

# Seventh Meeting of the Pan American Network for Drug Regulatory Harmonization Good Laboratory Practices Working Group

Lima, Peru  
July 19 - 22, 2010

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## *Trip Report*

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

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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 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**

Adrian Barojas travelled to Lima, Peru to attend the Seventh Meeting of the Pan American Network for Drug Regulatory Harmonization (PANDRH) Good Laboratory Practices Working Group (GLP/WG) July 20-22, 2010. Additionally, Mr. Barojas met with national stakeholders to discuss updates in work plan activities for the Amazon Malaria Initiative (AMI) and the South American Infectious Disease Initiative (SAIDI).

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## **Key Words**

Peru, PANDRH, GLP/WG, WHO, prequalification, ISO/IEC 17025:2005, quality assurance, quality control, AMI, SAIDI, OMCL, malaria, CNCC, PQM, USP

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- Mr. Anthony Boni and Dr. Peg Marshal at USAID/Washington for their support and advice.

## ACRONYMS

ACCLASS	Assured Calibration and Laboratory Accreditation Select Services
AMI	Amazon Malaria Initiative
CA	Central America
CAPA	Corrective and Preventive Action
CNCC	Centro Nacional de Control de Calidad
DIGEMID	Dirección General de Medicamentos, Insumos y Drogas
DQI	Drug Quality and Information
EOI	Expression of Interest
GLP	Good Laboratory Practices
GLP/WG	Good Laboratory Practices Working Group
GPPQCL	Good Practices for Pharmaceutical Quality Control Laboratories
HSS/MT	Health Systems based on Primary Health Care / Medicines and Health Technologies
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
INS	Instituto Nacional de Salud
ISO	International Organization for Standardization
LAC	Latin America and Caribbean
LIF	Laboratory Information File
MCH	Maternal Child Health
MRA	Medicine Regulatory Authority
OMCL	Official Medicines Control Laboratory
PAHO	Pan American Health Organization
PANDRH	Pan American Network on Drug Regulatory Harmonization
PQ	Prequalification
PQM	Promoting the Quality of Medicines
QA	Quality Assurance
QC	Quality Control
QM	Quality Manual
QMS	Quality Management System
QP	Quality Policy
RAVREDA	Red Amazónica de Vigilancia de la Resistencia de los Antimaláricos
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## Background

Since 2002, the U.S. Agency for International Development (USAID) has supported U.S. Pharmacopeia (USP) participation—first through the Drug Quality and Information (DQI) program and, currently, through the Promoting the Quality of Medicines (PQM) program—in the Amazon Malaria Initiative (AMI). Within the context of AMI, PQM has collaborated with the Pan American Health Organization (PAHO) Area of Health Systems based on Primary Health Care/Medicines and Health Technologies (HSS/MT) to improve the technical capacity of the Official Medicine Control Laboratories (OMCLs) in the Americas.

Within PANDRH, the Good Laboratory Practice Working Group (GLP/WG) was established in 2005 with the main objective of supporting the implementation of the World Health Organization (WHO) Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) in the OMCLs.

## Purpose of Trip

This primary objective of the trip was to attend the 7<sup>th</sup> Meeting of the PANDRH GLP/WG.

## Source of Funding

This trip was supported with funds from USAID/Peru for Amazon Malaria Initiative.

## Overview of Activities

*July 20 - 22, 2010*

See [Annex 1](#) for a detailed agenda and [Annex 2](#) for a full list of participants. For details of additional meetings with in-country partners, please see [Annex 3](#).

The primary objectives of the GLP/WG meeting were:

1. Harmonize and make official the Spanish translation of the newly published WHO Good Practices for National Pharmaceutical Control Laboratories (GPNPCL) (also referred to as WHO Good Laboratory Practices or “GLP”) (Annex 1 of WHO Technical Report Series, No. 957, 2010);
2. Update the GLP/WG Self-Evaluation Guide based on the new WHO GLPs
3. Elect GLP-WP coordinator and confirm the active and alternate members
4. Update the GLP/WG regarding the participation of OMCLs in the region in the WHO laboratory Prequalification (PQ) Programme
5. Discuss plan of action for the next two years

Highlights from the 7th Meeting of the PANDRH GLP/WG are the following:

1. Harmonize and make official the Spanish translation of the newly published WHO GPNPCL
  - The draft translation was well received and the WG was divided into eight subgroups to harmonize language and concepts. Each subgroup’s document was collected and will be compiled and reviewed by PAHO, USP, and PQM. Subsequently, the document will be made official and disseminated to the GLP/WG and the region’s OMCLs, as well as posted online on the GLP/WG homepage.

2. Update the GLP/WG Self-Evaluation Guide based on the new WHO GLPs
  - CNCC, Peru's OMCL, presented a proposed revision based on the new GLPs. The WG was divided into eight subgroups that reviewed Peru's proposal, made changes, and harmonized terminology to be consistent with the Spanish translation of the new GLP document. The WG coordinator (Dr. Maria Gloria Olate from Chile's OMCL) will compile the subgroups revisions then review and send them to the WG secretariat (Dr. Parisi from PAHO). Once the document is finalized, PQM will be responsible for translating it to English.
3. Elect GLP/WG coordinator and confirm the active and alternate members
  - The WG secretariat proposed that all the current permanent members renew their roles in the WG, and each accepted the nomination. The WG secretariat will communicate the permanent members' confirmations to all other members of PANDRH.
4. Update the GLP/WG regarding the participation of OMCLs in the region in the WHO laboratory Prequalification (PQ) Programme
  - Representatives from the OMCLs of Bolivia, Peru, and Uruguay presented their experiences with WHO PQ Programme inspections carried out in March 2010. All three labs have responded to the inspection observations and are awaiting WHO's final decision.
  - A representative from the Instituto Nacional de Controle de Qualidade em Saúde (INCQS – Brazil's federal reference lab) discussed their submission to the WHO PQ Programme. INCQS has received a response from WHO stating their Expression of Interest (EoI) has been received; however, WHO has not established a date for the onsite inspection.
  - Representatives from the Instituto Octávio Magalhães (IOM – the OMCL for the state of Minas Gerais in Brazil) expressed their interest in developing and submitting an EoI to participate in the WHO PQ Programme. The WG agreed to support IOM in developing their EoI. IOM has been granted ISO/IEC 17025:2005 accreditation by INMETRO, an internationally recognized accrediting body, for the majority of the medicine QC methodologies performed in the lab.
  - Adrian Barojas delivered a presentation on the three necessary components of submitting an EoI to participate in the WHO PQ Programme (See [Annex 4](#)).
5. Discuss plan of action for the next two years
  - The WG agreed upon key activities for the next two years, and the secretariat will disseminate the plan of action to the WG members.

## **Next Steps**

- PAHO, USP, and PQM will review the Spanish translation of the GLP and upon approval, will disseminate it to the WG, the region's OMCLs, and will post it on the GLP/WG homepage.
- The Self-Evaluation Guide will be reviewed by the WG coordinator and upon approval, will be disseminated to the WG, the region's OMCLs, and posted on the GLP/WG homepage. Once the document is finalized PQM will be responsible for translating it to English.
- The WG secretariat will follow up with Brazil representatives and USP to resolve their status as permanent members of the WG.
- The WG secretariat will coordinate support to IOM to participate in the WHO PQ Programme.
- The WG secretariat will disseminate the two-year plan of action to the WG members.

## AGENDA

*7<sup>th</sup> Meeting of the Working Group on Good Laboratory Practices (GLP/WG)  
(July 20–22, 2010 - Lima, Peru)*

Tuesday 20		
8:00– 10:00	1. Opening/ Welcoming (15 ´)	Dr. Valcarcel/ Amelia Villar (PAHO-Peru)
	2. Introduction and briefing of the GLP-WG since its creation. Objectives of the 7 <sup>th</sup> Meeting (20 ´)  Web/publications (10 ´)	Ma. Gloria Olate (Coordinator, WG)  Jose M. Parisi (Secretariat)
	3. Introduction of each participant (10 ´)	
	4. Statutes of the PANDRH– Constitution of the WG (15 ´)	Jose M. Parisi (Secretariat)
	5. Comparison of the norm ISO 17025 with the GLP recommended by WHO (15 ´)	Rosalba Alzate (PAHO Consultant)
	6. 44 <sup>th</sup> Report, Annex 1. Content and main differences with 36 <sup>th</sup> Report, Annex 3 (15 ´)	Ruben Szyszkowsky (PAHO Consultant)
10:00–10:30	coffee break	
10:30–12:30	7. 44 <sup>th</sup> Report, Annex 1- Preparation of the Spanish version	Catalina Massa (PAHO Consultant)
12:30-14:00	Lunch	
14:00-16:00	(preparation of the Spanish version)	
16:00-16:30	coffee break	
16:30-17:30	8. Actualization of the GLP Course modules (45 ´) (PAHO consultants)	Ruben/Catalina, Milagros, Carlos/Rosalba

Wednesday 21			
8:00 - 10:00	44 <sup>th</sup> Report, Annex 1- New self-evaluation Guide		Coordinator of OMCL from Peru (Ofelia Villalba)
10:00 - 10:30	coffee break		
10:30 - 12:30	(Self-evaluation Guide)		
12:30 - 14:00	Lunch		
14:00 - 16:00	(Self-evaluation Guide)		
16:00 - 16:30	coffee break		
16:30 - 17:30	9. Activities with WHO Expert Committee (15´)		Nilka Guerrero (Committee Expert)
	10. Election of the GLP-WP coordinator and confirmation of the active and alternate members (30´)		Coordinator: Jose M. Parisi
	11. Miscellaneous (15´)		
Thursday 22			
8:00 - 10:00	12. WHO Prequalification Program for OMCL	A – Generalities - Bases (20´)	Jose M. Parisi
		B – Preparation of EOI and LIF (20´)	Adrian Barojas
		C – OMCL participants in WHO program (15´ each) <ul style="list-style-type: none"> <li>▪ BOLIVIA</li> <li>▪ PERU</li> <li>▪ URUGUAY</li> <li>▪ BRASIL</li> <li>▪ JAMAICA</li> </ul>	Cecilia Garnica Ofelia Villalba Mónica Hirschhorn Eduardo Leal Lucette Cargill
10:00 - 10:30	coffee break		
10:30 - 12:30	13. Proficiency control programs	A – WHO (15´)	Lucette Cargill
		B – Inter-laboratories (25´)	Fernando Alba
		C – EQCP (20´)	Jose M.- Damian Cairatti
	14. Two years Working Plan (60´)		
12:30 - 14:00	Lunch		
	15. Preparation of the GLP/WG meeting final report		



## Lista de Participantes

*7ª Reunión del Grupo de Trabajo en Buenas Prácticas de Laboratorio (GT- BPL)  
(Julio 20–22, 2010 - Lima, Perú)*

### Miembros titulares:

1. COMUNIDAD ANDINA: Ma. Gloria Olate (CHILE)
2. SICA: Nilka M. Guerrero (PANAMA)
3. CARICOM: Lucette Cargill (JAMAICA)
4. MERCOSUR: Sigrid Mathison (URUGUAY)
5. NAFTA: Damián Cairatti (USP)
6. OPS: Rosalba Alzate (COLOMBIA)
7. OPS: Ruben Szyszkowsky (ARGENTINA)

### Miembros alternos:

1. COMUNIDAD ANDINA: Ofelia Villalba (PERU)
2. CARICOM: Mrs. Cheryl Scott-Alvarez (TRT)
3. NAFTA: Adrián Barojas (USP PQM)

### Miembros Experto Recurso:

1. Milagros Real Pérez (CNCC, PERU)
2. Catalina Massa (Universidad de Córdoba, ARGENTINA)
3. Carlos Saldarriaga (Universidad de Antioquia, COLOMBIA)

### Invitados Especiales:

1. LOCM BOLIVIA: Dra. Cecilia Garnica López (CONCAMYT)
2. LOCM URUGUAY: Q.F. Mónica Hirschhorn (CCCM)
3. LOCM PERU: Biólogo Fernando Alva Ruiz
4. LOCM BRASIL: Dr. Eduardo C. Leal
5. GGLAS/ANVISA -BRASIL: Dr. José A. Padilha de Castro
6. CNCC PERÚ: Dr. Rubén G. Tabuchi

### Miembros Observadores:

1. FUNED (Brasil): Julio César Martins Siqueira - IOM
  2. FUNED (Brasil): Amália Soares Santana- IOM
- 10 participantes a designar por la ARN de PERU

### Secretariado:

1. José M. Parisi (OPS/WDC)
2. Amelia Villar (OPS/PERÚ)

## Peru Visit: Additional Meetings

### Meeting with CNCC

July 19, 2010

Participants: Ruben Tabuchi (CNCC), Ofelia Villalva (CNCC), Adrian Barojas (PQM)

### **Meeting Proceedings and Conclusions:**

CNCC, Dirección General de Medicamentos, Insumos y Drogas (DIGEMID - Peru's Medicine Regulatory Authority), and PQM have been collaborating on Medicine Quality Monitoring (MQM) activities for two USAID funded initiatives:

1. Maternal and Child Health study, which focuses on evaluating the quality of emergency obstetric and neonatal medicines
2. SAIDI, which focuses on evaluating the quality of commonly used antibiotic (AB) and tuberculosis (TB) medicines.

Based on a preliminary list of sampled products, PQM sent CNCC Reference Standards (RS) needed to analyze the medicines. CNCC is in the process of clearing these RS from customs. Nonetheless, CNCC has begun to analyze some of the products that have already been sent by DIGEMID.

For CNCC to successfully analyze all of the SAIDI and MCH medicines they will need assistance with the following:

- The RS sent by PQM will not be sufficient to analyze all of the sampled medicines.
- Some monographs require the use of reagents for system suitability tests and typically these reagents are provided by the holders of the registration of the sampled medicine.
- Some products require the use of controlled or list RS and the process involved in obtaining adequate permits and delivery of these RS is extremely time intensive and costly. CNCC proposed that DIGEMID obtain these RS from the holders of the registration of the sampled medicines. PQM discussed this issue with DIGEMID (see comments in July 19, 2010 Meeting with DIGEMID).
- For a subset of the SAIDI medicines, CNCC will perform parallel compendial and Basic Test (BTs) analysis. PQM will finance this activity; however, the formal request cannot be sent until the final list of sampled medicines is compiled by DIGEMID.

Additionally, in the context of AMI, CNCC is providing QC services to PQM for a study aimed at evaluating the quality of antimalarial medicines sampled from the private and informal sector in Guyana. CNCC and PQM discussed the following issues:

- Reagents missing for analyzing Quinine and Primaquine samples
- PQM request to send data packets with the raw (original) data for a subset of the analysis
- Process for paying CNCC for their services

### **Next Steps**

- MCH and SAIDI Activities:
  - CNCC will send PQM a list of the missing RS. PQM will send the necessary RS to ensure the sampled medicines can be properly analyzed.

- CNCC will send PQM a list of the missing reagents (utilized for system suitability requirements). PQM will send or assist in the procurement of the necessary reagents. PQM will attempt to acquire these reagents concurrently with those necessary for AMI activities.
- Once the final list of medicines is compiled by DIGEMID, PQM will send an official request to CNCC for performing BTs on a subset of the sampled SAIDI medicines.
- AMI Activities :
  - CNCC will send PQM details regarding the missing reagents and the providers that have been contacted. PQM will assist CNCC in obtaining the necessary reagents to finish the QC analysis.
  - CNCC will provide electronic and hard copies of the data packets during PQM's visit.
  - CNCC will send PQM a detailed invoice per API. With this detailed invoice, PQM will make arrangements to send CNCC the payment for their services.

### **Meeting with Dirección General de Medicamentos, Insumos y Drogas (DIGEMID)**

July 19, 2010

Participants: Alfredo Castillo (DIGEMID), Flor Galindo Espinoza (DIGEMID), Adrian Barojas (PQM)

### **Meeting Proceedings and Conclusions:**

DIGEMID updated PQM on the results of the sampling of MCH and SAIDI medicines that was performed in the Macro Region Oriente (composed of five regional health departments: San Martin, Loreto, Ucayali, Madre de Dios, and Amazonas) in June and July 2010. The following highlight the meeting conclusions:

- DIGEMID has sent a subset of the samples to CNCC for analysis and will send the remaining samples shortly.
- PQM is supplying the RS for all of the medicines except for controlled and list RS. As required by the national legislation, the controlled and list RS will be supplied by the holder of the registration of the sampled medicines.

Additionally, PQM discussed AMI and SAIDI activities that are planned for the current FY and potential activities for the upcoming FY. In addition to the ongoing AMI, MCH and SAIDI activities, DIGEMID asked PQM for technical assistance (TA) in two specific areas:

- Improving capacity of GMP inspectors through:
  - Theoretical and onsite GMP trainings
  - Development of webinars (web-based theoretical courses) (ex: Evaluation methods validation protocols during an on-site inspection)
- Increase the amount of organizations participating in the national QC lab network and their throughput capacity

### **Next Steps**

- DIGEMID will provide continual updates to CNCC and PQM regarding the MCH and SAIDI MQM activities.
- PQM will update DIGEMID on FY 10 activities as they progress, particularly as related to improving the capacity of GMP inspectors.

- PQM will incorporate in the AMI and SAIDI WPs DIGEMID's request for TA for activities currently not covered by FY 10 WPs. If the proposed WPs are approved by the AMI and SAIDI Steering Committees, PQM will program accordingly with DIGEMID.

### **Meeting with USAID/Peru**

July 22, 2010

Participants: Armando Cotrina (USAID/Peru), Adrian Barojas (PQM)

### **Meeting Proceedings and Conclusions:**

PQM discussed the objectives and main findings of the GLP/WG meeting with USAID/Peru, which is responsible for coordinating AMI & SAIDI activities. Additionally, PQM provided updates on AMI, SAIDI and MCH activities for FY 10 and discussed tentative activities for FY 11.

USAID/Peru thanked PQM for the update and asked to receive frequent updates regarding AMI and SAIDI activities.

### **Next Steps**

- PQM will communicate any additional findings and provide USAID/Peru with frequent updates on AMI, SAIDI and MCH activities.
- PQM will submit to USAID/Peru the proposed AMI WP for FY 11 by the beginning of August.