

## **PQM Hands-on Compendial Microbiology Training**

**Hyderabad, India**

**February 27 - March 6, 2012**

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### ***Trip Report***

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

Implemented by U.S. Pharmacopeia

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**Cooperative Agreement # GHS-A-00-09-00003-00**

**Sponsoring USAID Missions:** USAID/Ethiopia, USAID/Ghana, and USAID/Mali

**Grantee:** Promoting the Quality of Medicines (PQM) Program

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**Language:** English

**Date of Publication:** August 8, 2012



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This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00, the President's Malaria Initiative (PMI) and the President's Emergency Plan for AIDS Relief (PEPFAR). The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID, PMI, or PEPFAR, or the United States Government.

## **Executive Summary**

PQM, in collaboration with USP-India, conducted hands-on compendial microbiology training for analysts from the following laboratories: Product Quality Assessment Directorate (PQAD) in Ethiopia, Food and Drugs Board of Ghana, and the Laboratoire National de la Santé (LNS) of Mali. The goal was to equip the analysts with skills needed to perform microbiology tests specified in pharmacopeial monographs. The training consisted of lectures and hands-on laboratory training in:

- Fundamentals of Microbiology
- Microbiological Best laboratory Practices
- Microbial Examination of Nonsterile Products:
- Sterility Tests
- Validation of Microbial Recovery from Pharmacopeial Articles
- Pyrogen and Bacterial Endotoxin Testing

Participants indicated they benefited from the topics covered during the training, particularly the lectures, and made recommendations for improving the practical component.

## TABLE OF CONTENTS

<a href="#"><u>Acknowledgements</u></a> .....	4
<a href="#"><u>Acronyms</u></a> .....	5
<a href="#"><u>Background</u></a> .....	6
<a href="#"><u>Purpose of Trip</u></a> .....	6
<a href="#"><u>Source of Funding</u></a> .....	6
<a href="#"><u>Overview of Activities</u></a> .....	6
<a href="#"><u>Conclusion</u></a> .....	7
<a href="#"><u>Next Steps</u></a> .....	7
<a href="#"><u>Annex 1: Training Agenda</u></a> .....	8
<a href="#"><u>Annex 2: Participant Evaluations</u></a> .....	9

### **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**

PQM would like to thank:

- Dr. Koduru Surendranath, Vice President, USP-India; and Mr. Ashok Dang, Director, Marketing and Technical Services, USP-India, for hosting the training
- Dr. Radhakrishna Tirumalai, for his time and for playing a leading role in the planning and delivery of the training
- Dr. Krishna Menon, Director-Biologics, USP-India; and Mr. Pradeep Kumar, Scientist, USP India for functioning as instructors for the training
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice

## ACRONYMS

DQI	Drug Quality and Information program
FDB	Food and Drugs Board
FMHACA	Food, Medicine and Health Care Administration and Control Authority
GLP	Good Laboratory Practices
LNS	Laboratoire National de la Santé
LSD	Laboratory Services Department
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malarial Initiative
PQAD	Product Quality Assessment Directorate
PQM	The Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## Background

The PQM program receives funding from the President’s Emergency Plan for AIDS Relief (PEPFAR) and the President’s Malaria Initiative (PMI), through USAID, to strengthen the capacity of official medicine control laboratories in several countries. Three of the laboratories that have benefited from the program are:

- The Product Quality Assessment Directorate (PQAD) of the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA)
- The Laboratory Services Department (LSD) of the Ghana Food and Drugs Board (FDB)
- The Ministry of Health’s (MoH) Laboratoire National de la Santé (LNS) of Mali

PQM’s technical training activities for these laboratories have, in general, focused on physicochemical tests for the quality control (QC) of medicines. Like the physicochemical tests, microbiological testing constitutes a critical component of QC.

## Purpose of Trip

PQM, in collaboration with USP-India, provided hands-on compendial microbiology training to five analysts from the above three laboratories. The specific objectives of the training were:

- Provide comprehensive training on microbiological tests used in QC of medicines
- Provide exposure to the practical aspects of performing compendial microbiology tests
- Equip participants with the skills needed to perform microbiology tests specified in pharmacopeial monographs in order to support sustainable medicine QC systems in the participating countries

## Source of Funding

These activities were funded by USAID/Ethiopia, USAID/Ghana, and USAID/Mali.

## Overview of Activities

The training activities are summarized in the table below:

Item	Description
Specific Objectives/ Expected Outcomes	At the end of the training, participants were expected to: <ul style="list-style-type: none"><li>• Understand better the requirements of microbiology general chapters in pharmacopeias</li><li>• Perform microbiological tests according to pharmacopeial standards</li><li>• Play a vital role in assuring the quality of medicines that require microbiological testing in their home countries</li><li>• Work in compliance with microbiology laboratory best practices</li></ul>
Venue/Location	USP-India Pvt. Limited, IKP Knowledge Park, Hyderabad, India
Organizer	PQM and USP-India
Trainers and Facilitators	<ul style="list-style-type: none"><li>• Dr. Radhakrishna Tirumalai</li><li>• Dr. Krishna Menon</li><li>• Mr. Pradeep Kumar</li></ul>
Agenda	See Agenda in <b>Annex 1</b> for detailed information

Trainees	<ol style="list-style-type: none"> <li>1. Tiringo Mengaw Minlik (<i>PQAD, Ethiopia</i>)</li> <li>2. Birhan Moges Ejigu (<i>PQAD, Ethiopia</i>)</li> <li>3. Afework Abebe Gebreyes (<i>PQAD, Ethiopia</i>)</li> <li>4. Sekou Dembele (<i>LNS, Mali</i>)</li> <li>5. Noble Selasi Gati (<i>FDB, Ghana</i>)</li> </ol>
Modules	<ul style="list-style-type: none"> <li>• Fundamentals of Microbiology</li> <li>• Microbiological Best Laboratory Practices</li> <li>• Microbial Examination of Nonsterile Products <ul style="list-style-type: none"> <li>○ Microbial enumeration</li> <li>○ Tests for Specified Microorganisms</li> <li>○ Acceptance Criteria for Pharmaceutical Preparations</li> </ul> </li> <li>• Sterility Tests</li> <li>• Validation of Microbial Recovery from Pharmacopeial Articles</li> <li>• Pyrogen and Bacterial Endotoxin Testing</li> </ul>
Closing	Certificates were presented to the participants
Training Evaluation	A summary of participant evaluations is provided in <b>Annex 2</b>
Participant Remarks	Participants indicated they benefited from the topics covered during the training, particularly the lectures, and made recommendations for improving the practical component.
Participant Recommendations	<ul style="list-style-type: none"> <li>• Increase the time devoted to the hands-on training</li> <li>• Training should cover testing of different kinds of samples</li> <li>• The training need to focus more on regulatory issues as most of the participants are from regulatory bodies.</li> </ul>
Conclusion	The objectives for the training were met. The participants provided valuable feedback, especially about the practical component of the course.
Next Steps	USP-India is committed to improving future offerings of the course based on the feedback received from the participants.

Agenda

February 27- March 6, 2012

Day	Activities
Feb 27	<p><b>Opening meeting</b></p> <ul style="list-style-type: none"> <li>○ Introductions</li> <li>○ Review agenda, training objectives, and expected outcomes</li> </ul> <p><b>Lectures</b></p> <ul style="list-style-type: none"> <li>○ Fundamentals of Microbiology</li> <li>○ Best Laboratory Practices (USP General Chapter &lt;1117&gt;)</li> <li>○ Enumeration (USP General Chapter &lt;61&gt;)</li> <li>○ Specified Microorganisms (USP General Chapter &lt;62&gt;)</li> <li>○ Sterility Tests (USP General Chapter &lt;71&gt;)</li> <li>○ Bacterial Endotoxin Tests (USP General Chapter &lt;85&gt;)</li> <li>○ Food Ingredient Testing</li> <li>○ Toxins</li> </ul>
Feb 28 - Mar 6	<p><b>Hands-on Lab Training</b></p> <ul style="list-style-type: none"> <li>○ Aseptic Practices</li> <li>○ Lab Layout and Design</li> <li>○ Handling and storage of Microbial Cultures Preparation of Media (Liquid and Solid)</li> <li>○ Sterilization</li> <li>○ Plating</li> <li>○ Enumeration (TAMC/TYMC)</li> <li>○ Specified Microorganisms (USP General Chapter &lt;62&gt;) – any one organism indicated in USP General Chapter &lt;62&gt;</li> <li>○ Membrane Filtration</li> <li>○ Detection of Contamination in Liquid Cultures (in place of a Sterility Test)</li> <li>○ Bacterial Endotoxin Tests-Gel Clot Test</li> </ul> <p><b>Closing Meeting</b></p> <ul style="list-style-type: none"> <li>○ Completion of Evaluation Forms</li> <li>○ Distribution of Certificates</li> </ul>

**Evaluation Form****A - Overall Evaluation of the Training Workshop**

TRAINING	Extent to which the training met your overall expectations			
	Exceeded Expectations	Met Expectations	Met Some Expectations	Unsatisfactory
Compendial Microbiology Training ( <b>Lectures</b> )		5		
Compendial Microbiology Training ( <b>Hands-on Lab</b> )			1	4

**B - Evaluation of Specific Aspects of the Training Workshop**

	Strongly agree	Agree	Somewhat disagree
Course objectives were relevant to my needs	1	4	
The training material helped me understand and better organize my data		4	1
I was able to understand the content of the materials presented		4	1
Overall, the course was useful and will help me do my job better		3	2
There were enough practical exercises to facilitate understanding of the course			5
The pacing of the various sessions was appropriate for my understanding of course materials		2	4
The sequence in which the sessions were presented was appropriate for my understanding		2	3
The instructors allowed an appropriate level of participation	1	4	
The instructors allowed an appropriate level of participation		4	1

**C - Other Comments/Suggestions**

- What did you like best about the course?
  - The theoretical part of the training covered most of the topics in pharmaceutical microbiology
  - Lectures have been presented with high precision
  - I enjoyed the interaction of participants and instructors during the training. The lectures given were also helpful and well planned. I enjoyed how friendly the facilitators were.
  - The lectures start from the scientific history and grow to the points we need. I like the sequences of lecture presentations.
- What did you like least about the course?
  - Less time was spent in the practical and the number of samples tested was very limited.
  - The practical exercises did not follow the lectures.
  - I expected different types of samples to be analyzed, so I will not face problems when I work on different samples in my lab.
  - The lab appeared to be not fully prepared for the training
- What are your recommendations/suggestions for improvement of the course?
  - Increase the time devoted to the hands-on training
  - Different kinds of samples should be used in the training for tests like the microbial limit tests, bacterial endotoxin tests microbial assay and efficacy tests.
  - Training should focus more on regulatory issues as most participants are from regulatory bodies.
  - Standard or previously tested samples must be tested to check if expected results are obtained.