

**Opening of National Laboratory for Medicines Quality Control (LNCQM)
LNCQM Temporary Quality Control Lab and Monograph Testing Training Workshop**

**Maputo, Mozambique
April 9-20, 2012**

Trip Report

**Regina Okafor, MBA
Associate Program Manager, Africa**

**Abdelkrim Smine, Ph.D.
Consultant**

**Matthew Morehouse
Instrumentation Associate**

Promoting the Quality of Medicines
Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1-301-816-8239)
Email: pqm@usp.org and rio@usp.org

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Executive Summary

Ms. Regina Okafor, Mr. Matthew Morehouse, and Dr. Abdelkrim Smine traveled to Maputo, Mozambique to set up the temporary refurbished LNCQM quality control (QC) lab, Mozambique's National Quality Control Laboratory (NQCL), and to train all lab staff on USP monograph compendia testing. PQM assisted LNCQM in qualifying and installing equipment and setting up all the laboratory supplies. In addition, the PQM team evaluated the progress of the Medicine Quality Monitoring (MQM) activities since the last comprehensive sampling and testing protocol training in October 2011.

PQM staff also met with USAID/Mozambique to discuss the building of the permanent LNCQM facility and provided technical suggestions and recommendations to fully furnish LNCQM.

Overall, the trip was successful and PQM was able to complete the lab set-up, install all available equipment, and demonstrate various tests. Consequently, LNCQM is able to weigh and prepare solutions as well as analyze samples utilizing several laboratory techniques.

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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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- Dr. Victor Machava, head of quality control at LNCQM, for his kindness and for coordinating the training and other activities
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing this trip report
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ACRONYMS

ACT	Artemisinin-based Combination Therapy
API	Active Pharmaceutical Ingredient
CMAM	Central de Medicamentos e Artigos Médicos (CMAM)
DF	Departamento Farmacêutico
DPS	Direção Provincial de Saúde
DQI	Drug Quality and Information Program
FDC	Fixed Dose Combination
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
ISCTEM	Instituto Superior de Ciências e Tecnologia de Moçambique
LNCQM	Laboratório Nacional da Qualidade de Medicamentos
MCH	Maternal and Child Health
MCHIP	Maternal and Child Health Integrated Program
MOH	Ministry of Health
MQDB	Medicines Quality Database
MSH	Management Sciences for Health
NAMCOL	Network of African Medicines Control Laboratories
PEPFAR	President's Emergency Plan for AIDS Relief
PMS	Post-Marketing Surveillance
PQM	Promoting the Quality of Medicines Program
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
RS	Reference Standard
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SP	Sulfadoxine Pyrimethamine
TB	Tuberculosis
TLC	Thin Layer Chromatography
UniLurio	Lurio University
UniZambezi	Zambezi University
USAID	United States Agency for International Development
USP	United States Pharmacopeia

Background

The U.S. Agency for International Development (USAID) and U.S. Pharmacopeia (USP) have been providing technical assistance to Mozambique through the Promoting the Quality of Medicines (PQM) program since 2010. Activities have focused on strengthening the quality control (QC) and quality assurance (QA) capabilities of Mozambique's medicines regulatory authority, the Departamento Farmacêutico (DF).

In December 2010, PQM conducted a rapid assessment of the QA/QC capabilities of the DF. Working with relevant stakeholders, PQM identified that the infrastructure, equipment, and staff of the DF's QC laboratory, the Laboratório Nacional da Qualidade de Medicamentos (LNCQM), were inadequate to provide QC services. However, with proper training and resources the LNCQM could become operational and begin conducting QC testing of medicines.

The rapid assessment also identified a lack of post-marketing surveillance of medicines within Mozambique. PQM and the DF established a partnership to develop a training program to conduct basic tests on the quality of medicines and to establish a medicines quality monitoring (MQM) program.

In October 2011, PQM trained stakeholders on basic testing of medicines using Minilabs[®] and developed a comprehensive MQM protocol.

Purpose of Trip

Dr. Abdelkrim Smine, Ms. Regina Okafor, and Mr. Matthew Morehouse traveled to Maputo to:

- 1) Train all lab staff on basic tests using USP monograph compendia testing
- 2) Install and qualify equipment
- 3) Set up the laboratory and equipment
- 4) Furnish the laboratory with appropriate equipment and supplies
- 5) Follow up on medicine quality monitoring (MQM)
- 6) Meet with USAID to discuss MQM activities, the workplan, and the status of LNCQM's new permanent facility

Source of Funding

This trip was funded by USAID/Mozambique through the President's Emergency Plan for AIDS Relief (PEPFAR).

Overview of Activities

Item	Description
Specific Objectives/ Expected Outcomes	<ul style="list-style-type: none">• Train all lab staff on basic tests using USP monograph compendia testing<ul style="list-style-type: none">○ Good Documentation Practices○ Safety in the Laboratory○ Weighing Practices○ How to Write Standard Operating Procedures (SOPs) and the Importance of SOPs○ Reading and Understanding the USP Monograph/General Chapters

	<ul style="list-style-type: none"> ○ Choosing a Monograph and Conducting Full Compendia Testing/USP General Notices ○ General Topics on Lab Techniques – from USP General Chapters ● Install and qualify equipment ● Set up the laboratory and equipment ● Furnish the laboratory with appropriate equipment/supplies ● Follow up on MQM ● Meet with USAID to discuss MQM activities, the workplan, and the status of LNCQM’s new permanent facility
Venue/Location	LNCQM (DF)
Organizers	PQM, USAID/Mozambique, DF, and LNCQM
Sponsors	USAID/Mozambique
Trainers and Facilitators	Dr. Abdelkrim Smine, Ms. Regina Okafor, and Mr. Matthew Morehouse
Trainees	5 staff from LNCQM; See Annex 1 for detailed information
Agenda	See Agenda in Annex 2 for detailed information
Opening Ceremony	<ul style="list-style-type: none"> ● Dr. Víctor Machava, head of QC at LNCQM ● Dr. Abdelkrim Smine, PQM ● Ms. Regina Okafor, PQM ● Mr. Matthew Morehouse, PQM
Modules	<ul style="list-style-type: none"> ● High Performance Liquid Chromatography (HPLC) (theory and hands-on) ● Good Documentation Practices (GDP) (theory and hands-on) ● Good Weighing Practices (theory and hands-on) ● Good Volumetric Techniques (theory and hands-on) ● Loss on Drying (LOD) (theory and hands-on) ● Ultraviolet-Visible spectroscopy (UV-vis) (hands-on) ● Thin Layer Chromatography (TLC) (hands-on) ● Reading and Understanding USP NF (theory and practical examples) ● pH (theory and hands-on) ● Safety in the Laboratory (theory)
Tour of lab by USAID	<ul style="list-style-type: none"> ● Mr. Benedito Chaúque, Logistics Activity Manager, USAID/Mozambique ● Mr. David Damiral, USAID/Mozambique Infrastructure team ● Mr. Manuel Machava, USAID/Mozambique Infrastructure team ● Mr. Michael R. Giddinge, Associate Vice President, AECOM (an engineering firm) ● Dr. Victor Machava, Head of Lab, LNCQM ● Ms. Regina Okafor, PQM ● Dr. Abdelkrim Smine, PQM ● Mr. Matthew Morehouse, PQM

Tour of the lab	<ul style="list-style-type: none"> • Dra. Felicidade Sebastião Siteo Macamo, Director, DF • Mr. Benedito Chaúque, Logistics Activity Manager, USAID/Mozambique • Dra. Isabel Chemane, Director, LNCQM • Dr. Victor Machava, Head of Lab, LNCQM • Ms. Regina Okafor, PQM
Closing Ceremony	<ul style="list-style-type: none"> • Dr. Victor Machava, Head of Lab, LNCQM • Ms. Regina Okafor, PQM • Dra. Isabel Chemane, Director, LNCQM • Valdemar Albano Timóteo, LNCQM • Clemente Alfonso Rodrigues, LNCQM <p>Certificates were given to the participants closing ceremonies</p>
Training Evaluation	See summary of participants' evaluation forms in Annex 3
Equipment Provided	See Annex 4 for a list of supplies, reagents, and equipment provided
Outcomes/Conclusion	<ul style="list-style-type: none"> • Set up the temporary LNCQM lab with equipment provided by USP/USAID and LNCQM (see Annexes 4, 5, and 6) • Trained participants on GDP and provided them with lab notebooks to document testing and results • Trained participants on Proper Weighing Techniques, Good Volumetric Techniques, and GLP • Trained participants on how to read and understand the USP/NF; used the Acetaminophen (Paracetamol) tablet monograph along with an actual tablet provided by PQM to conduct hands-on training on LOD, TLC, HPLC, and UV-vis • PQM also brought a commercial Prednisolone tablet that LNCQM will use to practice the techniques they were trained on; LNCQM will send PQM the results electronically • Discussed the outcomes of Round 1 MQM sample collection <ul style="list-style-type: none"> ○ LNCQM informed PQM that sample collection was not complete (Maputo province samples were not collected); additionally, sample testing was not completed
Next Steps	<ul style="list-style-type: none"> • Train LNCQM on Dissolution, Disintegration, and Karl Fischer since the related instruments were non-functional during the visit • LNCQM will complete Round 1 MQM sample collection and testing, and Round 2 sampling will start in June 2012. PQM would like to be present to oversee the activities and ensure collection is done properly • PQM proposes that the inauguration of the laboratory by the Permanent Secretary take place while PQM is in-country to further publicize the partnership between PQM, USAID, and LNCQM in strengthening medicine quality in Mozambique • PQM will procure additional supplies/reference standards/reagents pertinent for LNCQM to progressively and independently conduct pharmacopeial testing

Set-up of equipment and LNCQM lab, April 8-14, 2012

During the visit, PQM examined the refurbished facility and determined the appropriate locations for equipment. During the setup process, PQM evaluated all of LNCQM's equipment to determine which were operational and could be used for the training. It was determined that the Erweka Dissolution system, the Erweka Disintegration system, and the Orion Karl Fischer titrator were not functional. The Dissolution system was missing the shafts necessary to operate the system, the Disintegration system was missing an integral operational part on the right side, and the Karl Fischer was never operational since arrival to LNCQM.



Setup of temporary LNCQM Quality Control Lab

PQM team spent time clearing shipments from USP/PQM at customs and procuring supplies necessary to re-establish an active LNCQM. PQM installed the following equipment in order to get the lab operational:

- 2 fume hoods
- A water purification system
- Oven and drying supplies (for performing LOD)
- An HPLC and consumables
- 2 UV/VIS and consumables
- pH meter
- Vacuum system
- 3 weighing balances
- Lab supplies provided for weighing, preparation of solutions, and general lab and safety use
- USP/NF books
- USP reference standards for performing testing and qualifications
- 2 AC units, one for the laboratory and one for the office area



PQM trains LNCQM staff on filtering mobile phase



LNCQM staff get training on proper documentation

Visit by USAID and engineering firm to temporary LNCQM Quality Control Lab, April 10, 2012

Participants:

- David Damiral, Manuel Machava, and Benedito Chauque (USAID)
- Mike Giddinge, Architecture, Engineering, Consulting Operations and Management (AECOM) Engineer
- PQM team and LNCQM staff

The USAID team, along with the engineer, visited the new lab facility. They were welcomed by the PQM team and received an overview about the work completed in this temporary LNCQM facility. PQM also showed them equipment purchased or donated by PQM through USAID funding, as well as donated equipments from USP. Dr. Smine and Mrs. Okafor gave some details about what each piece of equipment is used for. PQM staff also explained to the USAID team all challenges faced in getting all of the lab equipment to function properly. The PQM team informed USAID that the floor paint is not appropriate; damage can be caused by the chemicals that are commonly used in a lab so an epoxy-based paint is needed for the floor. PQM gave also an overview of the planned activities for the two-week visit and the training of QC lab staff.

Dr. Smine discussed with the USAID team the plan for building the new permanent QC laboratory. Mr. Damiral explained that PQM should work with AECOM engineers to come up with a laboratory design and a complete budget before the end of September 2012. The plan and budget will be used to request the needed funding to complete this project. Dr. Smine agreed that PQM is ready to meet and work with AECOM engineers to complete the required work. Mr. Giddinge promised to connect the PQM team with the AECOM representative in charge of this project at US headquarters.

The USAID team expressed that they are delighted with PQM achievements regarding the refurbishing work that took place. This refurbished facility allows the Pharmaceutical Department (PD) the ability to focus on controlling the quality of medicines and building the needed quality control capacity. The PQM and USAID goal is for LNCQM to be fully staffed, trained, and operational so that they will be able to obtain ISO 17025 accreditation before the completion of the permanent LNCQM facility.

Meetings with new antiretroviral manufacturer, Sociedade Moçambicana de Medicamentos, SA

Participants:

- PQM team (Dr. Smine, Ms. Okafor, Mr. Morehouse) and Benedito Chauque (USAID)
- Noemia Muissa, Executive Director, SMM
- Roberto Camillo Castrignani, Head of Project, and Licia de Oliveira, Project Coordinator, Farmanguinhos (Brazil)
- Florencia Paula Cumaio Moises, Head of QC lab, SMM

PQM visited a new pharmaceutical company Sociedade Moçambicana de Medicamentos, SA (SMM). This company is built as a joint venture between the government of Mozambique and the government of Brazil. The Brazilian contribution consists of building the new part of the facility, remodeling some older parts (such as the warehouse), equipping the facility and its QC laboratory, and undertaking technology transfer for about 23 medicines, which include antiretroviral (ARV), antibiotic, anti-tubercular, anti-inflammatory, diuretic, hypertension, blood pressure, and anemia medicines. Two senior experts are in charge of the building and installation of equipment. The company plans to start operating next July. Technical staff from Farmanguinhos Brazil will be responsible to kick off the manufacturing, train local staff, and turn over the facility to be operated by Mozambican staff. Although SMM is a private company, the share holder is the Mozambican government. The Brazilian government will assist the plant until 2014.

The facility, which was built by a South African company that has an operating branch in Maputo, is modern and built to comply with all Good Manufacturing Practices (GMP) requirements. The PQM team had a tour of the plant given by the Brazilian project leaders. The equipment for manufacturing and QC are scheduled to arrive soon and are from well-known companies used in Europe and USA. The team had an excellent discussion with the SMM management team and discussed many opportunities for collaboration between PQM and SMM. Mr. Chauque agreed that with a company of this type, providing technical assistance to make sure that all processes are built on a solid GMP culture from the start can contribute to the good development of the pharmaceutical sector in Mozambique. This will also contribute to improving health systems since the company plans to manufacture key essential medicines with affordable prices. If the company qualifies as a WHO supplier, USAID/Mozambique could procure good quality medicines made locally.

Further discussion is needed to agree on the level of support that PQM could provide to SMM to assist the company in building its GMP capacity in collaboration with Brazilian partners.

Reviewing the progress of MQM activities with LNCQM

Dr. Smine and Ms. Okafor reviewed the data made available by the QC lab staff. The MQM teams did not complete the first round as was planned during the MQM training in October 2011. Dr. Victor Machava explained that the teams did not receive the support needed from the regional health offices. The major issues faced by the MQM teams during the first round of this program are:

- Only three sites were covered, and the Maputo province team has not conducted any sampling and testing
- Samples were collected but only 25-50% was tested at the sentinel site level. The plan was to test 100% of samples at sentinel sites.
- Based on LNCQM staff comments, it appeared that they did not receive the support needed from regional offices. Some of the regional directors changed the PQM sampling protocol by giving instructions to collect fewer than the required amount of samples.
- All regional personnel, with the exception of the school of pharmacy student trained in October 2011, did not participate in MQM activities.
- PQM is very disappointed that the teams did not adhere to the MQM protocol. PD should have insisted on using the staff who received training. PQM will be addressing this issue.
- The QC lab staff was not allowed to carry out MQM activities in Maputo because of a lack of human resources.
- The money allocated to MQM activities should be made available to carry out the planned activities by PD.
- The PQM team instructed the QC lab staff to complete the testing as soon as they can so that the second round could be done in August as planned.
- The PQM team emphasized to LNCQM and PD that all challenges encountered during the first round will be addressed and corrected before the start of the second round in June.



Collaboration with SIAPS

The PQM team met with Mr. Raouf Qawwas, Senior Technical Advisor, SIAPS, to see the new QC laboratory. Dr. Smine discussed PQM activities, details of refurbishing the old facility, and QC laboratory equipment made available for LNCQM either via donation from USP or those purchased with USAID funds. Mr. Qawwas is currently assisting the PD in the areas of drug regulation and registration.

Dr. Smine and Mr. Qawwas agreed that PQM and SIAPS should work more closely and collaborate in providing the best technical assistance needed to strengthen pharmaceutical systems in Mozambique.

Meeting with USAID and Director of the DF

PQM met with Dra. Felicidade Sebastião Siteo Macamo, Director of the DF, and Mr. Benedito Chauque, Logistics Activity Manager for USAID/Mozambique, to discuss the progress of the lab setup and the training. The following was the outcome of the meeting:

- Dra. Felicidade expressed her gratitude on behalf of the Mozambican government for the activities that PQM and USAID are providing for the lab and the country in general.
- PQM expressed how the team was pleased with LNCQM's desire and willingness to learn and apply all the lessons immediately.
- The PQM team mentioned to Dra. Felicidade their concerns regarding the incomplete collection and testing of samples for the first round of MQM. Dra. Felicidade assured PQM that the delay was due to an important visit from Global Fund that required key staff of LNCQM to be present. PQM reiterated the importance for the department heads at the provincial region to adhere to the MQM protocol and make available the trained staff to assist LNCQM staff in collecting and testing samples at the sentinel sites. She assured PQM that there will be better coordination between LNCQM staff and provincial staff for the second round of sampling and testing of medicines.
- PQM indicated that the temporary facility was operational, thus LNCQM should hire additional personnel as soon as possible so that all staff could be trained at the same time. This is important at this stage where the lab is starting to receive support in equipment and training to conduct QC testing following pharmacopeial methods. It will help all the staff to operate at the same level once LNCQM revamps the QC lab. Dra. Felicidade explained that the original staff members were sent to work at the hospital when the lab was shut down, and in order to get some of the staff back, she would have to make a formal request from the superiors at the hospital. This is because those staff members are now performing duties for the hospital. LNCQM will have to allow the hospital time to replace the staff moving back to the lab. Mr. Chauque also expressed his concern regarding this personnel issue and suggested that Dra. Felicidade should discuss the issue with the Minister of Health because the proper staffing and operation of the lab is important to the Ministry of Health. Dra. Felicidade expressed confidence in being able to get additional lab staff within two months.
- Mr. Chauque asked if it would be possible to recruit some personnel for the lab from local universities. Dra. Felicidade indicated that the Minister had to follow protocols and the process to recruit students is lengthy.
- The team also discussed PQM writing a memo to request using some of the funding that is available for training for applying the epoxy on the floor of the temporary lab instead.
- PQM also discussed the activities of the Network of African Medicine Control Laboratories (NAMCOL) and informed Dra. Felicidade how PQM was preparing the lab with necessary training and equipment/supplies to be ready to host the training for NAMCOL. Dra. Felicidade informed PQM that she will discuss NAMCOL with the Permanent Secretary and Deputy Prime Minister as soon as possible to get their approval for membership.
- PQM also informed Dra. Felicidade and Mr. Chauque about USP's Technical Assistance Program and the possibility of formally including Mozambique in this program. Mr. Chauque expressed how this would be good for Mozambique.

- The team discussed the formal inauguration of the temporary LNCQM facility, which will include the Permanent Secretary and the Prime Minister. Dra. Felicidade said that a formal letter has been sent and she is awaiting a response to set a date for the inauguration. PQM and USAID requested to be included in the inauguration. PQM proposed that the inauguration take place in June/July 2012 (when PQM will be in-country). USP can help with ensuring a media presence to announce the official opening of LNCQM. Additionally, USP will issue a press release to highlight the USAID-USP partnership and commitment to strengthening the quality of medicines in Mozambique.

Tour of temporary QC Lab by USAID and Director of the DF, April 20, 2012

Participants: Regina Okafor, Benedito Chaúque, and Dra. Felicidade Sebastião Siteo Macamo

Ms. Okafor gave Mr. Chaúque and Dra. Felicidade a tour of the completed temporary lab and described all the equipment and their functions as well as the importance of the materials, supplies, and equipment provided by USP and USAID. The group discussed some of the challenges faced during the PQM visit and some necessary equipment that PQM will be procuring so as to continue the progression of the LNCQM to full compendia testing. Dra. Felicidade and Mr. Chaúque were impressed with the lab and happy with the work that PQM did.

Closing Ceremony and Meeting with LNCQM April 20, 2012

Participants: Regina Okafor and all LNCQM staff

PQM awarded certificates to the trainees after the completion of the training. The LNCQM staff members were assigned homework by PQM so they can practice the skills covered during the training. A deadline of May 25 was given to LNCQM to provide data and results to PQM electronically.

PQM and the LNCQM management team also discussed all the materials that PQM will be providing the lab before the next PQM visit in June. PQM reiterated that all items must be received and/or cleared from customs before PQM arrives in country for the training. LNCQM and PQM also discussed the completion of Round 1 MQM activities, especially in Maputo province. LNCQM assured PQM that Maputo province sample collection will start the second week of May 2012. Additionally, PQM requested that LNCQM ensure that epoxy coating is applied to the floor in the lab. LNCQM assured PQM that they would contact the engineer responsible for this task to confirm that it is applied.

Next Steps (to be completed by the end of September 2012)

- PQM will assist LNCQM with any issues arising from the assigned work
- LNCQM will complete MQM Round 1 MQM and forward all results and data to PQM
- PQM will provide necessary equipment and other pertinent lab supplies for LNCQM to be able to conduct full monograph testing
- PQM will schedule training on Karl Fischer, Dissolution, Disintegration, and follow-up training
- PQM will supervise MQM Round 2 sample collection and testing to ensure that the protocol is followed. Additionally, PQM will provide copies of the MQM protocol to both DF and the provincial directors that will allow both organizations to adhere to the protocol.
- PQM will continue to work with stakeholders to hire a consultant for Mozambique.
- PQM will provide the LNCQM management team with a detailed list of equipment, supplies, and reagents supplied thus far, along with their monetary value.

Conclusions

PQM was satisfied with the setup of the temporary LNCQM Quality Control lab. Although many critical pieces of lab equipment are still needed by LNCQM (see **Annex 6**), the training provided to the staff was successful. PQM was pleased with the willingness of the LNCQM staff to learn and apply all lessons and exercises immediately. Furthermore, PQM is confident that LNCQM will be ready to host the NAMCOL training towards the end of FY 2012. It will require additional visits and training from PQM, but PQM is eager and prepared to assist LNCQM achieve this goal. Furthermore, PQM will ensure that LNCQM is able to successfully conduct MQM without further delays or deviations from the protocol.

**Opening of National Laboratory for Medicines Quality Control (LNCQM)
LNCQM Temporary Quality Control Lab and Monograph testing training Workshop**

**Maputo, Mozambique
April 9 – 20, 2012**

Participant List

Participant	Name	Organization
1	Clemente Alfonso Rodrigues	LNCQM
2	Victor Machava	LNCQM
3	Isabel Chemane	LNCQM
4	Valdemar Albano Timóteo	LNCQM
5	Julio Hamisse	LNCQM

Agenda

Agenda for Training at LNCQM			
Updated: 26 Mar 12			
	Day	Topics/Scope	PQM Lead
	Sunday	Setup of Lab and equipments	Regina/Karim & Matt and key lab staf
Week 1	Monday	<ul style="list-style-type: none"> • Introductions • Review Agenda & materials • Setting up of Lab • Review Acetaminophen Tab/Cap Monograph (Lecture) • General Notices (Lecture) 	Regina/Karim
		<ul style="list-style-type: none"> • Water system • Begin balances 	Matt
	Tuesday	<ul style="list-style-type: none"> • GDP (Lecture) • Safety (Lecture) Labeling solutions in lab/Assigning expiration dates Intro to USP NF (Lecture), Understanding how to read USP	Regina/Karim
		<ul style="list-style-type: none"> • Finish balances • pH meter • Hoods 	Matt
	Wednesday	<ul style="list-style-type: none"> • Core USP General Chapters (Lecture) <ul style="list-style-type: none"> o <11> USP RS o <21> Thermometers o <31> Volumetric Apparatus o <41> Weights & Balances o <731> LOD (Lecture and Hands-on demonstration) o <791> pH (Lecture and Hands-on demonstration) • <621> Chromatography (Lecture) • Begin Acetaminophen Assay (Hands-on) 	Regina/Karim
		<ul style="list-style-type: none"> • HPLC 	Matt
		Thursday	<ul style="list-style-type: none"> • Continue Acetaminophen Assay (Hands-on) • UV
	Friday	<ul style="list-style-type: none"> • <905> UDU (Lecture) • Perform Acetaminophen UDU Calculation 	Regina/Karim
		<ul style="list-style-type: none"> • Dissolution 	Matt

Week 2	Monday	<ul style="list-style-type: none"> • Finish Acetaminophen Assay (Hands-on) • <905> UDU (Lecture) • Perform Acetaminophen UDU Calculation • <201> TLC ID Test (quick overview - use MQM sample - if time permits) 	Regina/Karim
		<ul style="list-style-type: none"> • Finish incomplete work from Week 1 • Ovens 	Matt
	Tuesday	<ul style="list-style-type: none"> • <711> Dissolution (Lecture) • Review PVT (Lecture) • Perform PVT (Hands-on) 	Regina/Karim
		<ul style="list-style-type: none"> • Dissintegration 	Matt
	Wednesday	<ul style="list-style-type: none"> • Review notebooks & draft CoA (Working session) • Q & A session (Lecture) • Other hands-on activities - LOD (Lecture and Hands-on demonstration) pH (Lecture and Hands-on demonstration) 	Regina/Karim
		<ul style="list-style-type: none"> • KF 	Matt
	Thursday	<ul style="list-style-type: none"> • SOP (Lecture) • Share PQM developed SOP drafts • Draft and approve core SOPs (Working session) <ul style="list-style-type: none"> o Document Control o Workflow 	Regina/Karim
		<ul style="list-style-type: none"> • Review equipment records & logbooks • Other equipment issues 	Matt
	Friday	<ul style="list-style-type: none"> • Review homework assignment SOP (Lecture) • Develop LNCMQ testing schedule/priorities (Working session) • Identify activities requiring follow-up (Working session) • Identify more complicated monograph & set next training date (Working session) • Closing meeting & delivery of certificates 	Regina/Karim & Matt

Summary of Evaluation by Participants

PQM Training Workshop

Opening of LNCQM Temporary Quality Control Lab and Monograph Testing Training

Workshop

Maputo, Mozambique ♦ April 9-20, 2012

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs	4	0	-
2. I was able to understand the content of the materials presented	3	1	-
3. Overall the course was useful and will help me do my job better	4	0	-
4. There were enough practical exercises to facilitate understanding of the course	4	0	-
5. The pacing of sessions was appropriate for my understanding of course materials	2	2	-
6. The instructors were knowledgeable on the subject	4	0	-
7. The instructors allowed an appropriate level of participation in the class	4	0	-

Any other comments/suggestions:

1. Which topic(s) or aspects of the course should not be included in future workshops?
 - More HPLC practice
 - More practice time for all training,
 - More than 2 weeks to fully assess our progress

2. What are your recommendations/suggestions for improvement of the course?
 - Increase length of training to two weeks (9)
 - Conduct training in an actual lab facility (3)
 - More time for training
 - Conduct training in Portuguese

The participant evaluations and experiences of the facilitators during the course will be used to update the training materials at a later date.

Detailed list of equipments/supplies/reagents provided

List of Equipment for LNCQM				
Updated: 03 May12				
PQM Provided				
Type	Make	Model	Financial Value (in USD)	Comments
HPLC	Agilent	1100	\$25,000	Donated by USP, installed
UV	Shimadzu		\$5,000	Donated by USP, installed
Balance (top loading)	Mettler Toledo		\$1,000	Donated by USP, installed
Balance (analytical)	Mettler Toledo	AT201	\$1,000	Donated by USP, installed
Balance (micro)	Mettler Toledo		\$1,000	Donated by USP, installed
Fume hood	MISONIX AURA	750	\$581	Donated by USP, installed
USP/NF Book (English and Spanish)	USP/PQM	USP/NF 34	\$1,640	Donated by USP, installed
Fume hood	CAPTAIR FILTAIR	824	\$294	Donated by USP, installed
Total Donation			\$39,667	Donated by USP
MQM materials				Donated by USP
USP Reference Standards	USP/PQM	USP/PQM	\$4,152	Donated by USP
				shipped, received at LNCQM, installed
Water system	Millipore		\$9,500	
Total			\$9,500	
Dissolution materials				
4-liter Filter assembly, 47 mm	Third party vendor	N/A	\$540	shipped, received at LNCQM
47 mm filters for filtering flask	Third party vendor	N/A	\$137	shipped, received at LNCQM
Ceramic hot plate; 10.25 x 10.25 in.; To 400°C	Third party vendor	N/A	\$680	shipped, received at LNCQM
Stir Bar Retrievers, 12 in.	Third party vendor	N/A	\$33	shipped, received at LNCQM

Spinbar Octagonal Magnetic Stir Bar Kit,	Third party vendor	N/A	\$113	shipped, received at LNCQM
Vacuum pump	Third party vendor	N/A	\$460	shipped, received at LNCQM
Replacement neoprene diaphragm for Vacuum Pump	Third party vendor	N/A	\$25	shipped, received at LNCQM
Service kit for Vacuum Pump	Third party vendor	N/A	\$31	shipped, received at LNCQM
(in line) aspirator	Third party vendor	N/A	\$17	shipped, received at LNCQM
Sample filters -syringe	Third party vendor	N/A	\$319	shipped, received at LNCQM
Quartz glass UV curvets - 10mm	Third party vendor	N/A	\$845	shipped, received at LNCQM
Plastic Syringes	Third party vendor	N/A	\$78	shipped, received at LNCQM
Cannula with 43/8 in. Needle for 900mL Volume	Third party vendor	N/A	\$622	shipped, received at LNCQM
Cannula with 71/2 in. Needle for 500mL Volume	Third party vendor	N/A	\$666	shipped, received at LNCQM
PC and monitor for UV	Third party vendor	N/A	\$1,000	shipped, received at LNCQM
Lamps for UV (Shimadzu)	Third party vendor	N/A	\$425	shipped, received at LNCQM
UV Lamps (Thermo/Helios)	Third party vendor	N/A	\$700	shipped, received at LNCQM
Centering Gauge	Third party vendor	N/A	\$46	shipped, received at LNCQM
Mechanical calibration kit	Third party vendor	N/A	\$1,400	shipped, received at LNCQM
Digital thermometer	Third party vendor	N/A	\$2,900	shipped, received at LNCQM
Tachometer	Third party vendor	N/A	\$383	shipped, received at LNCQM
Stopwatches	Third party vendor	N/A	\$36	shipped, received at LNCQM
Bottles with caps	Third party vendor	N/A	\$500	shipped, received at LNCQM
Digital level	Third party vendor	N/A	\$360	shipped, received at LNCQM
Cuvette holder	Third party vendor	N/A	\$900	shipped, received at LNCQM
Dissolution vessels	Third party vendor	N/A	\$1,600	shipped, received at LNCQM
1L Beaker for Dissolution vessels	Third party vendor	N/A	\$170	shipped, received at LNCQM
Shafts and parts	Erweka/QLA	N/A	\$1,450	Ordered, to be shipped
Total			\$16,434	

Disintegration materials

ZT 302 Disintegration - basket with 6 stations	Erweka/QLA	N/A	\$2,712	Ordered, to be shipped
Total			\$2,712	
TLC materials				
Developing Tank with Nonslip Lid	Third party vendor	N/A	\$468	shipped, received at LNCQM
Silica Gel 60F254 plates with fluorescent indicator 5x10, 200/pk	Third party vendor	N/A	\$531	shipped, received at LNCQM
spotting capillaries, 10 micro liter	Third party vendor	N/A	\$30	shipped, received at LNCQM
UV Lamps	Third party vendor	N/A	\$321	shipped, received at LNCQM
weighing paper	Third party vendor	N/A	\$68	shipped, received at LNCQM
spatulas	Third party vendor	N/A	\$93	shipped, received at LNCQM
Pipette Filler Bulbs	Third party vendor	N/A	\$93	shipped, received at LNCQM
Pasteur pipettes Disposable Borosilicate Glass Pasteur Pipettes	Third party vendor	N/A	\$255	shipped, received at LNCQM
latex rubber bulbs for Pasteur pipets	Third party vendor	N/A	\$25	shipped, received at LNCQM
Kim wipes - tissues	Third party vendor	N/A	\$82	shipped, received at LNCQM
Total			\$1,966	
Loss on Drying materials				
LOD vessels, API drying vessels	Third party vendor	N/A	\$295	shipped, received at LNCQM
glass dessicator, large, uses 190mm interior plate	Third party vendor	N/A	\$454	shipped, received at LNCQM
Vacuum Oven	Third party vendor	N/A	\$2,600	Ordered, not shipped yet
Vacuum and parts	Third party vendor	N/A	\$3,000	Ordered, not shipped yet
190mm interior plate for glass dessicator	Third party vendor	N/A	\$140	shipped, received at LNCQM
Silica gel	Third party vendor	N/A	\$215	Ordered, not shipped yet
Total			\$6,704	
General lab materials				
brush, soft, 1 inch	Third party vendor	N/A	\$61	shipped, received at LNCQM

brush, soft, 2 inch	Third party vendor	N/A	\$40	shipped, received at LNCQM
brush, for tube cleaning	Third party vendor	N/A	\$41	shipped, received at LNCQM
brush, for flask cleaning	Third party vendor	N/A	\$49	shipped, received at LNCQM
weighing funnels	Third party vendor	N/A	\$52	shipped, received at LNCQM
buffer solution pH 4	Third party vendor	N/A	\$156	shipped, received at LNCQM
buffer solution pH 7	Third party vendor	N/A	\$152	shipped, received at LNCQM
buffer solution pH 10	Third party vendor	N/A	\$158	shipped, received at LNCQM
pH indicating paper	Third party vendor	N/A	\$133	shipped, received at LNCQM
parafilm 4 inch by 250 feet	Third party vendor	N/A	\$261	shipped, received at LNCQM
tape, marking, general purpose	Third party vendor	N/A	\$64	shipped, received at LNCQM
water squeeze dispensing bottle	Third party vendor	N/A	\$40	shipped, received at LNCQM
alcohol squeeze dispensing bottle	Third party vendor	N/A	\$40	shipped, received at LNCQM
cork ring for round flask	Third party vendor	N/A	\$64	shipped, received at LNCQM
Lab Notebooks with Regular Paper Pages	Third party vendor	N/A	\$491	shipped, received at LNCQM
Safety glasses	Third party vendor	N/A		shipped, received at LNCQM
Lab coats	Third party vendor	N/A	\$700	shipped, received at LNCQM
Gloves	Third party vendor	N/A	\$200	shipped, received at LNCQM
Whatman filters	Third party vendor	N/A	\$70	shipped, received at LNCQM
Benchtop Acid Cabinet	Third party vendor	N/A	\$447	shipped, received at LNCQM
Coloured Periodic Tables	Third party vendor	N/A	\$57	shipped, received at LNCQM

Portable Eyewash	Third party vendor	N/A	\$305	shipped, received at LNCQM
Emergency Eyewash Sign	Third party vendor	N/A	\$23	shipped, received at LNCQM
Eyewash Sign	Third party vendor	N/A	\$33	shipped, received at LNCQM
MSDS Sign	Third party vendor	N/A	\$26	shipped, received at LNCQM
Fire Extinguisher Sign	Third party vendor	N/A	\$39	shipped, received at LNCQM
Hazardous Materials Sign 3.5x2.5 (10 pack)	Third party vendor	N/A	\$16	shipped, received at LNCQM
Hazardous Materials Sign 11x8	Third party vendor	N/A	\$18	shipped, received at LNCQM
Hazardous Materials Sign 14x10	Third party vendor	N/A	\$24	shipped, received at LNCQM
First Aid Sign	Third party vendor	N/A	\$26	shipped, received at LNCQM
Danger Sign	Third party vendor	N/A	\$12	shipped, received at LNCQM
Goggles Required Sign	Third party vendor	N/A	\$9	shipped, received at LNCQM
Chemical Storage Area Sign	Third party vendor	N/A	\$24	shipped, received at LNCQM
Authorized Personnel Sign	Third party vendor	N/A	\$11	shipped, received at LNCQM
Flammables Cabinet (30 gal)	Third party vendor	N/A	\$942	shipped, received at LNCQM
Flammables Cabinet (45 gal)	Third party vendor	N/A	\$1,018	shipped, received at LNCQM
Kartell Pipette Washing Set	Third party vendor	N/A	\$414	shipped, received at LNCQM
Absorben Underpads (50 pack)	Third party vendor	N/A	\$38.64	shipped, received at LNCQM
Pipette Holder	Third party vendor	N/A	\$34	shipped, received at LNCQM
3/4 Gallon Ultrasonic Cleaner	Third party vendor	N/A	\$535	shipped, received at LNCQM
Face shield	Third party vendor	N/A	\$51	shipped, received at LNCQM
Broken Glass Disposal Boxes	Third party	N/A	\$25	shipped, received at LNCQM

	vendor			
Safety Bottle Carriers (2.5L)	Third party vendor	N/A	\$163	shipped, received at LNCQM
Safety Bottle Carriers (4L)	Third party vendor	N/A	\$192	shipped, received at LNCQM
First Aid Kit	Third party vendor	N/A	\$39	shipped, received at LNCQM
pH electrode and parts	Third party vendor	N/A	\$400	shipped, received at LNCQM
Reagents/Solvents	Third party vendor	N/A	\$2,210	Ordered via third party Vendor
Filters for Hood	Third party vendor	N/A	\$1,500	Ordered April 2012
Karl Fischer	Mettler Toledo	N/A	\$5,500	Ordered April 2013
Balance	Mettler Toledo	N/A	\$3,000	Ordered April 2014
Door replacement for balance	Mettler Toledo	N/A	\$900	Ordered April 2015
Power supply for Balance	Mettler Toledo	N/A	\$1,000	Ordered April 2016
Total		N/A	\$21,802	
HPLC materials				
Dell PC and Monitor	Dell	N/A	\$900	shipped, received at LNCQM, installed
Software - Chemstation	Agilent	N/A	\$1,400	shipped, received at LNCQM, installed
HPLC Columns	Agilent	N/A	\$2,524	shipped, received at LNCQM, installed
HPLC vials	Agilent	N/A	\$400	shipped, received at LNCQM
Total			\$5,224	
Sum of All Spent			\$128,684	As of May 3, 2012

National Laboratory for Medicines Quality Control (LNCQM) Equipments

LNCQM Warehouse			
Type	Make	Model	Comments
Disintegration	Erweka	ZT 302	Not functional
Disintegration	Erweka	2T3	Not functional
Dissolution	Erweka	DT 600	Not functional - missing correct shafts
Dissolution	Erweka	DT6	Not available
Balance (analytical)	Sartorius	BP 110 S	Not functional
Balance (analytical)	Adam	AAA 250 L	Not functional
Balance (precision)	Jadever	Snug- 150	Not functional
Incubator	Thermosi	SR 1000	Not needed
Incubator	Memmert		Not needed
Vortex	Selecta		functional - installed in lab
Manual mixer (shaker)	Selecta		functional - installed in lab
pH Meter	Orion	420	functional - installed in lab
KF	Orion	AF8	Not functional
Oven	Selecta		Functional - only to max temp of 70°C
Oven w/ Vacuum	Nuova Osar	65	In warehouse - not functional
Oven (drying)			Functional - for glassware
Oven (for sterilizing)			Not available
Refrigerator	Defy		Functional
Refrigerator	Ariston		Functional
Magnetic mixer	SBS		functional - installed in lab
UV-Vis	Helios Alfa		Functional - PQM installed new lamps
Incubator	Thermosi	SR 1000	In warehouse - not needed yet
Incubator	Memmert		In warehouse - not needed yet
Rotovap	Buchi	R 200	In warehouse - not needed yet
Autoclave	Selecta		In warehouse - not needed yet
Autoclave	Raypa		In warehouse - not needed yet
Safety cabinet			In warehouse - not needed yet

Detailed list of equipments still needed by LNCQM

Equipment & Materials Needed		
Type	Model	Estimated Cost
Large Hood (with exhaust)	TBD	\$6,000
Safety Shower combo	TBD	\$5,000
Large Sonnicators (bath combo)	TBD	\$2,000
Vortex	TBD	\$600
HPLC columns	TBD	\$8,000
FTIR	TBD	\$20,000
FTIR supplies/parts	TBD	\$5,000
Titration	TBD	\$15,000
Titration parts/consumables	TBD	\$4,000
HPLC (at least 2 more - Waters)	TBD	\$130,000
PC/Monitor/software - Waters	TBD	\$3,500
pH Meter	TBD	\$1,500
Washing Machine (Glassware)	TBD	\$11,000
Washing machine consumables	TBD	\$3,000
Laundry machine/Dryer combo (washing lab coats)	TBD	\$5,000
AC unit for Reagent Room	TBD	\$2,000
Storage cabinets - various sizes	TBD	\$4,000
Tool kit	TBD	\$600
Security door	TBD	\$2,000
Gas chromatography system	TBD	\$65,000
UV lamp (short and long)	TBD	\$2,000
Printers (for HPLC, UV)	TBD	\$2,000
Dissolution system (one additional)	TBD	\$25,000
Various Lab reagents/solvents	TBD	\$10,000
Nitrogen Generator	TBD	\$20,000
UPS systems (4-6)	TBD	\$60,000
Storage cabinets -for lab consumables	TBD	\$2,000
Waste drums	TBD	\$2,000
Total (not including overhead)		\$416,200
+ Shipping/freight (40% of total)		\$166,480
Sum Total		\$582,680

Justification for list of equipment still needed by LNCQM

Large Hood (with exhaust): A larger hood is needed that can accommodate more than one staff member during preparation procedures and also be able to accommodate at least a pH meter and/or titrator as some solutions might be too hazardous to be analyzed in the open laboratory.

Large Sonicator: A small sonicator is a must for any quality control lab that prepares solutions. However, a larger sonicator is pertinent in degassing bigger solutions like mobile phase or medium for dissolution testing.

Washing Machine (glassware): This machine is critical in cleaning the glassware properly utilizing the correct soap, water, and steam to remove any residue. Without properly cleaned glassware, all preparations and solutions, not to mention the time spent preparing them, are futile, and contaminated solutions can further damage very sensitive equipment that require pure solutions.

Nitrogen Generator: This is critical equipment for preserving equipment lifetime for any quality control laboratory where the power supply is not guaranteed. Without a generator, data could be lost during runs; constant interruption in power supply shortens the lifespan of any equipment and further prevents it from functioning properly.

Dissolution system: Currently the lab has only one system, which is older. It is critical to have more than one system for conducting a major analysis. If that instrument is not functioning properly, having an additional prevents a complete shutdown of analysis.

HPLC and columns: LNCQM only has one HPLC which was donated by USP; however, HPLC is a major test for any laboratory and thus it is critical that there is an additional one or two HPLCs so as not to handicap the lab staff waiting to use the equipment. Additionally, the case mentioned above for the dissolution system applies here for major tests. It is always a recommendation to have more than one piece of equipment in case one malfunctions.

FTIR: This equipment is necessary to perform a majority of identification of compounds in any compendia. LNCQM currently does not have one.

Various lab reagents/solvents: Without proper reagents and solvents, a lab cannot test any medicine. This is a critical component, especially in Africa, where procurement and receipt is often a laborious process. It is crucial to find and retain a third party vendor that is reliable who can provide needed reagents and solvents.

Uninterruptible Power Supply (UPS): A UPS is used to protect computers and equipment where an unexpected power disruption could cause injuries, serious business disruption, or data loss. Other critical issues that can affect data (and especially chromatograms from HPLC and UV) are voltage spike, brief or prolonged reduction in input voltage, noise transmitted in the form of oscillation and typically injected into the line by nearby equipment, and instability in frequency. To summarize, a generator is needed as well as a UPS to maintain constant power supply.

Storage cabinets: With limited space in the temporary lab, it is important that consumables, reagents, and solvents are stored correctly. Of critical importance is the mixing of incompatible

reagents and solvents; for example, corrosives should be separated, flammables segregated, and acids and bases separated. PQM procured some cabinets, but an additional supply of various sizes is still necessary.

Gas chromatographer (GC): This common chromatography technique is used to separate and analyze compounds that can be vaporized without decomposition. GC is used to test the purity of a particular substance or separating the different components of a mixture. A GC is equally as important in a laboratory as an HPLC since a number of compendia require GC instead of HPLC.

Security door: Another barricade or security door needs to be installed to the main entrance of the temporary lab so as to safeguard all the equipment and materials in the lab.

Toolkit: A toolkit is important for simple repairs of parts or tightening of loose parts. During the recent visit, PQM was able to use a company-provided toolkit to service and tighten loose parts in the lab. LNCQM has no toolkit to perform simple and minor repairs.