22 – April 26, 2013

DAY 1		Responsible
09:00-10:00	• Introduction of Participants • Presentation of the agenda/objective of the visit	NQCL representative PQM representative

10:00-12:00	• PQM pre-reassessment activities
	  • Status of Quality Manual and System
	  o Discuss any changes since the change in staffing. Present a copy of your quality manual if there have been any changes.
	  • Review of any changes to the WHO pre-qualification and future accreditation scope including uncertainty budgets.
	  • Management & Organization (4.1)
		NQCL representative
		PQM representative

12:00-13:00	**Lunch & Break**	

13:00-17:00	• PQM ISO 17025 Section 4 assessment activities continue
	  • Document Control (4.3)
	  o Master List (External Document Control)
	  o Distribution location
	  • Review of Suppliers/Purchasing (4.6)
	  • Customer Evaluations and Surveys (4.7)
	  • Complaints (4.8)
	  • Corrective and Preventative Action (4.9-12)
	  • Review of closure/implementation of prior non-conformities.
	  o Please present each finding, its solution, and evidence of closure. Solutions will be verified.
	  o Review of prior OFI
	  • Follow-up Activities
	  • Control of Records (4.13)
	  • Internal Audits (4.14)
	  • Management Review (4.15)
		NQCL representative
		PQM representative

DAY 2		
09:00-10:00	• Laboratory Inspection/Walkthrough • Sample receipt area • Chemical Receipt area • On-site Equipment/Backup Systems Review • Accommodation & Environment (5.3)	NQCL representative PQM representative

10:00-12:00	• PQM ISO 17025 Section 5 assessment activities
	  • Personnel Review (5.1)
	  o Training Records
	  o Education
	  o Authorization
	  o Technical Signature Authority
	  • Accommodation & Environment (5.3)
	  • Calibration and test methods & method validation (5.4)
	  • Equipment (5.5)
	  o <u>Software Master (List of all software used pertaining to your ISO accreditation)</u>
	  • Measure Traceability/ Uncertainty (5.6)
	  • Handling of calibration and test items (5.8)
		NQCL representative
		PQM representative

12:00-13:00	**Lunch & Break**	

13:00-17:00	• PQM pre-reassessment activities
	  • Assuring quality of calibration and test results (5.9)
	  • Reporting the results (5.10)
	  o <u>Trending Controls</u>
	  • Review of scope
	  • Review of all Proficiency Testing Activities and four-year plan
	  • Maintenance Planning
		NQCL representative
		PQM representative

DAY 3		

09:00-12:00	• PQM pre-reassessment Demonstration
	  • HPLC
	  • Dissolution
		NQCL representative
		PQM representative

12:00-13:00	**Lunch & Break**	

13:00-17:00	• PQM pre-reassessment Demonstration
	  • UV
	  • Content Uniformity
		NQCL representative
		PQM representative

DAY 4		

09:00-12:00	• PQM pre-reassessment Demonstration
	  • KF
	  • pH
	  • LOD
	  • Other
		NQCL representative
		PQM representative

12:00-13:00	**Lunch & Break**	
13:00-17:00	Wrap up and closing meeting • Discussion of all Deficiencies and OFI's found during PQM assessment • Review of all Deficiencies and OFI's found during Reassessment • Discussion on Sustainability and Strategic Plan	PQM representative NQCL representative

Annex 2

Training Participants – April 22-26, 2013		
no	**Participants**	**Institution**
1	Abdulkadir Omar	NQCL- Pharmacist
2	Beatrice Mutisya	NQCL- Laboratory Analyst
3	David Yano	NQCL- Finance Auditor
4	Eric Mutua	NQCL- Pharmacist
5	Eric Ngamau	NQCL- Laboratory Biological Analyst
6	Francis Naula	NQCL- Laboratory Technologist
7	Jane Matundura	NQCL- Laboratory Technologist
8	Khadija Hassan	NQCL- Pharmacist
9	Lorna Wangari	NQCL- Pharmacist
10	Mathayo Kwena	NQCL-Head of Wet Chemistry Section
11	Mercy Wandeto	NQCL-Head of Microbiology Section
12	Michael Sangale	NQCL- Laboratory Analyst
13	Sarah Kariuki	NQCL- Laboratory Analyst
14	Edward Abwao	PPB Eldoret sentinel site team leader - Head of Clinical Trials
15	George Muthuri	PPB Nairobi Sentinel site team leader - Senior Pharmaceutical Technologist
16	Patrick Kibiego	PPB Laboratory Liaison Officer- Kakamega Sentinel site team leader
17	James Kingori	PPB- Pharmaceutical Inspector – Mombasa -Sentinel site team leader
18	Peter Kiptoo	PPB- Head- Ports of Entry- Kisumu sentinel site team leader
19	Richard Muthoka	TB Division - Pharmacist
20	Moses Kigen	TB Division - Pharm Tech
21	Caroline Olwande	NASCOP - Pharmacist
22	Jayesh Pandit	PPB - Head of Pharmacovigilance Division
23	Andrew Nyandigisi	DOMC- Pharmacist
24	Steve Kimatu	PPB- Director- Focal point of MQM activities

Annex 3

Training Evaluation Summary

In order for PQM to evaluate the efficacy of each training module and improve the level of the courses, we ask all participants to kindly provide their feedback by filling out this evaluation sheet.

14 participants returned their forms.

A- Evaluation of Specific Aspects of the Training Workshop

TRAINING	EXTENT TO WHICH THE TRAINING MET YOUR OVERALL EXPECTATIONS			
	Exceeded Expectations	**Met Expectations**	**Met Some Expectations**	**Unsatisfactory**
Refresher training on minilab basic tests, sampling, testing and reporting data	10	4		

B- Overall Evaluation of the Training Workshop

	Strongly agree	**Agree**	**Somewhat disagree**
Course objectives were relevant to my needs	9	5	
The training material helped me understand and better organize my data	10	4	
I was able to understand the content of the materials presented	8	6	
Overall, the course was useful and will help me do my job better	11	3	
There were enough practical exercises to facilitate understanding of the course	9	5	
The pacing of the various sessions was appropriate for my understanding of course materials	10	4	
The sequence in which the sessions were presented was appropriate for my understanding	11	3	
The instructors were knowledgeable on the subject	12	2	
The instructors allowed an appropriate level of participation	11	3	

C- Other Comments/Suggestions:

1. **What did you like best about the course?**
   - The staining techniques very useful to have better quality of sample spots
   - Product information on TLC plate helpful to trace the sample source in case of lost of sampling forms
   - Sessions on how to improve sampling and testing were highly needed

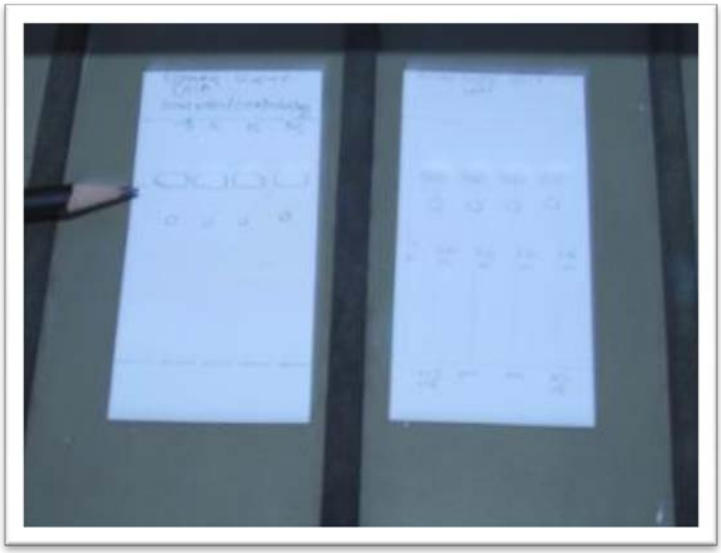
2. **What are your recommendations/suggestions for improvement of the course?**
   - Have more practice time for new trainees
   - More time should be dedicated to reporting results
   - Need to have separate groups according to the analyst laboratory skills

Annex 4

Photos from PQM Minilab® Training

PQM and GPHF trainers assist participants in learning or improving their Minilab® testing techniques during training held at the NQCL in Kenya in April 2013

NQCL staff conducted TLC during the training.



The plates are left to dry before they are completed.