

Workshops on Establishing a Medicine Quality Monitoring Program, Conducting Compendial Analysis on the Quality of Antimalarial Medicines, and Conducting a Baseline Survey on the Quality of Antimalarials in Selected Sites in Burma

Nay Pyi Taw, Burma
May 4-12, 2012

Trip Report

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PROMOTING THE QUALITY OF MEDICINES



President's Malaria Initiative

Executive Summary

With funding from the President's Malaria Initiative (PMI) and the United States Agency for International Development Regional Development Mission for Asia (USAID RDM/A), and with the support of the World Health Organization (WHO) country office, the Promoting the Quality of Medicines (PQM) program conducted three workshops in Nay Pyi Taw, Burma as part of its activities to stem the flow of artemisinin-resistant malaria in the Greater Mekong Sub-region (GMS). The three workshops conducted were:

- Training on the Establishment of a Medicine Quality Monitoring (MQM) program for antimalarials in targeted sentinel sites in Burma. The training was held for 25 central and regional staff from three different departments within the Ministry of Health (MOH): the Burma Food and Drug Administration (FDA), the Burma Department of Vector Borne Disease Control (VBDC), and the Department of Medical Research-Lower Burma (DMR-LB). The training, delivered by PQM staff and an expert from the Global Pharma Health Fund (GPHF), involved presentations and hands-on practice, explanations of correct and effective sampling protocols and documentation of selected antimalarial medicines, instruction on the GPHF Minilab[®], and the development of an MQM protocol document outlining the steps and activities involved in the program.
- Training on Conducting Compendial Analysis of Antimalarials Using Pharmacopeial Monographs Methods and Procedures was facilitated for 11 staff from the Burma FDA quality control (QC) laboratories (Nay Pyi Taw and Mandalay) and DMR-LB. The training involved presentations from PQM staff and practical work on a variety of compendial analyses.
- Workshop on Conducting a Baseline Survey on the Quality of Antimalarials in Selected States in Burma was attended by 31 participants from VBDC, DMR-LB, and Burma FDA.

Action items were also discussed and agreed upon by the workshop participants to lay down key steps that each of the involved parties will need to take to implement the projects in Burma.



Group photo of training workshop participants *Photo: FDA lab staff*

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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, PMI or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Dr. Richard Jähnke, GPHF Project Manager, for his expertise and participation as a trainer
- PQM's administrative and editorial staff for their logistical support and for editing this document

ACRONYMS

DQI	Drug Quality and Information Program
DMR-LB	Department of Medical Research – Lower Burma
FDA	Food and Drug Administration (Burma)
GMS	Greater Mekong Sub-region
GPHF	Global Pharma Health Fund
HPLC	High Performance Liquid Chromatography
MOH	Ministry of Health
MQM	Medicine Quality Monitoring
PMI	President’s Malaria Initiative
PMT	Project Management Team
PQM	Promoting the Quality of Medicines Program
PVT	Performance Verification Test
QC	Quality Control
RDM-A	Regional Development Mission – Asia
TLC	Thin Layer Chromatography
USAID	United States Agency for International Development
USP	United States Pharmacopeia
VBDC	Vector Borne Disease Control
WHO	World Health Organization

Background

Malaria remains a disease of public health importance in the GMS. Burma is no exception; however, the impact of the disease in this country is compounded by increasing concerns about specific “hot spots” where artemisinin-resistant malaria has emerged. In Burma, according to the PMI Malaria Operational Plan for FY12, areas of concern for artemisinin-resistance have been identified in Kawthoung and in the Tanintharyi Division, neighboring Ranong province in Thailand. Under the Burma Artemisinin-resistance Containment Project, the following areas have been classified as being of high concern: Tier 1, covering Bago East, Mon, and Tanintharyi; and Tier 2, including Kayin, Kayah, Kachin, and Bago West. Very little is known about the quality and availability of antimalarials, not only in the containment areas, but in the country in general.

PQM works to strengthen medicines quality assurance systems by providing technical assistance to national medicines quality control laboratories and national disease programs in the GMS. Since 2003, PQM has worked with the MOH in Cambodia, Laos, Thailand, Vietnam, and Yunnan province of China to develop mechanisms for ensuring the quality of medicines, including antimalarials, by equipping laboratories, providing expert training and protocol development, and serving as a resource for technical guidance on addressing medicines quality. Until May 2012, Burma was the only country in the GMS that had not been part of PQM’s MQM activities.

PQM’s FY12 goal in Burma is to understand the existing situation regarding the quality of antimalarials, including the types and sources available in the market, to help guide future appropriate intervention.

Purpose of Trip

- Conduct a training on establishing an MQM program in selected sentinel sites in Burma
- Conduct a training on compendial analysis for the staff of the Burma FDA and DMR-LB
- Organize a workshop on conducting a baseline survey on the quality of selected antimalarials in selected states in Burma

Overview of Activities

Training final preparation: May 4 and 6, 2012

On May 4, the PQM, WHO, and GPHF team (the “team”) met with the Director of the Burma FDA and senior management to update each other on the training preparation status and identify issues to be addressed prior to the training.

On May 6, the team and Burma FDA staff set up work stations and prepared all necessary supplies, reagents, and equipment for the trainings.

Training Proceedings: May 7-11, 2012

Establishing an MQM program for antimalarials in selected sentinel sites in Burma

Item	Description
Specific Objectives/ Expected Outcomes	Objective: Train Burma staff to conduct an MQM program Expected Outcome: Staff will be able to– <ul style="list-style-type: none"> ○ analyze medicines using the Minilab® ○ generate reliable result reports ○ maintain MQM activities to strengthen post-marketing surveillance
Venue/Location	Burma FDA Quality Control Laboratory, Nay Pyi Taw
Organizers	<ul style="list-style-type: none"> ○ PQM ○ WHO ○ Burma FDA ○ VBDC ○ DMR-LB
Sponsors	<ul style="list-style-type: none"> ○ PMI-USAID/RDMA (through PQM) ○ WHO
Trainers and Facilitators	<ul style="list-style-type: none"> ○ Souly Phanouvong, PQM ○ Sanford Bradby, PQM ○ Lukas Roth, PQM ○ Richard Jähnke, GPHF ○ Myo Naing, WHO
Trainees	25 staff from the Burma FDA, VBDC, and DMR-LB
Agenda	See Agenda in <i>Annex 1</i> for detailed information
Opening Ceremony	<ul style="list-style-type: none"> ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Theingi Zin, Deputy Director, Burma FDA ○ Dr. Thar Thun Kyaw, Deputy Director, VBDC ○ Dr. Myo Naing, Technical Officer, WHO ○ Dr. Souly Phanouvong, Manager, PQM ○ Dr. Richard Jähnke, Project Manager, GPHF
Modules	<ul style="list-style-type: none"> ○ GPHF – The impact of poor quality medicines (Theory) ○ Introduction to Basic Tests (Presentation) ○ Thin-Layer Chromatography (TLC) (Presentation and Hand-on Practice) ○ Physical/Visual Inspection (Presentation and Hand-on Practice) ○ Simple Disintegration (Presentation and Hand-on Practice) ○ Sampling Procedures (Presentation and Discussion) ○ Next Steps (Presentation and Discussion) ○ Use of Minilab® (Hands-on) – Simple Disintegration, Physical/Visual Inspection, and TLC
Closing Ceremony	<ul style="list-style-type: none"> ○ Dr. Saw Lwin, Deputy Director General, Ministry of Health ○ Dr. Zaw Win, Director, Burma FDA ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Thar Thun Kyaw, Deputy Director, VBDC ○ Dr. Souly Phanouvong, Manager, PQM ○ Dr. Richard Jaehnke, Project Manager, GPHF ○ Certificates provided

Equipment Provided	<ul style="list-style-type: none"> ○ 3 New Minilabs[®] were procured for the Burma FDA by WHO to accompany the two already at Burma FDA headquarters (which were supported by Japan International Cooperation Agency and WHO) ○ Additional equipment, supplies, and reagents procured by WHO to replenish the current Minilabs[®] are being shipped ○ Training supplies (lab coats, gloves, glasses, aprons, etc.)
Evaluation	See participant evaluations in <i>Annex 4</i> .
Outcomes/ Conclusion	<ul style="list-style-type: none"> ○ Participants conducted Minilab[®] testing of 5 antimalarial medicines: Chloroquine, Artesunate, Quinine, Mefloquine, and Artemether/Lumefantrine fixed-dose combination tablets ○ Although many participants had never conducted laboratory work prior to the training, all participants learned quickly and individually ran the complete method for Artesunate on the last day of training ○ Participants made crucial contributions to develop the MQM protocol, which will ensure the implementation of a robust program ○ A Project Management Team (PMT) was formed and consisted of Burma FDA and VBDC/MCP staff (to be assigned) who were charged with developing and submitting to PQM and WHO an action plan with itemized budgets for implementation of the project
Next Steps	<ul style="list-style-type: none"> ○ PMT will develop a budget (with input from training participants) ○ PMT will coordinate the medicine testing sites and subsequent sampling and testing of samples ○ Round 1 report of findings is expected by December 2012 ○ The sentinel sites include Kayin, Kachin, Mon, Shouthern Shan/Bago East, and Tarinntharyi. Except for Bago East, each will be equipped with a Minilab[®] which will be based at the VBDC facility. For 2012, one Round of sample collection will be conducted with an estimate of 50-60 samples of all priority antimalarials to be collected by each sentinel site from both the public and private sectors. The products of focus include: <ul style="list-style-type: none"> ○ Artesunate tablets ○ Artemether tablets/capsules ○ Artemether/lumefantrine tablets ○ Mefloquine tablets ○ Chloroquine tablets ○ Quinine tablets ○ Dihydroartemisin/piperazine tablets <p>Findings will be used for developing advocacy tools/materials to raise awareness among health professionals, the general public, and non-governmental organizations (NGOs). They will also be submitted to Burma FDA to facilitate enforcement actions if poor quality antimalarial medicines are found.</p> <p>Detailed next steps can be found in <i>Annex 2</i>.</p>



Dr. S. Phanouvong of PQM gives remarks at the opening ceremony. *Photo: Mr. L. Roth*



Dr. R. Jähne of GPHF gives a talk on the dangers of counterfeit medicines. *Photo: Dr. S. Phanouvong*



Participants conduct testing of the quality of antimalarial medicine samples by themselves after the 3rd day of training. *Photo: Dr. S. Phanouvong*



Reading TLC spots using UV lamp. *Photo: Dr. M. P. Kyaw*



Mr. L. Roth discusses test results with participants. *Photo: Dr. M.P. Kyaw*

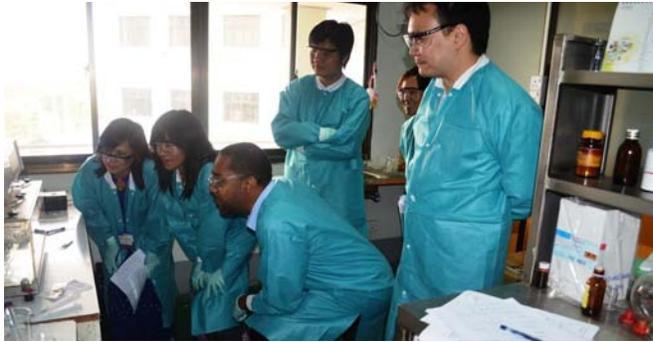


Participants enjoy the training. *Photo: Mr. L. Roth*

Compendial Analysis of Antimalarial Medicines

Item	Description
Specific Objectives/ Expected Outcomes	<p>Objective: Train participants in compendial analysis of antimalarial medicines</p> <p>Expected Outcomes: Staff will be able to–</p> <ul style="list-style-type: none"> ○ Understand and use the United States Pharmacopeia (USP) methods and procedures to analyze medicines ○ Properly use USP Reference Standards ○ Evaluate the quality of medicines through increased experience and skills in compendial analysis methods ○ Understand Good Laboratory Practices, Good Documentation Practices, and General Notices of USP
Venue/Location	Burma FDA Quality Control Laboratory, Nay Pyi Taw
Organizers	<ul style="list-style-type: none"> ○ PQM Program ○ WHO ○ Burma FDA ○ DMR-LB
Sponsors	<ul style="list-style-type: none"> ○ PMI-USAID/RDMA (through PQM) ○ WHO
Trainers and Facilitators	<ul style="list-style-type: none"> ○ Sanford Bradby, PQM ○ Asawin Likhitsup, PQM ○ Myo Naing, WHO ○ Souly Phanouvong, PQM
Trainees	11 staff from the Burma FDA and DMR-LB trained
Agenda	See Agenda in <i>Annex 3</i> for detailed information.
Opening Ceremony (combined with the Workshop 1 above)	<ul style="list-style-type: none"> ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Theingi Zin, Deputy Director, Burma FDA ○ Dr. Thar Thun Kyaw, Deputy Director, VBDC ○ Dr. Myo Naing, Technical Officer, WHO ○ Dr. Souly Phanouvong, Manager, PQM ○ Dr. Richard Jähnke, Project Manager, GPHF
Modules	<ul style="list-style-type: none"> ○ Introduction to Pharmacopeias and Compendial Testing ○ Good Laboratory Practices ○ Safety ○ Dissolution ○ High Performance Liquid Chromatography (HPLC) ○ Proper Weighing Practice ○ Volumetric Technique ○ Good Documentation Practice ○ pH ○ Loss on Drying ○ Uniformity of Dosage Units

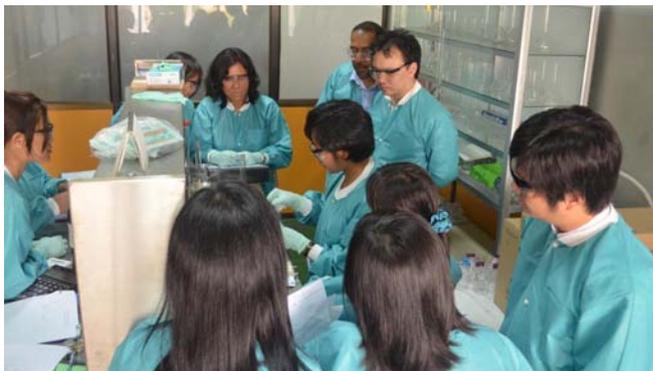
Closing Ceremony (combined with Workshop 1 above)	<ul style="list-style-type: none"> ○ Dr. Saw Lwin, Deputy Director General, MOH ○ Dr. Zaw Win, Director, Burma FDA ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Thar Thun Kyaw, Deputy Director, VBDC ○ Dr. Souly Phanouvong, Manager, PQM ○ Dr. Richard Jaehnke, Project Manager, GPHF ○ Certificates provided
Equipment Provided	<ul style="list-style-type: none"> ○ 4 HPLC columns for training purposes ○ 14 vials of Reference Standards for training purposes ○ Training supplies (lab coats, gloves, glasses)
Training Evaluation	See participant evaluations of the training course in <i>Annex 4</i>
Outcomes/Conclusion	<ul style="list-style-type: none"> ○ Training modules were completed on: <ul style="list-style-type: none"> ○ Introduction to Pharmacopeias and Compendial Testing ○ Good Laboratory Practices ○ Safety ○ Dissolution ○ HPLC ○ Proper Weighing Practice ○ Volumetric Technique ○ Good Documentation Practice ○ pH ○ Loss on Drying ○ Uniformity of Dosage Units ○ Pharmacopeial monographs on Artesunate, Chloroquine Phosphate, and Mefloquine tablets were reviewed and used to analyze samples for quality ○ Proper use of USP Reference Standards was demonstrated ○ A Performance Verification Test (PVT) of the dissolution tester was completed ○ An example dissolution procedure using Chloroquine Phosphate tablets was performed ○ Assay and Impurity procedures for the HPLC analysis of Chloroquine Phosphate, Mefloquine, and Artesunate tablets were performed
Next Steps	<p>Trainees will:</p> <ul style="list-style-type: none"> ○ Complete the PVT of the PharmTest Dissolution system using Apparatus 2 (paddles) and submit the calculation results to PQM for review ○ Test additional antimalarial samples using Pharmacopeial monographs and consult with PQM if difficulties arise (Jul-Nov 2012) ○ Plan to conduct confirmatory tests of samples submitted from the sentinel sites (Sep-Dec 2012)



Mr. S. Bradby, Dr. A. Likhitsup, and participants perform dissolution performance verification test.
Photo: Dr. M.P. Kyaw



Participants analyze an antimalarial medicine sample using UV spectrophotometric method.
Photo: Dr. M.P. Kyaw



Dr. A. Likhitsup and Mr. S. Bradby observe participants performing a test of an antimalarial medicine sample.
Photo: Dr. M.P. Kyaw



Mr. S. Bradby demonstrates proper technique in measuring test solution with accuracy and precision.
Photo: Dr. M. P. Kyaw

Workshop on conducting a baseline survey on the quality of selected antimalarials in selected states in Burma

Item	Description
Specific Objectives/ Expected Outcomes	Objective: Familiarize the participants on the baseline survey project and train them in sampling protocol and data recording measures Expected Outcomes: Staff will be able to understand and conduct the sample collection in compliance with the protocol
Venue/Location	Amara Hotel, Nay Pyi Taw
Organizers	<ul style="list-style-type: none"> ○ PQM ○ WHO ○ Burma FDA ○ DMR-LB ○ VBDC
Sponsors	<ul style="list-style-type: none"> ○ PMI – USAID/RDMA (through PQM) ○ WHO
Trainers and Facilitators	<ul style="list-style-type: none"> ○ Souly Phanouvong, PQM ○ Sanford Bradby, PQM ○ Lukas Roth, PQM ○ Dr. Myo Naing, WHO

Trainees	33 staff from the Burma FDA, DMR-LB, VBDC and WHO
Agenda	See Agenda in <i>Annex 5</i> for detailed information
Opening Ceremony (combined with the Workshop 1 above)	<ul style="list-style-type: none"> ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Myo Naing, Technical Officer, WHO ○ Dr. Souly Phanouvong, Manager, PQM
Modules	<ul style="list-style-type: none"> ○ Project Overview ○ Sampling Protocol ○ Sampling Handling, Storage and Documentation ○ Data Reporting and Management ○ Analytical Methods and Procedures ○ Implementation Plan
Closing Ceremony (combined with the Workshop 1 above)	<ul style="list-style-type: none"> ○ Dr. Myat Phone Kyaw, Director, DMR-LB ○ Dr. Myo Naing, Technical Officer, WHO ○ Dr. Souly Phanouvong, Manager, PQM
Outcomes/Conclusion	<ul style="list-style-type: none"> ○ The baseline survey will assess the quality of selected antimalarials in selected townships, specifically 5 (of 10) townships in Tanintharyi and 5 (of 10) townships in Mon and Shwegyin Township in Bago East ○ Guidelines were developed, which outline implementation of the project as well as next steps (see <i>Annex 6</i>) ○ The only potential limitation is the need to obtain authorization letters from either the Burma MOH or local governments approving the facilitation of sampling. Assuming these limitations are not encountered, the survey is scheduled to begin July 2012
Next Steps	See <i>Annex 6</i>



Group photo. Photo: FDA staff



Dr. S. Phanouvong presents sampling protocol of the survey.
Photo: Dr. R. Jähnke



Mr. S. Bradby presents analytical method of chloroquine sulfate. Photo: Dr. S. Phanouvong

Agenda: Establishing a Medicine Quality Monitoring Program in Burma

In collaboration with VBDC, Burma FDA and DMR-LB
May 7-11, 2012 – Nay Pyi Taw, Burma

Day/Time	Topic/Activity
Day 1	
	<ul style="list-style-type: none"> • Opening ceremony – Burma Ministry of Health (FDA, NMCP), WHO, PQM • Meeting with all stakeholders and participants • GPHF Minilab Presentation (Richard Jähnke) • Coffee break • Presentations on Establishing a Medicine Quality Monitoring Program (Souly Phanouvong) • Lunch • Presentations on Establishing a Medicine Quality Monitoring Program-Continued (Souly Phanouvong) • Coffee break (optional) • Presentations on Establishing a Medicine Quality Monitoring Program-Continued (Souly Phanouvong)
Day 2	
	<ul style="list-style-type: none"> • Introduction on basic tests and Minilabs[®] • Work group: Minilab[®] testing of Artesunate tablets (Facilitator – Souly Phanouvong)
Day 3	
	<ul style="list-style-type: none"> • Work group: Minilab[®] testing of Chloroquine tablets (Facilitator – Lukas Roth)
Day 4	
	<ul style="list-style-type: none"> • Work group: Minilab[®] testing of Mefloquine tablets (Facilitator – Richard Jähnke) • Work group: Minilab[®] testing of Artemether/Lumefantrine tablets (Facilitator – Souly Phanouvong)
Day 5	
	<ul style="list-style-type: none"> • Individual: Minilab[®] testing of medicine • Data Management and Reporting • Minilab Cleaning, Repacking and Safety Procedures • Next Steps – Action Plan • Closing ceremony and awarding of certificates

PLANNING FOR NEXT STEPS – AFTER TRAINING

1. Objectives

- Implement the project activities, i.e., carry out sample collection and perform basic testing, verification testing, and quality data documentation and reporting.
- Use findings to develop advocacy tools, raise awareness, and encourage Burma FDA to take appropriate measures to address the problem if poor quality antimalarial medicines are found.

2. Immediate Undertaking

- Form a Project Management Team (PMT) (if not yet done) consisting of:
 - State FDA
 - VBDC/MCP – lead institution
 - DMR-LB?
- The PMT is responsible for:
 - Developing a plan of action to implement the project and submitting it to WHO and USP PQM for approval/agreement
 - Coordinating the Field Drug Testing Facility sites in project implementation (including sample collection planning, sampling location selection, testing data documentation and reporting)
 - Communicating with PQM for any technical issues

3. Responsibility of trainees after completing this course

Trainees who complete this training workshop will be responsible for the following:

- Report about the training (objectives, outcomes, and plan of action for implementation of the program activities) to their relevant management/superiors and request their support.
- Participate in the management of VBDC, FDA, and DMR-LB to develop itemized budget proposal and submit to WHO and PQM for review and approval. The budget will cover the operation of the program activities (sample collection and field testing of antimalarials, and reporting by MQM focal point from each of the six pilot sentinel sites):
 - Mon & Kayin
 - Kachin
 - Tanintharyi
 - Southern Shan
 - Central VBDC and Bago

By the end of 2012, one Round of sample collection and testing should be completed. *The subsequent year, two Rounds should be carried out.*

Results/findings of Round 1 will be discussed and shared with relevant agencies and used to help determine whether or not the program should be expanded to other geographical areas and other medicines e.g., antituberculars, antiretrovirals, and antibiotics.

4. Budget Estimation and Request (See table outlined below, as example.)

Activity	Unit/ quantity/ number	Estimated cost in local currency (and in USD)/unit	Total	Remark
Sample collection (1 staff per site, max 5 day per round)				
Travel (air, bus, etc)				
Accommodation Meals				
Samples purchasing costs				
Testing (2 staff/site, 5 working days per round)				
Data reporting/documentation				
Supervision				
Discount Cost of testing at NLDQC				
Total				

Agenda: Compendial Analysis of Antimalarial Medicines

In collaboration with Burma FDA and DMR-LB
May 7-11, 2012 – Nay Pyi Taw, Burma

Day/Time	Topic/Activities
Day 1	
9:00–5:00 p.m.	<p>Introductions, Opening Ceremony, meeting with all stakeholders and participants Review Agenda & materials Intro to Pharmacopeias (Lecture) <ul style="list-style-type: none"> o Effectively Using USP/NF, The International Pharmacopeia, The British Pharmacopeia Good Laboratory Practice (GLP) (Lecture) Safety (Lecture) Dissolution Performance Verification Testing (PVT) (Lecture) USP General Chapters (Lecture) <ul style="list-style-type: none"> o <711> Dissolution o <851> Spectrophotometry UV Lab: Drying of Chloroquine Phosphate RS (16 hours at 105) Lab: PVT of Dissolution Tester (using Apparatus 2)</p>
Day 2	
9:00–5:00 p.m.	<p>HPLC, USP General Chapters (Lecture) <ul style="list-style-type: none"> o <621> Chromatography HPLC Lab: HPLC System suitability and assay of Chloroquine Phosphate Tablets Lab: Dissolution of Chloroquine Phosphate Tablets</p>
Day 3	
9:00–5:00 p.m.	<p>Proper Weighing Practice Volumetric Technique Good Documentation Practices Core USP General Chapters (Lecture) <ul style="list-style-type: none"> o <31> Volumetric Apparatus o <21> Weights & Balances o <1251> Weighing on an analytical balance Lab: HPLC System suitability and assay of Chloroquine Phosphate Tablets Lab: Dissolution of Chloroquine Phosphate Tablets</p>
Day 4	
9:00–5:00 p.m.	<p>pH - USP General Chapter <ul style="list-style-type: none"> o <791> pH (Lecture and Hands-on Demonstration) o <731> Loss on drying LAB: HPLC System Suitability and Assay of Artesunate Tablets</p>
Day 5	
9:00–5:00 p.m.	<p>Core USP General Chapters (Lecture) <ul style="list-style-type: none"> o <905> Uniformity of Dosage Units o <1058> Analytical Instrument Qualification Lab: HPLC: Related Compounds, Artesunate Tablets Identify activities requiring follow-up (Working session) Closing meeting & delivery of certificates</p>

Summary of Burma Training Evaluation Forms

Compendial Training**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
Effectively Using USP, BP, Ph. Int. (Lecture)	3	6	-	-
General Notices (Lecture)	1	8	-	-
Good Documentation Practices (Lecture)	-	8	1	-
Good Laboratory Practices (Lecture)	-	9	-	-
Effectively Using USP, BP, Ph. Int. (Lecture)	3	4	2	-
Safety (Lecture)	1	6	2	-
Dissolution and UV – Basics and PVT (Lecture and Hands-on)	5	4	-	-
Chromatography - (Lecture and Hands-on)	3	5	-	-
pH (Lecture and Hands-on)	1	8	-	-
Chromatography (Lecture)	1	6	1	-
Chromatography.(Hands on testing of anti-malarial tablets)	2	6	-	-
Good Weighing Practice (Lecture)	1	7	1	-
Uniformity of Dosage Units (Lecture and Practice Calculations)	1	7	1	-
Total (%)	22 (19.3%)	84 (73.7%)	8 (7.0%)	0

B- Overall Evaluation of the Training Workshop

	Strongly agree	Agree	Somewhat disagree
Course objectives were relevant to my needs	2	7	-
The training material helped me understand and better organize my data	3	6	-
I was able to understand the content of the materials presented	1	7	1
Overall, the course was useful and will help me do my job better	5	4	-
There were enough practical exercises to facilitate understanding of the course	-	6	3
The pacing of the various sessions was appropriate for my understanding of course materials	-	9	-
The sequence in which the sessions were presented was appropriate for my understanding	-	8	1
The instructors were knowledgeable on the subject	6	3	-
The instructors allowed an appropriate level of participation	4	5	-
Total (%)	21 (25.9%)	55 (67.9%)	5 (6.2%)

1. What did you like best about the course?

- HPLC Analytical method
- PVT
- HPLC system suitability
- Dissolution

2. What did you like least about the course?

- HPLC – difficult to see what was happening
- Not enough time

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

- Additional hands-on work
- Longer training
- Additional methods and instruments to gain better understanding
- Run full monograph of one compound instead of only some aspects
- Pre-course evaluation on trainees knowledge in order to tailor course

Basic Tests and Sampling Procedure for Establishing MQM

Indicator	Strongly Agree	Agree	Disagree Somewhat
1. Course objectives were relevant to my needs	7	16	
2. I was able to understand the content of the materials presented	6	14	3
3. Overall the course was useful and will help me do my job better	10	13	-
4. There were enough practical exercises to facilitate understanding of the course	7	15	1
5. The pacing of sessions was appropriate for my understanding of course materials	6	15	2
6. The instructors were knowledgeable on the subject	16	7	-
7. The instructors allowed an appropriate level of participation in the class	14	9	-
Total	66 (41.0%)	89 (55.3%)	6 (3.7%)

1. Which topics of aspects of the course should not be included in future workshops?

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

- Longer training
- Include more medicines for testing (eg. Anti-TB)
- Morning break is too close to lunch, remove
- Minilab materials weren't enough
- More training for additional participants, especially pharmacists (from hospitals and states)
- Refresher training every 1-2 years
- Additional basic theory and principles
- Smaller working groups

Agenda
Workshop on Baseline Survey on Priority Antimalarial Medicines' Quality in Selected
Areas of Burma

In collaboration with VBDC, Burma FDA and DMR-LB
 May 12, 2012 – Nay Pyi Taw, Burma

Time	Activity	Responsible
09:00-9:30	Registration	
09:30-09:45	Welcome and Introduction	VBDC USP PQM
09:45-10:45	<ul style="list-style-type: none"> • Overview of the Project • Sampling Protocol • Sample handling, storage and documentation 	Souly Phanouvong
10:45-11:00	Coffee/Tea break	ALL
11:00-12:00	<ul style="list-style-type: none"> • Sampling discussion continues • Project monitoring and supervision • Data reporting and management • Technical report 	Souly Phanouvong
12:00-13:00	Lunch	ALL
13:00-13:30	Analytical methods and procedures	Souly Phanouvong and Sanford Bradby
13:30-14:00	Set up survey team(s) and define responsibilities/assignments	Souly Phanouvong
14:00-14:30	Action items: implementation plan and timeline	Souly Phanouvong
14:30-15:00	Wrap up and workshop adjourns	
15:00-15:30	Coffee/Tea Break	ALL

Next Steps for Workshop on Baseline Survey

Goal: To make sure that the survey is carried out in accordance to the proposed plan and time line with concrete results.

Key implementing partners:

1. VBDC
2. Burma FDA
3. DMR-LB
4. WHO
5. PQM

Table 1. Planned Activities with Timeline

Activity	Timeline	Deliverable	Responsible
1. Consultation with key stakeholders	Feb/Mar 2012	Training date set	PQM
2. Develop sampling and testing protocols	April 2012	Protocol doc.	PQM
3. Conduct a one-day training	May 2012	Workshop	WHO, PQM
4. Sample collection from the sites	Jul-Sep 2012	Samples	VBDC, DMR-LB
6. Conduct analyses of samples	Sept-Oct 2012	Test reports	ISO labs
7. Test result data analysis	Nov-Dec 2012	Data documented	PQM
8. Write technical report with recommendations	Dec 2012	Report	PQM and partners
9. Present findings to relevant agencies and authorities for appropriate measures to address problems, if any	Dec 2012	Meeting and report dissemination	PQM and partners

Table 2. Other Tasks with Timeline

Task	Time line	Deliverable	Responsible
1. Develop detailed itemized budget plan for sampling	Jun 2012	Budget plan	VBDC, DMR-LB
2. Develop LOC – WHO to initiate clearance letter	Jun 2012	Authorization letter	WHO, PQM
4. Translate Sample Collection Form into Burma Language	Jun 2012	Form Annex 1	WHO
5. Transfer funds for operation	Jun 2012	Funds to ... (pending item 2)	PQM, WHO
6. Dispatch funds to local VBDC for sample collection	Jul 2012	Funds to VBDC	VBDC
7. Conduct randomization of sampling sites prior to actual sampling	Jul-Sep 2012	List of sites selected	VBDC, DMR-LB

Immediate Next Steps

1. Report your training participation to your superior and management as appropriate and request their support and cooperation
2. Prepare itemized budgets and the necessary tools, commodities (plastic bags, containers, adhesive tape, labels, permanent markers, and notebooks for sample collection) – 1 month process by WHO for local purchasing
3. WHO to write a letter with a summary of baseline survey protocol and submit it to the MOH/IHD for clearance and support the project implementation
4. PQM to revise the baseline survey protocol for WHO to attach to the letter
5. Keep the PQM and WHO focal points in the loop on any issues related to the project (e.g., change of personnel, anticipation of delay, etc.)