PANDRH Steering Committee February 12, 2004 Madrid, Spain

Report of the GMP Working Group

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CDER/U.S. FDA

2nd Meeting of the Working Group

Mexico City

4-5 August 2003

PANDRH
Steering Committee Priorities

Urgent Issues:

- **GMP (FDA)**
- BA/BE (FDA)
- GCP (ANMAT)
- Counterfeit (ANVISA)

Work plan of Working Group

- Working Group meeting
- Training program design
- Implementation of training programs
- Mechanism for monitoring GMP implementation
- Identify standard under development in other Forum (ICH) (Consultation GMP)
- Joint inspection/observation
  - Under consideration

GMP Working Group Members

- USA: Molzon Justina: Coordinator
- ARG: Rodolfo Monchetto /Carlos Chiale
- BRA: Suzana Machado/Antonio Becerra
- MEX: Saleta García
- CHI: Magdalena Reyes
- GUT: Jose Luis Aguilar
- CAN: France Dansenreau
- VEN: Elsa Castejón
- FIFARMA: Marco Vega (Alterno: Cindi Marin)
- ALIFAR: Marisela Benaim (Alterno: Miguel Maito)
- Resource Persons: Millie Barber and Rebeca Rodriguez (FDA)

BE Working Group Meetings

- March 3-4, 2002—Caracas
- May 5-7 2003—Mexico City

1st Meeting of the GMP Working Group

- Mission
  - To promote the knowledge and implementation of GMPs as a strategy for improving the quality of medications in the countries of the Americas

Prioritized Objectives

- Through individual and collective exercises the participants proposed for the GMP/WG the following objectives, listed in order of priority
  - Knowledge—Education/Training
  - Development of a harmonized Guideline for GMP inspection
  - Support to Regulatory Authorities

2nd Meeting of the GMP Working Group

- Topics for Discussion:
  - 3rd Pan-American Conference recommendations and decisions
- Guide for inspection of GMP
- Strategies to implement GMP inspection guide
  - Responsibilities of the group
  - Selection of Countries
  - Inspectors and places for the test pilot
- Education/training activities
  - Strategies for the second round of courses

GMP Inspection Guide

- Guide drafted by ANMAT
  - Follows WHO GMP 92
  - 12 chapters/areas of focus
  - 61 pages long
- WG proposed additional language and revisions to be incorporated into Guide
- Integrate WG recommendations by 5/30

Pilot Plan
Guide for Inspection of GMP

- Scheduled for July -- September 2003
- 3 participants
  - 2 DRA Inspectors + PAHO/WHO
- Confidentiality 100% guaranteed
- At least 3 inspections
- Recommended
  - 2 types of dosage forms/production lines
- Duration of inspection will be 5 days

Update of WG Activities

Regional Guideline for GMP Inspections

- A pilot to validate the guideline took place in November 2003.
- Draft report distributed to the WG/GMP for review.
- The team considered that the site for the pilot did not represent the average of drug manufacturers in Latin America.
- As a consequence, it was suggested that some members test the guideline as part of the pilot for validation in any drug manufacturer that is willing to cooperate with the process.

Update of WG Activities

- Selected members of the Group were requested to implement the Guideline in their country and send the Secretariat their results and recommendations.
- Proposed Plan
  - [Venezuela and ALIFAR] [Mexico and FIFARMA]
  - Need to involve the industry and the two members that are in the same country, to facilitate the test.
  - Results to be sent to Secretariat by 1 MARCH 04
- Waiting to hear from each team

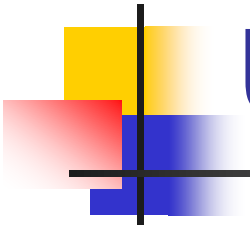
Update of WG Activities

- Comments on Guide at national level
  - Guatemala reviewed the Guideline and submitted comments
  - Comment are useful to the group and we would like to receive comments from a similar experience in other country
- Chile may also conduct a similar activity
- Comments requested by 1 MARCH 04.
- Waiting for response as to possibility

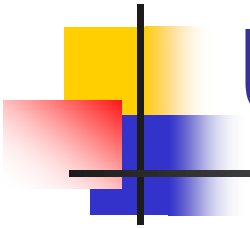
Update of WG Activities

Educational Seminars on GMP:

- WHO modules on Validation, Water and Air Systems have been translated into Spanish and to be posted on the web page
  - These modules were implemented at a workshop held in Argentina for MERCOSUR countries.
  - A national seminar on Validation has been proposed
    - FDA (Rebecca Rodriguez) asked to be the trainer along with another expert (possible a professor from national university).
    - Workshop to take place 3 days before the next meeting of the Group.
- Plans for national seminars for 2004 on specific aspects of GMP will be developed during the next meeting of the Group



Update of WG Activities



Update of WG Activities

Next Meeting of Working Group

- Spring 2004
- Discussion of impact of comments on the Guide from interested parties
- Quantify value of Guide based on Pilot
- Planning of training/education efforts