PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION

Second Meeting of the Working Group on Good Manufacturing Practices

Pan American Health Organization
Regional Office of the
World Health Organization

PAN AMERICAN NETWORK ON DRUG REGULATORY HARMONIZATION (PANDRH)

SECOND MEETING
WORKING GROUP ON GOOD MANUFACTURING PRACTICES

Mexico City, Mexico
5-7 May 2003

PARTICIPANTS

Elsa Castejón, MSDS Venezuela
Stephen McCaul, Health Canada (in lieu of France Dansereau)
Suzana Machado Avila, ANVISA
Magdalena Reyes, Instituto de Salud Pública de Chile
Rodolfo Monchetto, ANMAT (in lieu of Carlos Chiale)
Marisela Benaim, ALIFAR (in lieu of Miguel Maito)
Justina A. Molzon, FDA, Coordinator
Marco A. Vega, FIFARMA
José Luis Aguilar, MSPAS Guatemala (arrived a day later)

Resource Persons
Rebeca Rodríguez, FDA
Mildred Barber, FDA

Others
Suleta García, COFEPRIS
Rosa María Morales, COFEPRIS

Secretariat
Rosario D'Alessio, PAHO/WHO

AGENDA

1. **Overview of PANDRH and background information on the activities of the WG/GMP:** *Justina Molzon* (Annex 1)

2. **Past and Future Educational Activities**
   Justina Molzon presented details on the educational activities and the participants made several comments:

   - There is a need to increase educational activities
   - The WHO modules were considered less demanding than the WHO-1992 standards requirements
   - It is recommended to combine the content of both educational modules / programs: WHO education modules and FDA documents.
   - While some countries replicated national seminars, there are some that need more support and involvement of schools of pharmacy of universities to implement more educational activities
   - The GW/GMP recognized that the educational activities should be self-financed
   - Regional seminars and national seminars promoted by PANDRH should be primarily addressed to those that can replicate the activity at a national level
   - There is a need for a more appropriate and accurate selection of the participants to the regional and PANDRH courses
   - The ideal team to replicate the activities are universities, official inspectors and the industry
   - The next courses need to be focused on a specific area of GMP such as validation, water, etc. It was noted that WHO has recently prepared special modules.

3. **The III Pan American Conference on Drug Regulatory Harmonization: Review of the Recommendations and Decisions made to the WG/GMP:** *Justina Molzon*

4. **Review on the Updated Rules & Regulations of PANDRH Working Groups:** *Rosario D'Alessio* (Annex 2)
   - Emphasis was made on the responsibility of members to participate in the WG meetings, the membership continuity and the need to receive confirmation from the Ministry of Health regarding the members representing governments. The members were urged to send their CV to the Secretariat.

5. **Guideline for GMP Inspection**

   - The group reviewed the draft guideline previously distributed to all members. A. Monchetto, in lieu of C. Chiale (member from Argentina), presented the guideline.
   - The guideline has 12 chapters and is based on the WHO-92 requirements

- The group acknowledges that the guideline is being discussed at MERCOSUR and that so far they have reached consensus until chapter 8. Even though it was noted that the draft guideline is under discussion, the guideline will be considered from this moment as a draft for the WG work.
- The final draft of the guideline will include recommendations from each member of the group.
- Some of the main discussions included:

  - *Validation*: The guideline should have a separate chapter on this subject which should include validation of water, of processes and of information systems
  - *Segregation Areas (penicillin - cephalosporin):* Even though the majority of members agreed on the idea of having segregation areas for manufacturing avoiding cross-contamination, it was recognized that the requirements of WHO needed to be more clear and to include examples to avoid confusion and contradictory criteria on this subject.
  - R. Monchetto from Argentina was designated responsible for including the comments and recommendations of the members in the final version of the draft and for sending it to the Secretariat by the end of May 2003.
  - Major concerns regarding risk factors, flow and a possible need for inspectors training were expressed.

- General requirements should be considered previous to the inspection. Only manufacturers in operation should be inspected. The manufacturer should have:

  - A list of products with registration number and pharmaceutical forms
  - A quality control system in place
  - A continuous training program
  - Updated documentation (ISO 2000)
  - Statistical analysis of problems related to quality
  - Organizational structure with a clear separation of quality control from production and a clear definition of the staff responsibilities
  - A professional responsible of quality assurance with direct relation to the management of the company
  - An architectonic design of its facilities (water /air equipment location)
  - An official authorization to operate (national/local)

6. Process to validate the GMP Guideline

There will be two processes in parallel:

- A pilot phase for validating the use, comprehensiveness of the GMP guideline for inspections as it will be in its final draft (to be sent to PAHO by R. Monchetto by the end of May).

  - The guideline will be tested by a group of three inspectors.

- No member of the WG/GMP will be part of the team of inspectors. Two will be inspectors from regulatory offices and one from PAHO/WHO who will lead the team.
- The two inspectors from the regulatory offices should not be from the country where the inspection takes place. No representative from the industry will be part of the inspector team
- The members of the team to perform the pilot will be hired by PAHO/WHO
- The pilot's objective is to validate the guideline. Thus, it should focus on what in the guideline is not relevant; what is needed and not included; what is contradictory; what is a priority and what is complementary; and what needs to be supported by a national legislation.
- The information gathered during the pilot is confidential. The documents obtained from the inspections will be filed in the PAHO/WHO office.
- It was suggested to validate the guideline in manufacturers of at least two different lines of products
- The inspection will take five days at least
- The countries and the site for the inspections will be determined by FIFARMA and ALIFAR. It was recognized that since this is a validation of the guidelines, the manufacturer should voluntaries for inspections.

- As recommended by the III Conference (see Report), the guideline will be accessible to all interested parties through PAHO's webpage which will include an Internet address where comments can be sent to.
- There will be a post-pilot evaluation of the guideline.
- In May 2003, R. Rodriguez (FDA) will send the questionnaire used by the FDA to all members. S. Machado (Brazil) will consolidate comments.

Schedule of Implementation:

DATE	ACTION
30 May 2003	A. Mochetto will send the final draft of the guideline
30 May 2003	R. Rodriguez will send the questionnaire to evaluate the guideline
June 2003	PAHO will conform the inspectors team
June 2003	FIFARMA & ALIFAR will send names of manufacturers (site of inspections)
July 2003	Guideline in PAHO's webpage
July-September 2003	Guideline receiving comments through PAHO's webpage
August-September 2003	Inspections in place
October-December 2003	PAHO will consolidate comments
January 2004	Next meeting

Note: On 7 May 2003, the Steering Committee approved the proposal presented by the WG/GMP on the validation of the guideline.

7. **National Quality Assurance Systems presented by Venezuela**
   - NRA should implement a Quality Management System.
   - E. Castejo (Venezuela) will incorporate the requirements from Canada in the proposal.
   - The final proposal will be presented and submitted for approval at the Conference.

8. **Next Meeting**

Date: January
Place: To be determined
Subjects:
- Results from the pilot
- Review of the comments received through PAHO's webpage
- Possible training of inspectors for appropriate application of the guideline
- Quantitative qualification of the guideline (ponderation)

3rd Meeting of the PANDRH
Steering Committee
7-8 of May 2003
Mexico City

Report

GMP Working Group

Justina A. Molzon, M.S. Pharm., J.D.
Associate Director for International Programs
Center for Drug Evaluation and Research
U. S. Food and Drug Administration

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 2000--2001

- 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
- Tech Leads: Millie Barber, Rebeca Rodriguez
- ALIFAR: Miguel Maito/Maarisela Benaim
- Argentina: Carlos Chiale/Rodolfo Mocchetto
- Brazil: Antonio Bezerra/ Suzana Machado de Avila
- Canada: France Dansereau/Stephen McCaul
- Chile: Magdelena Reyes
- FIFARMA: Marco Antonio Vega
- Guatemala: Esmeralda Villagran/José Luis Aguilar
- Venezuela: Elsa Castejón

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 contributions from government and industry in the interested countries, include distance learning, and take advantage of the installed capacity of the Region.

SURVEY ON GMP

- To progress the topic, a survey concerning pharmaceutical GMP training was developed and sent to Latin American Regulators
- Responses from 12 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?

FDA SYSTEMS-BASED cGMP INSPECTION PROGRAM

- Concept adapted to UPR GMP training program as it represents state of the art
- More efficient use of resources
- More cGMP inspections in less time
- Coverage of 2 or more systems with mandatory coverage of Quality System
- Inspect minimum number of systems to provide basis for overall CGMP decision

National GMP Workshops Based on WHO Educational Modules

- Based on the WHO report 32 on GMPs
- First workshop in Jamaica, April 2000
- Translated into Spanish and implemented in all Latin American countries
- "Road Show" taught by Professors
  - University of Costa Rica
  - National University of Colombia
  - the Central University of Venezuela

The Pan American Network for Drug Regulatory Harmonization's

GMP Working Group

First Meeting
Caracas, Venezuela
3-4 March, 2002

Mission of Working Group

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

Promover el conocimiento y la implementacion de las Buenas Practicas de manufactura, como una estrategia para el mejorammientode la calidead de los medicamentios, en lospaises de las 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
- Monitoring GMP implementation
- Support to Regulatory Authorities

The Pan American Network for Drug Regulatory Harmonization

2nd GMP Working Group

Mexico City

May 5-7, 2003

RESUMEN

Buena Discussion

Mucho Trabajo y Esfuerzo

2nd Meeting of the Working Group Good Manufacturing Practices AGENDA

- III Pan-American Conference recommendations and decisions.
- Guide for Inspection of GMP, approval of a final proposal *SC*
- Strategies to implement Guide for Inspection of GMP *SC*
  - Responsibilities of the group
  - Selection of countries
  - Inspectors and places for the test pilot

2nd Meeting of the Working Group Good Manufacturing Practices AGENDA

- Education/Training Activities
  - Strategies for the second round of courses
- Review a proposal from Venezuela on strategies to implement/pursue GMP
- Revision of the plan of work
  - Present state
  - Responsibilities of each member

III Pan-American Conference Report of GMP Working Group

- Please refer to the reports distributed in English and Spanish
- Highlights
  - Mission (endorsed by the Conference)
  - Objectives and Work Plan (endorsed)
  - Report of Educational Activities
  - Initial Diagnostic Study (Spanish)

III Pan-American Conference Recommendations and Conclusions HIGHLIGHTS

- Continue training activities
- Encouraged adoption of WHO GMP 92
- Recognized GMP prior condition to BE
- Harmonized Guide for GMP Inspections
  - Post on PANDRH Web to facilitate accessibility/obtain comments
- Disseminate information on WGs efforts
- Indicators for implementation of GMPs

Guide for Inspection of GMP

- WG spent past two days discussing proposed document
  - 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

Strategies to Implement Guide for Inspection of GMP

- Post on PAHO Web for Comments
  - 2months
- PAHO to collect comments from Web
  - 4 months
- Anticipated sources of comments
  - Members of GMP WG
  - Drug Regulatory Authorities
  - Sub Region
  - Industry
  - Other interested groups and persons

Strategies to Implement Guide for Inspection of GMP

- Consolidate acceptable comments
  - 1 month
- Final Draft used for Pilot of Guide
- Review PIC/S SOP and apply to Guide
- Develop SOP for Guide
  - June 2003
- Evaluate Guide post Pilot
  - Possible use of FDA questionnaire used in Quality Systems Pilot

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

Next Meeting of Working Group

- December 2003 or January 2004
- Discussion of impact of comments on the Guide from interested parties
- Quantify value of Guide based on Pilot
- Planning of training/education efforts

Wrap up and Action Items

- Elaborar metas a largo plazo.
  - Resp: M. Vega, S. Maccaul
  - Fecha: Julio 2003

Entrenamiento

- Curso Avanzado en GMP, basado en Curso FDA, comparado con Reporte 32, 34 y 37 de la OMS.
  - Incluye: agua,aire , esterilización
  - Mayo: Enviar CD (R. Rodriguez)
  - Julio: Revisar comentarios
  - Agosto: Consolidar comentarios (Susana)
  - Septiembre: Teleconferencia

Entrenamiento

- Definir en Teleconferencia:
  - Financiamiento
  - Cuándo
  - Dónde (países)
  - Instructores

Gestion de calidad

- Se recomienda implementar por parte de las autoridades regulatorias de cada pais un sistema de gestion de calidad,
  - Se recomienda que el Steering Commitee solicite a la conferencia la implementacion de dicha gestion de calidad con los diferentes gobiernos

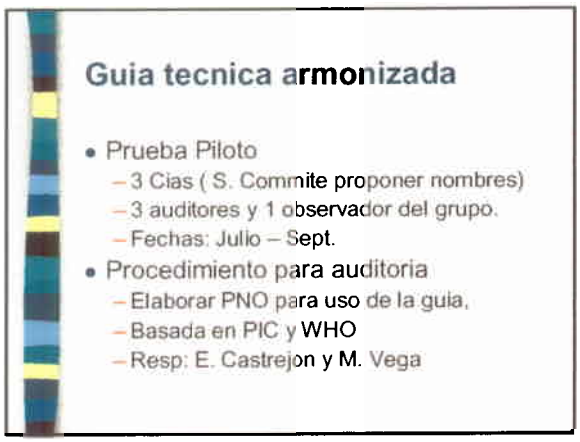
- Elaborar un documento con las recomendaciones basicas sobre que debe contener dicha gestion de calidad y recomendar herramientas como PICs Quality System Requirement for Pharmaceutical Inspectorates.
- Resp: E. Castrejon
- Fecha: 2 meses

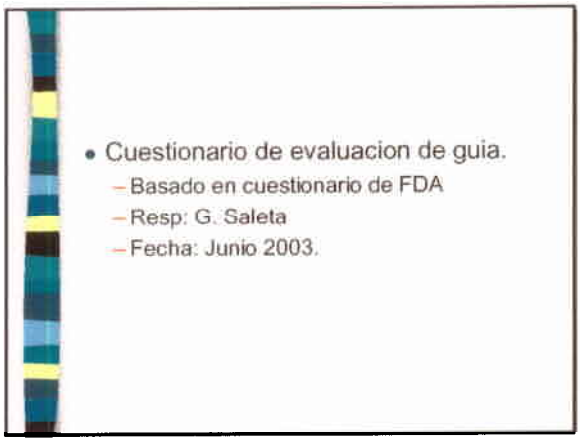
Comparacion de Regulaciones

- Cada pais revisara como comparan sus propias regulaciones contra la guias 32,34 y37 de la OMS
  - Se suguiere que por medio de PAHO se solicite dicha revision a los paises.
  - FIFARMA coordinara este esfuerzo, recopilara y organizara la informacion.

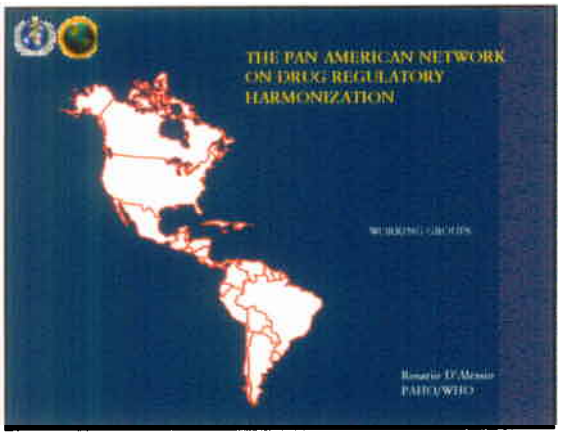
Cuestionario Armonizado

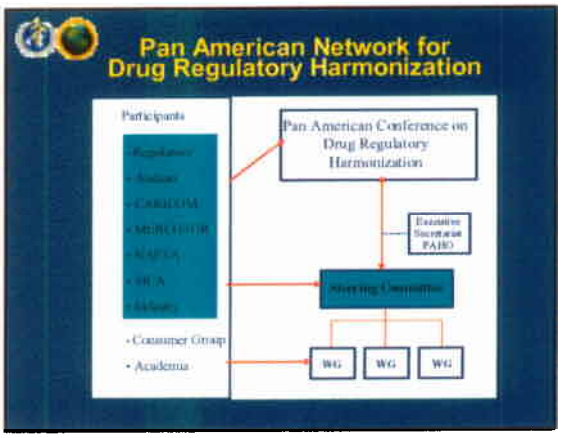
- Integrar el G.T. Mayo 30. (R. Monchetto)
- En Web. 1-2 meses
- Comentarios: 4 meses
- Consolidar: 1 mes (Rosario)
- Revisar G.T final: Prox. Reunion.


Guia tecnica armonizada
• Prueba Piloto
– 3 Cias (S. Commite proponer nombres)
– 3 auditores y 1 observador del grupo.
– Fechas: Julio – Sept.
• Procedimiento para auditoria
– Elaborar PNO para uso de la guia,
– Basada en PIC y WHO
– Resp: E. Castrejon y M. Vega


• Cuestionario de evaluacion de guia.
– Basado en cuestionario de FDA
– Resp: G. Saleta
– Fecha: Junio 2003.


Muchas gracias
Muito obrigada
Merci
Thank you





Working Groups
Pan American Network for DRH

1.	Good Manufacturing Practices (FDA)	12
2.	Bioequivalence and Bioavailability (FDA)	10
3.	Good Clinical Practices (ANMAT)	10
4.	Drug Classification (BRA)	7
5.	Counterfeit Drugs (ANVISA)	9
6.	Pharmacopoeia (USP)	6
7.	Medicinal Plants (CAN)	10
8.	Pharmacovigilance	10
9.	Drug Registration	8
TOTAL WORKING DRUG MEMBERS		82

WORKING GROUPS I

- WGs are established by the SC based on Conference recommendations
- WG plans of work shall be approved by the SC
- WGs are coordinated by DRA (except from the GW on Pharmacopoeias)
- Members are selected by the SC
- Members are experts in the field (theoretical/practical)
- Members represent government or institutions (The MOH shall confirm gov. representatives)
- Members are not remunerated
- Each WG has even number up to 9
- Outside experts can participate as observers
- The meetings are jointly organized with other activities

WORKING GROUPS II

- The Secretariat keeps a CV of WG members
- Members who cannot attend two consecutive meetings are no longer members
- A substitute member in two consecutive meetings, become the member of the group
- No one can be member of more than two WG
- Continuity of WG members are encourage to assure effectiveness
- WG representation will be balanced within and among countries
- All WG meeting shall be convened by the Secretariat
- Proposals for NEW WG should be approved by the Conference

WORKING GROUPS OBJECTIVES

- To assess comparative studies and identify gaps;
- To develop harmonized proposals to be approved by the Conference;
- To identify strategies to implement approved proposals;
- To follow up at national and/or sub-regional level;
- To plan cooperation between countries;
- To develop a working plan between Conferences;
- To disseminate knowledge as the advantages of regulatory harmonization.

WG Aspects to review by the Steering Committee

1. **Member:**
   - Selection (also coordinators)
   - Expertise, sub-regional representation
   - Member performance and continuity
2. **Mission and Objectives**
   - Relevance to Conference recommendations
3. **Plan of Work**
   - To approve the Plan of work
   - To follow up plan implementation
   - To recommend issues to be addressed
4. **Impact on processes and results (Group Indicators)**
   - At National
   - At sub-regional levels

GMP (FDA)

- Members (10): EUA, ARG, BRA, CAN, GUT, CHI, MEX, VEN, ALIFAR, FIFARMA
- Assessment on GMP
- Workshops: two in UPR (FDA); One in CARICOM (WHO); and 18 in LA (WHO/GMP)
- GMP/WG work:
  - Harmonized guideline for GMP inspection
  - Indicators to follow up GMP implementation
  - Plan of work

WG/GMP (2002 - 2004)

- Harmonized Guideline for GMP inspection developed and tested in two countries
- Joint inspection developed and implemented in at least three countries using the harmonized guideline
- Designed a proposed Plan to follow up GPM implementation by the industry
- Identified the minimal requirement for Drug Regulatory Agencies
- Training material for specific areas of GMP developed jointly with WHO / FDA
- Implementation of at least six educational activities with at least 180 professionals trained and updated in specific areas of GMP
- Report of Activities

WG/BE (FDA)

- Members (12): EUA, ARG, BRA, CAN, CHI, JAM, VEN, ALIFAR, USP, U. Texas, ALIFAR, FIFARMA
- Assessment on BE
- Designed and structured BE seminars (FDA)
- Sub-regional seminars: AA , CA
- Upcoming meetings: Mercosur, Mexico and Caribbean
- Approved proposals on:
  - Product of reference
  - Prioritization of BE studies
  - Indicators

BE Plan of Work 2002 - 2004)

- Criteria for prioritizing categories of drugs for BE testing and testing methodology analyzed and a proposal formulated
- Defined criteria for prioritize BE studies for low risk drugs
- Definitions of Generic drug and multisource drug in countries of the Americas identified and a harmonization proposal formulated
- Indicators for BE implementation identified
- Implementation of a new diagnostic study with quantitative data and changes from the previous study implemented in 2000 identified
- Training material (Module 1, 2 & 3) finalized by the FDA
- Training Seminars (Module 1, 2) in MERCOSUR, Mexico and Caricom (80 part.)
- Advance Training Seminar (Module 3) in at least one Subregion (35 part.)
- Nationals seminars in BE in at least three countries (90 partic.)
- Report of the WG

GOOD CLINICAL PRACTICES (GCP) ANMAT, Argentina

- Members: (10) ARG, BRA, CARICOM, COR, CHI, CUB, EUA, VEN, ALIFAR, FIFARMA
- Assessment on GCP
- Status of GCP: Mission and objective of the WG
- TWO National Seminars on GCP (GUT, PER)
- Approved harmonized proposal on:
  - Ethic Committee
  - Proposal on Informed Consent
  - Plan of work
- The III Conference suggested:
  - Meeting (Americas - Europe) on use of placebo
  - Sub-group on pediatric

GOOD CLINICAL PRACTICES (GCP)
Plan of Work 2002 - 2004

- Responsibilities of Researchers and of sponsors, developed
- Guidelines of GCP for vulnerable groups: a) Pediatrics; b) Patients in emergency services; c) Illiteracy; d) Indigenous; e) Handicapped.
- Training programs being developed in the Americas identified
- 3 National Seminars on GCP implemented (PER, X, Y)
- Proposal on Use of Placebo discussed and formulated
- Proposal on evaluation of clinical protocols defined
- Identified Clinical Research on Medicinal Plants (w/ WG-Med. Plants)
- Guideline for GCP inspection developed and tested in two countries
- Mission and objectives for the GCP group reviewed
- Indicators of GCP implemented
- Report of the Group

DRUG CLASSIFICATION
(2002 - 2004)

- Members (7): ARG, BRA, COR, COL, CAN, GUT, FIFARMA
- Comparison study including a matrix on Drug Classification criteria of all countries (including other regions), identifying common criteria
- Different expertise are required to address classification between nutraceutics cosmeceutics, etc in this regard, the WG will limit its actions to gathering information (Jointly w/Med. Plants)
- Harmonized Proposal on definition and criteria for drug classification (prescription vs OTC)
- Ethical criteria for drug promotion emphasizing OTC and prescription drugs
- Report of the WG

COUNTERFEIT (ANVISA, Brazil)

- Members (9): ARG, BRA, CAN, COL, PAR, VEN, CARICOM, ALIFAR, FIFARMA
- Regional Assessment
- Approved proposal
  - Definition
  - Action Plan: regional and national strategies

COUNTERFEIT (ANVISA, Brazil)
(2002 - 2004)

- Budget proposal for implementing the Plan of Action developed
- Data Base design and implemented in at least three countries linked with the WHO database
- Educational modules for seminars on How to Combat counterfeit drugs developed
- Educational national seminars implemented in at least three countries
- Standard guideline for notification of counterfeit drugs developed
- Network of national focal point on Combating drug Counterfeit, established
  - Work plan for implementing mechanism
- Report of the WG

PHARMACOPEIAS

- Members (5): USA, BRA, MEX, ARG, COL
- Agreements:
  - Extranet development (USP)
  - Database of Monographs (BRA)
  - Regional Format for Monographs (ARG)
  - Compendium "Pharmacopoeia of the Americas"
    - New pub 2005
  - Approved proposals on
    - Plan of work
    - Establishment of an Expert Body (PAHO,USP, CANADA)

Pharmacopoeia & EQCP
(2002 - 2004)

- Standardized format of database
- Standardized format for drug monograph
- Steering Committee of the Pharmacopoeia Group established
- Expert Group to support the Ph WG established
- External Quality Control Program:
  - Second and third phase of the program implemented
  - Cuba and the Caribbean official drug quality control labs participating in the Program
  - Plan of training seminars formulated
  - Training seminars implemented in at least three countries (40 parts)
  - Network of Official Drug Quality Control laboratories, reestablished and a collaborating program among them formulated
- Report of the WG

MEDICINAL PLANTS (CANADA)

- Members (11) CAN, BOL, BRA, MEX, COR, GUT, PER, JAM, BOL Univ. Chicago, Uni PAN
- The group will be officially established and operational
- Network for information exchange
- Harmonization of Glossary of terms
- Strategies for implementation of GACP
- The Mission and objectives will be established
- A plan of work will be prepared and initiate

PHARMACOVIGILANCE (2002 - 2004)

- Members (10) ARG, BRA, CHI, COL, COR, USA, GUT, PAR, CUB, FIF
- The group will be officially established and operational
- The Mission and objectives will be established
- A plan of work will be prepared and initiate
  - Criteria for immediate report and annual report of DRA (FDA, ICH, WHO)
  - Strategies for improving DAR reporting from physicians
  - Strategies to improve communication to people on risk products from DRA
  - Strategies to strengthen already existing WHO international network
  - Training activities in the Region on pharmacovigilance will be identified and their programs reviewed

DRUG REGISTRATION 2002 - 2004

- Members (8) BRA, JAM, BAR, BOL, ELS, VEN, ALI, FIF
- The group will be officially established and operational
- The Mission and objectives will be established
- A plan of work will be prepared and initiated
- Drug registration requirements is the first issue to be addressed by the Group

PENDING SUBJECTS TO BE ADDRESSED BY WGs

- Countries of reference- Manufacturer certification - Row materials - WHO GMP Certificate
- Pre-qualification of products for international market
- Pharmacological Norms
- Antimicrobial resistance
- Consumer / Patient Advocacy
- DRA Evaluation and Accreditation
- Transparency, Ethics & Conflict of Interest
- Drug marketing network & Pharmacy location and property
- Impact of Health Sector Reform in Drug Regulation

SPECIAL STUDIES

- Protocol to identify the impact of the pharmacists in community pharmacies developed by a regional Group and tested in at least two countries. Advance Report
- Protocol for a diagnostic study on Good Distribution and Good Dispensing Practices defined and tested in at least two countries. Advance Report
- A work plan for a feasibility study for a regional / subregional entity, developed

FROM THE III PAN CONF (May 2002- May 2003)

- III Pan American Conference
- GMP National Seminars
- Conclusion of Special Studies on DRA
- WEB page
- WG/GCP Meeting
- WG/BE
- Regional TRM & WG/Medicinal Plants
- WG/ GMp, D Class % SC

COST OF IMPLEMENTED ACTIVITIES (May 2002- May 2003)

• III Pan American Conference:	130.000 (75.000)
• GMP National Seminars:	221.000 (66.300)
• Special Studies on DRA:	5.000
• WEB page	
• EQCP	
• WG/GCP Meeting:	20.000
• WG/BE:	20.000 (9.000)
• TRM & WG/Medicinal Plants:	36.000 (36.000)
• WG/ GMp, D Class % SC	45.000
•TOTAL:	477.000 (186.300)

WORKING GROUP MEETINGS

- (Pharmacopoeia not included)

•once/year	twice/year
•Med. Plants	GMP
•Pharmacovigilance	BE
•Classification	GCP
•Drug registration	Counterfeit

UNTIL THE IV PAN CONFERENCE NOV 2004

•---MAY 03	AGO 03	FEB 04*	AUG 04
•GCP	GCP	GCP	GCP
•MPI	----	MPL	----
•BE	BE	BE	BE
•Class ----		Class	----
•-----	Vigil	----	Vigil
•GMP	-----	GMP	GMP
•----	Count	Count	Count
•----	Regist	-----	Regist
•SC	----	SC**	----

•*Meet before ICDRA Madrid
•** Meet as pre-ICDRA (TBC)

Working Groups Pan American Network for DRH

1.	Good Manufacturing Practices (FDA)	12
2.	Bioequivalence and Bioavailability (FDA)	10
3.	Good Clinical Practices (ANMAT)	10
4.	Drug Classification (BRA)	7
5.	Counterfeit Drugs (ANVISA)	9
6.	Pharmacopoeia (USP)	6
7.	Medicinal Plants (CAN)	10
8.	Pharmacovigilance	10
9.	Drug Registration	8
TOTAL WORKING DRUG MEMBERS		82
To be financed: Not included WG/P, FIFARMA, ALIFAR, and including a rep from the Secretariat:		64

EDUCATIONAL ACTIVITIES

UNTIL THE IV PAN CONFERENCE
NOV 2004

- SIX GMP National Educational Seminars (20.000 each)
- TWO GCP (jointly w/WG meeting. No additional cost)
- Three BE (Caribbean, Argentina) (35.000)
- One BE (MEX) (10.000)
- One BE Statistics (TBD) (35.000)
- TOTAL FUNDS: 100.000

PANDRH BIENIAL OPERATING COST

- WG/meetings (90.000 x 2/year: 180.000) (360.000/biennium)
- Annual SC meeting (20.000 x 2: 40.000)
- Educational Seminars (100.000)
- Studies / GMP inspections (50.000)
- Conference (150.000)
- TOTAL: US$ 680.000/ biennium (500.000 2003-2004)