

**Training Workshop: Assessment of the Quality Part of the Dossier
Copenhagen, Denmark**

January 20 -22, 2010

Trip Report

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Cooperative Agreement # GHS-A-00-09-00003-00
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: PQM Staff
Language: English
Date of Publication: March 23, 2010



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 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 or the United States Government.

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 leadership 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.

Abstract

PQM staff (Kennedy Chibwe and Edwin Toledo) traveled to Copenhagen, at the invitation of the World Health Organization (WHO) Prequalification Team, to participate in the Training Workshop: Assessment of the Quality Part of the Dossier. The workshop helped increase the knowledge of key dossier requirements and some commonly encountered deficiencies and how to provide better technical assistance to manufacturers interested in pursuing WHO prequalification for second-line tuberculosis (TB) drugs.

Recommended Citation

Chibwe, K.M., and Toledo, E., January 2010 *Training Workshop: Assessment of the Quality Part of the Dossier, Copenhagen, Denmark, December 20-22, 2010* Submitted to the U.S. Agency for International Development by the Promoting the Quality of Medicines Program. Rockville, Maryland: United States Pharmacopeia.

Key Words

WHO Prequalification, dossier, second-line anti-TB medicines

Table of Contents

<u>Acknowledgements</u>	4
<u>Acronyms</u>	5
<u>Background</u>	6
<u>Purpose of Trip</u>	6
<u>Source of Funding</u>	6
<u>Overview of Activities</u>	6
<u>Conclusions</u>	6
<u>Annex 1: Participant List</u>	8
<u>Annex 2: Agenda</u>	10

ACKNOWLEDGEMENTS

The authors would like to thank:

- Dr. M. Stahl, Medical Officer, Head of Assessments Quality Assurance & Safety: Medicines Policy and Standards ,World Health Organization (WHO)
- PQM editors and administrative staff for editing this report and assisting with logistics
- Mr. Anthony Boni and Ms. Veerle Coignez at USAID in Washington, D.C. for their support and advice

ACRONYMS

ATB	Anti-tuberculosis medicine
DQI	Drug Quality and Information Program
GDF	Global Drug Facility
GLC	Green Light Committee
GMP	Good Manufacturing Practices
MDR-TB	Multi-drug resistant tuberculosis
PQM	Promoting the Quality of Medicines Program
TB	Tuberculosis
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Background

Despite efforts by the WHO Prequalification program, Global Drug Facility (GDF), and the Green Light Committee (GLC) to increase access to essential anti-tuberculosis medicines (ATBs), there are not enough WHO-prequalified second-line ATBs and manufacturers available. There is also an inadequate supply of products to treat patients with multi-drug resistant TB (MDR-TB). DQI (now PQM) has been assisting GDF in its efforts to increase the availability of good quality second-line ATBs. To expedite the prequalification process and thereby expand the pool of viable manufacturers, PQM is providing technical assistance to interested companies to:

- Prepare their product dossiers for submission to the WHO prequalification program in a manner that fulfills the prequalification requirements
- Facilitate discussions with WHO to remedy incomplete dossiers or to respond to WHO comments
- Guide manufacturers onsite to comply with the principles and guidelines of WHO Good Manufacturing Practices (GMP) and the requirements of the prequalification program

Purpose of Trip

Mr. Toledo and Dr. Chibwe traveled to Copenhagen to participate in the Training Workshop: Assessment of the Quality Part of the Dossier Training to increase their knowledge of key dossier requirements and gain insight into some commonly encountered deficiencies.

Source of Funding

This trip was supported with Core funds for TB.

Overview of Activities

Training Workshop: Assessment of the Quality Part of the Dossier

January 20-22, 2010

The workshop was held in UNICEF supply division headquarters in Copenhagen, Denmark. After brief introductions by Dr. Stahl and the participants (see *Annex 1* for the full list of participants), Linda Palahniuk, Wondiyfraw Worku, Satish Mallya, and Theo Dekker led the training (see *Annex 2* for the agenda). The training covered background to prequalification to drug development to final medicine product. Participants were given an opportunity to review and provide solutions to different case study scenarios, and one-on-one meetings with the trainers were held on the last day of the workshop.

Presentation Materials

Presentations will be posted at <http://apps.who.int/prequal/> under “Training material, workshops and meetings.”

Conclusions

Both Mr. Toledo and Dr. Chibwe found the training useful and trust this will further enhance PQM’s ability to offer timely and relevant technical assistance to manufacturers seeking to undergo the WHO prequalification process for their medicines.



Participants and Trainers
Training Workshop: Assessment of the Quality Part of the Dossier, Copenhagen, January 2010

ANNEX 1

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Assessment Training
Copenhagen, 20 to 22 January 2010



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ANNEX 2

Agenda: Quality Assessment - Training Workshop January 20-22, 2010

Wednesday January 20, 2010:

- 8:30-8:45: Welcome and introduction: Matthias Stahl
- 8:45-9:00: 1-1 **Training Session Outline and Objectives:** Lynda Paleshnuik
- 9:00-10:00 1-2 **Prequalification: what it means, how it works, why we do it (the view from Geneva):** Wondiyfraw Worku
- 10:00-10:20: Break
- 10:20-11:00 1-3 **API Sections: Tips and Common Deficiencies:** Lynda Paleshnuik
- 11:00-12:00: 1-4 **API Specifications:** Wondiyfraw Worku
- 12:00-13:00: Lunch
- 13:00-14:00 1-5 **API Stability:** Lynda Paleshnuik
- 14:00-14:20 Break
- 14:20-16:00 1-6 **Pharmaceutical Development:** Satish Mallya
- 16:00-17:00: Exercise on Day 1 material

Thursday January 21, 2010

- 8:30-8:45: Questions on Day 1 Material
- 8:45-10:15: 2-1 **Dissolution as applied to development, specifications and biowaivers:** Theo Dekker
- 10:15-10:35: Break
- 10:35-12:00: 2-2 **FPP specifications:** Wondiyfraw Worku
- 12:00-13:00: Lunch
- 13:00-14:30: 2-3 **Process Validation:** Satish Mallya
- 14:30-14:50 Break
- 14:50-16:00: 2-4 **FPP Sections: Tips and Common Deficiencies:** Lynda Paleshnuik
- 16:00-17:00: Exercise on Day 2 material

Friday January 22, 2010

- 8:30-8:45: Questions on Day 2 Material