PARTICIPANTS

Members
• Justina Molzon, FDA, Coordinator
• Rodolfo Mocchetto, ANMAT/Argentina
• Elsa Castejón, MSDS Venezuela
• Magdalena Reyes, ISP-Chile.
• France Dansereau, Health Canada
• Suzana Avila Machado, ANVISA/Brazil
• Saleta García, COFEPRIS-SSA, México
• Marisela Benaim, ALIFAR
• Marisela G. Poot, FIFARMA (unable to attend)
• Rosamary Jo, MS Guatemala
• Sonia Sequeira Martínez, Costa Rica

Secretariat (PAHO/WHO):
Juanita Mejía de Rodríguez, PAHO/WHO, Guatemala
Shelly Audon, PAHO/WHO, Guatemala

Technical Resource:
Rebeca Rodríguez, (FDA)
Mildred Barber, (FDA)

MINUTES

1. The Working Group (WG) was welcomed to Guatemala and Antigua by Juanita Mejía de Rodríguez, PAHO-Guatemala. Members of the WG thanked her for selecting such a beautiful and historic venue for its meeting.

2. Justina Molzon provided an update of the meeting of the PANDRH Steering Committee (SC) taking place in Madrid, prior to WHO’s 11th ICDRA in February 2004. She reported that Argentina was selected to represent PANDRH in ICH's Global Cooperation Group. She also provided the group with the report she gave to the PANDRH SC detailing the GMP WG’s activities since the last SC meeting in Mexico, August 2003.

During the discussion following the presentations on PANDRH activities, members of the working group emphasized the importance of having access to documents being drafted by other PANDRH working groups. Justina explained that the PANDRH
Secretariat is working on a website devoted to PANDRH activities. Further, to increase awareness of PANDRH activities, it is intended that documents developed by PANDRH WGs be posted for comment on the website and also distributed to PAHO country representatives, regional DRA and the network of PANDRH WG members.

Members of the WG suggested that a complete grid of WGs and WG members and their contact information be distributed to all those involved in PANDRH. This would facilitate communication and promote discussion and distribution of documents under development. The current PANDRH directory of SC and WG members was obtained from PAHO during the WG meeting and distributed to the members of the WG along with other PANDRH background information.

3. Review of Comments received by the Secretariat on the Regional Guideline for Good Manufacturing Practices Inspections.

_The Guideline prepared by Argentina and reviewed by the WG during its previous meeting (May 5-7, Mexico 2003), was implemented in a pilot inspection and was reviewed by official inspectors and by manufactures. Their comments were included in the version of the Guideline reviewed by the WG/GMP._

_The approval of a Regional guideline for GMP inspections is a major task of the WG/GMP in the advance in harmonization processes; in improving the quality of drugs in the market and in building trust among drug regulatory agencies. A decision on the final version of the Guideline should be made in this meeting, although the Guideline will be under a permanent revision by the WG._

The WG spent most of the meeting editing the Guideline based on comments received. Specific and detailed information deleted during the editing process was captured for use in training programs for implementation of the Guideline.

ALIFAR developed an additional chapter, Chapter 14, covering basic principles of validation. The additional chapter serves as a good summary of validation principles. However, it may not be sufficiently comprehensive for those not trained in validation. Therefore, some specific information may be helpful in the general chapters. As the WG went through the document, validation issues for each chapter were evaluated as to whether they were covered by the general chapter or specifics needed to remain in the chapter being discussed. The WG noted that it is important that training be provided on specific validation topics such as the one offered in Guatemala City this week on water for pharmaceutical use and air handling systems.

The group was faced with the difficult task of reviewing the Guideline that is now 100 pages in length. The comments received represented 40 pages of the document and generated discussion essential to the progress of the guide. The group did its best to complete the document but was only able to review and edit 8 of the 14 chapters in the three days allocated to the WG meeting. As a result the group suggested another meeting one week in length before the Conference in November to complete review of the remaining chapters which are lengthy and complex in nature (5-Warehouses, 8-Documentation of Production, 10-Central de Pesadas, 11-Production, 12-Control of Quality, and 14-Validation). If an additional meeting is not possible before the Conference, the group will report on its progress to date in November.

The WG noted the need to include a glossary of terms. Before doing so, the glossary developed will be checked to make sure they are not already defined in the glossary
developed by PAHO. Terms of concern are: sistema de agua abierto, continuo, no continuo, sistema de calidad, garantia de calidad, control de calidad, fabricación and production.

The WG also noted need to include a specific chapter on manufacture’s contracts, quality controls, and by other third parties.

4. Possible quantitative/qualification (ponderation) of the Guideline.

During the previous meetings the WG initiated the discussion of assigning quantitative value to most questions in the Guideline. This possibility should be fully discussed and a decision should be made during this session even tough the actual assignment of the value (if the decision is positive) could be taken place during another meeting.

The group decided that the concept of assigning specific point values to each question was impeding discussion and progress on the guide. Several regulators mentioned that point systems used in the past proved to be problematic and their regulatory agencies have moved away from this concept. Instead, categories such as critical, major, minor and informative have been used in a systematic approach. Such an approach promotes focusing on priority areas such as production and manufacturing. The group decided that certain chapters in the Guideline could be described as important to highlight the priority topics.

Inspection guides from Chile, Guatemala, Costa Rica, Colombia and Andean Community Nations (CAN) were provided as examples of methods of quantification being used in the Region. Copies of the document from Colombia, representing a good example of the use of categories instead of points, were distributed to the group.


5.1 Workshop on Validation
- 3-6 May 2004, Guatemala (done)
- 21-23 June 2004, Honduras
- 21-23 July 2004, Chile
- August 2004, one sub-regional course in the Caribbean
- Two more courses in September & October 2004 (TBA)

Two main issues should be discussed: a) participation of members of the WG as instructors; b) presentation of national experiences by an inspector (in Guatemala course Rebeca Rodriguez from FDA participated. Is it possible for the FDA to participate in all national courses? What other country from the WG can participate presenting their experience?

Rebeca agreed to provide her presentation on process validation and FDA requirements to anyone volunteering to help in teaching the courses this summer as it is probably not possible for her to participate. It was suggested that the next time the course was taught that it be video or audio taped as a back up for professors unable to attend scheduled training programs. The WG also discussed the concept of train the trainers, as a mechanism to recruit professors for future courses as well as video conferencing with professors unable to travel. It was suggested that the talks presented in Guatemala this week be posted on the PAHO PANDRH web site.
Sonia Sequeira Martinez volunteered Costa Rica as a site for validation training in October.

Training schedule to be clarified by Rosario.

5.2 Possible Training of Inspectors for appropriate application of the Guideline for GMP Inspection

A regional training for inspector in using the guideline (after its approval) should take place. When and who would be the instructors?

This topic will be discussed after completion of the guideline.

6. Consideration of the Vision for the WG/GMP presented by FIFARMA

The WG has its Mission, Objectives and Strategies already approved by the III Conference. The proposal on the Vision of the WG presented by FIFARMA should be reviewed jointly with the Mission, Objectives and Strategies for possible overlap.

The document provided by FIFARMA was preliminarily discussed. However, because the FIFARMA representative was unable to attend and the guidance on inspections was not yet finalized, decisions and recommendations on the topic were postponed until the next WG meeting.

A possible recommendation to the Conference could be that the WG develop a Workplan listing objectives, detailing activities and indicators (short, medium and long term) to presented to the PANDRH SC for approval.

7. Vaccines and Biologics: a separate WG or an extension of the WG/GMP?

The Secretariat received informal requests to constitute within the scope of PANDRH a WG on Quality of Vaccines and/or in Biologics. Even though the establishment of WGs is a prerogative of the Conference, it would be appropriate to have the opinion of this WG before presenting a proposal to the next Conference.

The WG discussed the above request and determined that the addition of issues related to vaccines and biologics may require some additional experts on specific topics. However, it was felt that most of the WG members had sufficient knowledge on the topics to cover most issues of concern.

Because there are few companies in Latin American producing biologicals, it was suggested that a survey be conducted to assess the need to focus on this topic. It was also mentioned that training blood components and blood derivative inspections would be more of a priority than biologicals (vaccines and serums). The question of what was meant by biologicals was also brought up.

Several WG members explained the situation in their country. Most notably, it was felt that formulation of biologics does not differ that much from non-biologicals and that processing concepts would be the area of concern as well as pharmacovigilance. Therefore the application of GMPs would be similar and only a few biologics experts would be needed to supplement the WG. These experts
would be included in the discussion when the topic was to be discussed and not serve as permanent members of the WG.

In terms of vaccines, there are already WHO Collaborating Centers focused on these products, they undergo batch release and if exported are inspected by the importing country. During the discussion, more concern was voiced for the need of a subgroup on active pharmaceutical ingredients as this was felt to pose a greater problem on the quality of medicinal products in the region. Finally, the WG emphasized the need to finish editing the Guideline before taking on additional tasks and assignments.

8. IV Conference: Report and issues to be presented for approval and for information.

9. Next meeting: issues and date

   Issues: Finish document editing. Discuss mission and vision

   Dates: The Secretariate should survey WG members for dates August through September for possible dates ASAP as their calendars are filling up.