Pan American Network for Drug Regulatory Harmonization
2nd Steering Committee Meeting
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Report on the GMP Working Group

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Pan American Network for Drug Regulatory Harmonization

Work Plan 2000 - 2001

- **Priorities Approved by the Steering Committee**
  - **First:Urgent Issues**
    - Good Manufacturing Practices
    - Bioequivalence
    - GCP
    - Counterfeit
  - **Second:Important Issues**
    - Classification
    - Drug Regulatory Agency
  - **Third: Recommended Issues**
    - Pharmacopoeia

GMP WORKING GROUP WORKPLAN

- 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 (sharing documents)
- Working Group meeting

GMP WORKING GROUP TEAM MEMBERS COORDINATOR: FDA/USA

- Contact Person: Justina Molzon
- Topic Lead:
- ALIFAR:
- Argentina: Carlos Chiale
- Brazil: Antonio Bezerra
- Canada: France Dinasarau
- FIFARMA:
- Guatemala: Esmeralda Villagran

GMP INITIATIVES

- Two initiatives running in parallel with the same intent, GMP training for regulators from the Americas
  - Pan American Network for Drug Regulatory Harmonization--GMP WG
  - FDA/USDA partnership with the University of Puerto Rico

FDA/UPR GMP Efforts

- The UPR initiative is a reaction, in part, to numerous requests for GMP training
- Due to decreasing FDA resources it is difficult to meet these requests
- UPR an ideal bridge to enable FDA to respond to hemispheric requests
- Located in a US territory
- Spanish curriculum in pharmacy
- Would provide FDA outreach capability

The Second Pan American Conference on Drug Regulatory Harmonization Washington, D.C., 2-5 November 1999

Recommendations on GMPs

- The training program for GMPs that the FDA proposes to carry out with the UPR and PAHO/WHO should be institutionalized
- The program should rely on contribtutions from government and industry in the interested countries, include distance learning, and take advantage of the installed capacity of the Region.

SURVEY ON GMP

- Planning survey for pharmaceutical GMP training program developed
- Responses from 12 Latin American countries
- Used to prepare for a meeting of interested parties to the pharmaceutical activities under the FDA/USDA and University of Puerto Rico Partnership
- Latin American regulators invited to attend

SURVEY QUESTIONS

- Are GMPs legally required of drug manufacturers?
- Are these spelled out in laws or regulations?
- How many manufacturing sites in the country and how many full-time inspectors perform inspections and enforce compliance?
- Are certificates of GMP compliance issued?
- Is there a legal requirement for imported pharmaceuticals to be manufactured under GMP?
- How is compliance determined?
- What kinds of GMP training would be useful for your country?

ASSESSMENT OF GMP TRAINING NEEDS
San Juan, Puerto Rico
April 5, 2000

- Followed 1st meeting of PANDRH Steering Committee meeting, April 3-4, 2000
- Steering Committee members invited
- Met with UPR and FDA staff to assess the GMP training needs in the Americas
- Over 30 participants from 8 countries
- Survey responses facilitated discussion
- Focussed discussion on GMP training topics

GMP CURRICULUM DEVELOPMENT

- Based on input and comments from the GMP Assessment meeting
- FDA staff met with UPR staff
- A series of 40 lectures were proposed as the basis of a curriculum
- “An Introduction to Good Manufacturing Practice for for Pharmaceutical Products”

GMP CURRICULUM DEVELOPMENT

- It was further proposed the break the lectures into five modules
  - QC/QA
  - Documentation
  - Starting materials
  - Building, equipment
  - Validation

GMP CURRICULUM DEVELOPMENT

- Based on the lecture break down, it was determined that there should be an emphasis on **Quality Assurance** and **Quality Control**
- A series of 18 lectures proposed
- Matched with FDA Basic Drug School lectures for materials
- **THEN**--FDA decided to initiate a pilot program on system based inspections
- Curriculum changed to reflect new approach

SYSTEMS BASED INSPECTIONS

- More efficient use of resources
- GMP inspections oriented towards systems
- Coverage of 2 or more systems with mandatory coverage of Quality System
- Inspect minimum number of systems to provide basis for overall CGMP decision
- Concept adapted to UPR GMP training program

GMP CURRICULUM DEVELOPMENT

- 5 day training program to be offered twice during Summer 2001
  - May 29-June 2, 2001 (FDA>UPR)
  - June 18-22, 2001 (UPR>FDA)
- To be held at the University of Puerto Rico
- 20-25 participants, 2-3 from 5 or 6 countries
- Taught in Spanish
- Accommodations on campus

GMP CURRICULUM DEVELOPMENT

- FDAs San Juan District Office/ORA
- FDA HQ staff from the Office of Compliance
- UPR faculty participate then teach
- Lectures 8:00--16:30
- Case studies for interaction
- Laboratory exercises
- Site visit and simulated inspection using systems approach

GMP CURRICULUM LOGISTICS

- Participants needed by April for first course
- Participants needed for second course
- Funding for materials and administration
- Offer the course on an on-going basis to meet needs of the Americas
- Possibly extend to other universities in Latin America
- **NEXT STEPS?**