

AGENDA

Sixteen Years Promoting
Good Regulatory Practices in the Region of the Americas

5-7 September 2013, Delta Ottawa City Centre, Ottawa, Canada

5 September 2013 (Day 1)			
Registration (8:30 – 9:00) All Day in Ballroom A & B			
9:00	Opening: Welcome to participants [PAHO, WHO, Health Canada] Regional context, lessons learned and rationale for the PANDRH Strategic Development Plan 2014-2020 [J. Fitzgerald; PAHO, WHO]		
10:00	Strategic objective 1 (SO): "To promote effective governance of PANDRH and active participation of NRAs towards regulatory convergence and harmonization" [Moderators: 2 ARNs (MEX; CAN)] <i>Introductory presentations:</i> Governance models of other networks. Lessons learned from APEC, EMA, ICH, IMDRF, amongst others. [Presenters: NRAs (CAN; USA)]		
Coffee and Tea Break: Poster Session (11:00 - 11:30) Joliet Salon and Ballroom Foyer			
11:30	Working Group 1 Group moderator: MEX	Working Group 2 Group moderator: CAN	Working Group 3 Group moderator: CUB
12:30 – 13:00 Plenary Discussion: Strategic Objective 1- conclusions and recommendations [CAN]			
LUNCH (13:00 – 14:00)			
14:30	Strategic objective 2: "Defining priorities, strategies and mechanisms for regulatory convergence and harmonization, and supporting their dissemination, adoption and implementation by NRAs" [Moderator: 2 NRAs (BRA; USA)] <i>Introductory presentations :</i> A- Overview of priorities identified by NRAs based on survey results [Speaker: Murilo Freitas] B- National regulatory capacity in the Americas based on PRAIS data Speaker: TBD		
Coffee and Tea Break: Poster Session (15:30 – 16:00) Joliet Salon and Ballroom Foyer			
16:00	Working Group 1 Group moderator: BRA	Working Group 2 Group moderator: USA	Working Group 3 Group moderator: COL
16:30 – 17:00 Plenary Discussion: Strategic Objective 2- conclusions and recommendations [BRA]			
NETWORKING – COCKTAIL RECEPTION (18:00 – 21:00) Pinnacle/Panorama Salon			

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6 September 2013 (Day 2)		
8:30-13:00 in Ballroom A & B		
8:30	Strategic objective 3: "To promote the strengthening of competencies in Good Regulatory Practices and Regulatory Science" [Moderators: 2 ARNs (ELS; PER)] <i>Introductory presentations:</i> A- Good Regulatory Practices [Speaker: Regional reference NRA] B- Regulatory Sciences - What does it means and what do we need? [Speaker: USA] C- Regulatory curriculum (Capacity building): An integral plan for capacity development within the Americas [Speaker: PAHO in coordination with countries]	
	Working Group 1 Group moderator: ELS	Working Group 2 Group moderator: PER
	Working Group 3 Group moderator: CHI	
Coffee and Tea Break: Poster Session (10:30 – 11:00) Joliet Room and Ballroom Foyer		
11:00	11:00-11:25 Plenary Discussion: Strategic Objective 3- conclusions and recommendations [ELS] Strategic objective 4: "To promote the exchange of experiences and regulatory knowledge between NRAs inside and outside PANDRH" [Moderators: 2 NRAs (BAR; ARG)] <i>Introductory presentations:</i> A- Lessons learned from international effective cooperation agreements in relation to regulatory functions (bilateral and sub-regional case studies) [Regional reference NRA; CARICOM-FDA; CENTRAL AMERICA-MEX; CANADA EXPERIENCE] B- Regulatory information exchange mechanisms: PRAIS as a tool for technical cooperation among countries [Speaker: TBD]	
LUNCH (13:00 – 14:00)		
14:00 – 15:30: PANDRH Steering committee meeting - Closed session for members only Richelieu/Frontenac Salon		
Coffee and Tea Break: Poster Session (15:30 – 16:00) Joliet Room and Ballroom Foyer		
THEMATIC SESSIONS		
16:00	Richelieu/Frontenac Salon	Ballroom A & B
	Pharmacovigilance and patient safety [Coordination: PAHO/WHO]	Parallel session on biotherapeutic products Speakers : WHO, CAN, BRA, CUB, Industry [Moderator: Maria L. Pombo – PAHO; Ivana Knezevic – WHO] General Discussion
17:15	Richelieu/Frontenac Salon Substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medicines: Global and Regional perspectives [Coordination: PAHO/WHO, ANMAT and FDA]	
Day ends at 18:30		

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7 September 2013 (Day 3)	
THEMATIC SESSIONS (continued)	
8:30	Ballroom A & B Parallel session on medical devices regulation <i>[Moderator: A. Lemgruber - PAHO]</i>
Coffee and Tea Break: Poster Session (10:30 – 11:00) Joliet Room and Ballroom Foyer	
11:00	Ballroom A & B Implementation of bioequivalence regulation - Case studies <i>[ARN (ARG; BRA; MEX; CHI)]</i> <i>Moderator: Jose D. Peña - PAHO</i>
12:00	Presentations of recommendations from the 7th PANDRH Conference <i>[Speaker: PANDRH Secretariat]</i> Special recognition for posters Closing remarks <i>[TBD]</i>
Attendance Certificates (13:30 – 14:30)	