

# PQM Evaluation of the Laboratory Quality Management System: Food and Drug Quality Control Center (FDQCC)

Vientiane, Laos  
February 18-19, 2013

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## *Trip Report*

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## **Executive Summary**

Dr. Charles and Dr. Phanouvong traveled to Laos to conduct a follow-up evaluation of the Food and Drug Quality Control Center (FDQCC) to identify a proposed scope of accreditation, establishes priorities, and develop an ISO 17025 implementation plan and procedures.

The FDQCC is not ready for formal ISO 17025 pre-assessments by an accreditation body. The laboratory needs to generate quality management system (QMS) documentation in their primary language and update their Standard Operating Procedures (SOPs), work instructions, forms, and policies. The laboratory should continue conducting testing provided by their proficiency test provider to strengthen the laboratory.

PQM was satisfied with the outcome of the trip, as ISO 17025 accreditation preparations are progressing. FDQCC shows strong interest in documentation development, method development, and measurement uncertainty training.

**A full, confidential report of PQM's evaluations has been sent directly to FDQCC.**

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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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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

## ACRONYMS

|        |  |
|--------|--|
| DQI    | Drug Quality and Information Program               |
| FDD    | Food and Drug Department                           |
| FDQCC  | Food and Drug Quality Control Center               |
| HPLC   | High Performance Liquid Chromatography             |
| ISO    | International Organization of Standardization      |
| MOH    | Ministry of Health                                 |
| NOMCOL | Network of Official Medicine Control Laboratory    |
| OFI    | Opportunity for Improvement                        |
| PMI    | President's Malaria Initiative                     |
| PQM    | Promoting the Quality of Medicines Program         |
| QA     | Quality Assurance                                  |
| QC     | Quality Control                                    |
| QMS    | Quality Management System                          |
| RDM/A  | Regional Development Mission for Asia (USAID)      |
| SOP    | Standard Operating Procedure                       |
| USAID  | United States Agency for International Development |
| USP    | United States Pharmacopeia                         |
| UV     | UV Spectrophotometer                               |
| WHO    | World Health Organization                          |

## **Background**

With financial support from the U.S. Agency for International Development (USAID), the U.S. Pharmacopeia (USP) has been providing technical assistance to Laos since 2003. In Laos, activities have focused on strengthening the capacity of the Food and Drug Department (FDD) by providing training on post-marketing surveillance, laboratory techniques, and ISO 17025 Quality Management System awareness.

The goal for the Food and Drug Quality Control Center (FDQCC) is to become ISO 17025:2005 accredited, and at a later stage, World Health Organization (WHO) Prequalified. Attaining working conditions that conform to these stringent standards will provide Laos's Ministry of Health—especially the FDD—with a quality control (QC) laboratory capable of producing trustworthy and valid results, while assuring that FDQCC's QMS, administrative, and technical operations are functioning at the highest internationally recognized standards.

## **Purpose of Trip**

The purpose of this visit is to review FDQCC's progress to assess their capability for future accreditation, review the established priorities and implementation plan, and further develop an ISO 17025 and future WHO prequalification implementation plan.

## **Source of Funding**

These activities were supported by the President's Malaria Initiative (PMI) through USAID's Regional Development Mission for Asia (USAID/RDMA).

## **Overview of Activities**

The full agenda of the trip is included in *Annex 1* and a list of participants in *Annex 2*. **A full, confidential report of PQM's evaluations has been sent directly to FDQCC.**

During Dr. Charles' visit to FDQCC, there were four specific objectives:

- Evaluate FDQCC's current Quality Management System (QMS)
- Evaluate FDQCC's equipment (within the current laboratory)
- Observe staff competency and training
- Communicate ISO 17025 Standards

Discussions regarding various aspects of QMS and other relevant topics were held with FDQCC staff. Some of the discussions focused on:

- Pharmacopeial methods vs. manufacturer provided methods
- Proficiency and inter-laboratory testing
- Flexible scope expansion
- Timeline for obtaining ISO/IEC 17025:2005 from a regional accreditation body
- Sustainability and maintenance after accreditation
- Participation in the Network of Medicine Quality Control Laboratories (NOMCOL)
- Documentation
- Lab methodology and equipment
- English language training

FDQCC is interested in an internationally accredited equipment calibration company in addition to the current regional calibration company provider. PQM identified an ISO 17025 calibration organization, Kim Long Survey JSC, as a potential provider.

The FDQCC staff understands the concepts pertaining to ISO 17025 standards. The potential scope of accreditation will be limited to TLC, HPLC, Dissolution, and UV, all tests for which the lab has duplicate equipment.



### **Conclusion**

The FDQCC is not ready for formal ISO 17025 pre-assessments by an accreditation body. The laboratory must generate QMS documentation in their primary language (by 2014) and update their Standard Operating Procedures (SOPs), work instructions, forms, and policies to comply with the standard. The laboratory should continue conducting testing provided by their proficiency test provider to strengthen the laboratory.

### **Next Steps**

- PQM will begin providing templates to FDQCC in May 2013
- FDQCC will draft 25+ ISO 17025 Section 4 documents using the templates that PQM provides starting May 2013
- FDQCC will complete 25+ ISO 17025 Section 4 documents within 180-240 days.
- FDQCC will begin categorizing and organizing all records—that are available to them during the time period of May-September 2013—pertaining to the proposed scope of accreditation
- FDQCC Management will select a Lead Internal Auditor by April 2013 to support lab audits, inspections, and management review
- FDQCC will report progress and issues encountered to the PQM QMS Manager regularly
- FDQCC will document performance checks of all equipment calibrated by internal and external providers.

**PQM Trip Agenda**

The Food Drug and Quality Control Center

Vientiane, Laos

February 18-19, 2013

| <b>Time/Date</b>     | <b>Activity</b>   |
|----------------------|---|
|                      | <b>Day 1</b>  |
| 0900                 | Arrival, Opening meeting; introductions   |
| 0930                 | Tour of Laboratory  |
| ISO Section 4 Review |   |
| 1000                 | Review Management Requirements including management reviews, internal audit corrective actions, non-conforming work, complaints, client services, preventive actions, request tender and contract, subcontracting, purchasing services, measurement uncertainty, document control, measurement uncertainty, record control, job descriptions and responsibilities, personnel training, PT testing and other quality system elements |
| 1200-1300            | Lunch   |
| 1300                 | Quality system review continued, Sample log-in  |
| 1630                 | Daily Wrap Up   |
|                      | <b>Day 2</b>  |
| 0900                 | Arrival   |
| ISO Section 5 Review |   |
| 0900                 | Lab and Equipment Inspection  |
| 1000                 | Observe Chemical Testing (Weight, pH methods)<br>Continue Observe Chemical Testing (HPLC, Dissolution)<br>Review test methods<br>Review representative data packages<br>Staff Interviews  |
| 1200-1300            | Lunch   |
| 1300                 | Review test methods<br>Extraction and preparation methods<br>Review representative data packages<br>Staff Interviews  |
| 1700                 | Wrap Up, Discuss Open Assessment Issues, Scope discussion and expansion, flexible method based scopes , and Writing time for report   |
| 1800                 | Depart  |

**PQM Trip: Lists of Participants**  
 The Food Drug and Quality Control Center  
 Vientiane, Laos  
 February 18- February19, 2013

**Opening and Closing Meeting with Management and PQM Review**

| <b>Participant</b>     | <b>Institution</b>                              |
|------------------------|---|
| Chanssapha Pamanivong  | FDQCC- Technical Staff                          |
| Douangchay Malyvanh    | FDQCC- Head of Food Division                    |
| Khamphay Phoumanivoug  | FDQCC-Head of Quality Assurance Division        |
| Maliseng Praseuth      | FDQCC-Deputy Head of Administration Division    |
| Paniphone Meksavanh    | FDQCC-Technical Staff                           |
| Phatsaly Oudomsack     | FDQCC-Deputy Head of Drug and Cosmetic Division |
| Sengchan Phongsavath   | FDQCC-Deputy Head of QA Division                |
| Vongsavah Insixiengmay | FDQCC- Head of Administration Division          |
| Donnell Charles        | PQM   |