

Conference Report: World Health Organization Prequalification Meeting with Technical Experts and Co-Inspectors

**Geneva, Switzerland
May 30-June 1, 2013**

Trip Report

Allan Hong, GMP Manager

Promoting the Quality of Medicines

Implemented by U.S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (+1-301-230-7419)
Email: pqm@usp.org and ajh@usp.org

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Executive Summary

The World Health Organization Prequalification Meeting with Technical Experts and Co-Inspectors was held in Geneva, Switzerland May 30 - June 1, 2013. The main purposes of the conference were to:

- Provide a forum for exchanging information about best practices with respect to GMP inspections
- Adopt a common position regarding the most common inspection observations
- Encourage general debate between attendees on issues raised during the meeting and discuss options for implementation of information in the relevant WHO guidelines
- Suggest working practices which will best contribute to acceptable GMP compliance by manufacturers participating in the WHO PQ Program.

During the conference, the attendees were able to exchange information and discuss best working practices, draft a Q&A document regarding the most common inspection observations, and review and provide feedback for three proposed WHO guidelines: GMP Principles, Validation, and Hold Time.

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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
GMP	Good Manufacturing Practices
PQ	Prequalification
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

Tuberculosis (TB) is a global concern, and PQM has actively contributed to the USAID strategic objective of “increased use of effective interventions to reduce the threat of infectious diseases, including tuberculosis” (P.E.1.2 -TB). PQM assists countries to implement anti-TB medicine quality monitoring, and in 2008, began providing technical assistance related to current Good Manufacturing Practices (GMP) to interested companies on the preparation of medicine dossiers they submit to the World Health Organization (WHO) with their "Expressions of Interest" for the WHO Prequalification (PQ) Program.

Purpose of Conference

- Provide a forum for exchanging information about best practices with respect to GMP inspections of finished pharmaceutical products and technical assistance provided to manufacturers.
- Adopt a common position, to be defined in the form of a Q&A document, regarding the most common inspection observations.
- Encourage general debate between attendees on issues raised during the meeting and discuss options for implementation of information in the relevant WHO guidelines
- Suggest working practices which, through technical assistance and inspections, will best contribute to acceptable GMP compliance by manufacturers participating in the WHO PQ Program.

Conference Title and Theme

World Health Organization Prequalification Program Meeting with Technical Experts and Co-Inspectors

Conference Deliberations

Opening Statements

- Kees de Joncheere, Director of the Essential Medicines and Health Products Department, WHO PQ
- Dr. Harald Rothenfluh, Program Manager, WHO PQ

Highlights of Conference Deliberations and Presentations

- The most common deficiencies observed during WHO PQ inspections/technical assistance include:
 - Product Quality Review
 - Deviations, Out of Specifications, and Investigation Practices
 - Root Cause Analysis and Risk Management
 - Heating, Ventilation, and Air Conditioning Systems
 - Hazardous Substances
- Arrangement of inspections and technical assistance is satisfactory with no interference between the inspectors and those providing technical assistance
- WHO PQ has separated the roles of inspectors and assisting experts by having different teams for each role

Outcomes of the Conference

- Agreement was reached regarding the most common inspection observations and a Q&A document was drafted

- Attendees gave feedback on the newly proposed WHO guidelines on GMP Principles, Validation, and Hold Time study

Conference Materials

The conference presentations can be obtained from Dr. Allan Hong (AJH@usp.org).

Conclusion

The conference was successful, with attendees given opportunities to exchange information and discuss best working practices. A Q&A document regarding the most common inspection observations was drafted during the conference. In addition, the attendees were able to review three proposed WHO guidelines and provide feedback on their content.

Next Steps

- Attendees will further refine the Q&A document in the coming weeks

Annex 1: Workshop Agenda

Thursday, 30 May 2013

Time	Mins	Topic	Moderator
08:00– 0830	30	Arrival (WHO security clearance process)*	<i>All</i>
0830 - 0900	30	Registration	<i>All</i>
0900 – 0915	15	Welcome address	<i>Kees de Joncheere</i>
0915 – 0930	15	Welcome remarks Purpose and methodology of the workshop	<i>Harry, Milan</i>
0930 – 0945	15	Common observations from inspections and technical assistances	<i>Deus</i>
0945 – 1030	45	Experience gained during provision of technical assistance to manufacturers	<i>USP, Concept, and invited experts</i>
1030 - 1100		Coffee /Tea break	
1100 – 1130	30	Experience gained during provision of technical assistance to manufacturers continued	<i>USP, Concept, and invited experts</i>
1130 – 1150	20	Product Quality Review (PQR)	<i>Ian</i>
1150 – 1230	40	Discussion on PQR	<i>Ian and Stephanie. Vimal</i>
1230 - 1330		Lunch	<i>All</i>
1330 – 1350	20	Deviations, Out of Specifications (OOS) and Investigation Practices	<i>Diane Morris</i>
1350 – 1440	50	Discussion on Deviations, OOS and Investigation Practices	<i>Diane Morris, and Ian. Xingyu</i>
1440 - 1500	20	Root Cause Analysis and Risk Management	<i>Luisa Stoppa</i>
1500 - 1530		Coffee /Tea break	
1530 – 1600	30	Discussion on Root Cause Analysis and Risk Management	<i>Luisa Stoppa, Iveta and Vimal</i>
1600– 1620	20	Heating, Ventilation, and Air Conditioning (HVAC) System (design aspect for OSD)	<i>Andre van Zyl</i>
1620– 1730	70	Workshop on HVAC – discussion time	<i>Andre van Zyl, Deus, Stephanie</i>
1730– 17.45	15	Agreement on incorporation of additional topics to workshop agenda (on day 2)	<i>Deus, Milan</i>
17.45		Cocktails	<i>All</i>

Friday, 31 May 2013

Time	Mins	Topic	Moderator
0900–0920	20	Hazardous Substances	<i>Humberto Zardo</i>
0920-1030	70	Discussion and workshop on Hazardous Substances (taking into consideration requirements for potent hormones versus less potent hormones)	<i>Humberto Zardo and Vimal, Ian</i>
1030-1100		Coffee /Tea break	<i>All</i>
1100–12.00	60	Arrangements of inspections and technical assistance and roles of inspectors and assisting experts	<i>Milan, Deus</i>
1200-1300		Lunch	
1300-1400	60	Discussion on role of inspector, co-inspector and assisting expert), classification of observations Working practices optimizing effect of technical assistance and inspections and contributing best to acceptable GMP compliance.	<i>Deus, Ian and Milan</i>
1400–1515	75	New topics for discussion	<i>Ian, Deus, Milan</i>
1515–1545		Coffee /Tea break	<i>All</i>
1545-1700	75	Agreement on drafted Q&A and recommendations	<i>Deus, Ian, Milan, Vimal</i>

Saturday, 01 June 2013

Time	Mins	Topic	Moderator
0900– 9.45	45	Review of and feed-back to revisions and newly proposed WHO guidelines: - GMP Principles	<i>Sabine Kopp</i>
9.45-1030	45	Review of and feed-back to revisions and newly proposed WHO guidelines: - Hold time study	<i>Sabine Kopp</i>
1030- 1100		Coffee /Tea break	
1100– 1145	45	Review of and feed-back to revisions and newly proposed WHO guidelines: - Validation	<i>Sabine Kopp</i>
1145– 1200	15	Comments, recommendations on existing guidelines and any suggestion for new guidelines	<i>Sabine Kopp</i>
1200– 1230	30	Workshop evaluation by participants, Agreement on additional drafted Q&A generated from Saturday discussions and next steps Closing of the workshop	<i>All</i>