Join Global Regulators, Industry and Academia to Engage in Strategic Discussion on the Current Regulatory Landscape, Future Research and Drug Development in Latin America

Based on the success of previous Latin American Regulatory Conferences (LARC) in 2008, 2009, and most recently, 2011, DIA will continue to present this dynamic symposium involving key stakeholders to influence the advancement of regulatory convergence initiatives within Latin America.

FEATURED TOPICS:
• Regulatory Landscape and Regulatory Convergence Framework
• Efforts Underway by Regulatory Convergence Initiatives
• GMP Reviews and Inspections
• Ethics Committees and Research in the Region
• Post Market Research Studies and their Influence on Efficacy of Medicines
• Perspectives and Regulation of Pediatric Studies
• Drug Safety, Monitoring and Quality Control Monitoring
• Regulatory Concerns: Health Systems and Security of the Supply Chain
• Current Regulations of Biologics and Biosimilars
• Emerging Topics

LEARNING OBJECTIVES
• Define the various initiatives related to global regulatory environment and their impact on the access of medicines and future R&D in Latin America;
• Discuss the progress of the PANDRH Convergence process and the current working groups.

Simultaneous Translation will be available in English and Spanish.
TARGET AUDIENCE
This program will benefit individuals involved in:

- Drug regulation
- Clinical research and development
- Clinical safety and pharmacovigilance
- Clinical trial and project management
- Drug development and discovery
- Medical and scientific affairs
- Preclinical development
- Quality assurance
- Research and development
- Strategic sourcing/planning
- Regulatory affairs

Visit www.diahome.org for information on this and other events!

SUNDAY, SEPTEMBER 30, 2012
4:00-6:00 PM CONFERENCE REGISTRATION

DAY 1 | MONDAY, OCTOBER 1, 2012

Program Agenda
Theme: Regulatory Convergence, Regulatory Landscape and Clinical Trials in the Latin American Region

7:00–8:30 AM CONFERENCE REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45 AM WELCOME AND OPENING COMMENTS
PROGRAM COMMITTEE CHAIRPERSONS

Justina Molzon, MS Pharm, JD, CAPT. USPHS
Associate Director for International Programs, Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA), USA

8:45-9:00 AM KEYNOTE SPEAKER
Dr. Federico Argüelles Tello (Invited)
Commissioner of Health Approval
COFEPRIS
Mexico

10:45-11:15 AM MORNING REFRESHMENT BREAK

9:00-10:45 AM SESSION 1
Efforts for Regulatory Convergence for Promoting Public Health
SESSION CHAIRPERSON

Mike Ward
Manager, International Programs Division
Health Canada
Canada

Lead Facilitator
APEC Convergence

Mike Ward
Manager, International Programs Division
Health Canada
Canada

11:15 AM-1:00 PM SESSION 2
Trends in Education and Certification of Clinical Research Professionals
SESSION CHAIRPERSON

Honorio Silva, MD
President
Inter American Foundation for Clinical Research,
New York, NY, USA
Director/Treasurer, Pan American Federation of Associations of Medical Schools, Caracas, Venezuela

SESSION PRESENTERS
Globalization of Clinical Research: Accreditation and Certification initiatives
Honorio Silva, MD
Inter American Foundation for Clinical Research
Pan American Federation of Associations of Medical Schools
DAY 2 | TUESDAY, OCTOBER 02, 2012

Theme: Integrity of Supply Chain/Good Manufacturing Practices (GMP), Biosimilars and Pharmacovigilance

7:30 – 8:30 AM CONFERENCE REGISTRATION AND CONTINENTAL BREAKFAST

8:30-9:30 AM SESSION 4

Integrity of Supply Chain

SESSION CHAIRPERSON

Mark Paxton, MS, JD
Regulatory Counsel
Office of Compliance, CDER
US Food and Drug Administration, FDA

SESSION PRESENTERS

Good Manufacturing Practices (GMP) Issues
Mark Paxton, MS, JD
Regulatory Counsel
Office of Compliance, CDER
US Food and Drug Administration, FDA

Supply Chain /Security-Industry Perspective
Mexico Representative

Supply Chain /Security-Industry Perspective (Lifecycle Approach)
Brian Johnson
Senior Director Supply Chain Security
Pfizer Global Supply

9:30-10:00 AM QUESTION AND ANSWER

10:00-10:30 AM MORNING REFRESHMENT BREAK

10:30-11:30 AM SESSION 5

Biosimilars

SESSION CHAIRPERSON

Thomas Kirchlechner, PhD
Head Regulatory Affairs RoW
Sandoz Biopharmaceuticals Development (Novartis), Austria

SESSION PRESENTERS

Considerations when Designing Trials for Biosimilars (SEBs in Canada)
Agnes Klein, MD, DPH
Director, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics
Biologics and Genetic Therapies Directorate
Health Canada

Biological Product Variability and Patient Safety / Immunogenicity
Dr. Maria-Teresa Ibarz
Head Biologics Review Unit
Venezuela Regulatory Agency
Caracas

4:30-5:00 PM QUESTION AND ANSWER DISCUSSION

5:30-7:00 PM RECEPTION AND NETWORKING OPPORTUNITY

11:30 AM-12:00 PM QUESTION AND ANSWER
12:00-1:00 PM  NETWORKING OPPORTUNITY AND LUNCHEON

1:00-2:00 PM  SESSION 6
Pharmacovigilance
SESSION CHAIRPERSON
Justina Molzon, MS Pharm, JD, CAPT. USPHS
Associate Director for International Programs,
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA), USA

SESSION PRESENTERS
Presentation Title
Lembit Rago, MD, PhD
Coordinator for Quality and Safety of Medicines
World Health Organization (WHO)

Presentation Title
María Del Carmen Becerril Martínez, QFB
Executive Director of Pharmacopoeia and Pharmacovigilance
Director
COFEPRIS

2:30-3:00 PM  QUESTION AND ANSWER

3:00-4:30 PM  SESSION 7
Regulatory Panel-Increased Collaboration and Catalysts for Regulatory Convergence: Next Steps Planning Discussion for the 5th LARC
This session will promote discussion with the panel to reach decisions on emerging issues facilitated by the program chairpersons to accomplish the following objectives: 1) Think about how we can move the outcomes of this conference forward; engage in discussion and agree on potential action items, and 2) What are we doing to collaborate and what is the path forward for regulatory convergence?

SESSION CHAIRPERSON
Mike Ward
Manager, International Programs Division
Health Canada
Canada

4:30-4:45 PM  CLOSING REMARKS AND CONFERENCE ADJOURNED

SESSION PRESENTERS
CDER-FDA
Justina Molzon, MS Pharm, JD, CAPT. USPHS
Associate Director for International Programs,
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA), USA

INHRR
Dr. Maria-Teresa Ibarz
Head Biologics Review Unit
Venezuela Regulatory Agency
National Institute of Hygiene “Rafael Rangel”
Caracas

CENCEC
Maria Amparo Pascual, MD
Director, National Center of Clinical Trials
Cuba

INVIMA
Dr. Blanca Elvira Cajigas de Acosta (Invited)
Director General
National Institute of Drug Surveillance and Food
Colombia

PAHO/WHO
James Fitzgerald, PhD (Invited)
Senior Advisor, Essential Medicines and Biologicals
USA

Industry
Anthony Ventura
Head of Latin America Region
Worldwide Regulatory Strategy - International
Pfizer

Dr. Noe Soria
Coordinator of Clinical Investigation
Probiomed/Grupo Unificado
Mexico

Benefit from DIA Membership
- Stay informed
- Build professional relationships
- Develop your career