

# Evaluation of the Laboratory Quality Management System: Bureau of Drugs and Narcotics

Bangkok, Thailand  
August 29, 2013

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## *Trip Report*

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### **Promoting the Quality of Medicines**

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PROMOTING THE QUALITY OF MEDICINES

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## **Executive Summary**

Ms. Okafor traveled to Thailand to conduct a preliminary assessment of the preparedness of the Bureau of Drugs and Narcotics (BDN) to pursue ISO 17043:2010. PQM also discussed the lab changing from its current use of product-based ISO 17025 accreditation to test-based accreditation.

PQM will be able to provide technical assistance in identifying the methods for test-based ISO 17025 and ensuring that an appropriate accreditation body is identified. Additionally, BDN is well advanced in preparations for ISO 17043 accreditation and has been serving as a proficiency testing provider for many years. With technical assistance from PQM, the lab should be ready for an assessment from an accreditation body within the next 8-12 months.

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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.

## **ACKNOWLEDGEMENTS**

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- Management and staff of the Bureau of Drugs and Narcotics, especially Ms. Nidapan Ruangrittinon, Dr. Wiyada Akarawut, Ms. Suratchanee Savetsila, and Ms. Siriphorn
- Dr. Aye Aye Thwin, Director; Dr. Wayne Stinson, Regional Malaria Advisor; Mr. Christopher Barrett, Deputy Director; and Ms. Sharlene Bagga-Taves, Health Officer, Office of Public Health, USAID/Thailand
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

## **ACRONYMS**

BDN	Bureau of Drugs and Narcotics
DQI	USP Drug Quality and Information Program
JPMA	Japanese Pharmaceutical Manufacture's Association
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
PT	Proficiency Testing
QC	Quality Control
QMS	Quality Management System
RDMA	Regional Development Mission for Asia
USAID	United States Agency for International Development
USP	U.S. Pharmacopeial Convention

## **Background**

With financial support from the U.S. Agency for International Development (USAID), the U.S. Pharmacopeial Convention (USP) has been providing technical assistance to Thailand since 2002. Under the current program, Promoting the Quality of Medicines (PQM), activities in Thailand have focused on strengthening the capacity of the Bureau of Drugs and Narcotics (BDN) by providing training on post-marketing surveillance, laboratory techniques, and ISO 17025 Quality Management System (QMS) awareness.

BDN's goal is to strengthen their capabilities as a quality control (QC) laboratory by broadening their current ISO 17025 scope of accreditation, changing from product-based accreditation to test-based, and becoming ISO 17043 accredited. While ISO 17025 covers the general requirements demonstrating a lab's competence related to testing and calibration, ISO 17043 is the standard developed for proficiency testing (PT) providers to demonstrate their competence by complying with guidelines for the planning and implementation of PT programs.

## **Purpose of Trip**

The purpose of this visit was to conduct a preliminary assessment of BDN's preparedness for pursuing ISO 17043:2010. PQM also wanted to discuss the lab changing from product-based accreditation to test-based accreditation for its ISO 17025 accreditation status.

## **Source of Funding**

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

## **Overview of Activities**

A meeting was scheduled to discuss the status of BDN's QMS and ascertain its level of preparedness for ISO 17043 accreditation. This meeting helped show how PQM can more efficiently prepare the lab for ISO 17043 accreditation and for switching to test-based accreditation. See *Annex 1* for the Participant List.

### ***Thursday, August 29, 2013 – Opening meeting and discussion with BDN Key Laboratory Staff***

Opening remarks were given by the BDN laboratory Deputy Director, Dr. Wiyada Akarawut, who welcomed Ms. Okafor and discussed the structure and functions of BDN; this was followed by a short presentation. Activities regarding PT, which the lab has been conducting with laboratories from local pharmaceutical industry, regional medical science centers, the Department of Livestock, and other Association of South-East Asian Nations (ASEAN) countries (Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, and Vietnam). BDN also conducts a PT program for the labs of the Narcotics Control Board, forensic labs of the Royal Thai Police, and labs of Narcotics and Illicit Drugs.

Ms. Okafor and Dr. Wiyada also discussed how PQM can provide BDN the technical assistance necessary to achieve ISO 17043 accreditation. After accomplishing this goal, BDN and PQM can collaborate on how BDN could



provide PT services to other PQM partners globally. It has often proved challenging to locate an ISO 17043 accredited organization that can provide PT services to PQM partners seeking ISO 17025 accreditation. Dr. Wiyada seemed pleased to hear of this potential collaboration and expressed gratitude to receive technical assistance from PQM.

Dr. Wiyada also informed PQM that she would like a pre-audit visit from PQM before the end of the calendar year to see what BDN needs to complete before an accreditation body conducts a full assessment. She would also like for BDN to become ISO 17043 accredited by September 2014. Preferably, Dr. Wiyada would like PQM to audit their documents and system by the end of this calendar year and the accreditation body to conduct the official assessment by May 2014.

The group also discussed the technical sponsorship that BDN receives from the Japanese Pharmaceutical Manufacturer's Association (JPMA). BDN proposes to request training from JPMA on biosimilars and for capacity-building. BDN looks to JPMA in this area since they are very advanced and experienced. BDN plans to open a biotechnology department, modeling it after JPMA, and to conduct dossier evaluation as well as bioequivalence testing.



## **Conclusion**

BDN is already an ISO 17025 accredited lab, and it would be fairly easy to transition to test-based accreditation. PQM can provide technical assistance in identifying the methods and to ensure that an appropriate accreditation body is identified. Additionally, BDN has been serving as a PT provider for many years for free and, based on PQM's observations, is well advanced in preparations for ISO 17043 accreditation. There are many documents that BDN will have to draft; however, with technical assistance from PQM, the lab should be ready for assessment from an accreditation body within the next 8-12 months.

## **Next Steps**

- BDN will continue to prepare all documents necessary for ISO 17043 accreditation and notify PQM of documents and Standard Operating Procedures drafted. (by October 2013)
- PQM will provide assistance by contacting an accreditation body, serving as liaison between the accreditation body and BDN, and providing answers to questions regarding the necessary requirements for ISO 17043. (by November 2013)
- BDN and PQM will decide which methods will be included in the scope of accreditation for ISO 17025. (by November-December 2013)
- BDN will prepare all documentation necessary for this transition, and PQM will provide technical assistance in drafting necessary documents. (by December 2013)



**Evaluation of BDN Laboratory QMS  
List of Participants**

Bureau of Drugs and Narcotics  
Bangkok, Thailand  
August 29, 2013

<b>Participant</b>	<b>Institution</b>
Wiyada Akarawut	BDN-Deputy Director Laboratory
Suratchanee Savetsila	BDN-Quality Assurance Manager
Phatcharia Nuanqsai	BDN-Medical Scientist
Adisak Manlin	BDN-Medical Scientist
Orapin Tanankut	BDN-Medical Scientist
Angkana Kritpitakngoen	BDN-Medical Scientist
Anongnut Noeimuangpak	BDN-Senior Pharmacist
Maswalai Likitthanasvat	BDN-Pharmacist
Siripphorn Laomanacharoen	BDN-Pharmacist
Naliluk Mutapatara	BDN-Pharmacist
Regina Okafor	PQM