V CONFERENCE OF THE PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH)
Buenos Aires, Argentina
November 17th – 19th, 2008

Agenda

November 16th
5:00 - 7:00 PM        Registration *

November 17th
8:00 - 9:00 am        Registration*

9:00 - 9:30 am
Opening: Welcoming speech of the National and PAHO/WHO authorities.

9:30 - 10:00 am
Regulation and Public Health. Video of Dr. Mirta Roses, Director of PAHO/WHO.

10:00 -10:30 am
PANDRH: Working methodology. PAHO/WHO Secretariat

10:30 - 10:45 am
Coffee break

10:45 - 12:30 am
Panel: Harmonization Initiatives of Pharmaceutical regulation. Coordination: NRA of Colombia. ICDRA: Lembit Rago (WHO); ICH: Justin Molzon (FDA); PANDRH: José Luis Di Fabio (PAHO/WHO); ASEAN: Selvaraja Seerangani (Ministry of Health, Malaysia)

12:30 - 2:00 pm
Lunch

2:00 - 2:45 pm
The self assessment and recognition of Regulatory Authorities. Rafael Pérez Cristiá, CECMED-Cuba and José Peña, PAHO/WHO.

2:45 - 4:15 pm

4:15 - 5:30 pm
Coffee Break and discussion sessions of the working groups.

5:30 - 6:30 pm
PANDRH session

* (4th floor of the NH City hotel, Bolívar 120)
November 18th

8:30 - 9:15 am
Essential functions in medicines regulation and challenges for the Regulatory authorities.
José Luis Di Fabio, PAHO/WHO.

9:15 - 09::45 am
Valerio Reggi, WHO.

09:45 - 10:15 am
The prequalification system of WHO.
Lembit Rago, WHO.

10:15 - 10:45 am
Coffee break

10:45 - 12:30 pm
Presentation of the progress and achievements of the working groups (WG).
Coordination: NRA of Argentina.
Medicines Registration (DR): María Teresa Ibarz (INHRR, Venezuela).
Good Laboratory Practices (GLP): María Gloria Olate (ISPCH, Chile).
Counterfeit medicines (CDC): Tiago L. Rauber (ANVISA, Brazil).

12:30 - 2:00 pm
Lunch

2:00 - 3:30 pm
Presentation of the progress and achievements of the working groups (WG).
Coordination: NRA of Jamaica.
Good Clinical Practices (GCP): Analía Pérez (ANMAT, Argentina)
Medicines promotion (DP): María José Delgado (ANVISA, Brazil)
Good Manufacture Practices (GMP): Justin Molzon (FDA, USA), Rodolfo Mochetto (ANMAT, Argentina), Rosalba Alzate de Saldarriaga (consultant, PAHO/WHO).

3:30 - 4:30 pm
Coffee Break and discussion sessions of the working groups.

4:30 - 6:30 pm
PANDRH session.

November 19th

8:30 - 9:00 am
The rational use of medicines as a component of regulatory decisions.
Perla de Buschiazzo, CUFAR, Collaborating Center of PAHO/WHO, Argentina.

9:00 - 10:30 am
Round table: Biotechnological biologic products.
Coordination: María Ángeles Cortes Castillo, PAHO/WHO.

10:30 - 11:00 am
Coffee break

11:00 - 12:30 am
Panel: Progress in the incorporation of PANDRH´s recommendations in the Regional integration processes.
Coordination: NRA of Brazil.
MERCOSUR: , ANDEAN COMMUNITY: , COSTUMS ORGANIZATION: Julio Valdés, CARICOM:

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12:30 - 2:00 pm  
Lunch

2:00 - 4:00 pm  
Conclusions and Recommendations.

4:00 - 4:45 pm  
Closing session.
ANMAT, PAHO/WHO, ALIFAR, FIFARMA, Directive committee of the PANDRH.