

PQM Evaluation of the Laboratory Quality Management System: National Health Product Quality Control Center (NHQC)

Phnom Penh, Cambodia
February 13-15, 2013

Trip Report

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Executive Summary

Dr. Charles and Dr. Phanouvong traveled to Cambodia to conduct a follow-up evaluation of the National Health Product Quality Control Center (NHQC) to identify a proposed scope of accreditation, establish priorities, and develop an ISO 17025 implementation plan and procedures.

NHQC is not ready for formal ISO 17025 pre-assessments by an accreditation body. The lab is currently in transition as they prepare to move to a new facility by 2015. NHQC should focus on updating their standard operating procedures (SOPs), work instruction, forms, and policies to comply with the standard.

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

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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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ACRONYMS

DQI	Drug Quality and Information Program
HPLC	High Performance Liquid Chromatography
ISO	International Organization of Standardization
MOH	Ministry of Health
NHQC	National Health Product Quality Control Center
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
SOP	Standard Operating Procedure
TLC	Thin Layer Chromatography
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 Cambodia since 2003. In Cambodia, activities have focused on strengthening the capacity of the National Health Product Quality Control Center (NHQC) by providing training on post-marketing surveillance, laboratory techniques, and ISO 17025 Quality Management System (QMS) awareness.

The goal for the NHQC 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 Cambodia's Ministry of Health with a quality control (QC) laboratory capable of producing trustworthy and valid results, while assuring that NHQC'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 NHQC'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 USAID/Cambodia.

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 NHQC, there were four specific objectives:

- Evaluate NHQC's current Quality Management System (QMS)
- Evaluate NHQC'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 NHQC 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
- Discussing timeline for obtaining ISO/IEC 17025:2005 from a regional Accreditation body based upon relocation of the current facility.
- Sustainability and Maintenance after accreditation



After identifying gaps and providing planning, the NHQC staff asked several questions during the session about documentation, lab methodology, and equipment. Each staff member was provided a copy of the ISO 17025:2005 International Standard to review to become more familiar.

The potential scope of accreditation will be limited to TLC, HPLC, Dissolution, and UV, all tests for which the lab has duplicate equipment. Further expansion into the Microbiology area will occur at a later date.

Conclusion

NHQC is not ready for formal ISO 17025 pre-assessments by an accreditation body. The lab is currently in transition as they prepare to move to a new facility by 2015. NHQC should focus on updating their standard operating procedures (SOPs), work instruction, forms, and policies to comply with the standard.

Next Steps

- PQM will begin providing templates to NHQC in March 2013, with all templates delivered by May 2013
- NHQC will draft 25+ ISO 17025 Section 4 documents using the templates that PQM provides starting in March 2013
- NHCQ will complete 25+ ISO 17025 Section 4 documents within 180-240 days.
- NHQC 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
- NHQC Management will select a Lead Internal Auditor by April 2013 to support lab audits, inspections, and management review
- NHQC will report progress and issues encountered to the PQM QMS Manager regularly

PQM Trip Agenda
National Health Product Quality Control Center
Phnom Penh, Cambodia
February 13 – February 15, 2013

Time/Date	Activity
	Day 1
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
	Day 2
0900	Arrival
ISO Section 5 Review	
0900	Lab and Equipment Inspection
1000	Observe Chemical Testing (Weight, pH methods) Continue Observe Chemical Testing (HPLC, Dissolution) Review test methods Review representative data packages Staff Interviews
1200-1300	Lunch
1300	Review test methods Extraction and preparation methods Review representative data packages 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
 National Health Product Quality Control Center
 Phnom Penh, Cambodia
 February 13 – February 15, 2013

February, 2013 – Opening and Closing Meeting with Management and PQM Review

Participant	Institution
Khuon Vilavann	NHQC-Director Laboratory
Nam Nivanna	NHQC- Advisor to the Laboratory Director
Ngy Pich Praseth	NHQC-Head of Microbiology Section
Nguon Henry	NHQC-Head of Chemical Section
Pin Yossuchivy	NHQC-Chief of R&D Section
Prav Chheang Hor	NHQC-Deputy Director
Tep Keila	NHQC-Deputy Director
Tey Sovannarith	NHQC-Deputy Director
Ung Sothavy	NHQC- Chief of Technical Bureau
Donnell Charles	PQM
Siv Lang	PQM- Consultant