

SESSION 5: Quality of the ANTIMALARIALS

*Strengthening of the medicines quality control
laboratories
in the region of the Americas
and the support of AMI/RAVREDA*

Jose M. Parisi - Quality Assurance and Safety of Pharmaceuticals (PAHO/WHO)
Phone: (1-202)974-3496 - E-mail: parisijo@paho.org

PRESENTATION SCOPE

I - Activities of PAHO with the OMCL

- A. Pan-American network of Official Medicine Control Laboratories (OMCL)
- B. External Quality Control Program (EQCP)
- C. WHO Prequalification Program for National Laboratories

II - The support of AMI/RAVREDA to the Strengthening of the medicines quality control laboratories

*To assure the quality of pharmaceuticals
in the Region of the Americas*

is necessary

A GOOD OMCL PERFORMANCE

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graph TD; A([A GOOD OMCL PERFORMANCE]) --> B[Adequate facilities]; A --> C[Equipment and supplies]; A --> D[Human Resources well trained]; A --> E[Quality Assurance System implemented];
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The diagram illustrates the components necessary for a good OMCL performance. A central light green oval labeled 'A GOOD OMCL PERFORMANCE' has four arrows pointing downwards to four text elements: 'Adequate facilities', 'Equipment and supplies', 'Human Resources well trained', and 'Quality Assurance System implemented'.

Adequate facilities

Equipment and supplies

Human Resources well trained

Quality Assurance System implemented

Pan American Network of OMCL

- *Started in 2000 with the 2nd Pan American Conference of Drug Regulatory Harmonization*
- *25 Official Medicine Control Laboratories from 23 countries (represented MERCOSUR, ANDEAN COMMUNITY, SICA, CARICOM, NAFTA)*
- *Secretariat (PAHO) Jose M. Parisi*

23 countries in the Network

1. ARGENTINA
2. BOLIVIA
3. BRASIL (2)
4. CHILE
5. COLOMBIA
6. COSTA RICA (2)
7. CUBA (2)
8. ECUADOR
9. EL SALVADOR
10. GUATEMALA
11. GUYANA
12. HONDURAS
13. JAMAICA
14. MÉXICO
15. NICARAGUA
16. PANAMÁ
17. PARAGUAY
18. PERÚ
19. DOMINICAN REPUBLIC
20. TRINIDAD & TOBAGO
21. URUGUAY
22. VENEZUELA
23. SURINAME

Pan American Network of OMCL

MISSION

Strengthen the performance of the Official Medicines Control Laboratories (OMCL) in the countries of the Region of the Americas through implementation of Good Laboratory Practice

OBJECTIVES

- *Improve the performance of the quality control laboratories*
- *Promote implementation of GLP self evaluation guidelines*
- *Harmonization of methodologies to facilitate the acceptance recognition of obtained results among countries*
- *Increase the communication and exchange of information between the OMCL, local pharmaceutical manufacturers, and the academia*

EXTERNAL QUALITY CONTROL PROGRAM (EQCP)

Technical activity carried out by PAHO in collaboration with the USP (United States Pharmacopeia) and the participation of the OMCL network

OBJECTIVES

- *To evaluate the quality of medicines used in priority programs (TB, Malaria, HIV, Neglected diseases)*
- *To optimize testing capacity and analytical reporting*
- *To identify the areas that demand technical cooperation*
- *To develop the concept of reference QC laboratories throughout the region*

DEVELOPMENT

- *Phase 1: Diagnostic study of the OMCL*
- *Phase 2: Performing test*
- *Phase 3: Training of human resources*

PHASE 1: Diagnostic study of the OMCL

The main results indicated:

- *100% have HPLC and equipment for dissolution tests*
- *50% have adequate facilities to implement GLP*
- *24% have sufficient staff*
- *24% have operational manuals as requested by ISO 17025*
- *20% have a self-financed system*

PHASE 2 (Performing test)

The EQCP measures the performance of the OMCL sending to them blind samples and corresponding standards for analysis, indications of the methodology to use and the form to report their results.

Results are evaluated by the United States Pharmacopeia (USP) classifying the laboratories in three groups:

Group 1: Laboratories that have performed an Excellent Job in all the tests

Group 2: Laboratories that have performed a Good Job. In this group, labs can miss some of the tests, or may have minimal errors to be corrected with appropriate training of their staff

Group 3: Laboratories that have performed a very Poor Job

PHASE 2 (Performing test)

To date the EQCP include 9 stages:

- 1) Acetyl salicylic acid (Aspirin) Ibuprofen (2001)*
- 2) Acetaminophen (2001-2002)*
- 3) Streptomycin powder for injection (2002)*
- 4) Acyclovir (2003)*
- 5) Zidovudine (2004)*
- 6) Isoniazide (2005-2006)*
- 7) Ciprofloxacin (2007-2008)*
- 8) Oseltamivir (2009-2010)*
- 9) Mebendazole (2011)*

PHASE 3: Training of human resources

Training workshops and seminars are planned and implemented in countries that need more assistance to overcome their difficulties, according with the results at the performing evaluation (PHASE 2)

To date the following activities have been implemented:

- *21 countries received GLP training Workshops and implementation of PANDRH self inspection guidelines*
- *17 countries received training in HPLC, Dissolution test, and Microbiologic methodologies*
- *15 countries received Evaluation of the Quality Management System of the OMCL*

PREQUALIFICATION OF QUALITY CONTROL LABORATORIES

Procedure for assessing the acceptability of quality control laboratories for use by United Nations agencies, for the analysis of pharmaceutical products meet the requirements recommended by WHO

This is done through a standardized quality assessment procedure to evaluate whether the quality control laboratories to be used for the analysis of pharmaceutical products meet the requirements recommended by WHO for such laboratories

WHO Prequalified OMCL for use by United Nations agencies

(2010/2011)

- *BOLIVIA: CONCAMYT*
- *BELO HORIZONTE, BRASIL: FUNED*
- *PERU: CNCC*
- *URUGUAY: CCCM*

Evaluation of the Quality Management System

10 OMCL are preparing for the WHO Prequalification and have received Evaluation of the Quality Management System by the other Prequalified in the region (Bolivia, Brazil, Peru, and Uruguay)

Jamaica

Chile

Guatemala

Honduras

Colombia

Brazil (INCQS)

Panama

Costa Rica (2)

Dominican Republic

The support of AMI/RAVREDA to the strengthening of the medicines quality control laboratories in the region of the Americas, has contributed to

- *improve the OMCL performance in the Andean, Caribbean, and Central America countries, with the QC of antimalarial and other medicines for TB, HIV and neglected diseases*
- *harmonize the quality control methodology for artesunate, mefloquine, arthemeter, lumefantrine, chloroquine, and primaquine*
- *train in QA/QC (quality assurance/quality control) and quality management system (QMS)*
- *give technical assistance in rehabilitation of the facilities and provision of new equipment, reagents, and reference standards*
- *give assistance for the WHO Prequalification Program*

Rehabilitation of facilities

General Storage (racks for glass and reagents storage)

Drug Chemistry Laboratory (counter, workbenches)

Microbiology section (washing and sterilization sectors)

Provision of new equipment

Analytical balance

Anti-vibration table

Refrigerator/freezer

Melting point apparatus

Karl Fisher titrator

HPLC system

Dissolution test equipment

Security shower

Equipment and reagents purchased

Dissolution test equipment

Karl Fisher titrator

HPLC (High Performance Liquid Chromatography)

Pump & vacuum systems

Analytical balance with anti vibration table

Refrigerator with freezer

Melting point apparatus

Emergency shower and eyewash equipment

USP-Reference standards

Reagents for Antimalarial drugs quality control testing





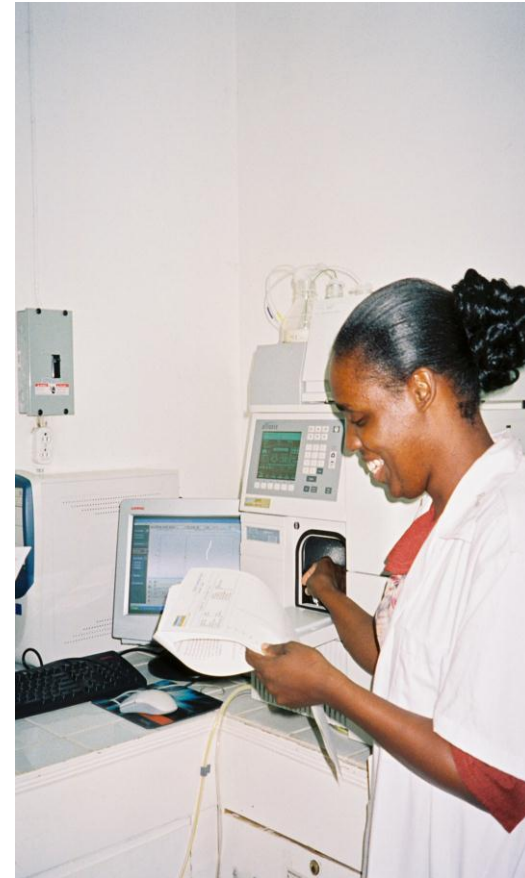




Regional training workshops

ACTIVITY	DATE	PLACE	COMENTS
Regional training workshops	Nov 2003	Ecuador	To improve the OMCL performance in the Andean countries
(9)	Oct 2004	Bolivia	Harmonization of a quality control methodology for ARTESUNATE and MEFLOQUINE, due to limited international compendia information
	Dec 2005	Guyana	Training in anti-malarial 1st line drug quality control (Chloroquine and Primaquine)
	Jun 2007	Guyana	To improve the Amazon and Caribbean OMCL performance and review the QC methodology for Coarten (Artemether + Lumefantrine)
	May 2008	Colombia	Training in management supply systems
	Nov 2008	Guatemala	Training in QA and management supply systems
	Aug 2009	Lima, Peru	Strengthening in QA/QC of the OMCL
	Nov 2011	Colombia	Three-level Approach for the Quality Control of Medicines in the supply chain, function of the OMCL and medicine quality monitoring
	Apr 2012	Suriname	To improve the performance of the Amazon (BRA, GUY, SUR) and Caribbean (TRT, JAM, BLZ) OMCL in quality control methodologies for Coarten (Artemether + Lumefantrine)







Quality Management System (QMS)

ACTIVITY	DATE	PLACE	COMENTS
Evaluation of the Quality Management System (QMS)	Mar 2003	Ecuador, Peru	To evaluate capacity in antimalarial QC testing
(10 audits)	Mar 2004	Suriname	To evaluate capacity in antimalarial QC testing
	Dec 2004	Guyana	To evaluate capacity in antimalarial QC testing
	Dec 2005	Guyana	To update the study of current conditions of the Food and Drug Department, FDD
	Jul 2006	Brazil	To evaluate capacity in antimalarial QC testing, in Belo Horizonte, Para y Amapa
	Jun 2008	Guyana	Technical support to the OMCL (FDD) relocated in the IAST building, University of Guyana
	May 2008	Colombia	Assist at the INVIMA in preparation for WHO Prequalification
	Sep 2010	Guatemala	Follow up at the QMS audit performed by PQM at the OMCL (LNS)
	Mar 2011	Panama	IEA, Panama University, to evaluate capacity in antimalarial QC testing
	Nov 2011	Suriname, Trinidad-T	To update the study of current conditions at the BGVS (SUR) and the Chemistry FDD (TRT)

Finally,

- A) The seven AMI-countries have their own OMCL
(last one was SUR with the BGVS, 2011)*
- B) Three laboratories have been Prequalified by WHO as Reference
laboratories for the UN agencies (BOL, BRA, PER)*
- C) Three countries implement their National network of QC
Laboratories (BRA, COL, PER)*
- D) All the OMCL are participating in the annual international
performing control with the EQCP*

Future Perspectives

***Training in QA/QC (quality assurance/
quality control) and quality
management system (QMS)***

***Amazon: ECU, GUY, SUR
Central America: GUT, HON, NIC***

***Giving assistance for the WHO
Prequalification Program***

DOR, COL, BRA (6)

***Implementing National network
of QC Laboratories***

BRA, COL, PER

***Improving the OMCL performance
with the EQCP***

all the network

***Evaluation of the Quality Management System by the other Prequalified in the
region***

Jamaica, Chile, Panama, Costa Rica (2)