Organización Panamericana de la Salud

Oficina Regional de la Organización Mundial de la Salud

PAN AMERICAN NETWORK FOR THE HARMONIZATION

TRAINING WORKSHOP ON

GOOD PRACTICES FOR OFFICIAL MEDICINE CONTROL LABORATORIES

PAN AMERICAN NETWORK FOR THE DRUG REGULATORY HARMONIZATION (PANDRH Network)

Background

The **Pan American Network** for the Drug Regulatory **Harmonization** (PANDRH Network) through the Technical Working Group in GLP (GLP/WG) developed a proposal for a Workshop in Good Practices for Official Medicine Control Laboratories that has been implemented in several countries of the Region . This has been presented to the V Pan American Conference for the Drug Regulatory Harmonization which held in November 2008.

Objectives of the Workshop

- Promote the use of the GLP recommended by WHO in 36 Report, Annex 3 (Series of technical reports, Nº 902, 2002)
- Improve the performance of the quality control laboratories
- Know and promote the use and correct implementation of the GLP Self-evaluation Guide of the PANDRH Network
- Increase communication and exchange of the information between official medicine control laboratories, the local manufacturers, and academia
- Bring the staff members of the MOH and the academia up to date in the knowledge of the latest recommendations of WHO on GLP.

Objectives of the implementation of the GLP Self-evaluation Guide

- Help establish the standards for the GLP inspections;
- Serve as instrument of common work in the countries of the region;
- Promote the standardization of criteria in the self inspections of the official medicine control laboratories;
- Know the status of the Laboratory regarding compliance with the recommendations of 36/WHO Report, Annex 3.
- To improve the performance of the laboratory through the implementation of 36/WHO Report, Annex 3 based on the results obtained.

Duration

Four days (36 hours) with all participants and an additional half day (5th day) with only the official participants and facilitators for implementation of the Guide of Self-evaluation in the official medicine control laboratory (local manufacturers do not participate in this session)

Schedule

The workshop begins Monday at 8:30 a.m. and ends Thursday at 5:00 p.m. with an opening session of thirty minutes with the participation of national authorities and PAHO´s office in the country, and a closing session.

To whom is directed

This workshop is directed towards the pharmaceutical control laboratories that provide support to the regulatory authority to guarantee patient safety. This will serve as an adequate basis for any administrative regulation and subsequent legal action in a national drug control system.

The quality control laboratories of the manufacturers are also invited to attend since they commonly carry out repetitive sample analyses of active pharmaceutical ingredients or of a limited number of pharmaceutical products.

Sponsors

The workshop will be organized jointly between:

- The Pan American Health Organization
- The Ministry of Health through the Official Medicine Control Laboratory
- Academia (School of Pharmacy)

Implementation

A PLAN of Implementation of this workshop has been prepared in all the countries of Latin America and the Caribbean in Spanish, Portuguese, and English. The PAHO/WHO Representative Offices in the countries should process the consent of the authorities and support the carrying out of the Workshop. The PLAN is being implemented due to the need for serving all the countries equally and was prepared in accordance with the availability of the facilitators. The Workshop has already been implemented in 18 countries.

Facilitators/instructors

For each workshop the team of instructors includes three professionals following these two basic criteria:

- All the courses should have at least one of the facilitators of the academia (teaching experience) and another one of an official laboratory (practical experience)
- It is advisable that the facilitators be from different countries since this enriches the discussion. Generally, they are from three different countries and in all cases it is emphasized that they be from at least two countries.

A professional from the American Pharmacopeia (United States Pharmacopeia–USP) will also be present to explain the correct use of the USP-NF and present a DVD on a technique in common use (TLC, HPLC, etc.)

The group of facilitators

- Ruben Szyszkowsky (University of Buenos Aires, Argentina)
- Carlos Saldarriaga Alzate (University of Antioquia, Medellin–Colombia)
- Milagros Real Perez (INS–Center National of Quality Control/INS, Peru)
- Catalina Massa (University of Córdoba, Argentina)
- Rosalba Alzate (University of Antioquia, Medellin–Colombia)
- Antonio Hernández Cardoso (United States Pharmacopeia–USP)
- José M. Parisi (PAHO/WHO)

The facilitators' CV will be sent as appropriate

Structure of the workshop

During four days the facilitators will conduct the workshop with a combination of exhibitions of practical exercises specially selected for better interpretation of the critical topics of GLP. Hence, it is important that the participants know the content of the standard. The structure of the workshop includes a visit to the control laboratory the last day (5th day), for Implementation of the Guide of Self-evaluation, but only with the official participants.

Programming Contents

Part One. Management and infrastructure

1. Organization and management
2. Quality system
3. Control of documentation
4. Records
5. Data- processing equipment
6. Personnel
7. Premises
8. Equipment, instruments, and other devices

Part Two. Materials and setting-up of equipment, instruments, and other devices

9. Specification archive
10. Reagents
11. Reference materials
12. Calibration, validation, and verification of equipment, instruments, and other devices
13. Traceability

Part Three. Working procedures

14. Incoming samples
15. Analytical worksheet
16. Testing
17. Evaluation of test results
18. Retained samples

Part Four. Safety

19. General rules

- Model analytical test report for active pharmaceutical ingredients, excipients, and pharmaceutical products

- Equipment for a first-stage and medium-size pharmaceutical control laboratory

Support Material

The workshop includes educational material in the form of power point presentations prepared by the team of facilitators and the GLP-WG. The material has been validated in two pilot studies of the workshop (6 to 10 March 2006 in Santo Domingo, Rep. Dominican and 28 August to 1 September 2006 in Santiago, Chile) and subsequently adjusted. These presentations are based on the identification of subjects of critical importance in the GLP (36 Report, Annex 3 of WHO). These items are also delivered to the participants:

- Spanish version of the 36 Report Annex 3
- Chapters of Quality Control/Quality Assurance corresponding to the GMP Guide-PANDRH Network
- Formats of analytical work sheets
- CD with all the previous information and bibliography

This material is prepared and sent by the PAHO office in Washington to PAHO host country of the workshop.

Participants

The workshop is expected to have 50 national participants that come from the public sector, manufacturers and academia:

- Thirteen participating officials are exempted from paying registration. They can be of the OMCL,, MOH, SS or another governmental institution;

- Two participants of academia (National University) are also exempted from paying registration, but they must be professors of pharmaceutical technology and jointly with the National Regulatory Authority must commit to replicating the workshop within the next 12 following months.

- The other 35 participants will come from the manufacturer sector and should pay the registration cost.

Profile of the participant

The selection of the participants (of any of the sectors aforementioned) will be in accordance with the following criteria:

- Be professional in practice in the area of Quality Control/Quality Assurance.
- Work in the Official Medicine Control Laborat ory,, in a laboratory of the pharmaceutical industry, or be teaching academic of some University of the country.

Coordinator of the Workshop

Each workshop has one of the facilitators designated as coordinator of the workshop to facilitate the management of the workshop, to share academic burden, to monitor the fulfillment of the schedules and to implement the Guide of Self-evaluation in the OMCL. The Coordinator should establish contact with the person in charge of PAHO in the country and work jointly to:

- Ensure the existence and good operation of all the equipment and implements necessary for the management of the workshop
- Welcome the participants and spell out the general objectives of the workshop
- Present the group of facilitators
- State the general content of the workshop and its relation to the activities of the GLP/WP of the PANDRH Network
- Start up and conclude each day's activities and ensure the fulfillment of the activities programmed and the schedule
- Organize and moderate the round tables discussion
- Prepare the list of participants with their personal data (name, e-mail, institution, position, etc.)
- Coordinate with the country's PAHO office the preparation of the corresponding certificates
- Request that the participants complete the survey of evaluation of the workshop and facilitators (Annex Nº 2)
- Direct the final meeting of the facilitators for review of the surveys and discussion and assessment of the results
- Prepare a brief report on the results of the workshop identifying aspects that should be improved and/or modified.
- Send list of participants with their personal data, surveys and report to the secretariat (through the country's PAHO office where is presented the Workshop) who will derive them the person in charge of the coordination of the GLP/WG
- Deliver a list of participants to each facilitator for probable later consultations
- Participate in the closing ceremony thanking the organizers, facilitators and participants.
- Explain during the exposure of the general content of the workshop (first day) the activity of implementation of the Guide of Self-evaluation in the OMCL. Delivering to the personnel of the OMCL Guides it so that they read it with advance notice and are prepared to clarify the doubts and/or carry out consultations during the day of the visit.
- Coordinate during the first day of the workshop, with the Director of the laboratory and/or the one in charge of Quality at the OMCL, the visit to the laboratory for the implementation of the Guide. Organize with them the working groups, subjects, and distribution of times to carry out the implementation activities
- Control the activities of implementation during the visit to the OMCL moderating the final meeting of discussion with all staff of the OMCL
- Request preferably to the Person in Charge of Quality at the OMCL or to the Director of the Laboratory, the results of the self-evaluation within a period of 15 days through the country's PAHO office

Place of organization of the Workshop

Preferably in a hotel in downtown where there will be lodged the facilitators and is available a conference room for 50 people. There should also be considered the service of luncheon for the

participants and facilitators and two services of coffee, one at mid morning and another one at mid afternoon.

Evaluation

The participants will have the opportunity to evaluate the organization of the training program, the logistics of the workshop and the performance of the facilitators. There are not examinations of the workshop. The steadiness or credential only should say participation and not approval.

Certificates

The participants will receive at the end a certificate of participation *in the Workshop of 36 hours on "Good Laboratory Practice of Medicine Control."* The workshop can be credited or recognized (credits) by the Academia or by the School of Pharmacist depending on every country.

Financing and Registry Cost

The workshop is financed with seed funds located in the project Best Laboratory Practices (of the PANDRH) in PAHEF and its replication in the countries depends that in every case recover the costs. The workshop is designed so that 35 of the 50 participants pay a cost of registry of US$350, equivalent in local currency.

The number of participants has been determined in relation to the cost recovery which means that it should remain that number (50) of which 35 pay in order to obtain an approximate total of US$12,250.

The payment exemption cannot be accepted for a number large than 15 participants. Those countries with great demand can repeat the workshop eit her replicating it with the national instructors or requesting a new international training.

If expenses are less than expected, it would be used to pay for those workshops with losses.

Funds will be used for:

- Payment of ticket and per Diem for the three facilitators. In some cases, the per diem can be an ad hoc per diem and is financed separately the hotel and the foods. This depends on each case. The facilitators without any official restrictions are in addition paid a subsidy for their work. There are countries that do not allow its staff members to receive payments of any nature which means that in those cases, the facilitator will not receive the subsidy. This payment will be made through PAHO 562 or of CTA according to the procedures of PAHO.
- Books, materials, pamphlets, and reproduction of the presentation material. This material will be organized by PAHO Washington and will be sent to the PAHO´s office at the host country of the workshop.
- Local cost in order to cover additional photocopies (that will remain to the minimum), income of equipment, room (in the majority of the cases PAHO´s office collaborates providing the equipment of projection and facilitating photocopies), coffee and luncheons

for the participants and the facilitators. These expenditures will be covered by means of an authorization by US$2000 to PAHO´s office at the host country.

Method of payment

PAHO´s office in the host country should designate someone (can be of the Administrative department) in charge of the administrative management of the workshop.
The participants should make the payment in checks in local currency and PAHO staff (Administration) should deposit it in the account of PAHEF GL PFG100-5201. In such transaction it should mention the concept of payment: registration fee for Workshop GLP and that deposit belongs to PAHEF, to the account of Best Practices of Laboratory.
The contact person should notify by E-mail when that transaction is done, copying the following people:

In PAHEF-Pilar M. Torres -torrespi@pahef.org

In PAHO-Juan Carlos Marín -marinjua@paho.org
José M. Parisi- parisijo@paho.org

ANNEX 1: Program

WORKSHOP IN GOOD PRACTICES FOR OFFICIAL MEDICINE CONTROL LABORATORIES			
DATE	**HOUR**	**SUBJECT**	**RESPONSIBLE**
Day 1			
	8:30–9:00	Opening Act	PAHO/ MPH
	9:00–9:30	Introduction: PANDRH Network and GLP/WG	
	9:30–10:30	Generalities: Quality parameters	
	10:30–11:00	COFFEE BRAKE	
	11:00–11:45	Contents of the standard and comparison with ISO 17025	
	11:45–13:00	Part 1: MANAGEMENT AND INFRASTRUCTURE Quality System; Installations; Registries, Personnel	
	13:00–14:00	LUNCHEON BRAKE	
	14:00–15:30	Efficient use of the USP-NF in Spanish (CD)	
	15:30–16:00	Sampling (Income of samples; Registry; Specifications; Analysis; Reports; File)	
	16:00–16:30	COFFEE BRAKE	
	16:30–17:30	Application demonstration: Workshop on Sampling	
Day 2			
	8:30–10:30	Measurement: uncertainty; traceability of measurements Program of metrological assurance	
	10:30–11:00	COFFEE BRAKE	
	11:00–13:00	Application demonstration: Workshop of Measurement/Uncertainty	
	13:00–14:00	LUNCHEON BRAKE	

	14:00–15:00	Guiding Part 3 GLP: WORK PROCEDURES Samples; Analytical work Sheets; Results	
	15:00–16:00	Part 2: MATERIALS, CONDITIONING OF EQUIPMENT, INSTRUMENTS, AND OTHER DEVICES (Reagents; Reference standards; Calibration and Verification of equipment)	
	16:00–16:30	COFFEE BRAKE	
	16:30–17:30	Part 2 (continuation)	

Day 3			
	8:30–10:30	Validation of physical chemical analytical methods	
	10:30–11:00	COFFEE BRAKE	
	11:00–12:00	Validation of microbiological methods	
	12:00–13:00	Application demonstration: Workshop on Validation	
	13:00–14:00	LUNCHEON BRAKE	
	14:00–15:30	Workshop on Validation (continuation)	
	15:30–16:00	Demonstration of application GLP: TLC (DVD)	
	16:00–16:30	COFFEE BRAKE	
	16:30–17:30	Round table: discussion, questions/responses	
Day 4			
	8:30–9:30	Safety elements, management of waste. Management of reagents	
	9:30–10:30	Audits of Systems of Quality Assurance: ISO 9001, ISO 17025, GMP/WHO, GLP/WHO enclosed 3 report 36, auto inspection, external audits	
	10:30–11:00	COFFEE BRAKE	
	11:00–13:00	Application demonstration: plan of audit, checklist, not conformities, guide of verification GMP Chapter 12	
	13:00–14:00	LUNCHEON BRAKE	
	14:00–15:30	Application demonstration: Virtual audit to the laboratory	

	15:30–16:00	Evaluation of the Workshop by the participants	
	16:00–16:30	COFFEE BRAKE	
	16:30–17:00	Round table: final conclusions	
	17:00–17:30	Closing of the event–Delivery of Certificates	
Day 5			
	8:30–12:30	Introduction Implementation of the guide of self evaluation in the OMCL	
	12:30–13:30	LUNCHEON - Farewell	

ANNEX 2: EVALUATION SURVEY

1.- How was the content of the workshop by importance and effectiveness?

Very good	Good	Average

2.- How was the support material (notes, projections, transparencies, etc.)?

Very good	Good	Average

3.- Which was its general impression of the workshop?

Very good	Good	Average

4.- How was the professor command and knowledge on the matters discussed in the workshop?

	Very good	Good	Average
Catalina			
Carlos			
Milagros			
Antonio			
Ruben			
Rosalba			

5.-/ How was the approach to the facilitator upon balancing the theoretical and practical aspects?

	Very good	Good	Average
Catalina			
Carlos			
Milagros			
Antonio			
Ruben			

6. - What subjects of the workshop should be deepened?

7. - What subjects or new aspects should be incorporated in this workshop?