

Training for the National Quality Control Laboratory (LNCM) on Karl Fischer Titration, Loss on Drying, pH Meter, and Good Documentation Practices According to ISO 17025 Requirements

**Dakar, Senegal
January 28–February 1, 2013**

Trip Report

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Executive Summary

PQM staff provided hands-on training to the staff of the National Quality Control Laboratory in Senegal on three procedures: Titration by Karl Fischer, pH-Meter, and Loss on Drying. Because these techniques are included in the scope of the laboratory's pursuit of ISO 17025 accreditation, the training focused on the ISO 17025 requirements. In addition to the training, PQM staff provided presentations on Good Laboratory Documentation and how to use USP General Chapters.

Additionally, Dr. El Hadri conducted other meetings with relevant partners and discussed the planning of FY12 activities.

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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 leadership 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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- Coordinator of the National Malaria Control Program and his deputy for convening a meeting with the lab chief and the focal point of the Monitoring the Quality of Medicines (MQM) program
- Chief of the National Quality Control Laboratory (LNCM) and his staff for their contributions to the planning of and participation in the training
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report



ACRONYMS

AM	Antimalarial
ARV	Antiretroviral
ATB	Anti-tuberculosis
CDC	U.S. Centers for Disease Control and Prevention
DPM	Direction de la Pharmacie et Médicaments (Department of Pharmacies and Medicines)
DQI	Drug Quality and Information Program
DGS	Director Général de la Santé (General Director of Health)
FY	Fiscal Year
GHIP	Global Health Impact Programs
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ILAC	the International Laboratory Accreditation Cooperation
LNCM	Laboratoire National de Contrôle des Médicaments (National Quality Control Laboratory)
MCR	Medecin Chef Regional (Regional Chief Doctor)
MQM	Monitoring the Quality of Medicines
pH	Measure of how acidic or basic an aqueous solution is
PMI	President's Malarial Initiative
PNA	Pharmacie Nationale d'Approvisionnement (Central Medical Store)
PNLP	Programme Nationale de Lute contre le Palludisme (Malaria National Control Program)
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
TA	Technical Assistance
USAID	United States Agency for International Development
TUNAC	Conseil National d'Accreditation (Tunisian Accreditation Council)
USP	United States Pharmacopeial Convention

Background

The U.S. Agency for International Development (USAID) and the U.S. Pharmacopeial Convention (USP) have been providing technical assistance to Senegal since 2002 to strengthen the quality control (QC) and the quality assurance (QA) systems for medicines. Since then, PQM has helped launch a Medicines Quality Monitoring (MQM) program, establishing five sentinel sites. In 2009, with funding from the President's Malaria Initiative (PMI) and contributions from other major health programs, PQM expanded this activity to include four additional sentinel sites and to cover not only antimalarial, but also anti-retroviral (ARV) and anti-tuberculosis (TB) medicines as well as contraceptives.

As part of strengthening the quality assurance in Senegal, in 2012 PQM began assisting the country's national quality control laboratory (LNCM) to become ISO 17025 accredited. First, PQM staff conducted an assessment (mock audit) of the lab according to international standards and evaluating the LNCM's technical capacity, based on ISO 17025 requirements. Next, PQM monitored the progress of the LNCM's implementing the ISO 17025 action plan, revised the lab's Standard Operating Procedures (SOPs), and the management in selecting their accrediting bodies. During a October 2012 visit, PQM presented to major stakeholders what was involved in the process of ISO 17025 accreditation and shared with them the LNCM's need for the equipment and training required to accomplish this milestone.

Purpose of Trip

As part of LNCM's scope of ISO 17025 accreditation, PQM staff members, Latifa El Hadri and Regina Okafor, traveled to Senegal to:

- Provide lab training on Karl Fischer Titration, pH Meter, Loss on Drying, and the use of Good Documentation Practices (GDP) according to ISO 17025 requirements, and,
- Determine what training the lab staff will need for ISO ... and schedule training dates with LNCM.

To begin implementing approved FY12 Workplan activities, Dr. El Hadri conducted the following:

- Followed up on action plans from the previous meeting with major stakeholders at the MOH;
- Planned a workshop for the medicines regulatory authority (DPM) and enforcing entities, i.e., customs officers and judiciary police; and,
- Presented planned FY 12 activities to relevant stakeholders and started planning MQM activities.

Source of Funding

These activities were funded by USAID/Senegal through the President's Malaria Initiative.

Overview of Activities

The training activities conducted during this visit are listed in the Agenda ([Annex 1](#)); the main activities are summarized in the table below.

Item	Description
Specific Objectives	<ul style="list-style-type: none"> • Install a new Karl Fischer Titrator • Provide lab training on Karl Fisher Titration, pH Meter, and the use of Good Documentation Practices (GDP) according to ISO 17025 requirements • Determine what training the LNCM lab staff will need for LNCM ISO 17025 accreditation and schedule
Venue/Location	Dakar, Senegal
Institution Evaluated	Laboratoire National de Contrôle des Médicaments (LNCM)
Trainers and Facilitators	See Annex 2 for List of Participants.
Agenda	See Annex 1 for Agenda.
Modules	pH, Karl Fischer, Loss on Drying, Good Documentation Practices
Training Evaluation	See Annex 3 for Participants' Evaluation.
Conclusion	<ul style="list-style-type: none"> • LNCM has made noticeable improvement since the PQM visit in October 2012: <ul style="list-style-type: none"> – The lab was noticeably cleaner and organized than was previously observed, and, – Some SOPs and documentation critical to meet ISO 17025 requirements have been completed. There are, however, some major documents and components that are still missing in order to satisfy ISO requirements and that need to be completed before scheduling a pre-assessment by the accreditation body. • GDP training revealed that LNCM needs to improve its internal audit frequency to ensure implementation of SOPs, particularly since this still remains a critical challenge. • During the training it was noted that the majority of the staff did not document analyses in a laboratory notebook. • Common mistakes and weighing errors were observed by Ms. Okafor that could immediately be corrected. LNCM staff who were observed making some of these lab practice errors were given time to repeat the analysis correctly under observation by Ms. Okafor. <p>PQM recommends skill-strengthening on techniques for the scope of accreditation, especially GDP, Karl Fischer, and Loss on Drying; for example, more attention should be paid to details during the weighing process to avoid making critical mistakes that will affect the final result.</p>
Next Steps	Provide training refresher on GDP, Dissolution/ Performance Verification Test, and Assay.

Report on PQM Training for LNCM according to ISO 17025 Requirements



Hands-on laboratory training



Theory training in classroom



LNCM staff testing for quality



Supplies procured for the lab training



Prep for lab training



LNCM staff running tests

Meeting at USAID Mission

On January 28, Dr. El Hadri briefed Mr. Birame Diouf, PMI Malaria Advisor, and Miss Julie Thwing, Malaria Advisor for U.S. Centers for Disease Control and Prevention (CDC), on the activities planned for the week and shared the training agenda with them.

Dr. Diouf expressed his support and asked to attend the meetings with the General Director of Health and with the Malaria Control Program (PNLP) and MQM teams. Dr. El Hadri gave an overview of the objectives of the training and explained that the training are within the scope of the ISO 17025 accreditation the lab is pursuing. Miss Thwing inquired about the remaining training the lab needs and how it will help advance the accreditation process. Dr. El Hadri confirmed that the training list will be finalized with LNCM staff during this trip.

Meeting with LNCM Staff

Dr. El Hadri introduced Regina Okafor, PQM Program Manager, to the lab staff and gave them the training agenda. Pr. Yerim, LNCM chief, thanked PQM staff for their technical assistance and for procuring and delivering the new Karl Fischer and all the supplies for the training.

Ms. Okafor gave an overview of the training modules and emphasized to lab staff the importance of conducting the training according to ISO 17025 requirements. She informed them that after the theory training, each group would perform Loss on Drying (LOD) on Albendazole, pH determination on Amoxicillin for oral suspension, and Karl Fischer (water determination) for practical application. Ms. Okafor also asked questions about the different modules to determine the LNCM staff's level of understanding. During the training process, practical laboratory examples were used to illustrate the theories of each module.

Meeting with the General Director of Health

Participants: Mr. Papa Amadou Diack, Senegal General Director of Health
Dr. Birame Diouf, PMI Malaria Advisor
Pr. Yerim Diop, LNCM Chief
Latifa El Hadri, Program Manager, PQM

PQM and LNCM arranged this meeting with Mr. Diack, General Director of Health (DGS), because he had been unable to attend the briefing in October 2013, at which time Dr. El Hadri explained the ISO 17025 accreditation process and needed equipment and training for the LNCM. Pr. Yerim briefed Mr. Diack about that meeting and asked him to support the lab accreditation.

Mr. Diack welcomed the audience and thanked USAID and PQM for their support. He asked Pr. Yerim to present an action plan with the lab's needs and an itemized budget, as well as road map of ISO 17025 and timeline for reaching accreditation, to the MOH coordination meeting that will be held in two weeks. Mr. Diak assured the group that he would submit the supporting document for the lab accreditation to the Minister of Health. As part of supporting lab accreditation, Mr. Diak promised the lab chief to change the status of selected lab staff from contract to permanent positions, which will motivate them to stay in the lab and work hard toward ISO 17025 accreditation.

Finally, Dr. Diouf asked the DGS to support a planned workshop between DPM and the customs and judiciary police. Mr. Diack said he would ask Pr. Papa Diop, DPM Director, to invite the director of customs and other higher officials of enforcement agencies to attend the upcoming inter-Ministerial meeting and to share with them the objective of the planning of the workshop.

Meeting of Partners at the Malaria Control Program Office

Participants: Dr. Birame Diouf, PMI Adviser, USAID/Rwanda
Dr. Mady Ba, National Coordinator, PNLP
Dr. Ibrahim Diallo, Technical Counselor, Quality Control and Pharmacovigilance
Pr. Yerim Diop, Chief, LNCM
Dr. Adama Diedhiou, MQM focal point and head of Metrology Department, LNCM
Dr. Latifa El Hadri, Program Manager, PQM

Dr. El Hadri organized a meeting at the PNLP office to discuss the planned FY13 MQM activities and to begin implementation. Dr. Diallo welcomed the attendees, thanked Dr. Diouf for his continuing support of PMI activities and assisting with the meeting, and opened the meeting for discussion. Attendees planned to present the 2011 and 2012 MQM results and implement of the 2013 round, and discussed support of PQM activities in the field with the following outcomes:

- For the 2013 MQM round, PQM staff proposed that Dr. Diedhiou meet with the heads and other representative of major health programs and plan the sampling and testing, timeline, and budget and ask them to contribute during the implementation of MQM activities in the field.
- It is important to have all post-marketing activities under one MQM program and to share the results in a timely manner with all concerned parties for the program to be effective.
- MQM results should be presented at the MOH cabinet office with the Regional Chief Doctors of the nine sentinel sites and other partners in attendance. The agenda should include the presentation and review of the MQM protocol, sharing information, and ensuring regular feedback. PQM should present on PQM activities and include lab accreditation advocacy documents.

In closing, Dr. Diouf asked working groups to meet frequently and discuss any technical aspects with Dr. El Hadri while she is available in-country. Dr. Ba thanked the USAID Mission for their continuous support and PQM for their technical assistance. He also stated that DPM should maintain leadership of MQM activities and participate actively in planning the MQM meeting.

Meeting with the Director of Customs Operations

Participants: Colonel Aliou Ndiaye, Director, Customs Operations
Pr. Papa Diop, Director, DPM
Dr. Madicke Diagne, Chief of Inspection, DPM
Dr. El Hadri, Program Manager, PQM

The department of pharmacy and medicines has been taking regulatory actions on expired, non-registered, and failed samples found and reported after each round of MQM, however, there is no effective mechanism in place for DPM, customs, and the judiciary police to collaborate and coordinate their efforts to enforce such regulatory actions. The PQM work plan includes

conducting a workshop with this purpose in mind and met with Colonel Aliou Ndiaye, Director of Customs Operations, to begin planning. Pr. Diop, DPM Director, facilitated this planning meeting.

Col. Ndiaye welcomed the idea of the workshop and expressed great interest in being involved at all stages of the planning. After discussing with the workshop objectives, Col. Ndiaye asked Dr. Diagne, DPM Chief of Inspection, to include the following in the workshop:

- Establish a platform/communication tool for the exchange of information related to the quality of medicines and enforcement actions;
- Harmonize a Legislative Act for Customs and DPM to regulate pharmaceutical products and specifically address counterfeit and substandard products;
- Train enforcement agents how to detect non-conforming pharmaceutical products; and,
- Build new data base or improve the existing one at the custom level to share information and optimize use of and access to registered medicines in country, reports on alleged counterfeiters and counterfeit medicines.

Col. Ndiaye said he will share planning of the workshop with other Customs divisions and will send a list of potential participants to Pr. Diop. Dr. Diagne offered to work closely with Col. Ndiaye and PQM to plan the workshop; to begin, he will provide Col. Ndiaye with background information and a tentative agenda to cover the items suggested during the meeting.

Debriefing of USAID/Senegal

Ms. Okafor and Dr. El Hadri met with Dr. Diouf and debriefed him on the outcome of the activities conducted during this trip, focusing on the training conducted at LNCM, particularly:

- High motivation of the LNCM staff in participating at the training.
- The training was expanded to include the microbiology department staff, as they had expressed interest in becoming part of the analytical chemistry lab and had requested include Microbiology in the scope of the lab's ISO 17025 accreditation.
- PQM finalized the list of training needed by the lab; the list was requested by Mrs Thwing ([Annex 4](#)).
- Some of the LNCM staff have demonstrated great interest, and it will be important to cultivate this interest by following up on activities and conducting additional training.

Next Steps

PQM

- Follow up on the post-training exercise requested by the lab staff.
- Finalize the planning and logistics for conducting the 2013 MQM round, then submit the MQM contract to DPM by end of March 2013.
- Discuss the results of the assignments given to LNCM staff during the January 2013 training by April 15, 2013.

DPM

- Take the lead in organizing the meeting to share result of 2011 and 2012 MQM. Finalize meeting dates for April 2013 with Pr. Diop.

Report on PQM Training for LNCM according to ISO 17025 Requirements

- Present the regulatory action taken by DPM during the course of 2011 and 2012 MQM rounds
- Agenda of the meeting should be prepared in collaboration with PQM, PNLP and LNCM

LNCM

- Prepare the lab accreditation document to be presented at the MQM meeting and the coordination meeting at the MOH by LNCM staff by the end of April 2013.
- Provide a final report on MQM activities before the MQM meeting by mid-March 2013.
- Share MQM results with stakeholders by the end of April 2013.
- Provide PQM with the assignment results



Annex 1

PQM Training on Karl Fischer, pH, and Good Documentation Practice Laboratoire National de Contrôle des Médicaments Dakar, Sénégal ♦ January 28–February 1, 2013

AGENDA

Visit Objectives

- Install Karl Fischer Titrator
- Provide training on Karl Fischer (KF)
- Provide training on pH Meter
- Meet with QA Manager to assist in strengthening Quality System
- Follow up on assistance PQM provided to the Quality Assurance Unit at LNCM
- Meet with USAID/Senegal Team

PQM Staff

- Latifa El Hadri, Program Manager, Promoting the Quality of Medicines (PQM) Program, U.S. Pharmacopeial Convention
- Regina Okafor, Program Manager, PQM Program, U.S. Pharmacopeial Convention

Day	Session	Activities	PQM Lead	LNCM Participants
Monday	Morning	<ul style="list-style-type: none"> • Opening meeting: <ul style="list-style-type: none"> ○ Update on current lab usage of the KF ○ Discuss objectives and expectations of visit ○ Adjust agenda as necessary 	R. Okafor L. El Hadri	All Staff
		<ul style="list-style-type: none"> • Opening Workshop – <ul style="list-style-type: none"> ○ Install Karl Fischer ○ Discussion on Karl Fischer and proficiency level of staff 	R. Okafor L. El Hadri	All technical staff
	Afternoon	<ul style="list-style-type: none"> • Begin training on KF <ul style="list-style-type: none"> ○ Working sessions with staff - installation ○ Answer questions on KF ○ LNCM staff participation 	R. Okafor L. El Hadri	All Technical staff
Tuesday	Morning	<ul style="list-style-type: none"> • Theory on KF training <ul style="list-style-type: none"> ○ Hands-on practice ○ Start working session with staff ○ Divide staff in groups – Group participation 	R. Okafor L. El Hadri	All technical staff
	Afternoon	<ul style="list-style-type: none"> • Continue working KF session • Troubleshooting KF tips 	R. Okafor L. El Hadri	All technical staff
Wednesday	Morning	<ul style="list-style-type: none"> • Complete any troubleshooting tips <ul style="list-style-type: none"> ○ Evaluate performance on KF ○ Evaluate other issues related to KF discussion with lab staff ○ Start pH training - theory 	R. Okafor L. El Hadri	All technical staff
	Afternoon	<ul style="list-style-type: none"> ○ Meet with QA Officer to discuss SOPs ○ Complete pH training 	R. Okafor L. El Hadri	All technical staff
		<ul style="list-style-type: none"> • Discussion on Loss on Drying – theory • Loss on Drying - practice 	R. Okafor L. El Hadri	All technical staff
Thursday	Morning	<ul style="list-style-type: none"> • Working Session with QA Officer to determine other SOPs to help develop pertaining to scope of accreditation pH SOP, HPLC SOP, Loss on Drying SOP, UV SOP, and Dissolution SOP • Start GDP training 	R. Okafor L. El Hadri	NA
	Afternoon	<ul style="list-style-type: none"> • Continue GDP training with staff • Practical examples and evaluation of staff notebook 	R. Okafor L. El Hadri	All LNCM staff
Friday	Morning	<ul style="list-style-type: none"> • USAID Debrief • Complete any training outstanding • Open discussion about other lab concerns or questions 	R. Okafor L. El Hadri	NA
	Afternoon	<ul style="list-style-type: none"> • Closing meeting: <ul style="list-style-type: none"> ○ Distribution of certificate 	R. Okafor L. El Hadri	All LNCM staff

**PQM Training on Karl Fischer, pH, and Good Documentation Practice
Laboratoire National de Contrôle des Médicaments
Dakar, Sénégal ♦ January 28–February 1, 2013**

List of Participants

1. Mme. Mame Ndack NDIAYE
2. Mme. Awa SY
3. Mme. Ndoussé COUNDOUL
4. Mme. Fatou NDIAYE
5. M. Mamadou Ibra NGOM
6. Mme. Diabou DIALLO
7. Dr. Ndèye Maguette DIAO
8. Dr. Serigne Omar SARR
9. Dr. Adama DIEDHIOU
10. M. Mouhamadou NIANG
11. Dr. Ibrahima TOURE

PQM Training on Karl Fischer, pH, and Good Documentation Practice
 Laboratoire National de Contrôle des Médicaments
 Dakar, Sénégal ♦ January 28–February 1, 2013

Training Evaluation by Participants

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.

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
Training on LOD, KF titration, pH meter, and Good Laboratory Practices	8	3	1	0

B- Overall Evaluation of the Training Workshop

	Strongly agree	Agree	Somewhat disagree
Course objectives were relevant to my needs	8	4	
The training material helped me understand and better organize my data	9	3	
I was able to understand the content of the materials presented	7	4	1
Overall, the course was useful and will help me do my job better	9	3	
There were enough practical exercises to facilitate my understanding of the course	9	3	
The pacing of the various sessions was appropriate for my understanding of course materials	8	4	
The sequence in which the sessions were presented was appropriate for my understanding	9	3	
The instructors were knowledgeable on the subject	10	2	
The instructors allowed an appropriate level of participation	11	1	

C- Other Comments/Suggestions:

1. What did you like best about the course?

- The training modules were very useful and explain how to conduct each training skills.
- The hands-on part was instructive specially to microbiology team

2. What are your recommendations/suggestions for improvement of the course?

- Increase the period of training specially the hands- on part.
- Provide more training in French language
- Need to have exercises on the results and interpretation of data
- Prioritize some training activities and decrease the number of training group



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Annex 4

Numéro de la formation	Libellé	Personnel concerné	Formateur (s)/lieu de formation	Dates prévisionnelles
1.	Formation sur l'utilisation des monographies (USP, EP, BP, IP, ...)	Tout le personnel		
2.	Maîtrise des incertitudes de mesure.	Tout le personnel		
3.	Gestion des données brutes générées lors des essais.	Tout le personnel		
4.	Maîtrise des Bonnes Pratiques de HPLC , traitement et exploitation des données brutes	Tout le personnel		
5.	Maîtrise des Bonnes Pratiques de spectrophotométrie UV visible	Tout le personnel		
6.	Maîtrise des Bonnes Pratiques de l'essai de dissolution	Tout le personnel		
7.	Bonnes Pratiques de KF ,LOD, GDP	Déjà effectuée	PQM Staff at LNCM	Completed during Jan 28-Feb1, 2013
8.	Gestion des anomalies et des déviations	Tout le personnel		
9.	Formation sur l' audit interne	Tout le personnel		
10.	La métrologie au laboratoire d'essai	Tout le personnel		
11.	La gestion documentaire	Tout le personnel		
12.	Sécurité au laboratoire	Tout le personnel		



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13.	Notions de chimométrie	Tout le personnel		
14.	Evaluation des dossiers techniques des médicaments	Tout le personnel		
15.	Validation restreinte de méthodes d'analyses	Tout le personnel		
16.	Formation à l'utilisation de la GC-MS Perkin	Tout le personnel		
17.	Formation aux premiers secours et à l'utilisation des extincteurs.	Tout le personnel		
18.	Gestion des déchets	Tout le personnel		
19.	Entretien d'une souche bactérienne	Microbiologie		
20.	Reconstitution et entretien des souches de référence	Microbiologie		
21.	Interprétation des résultats de l'activité antibiotique	Microbiologie		
22.	Test de stérilité	Microbiologie		
23.	Dosage des endotoxines bactériennes	Microbiologie		
24.	Culture cellule vero	Microbiologie		

Visa RQ

Visa Chef de service