The only truly impartial and neutral forum for all stakeholders in the region.

Latin American Regulatory Conference (LARC) 2013:

*"Pharma-Co-Vergence"***

May 15-16, 2013

Radisson Royal Bogotá Hotel | Bogotá, Colombia

KEYNOTE SPEAKER

Claudia Vaca, MD
Advisor on Medicines
Ministry of Health and Social Protection, Government of Colombia

COMMITTEE CO-CHAIRS

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

Mike D. Ward
Manager, International Programs Division
Health Canada, Ottawa, Canada

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Chair, DIA Advisory Council for Latin America

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Director, Quality and Regulatory Policy (QRP)
Pfizer Inc., US

Arturo Rodriguez Jacob, Eng
President
Mexican CROs Alliance (ACROM), Mexico

Nazly Cuevas, MD
Medicines for Human Use Department, Clinical Trials Division Spanish Agency Medicine and Sanitary Products (AEMPS) Spain

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 harmonization process and the current working groups.

Simultaneous Translation will be available in English and Spanish.

DIA WORLDWIDE HEADQUARTERS
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Basel, Switzerland | Tokyo, Japan | Mumbai, India | Beijing, China

******Pharma****—pertaining to pharmaceuticals;* ***co****—together, joint, jointly, mutually;* ***verging****—being on the edge or margin of something—the limit or point beyond which something begins or occurs*

*"****Pharmacoverging****" describes drug regulatory authorities working in a collaborative way to best utilize resources for promoting improved public health globally; thus "****pharmacovergence****" is the goal/result of working together.*

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

CONFERENCE OVERVIEW

Based on the success of previous Latin American Regulatory Conferences (LARC) in 2009, 2011 and most recently, 2012, DIA will continue to present this dynamic symposium involving key stake holders 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, Marketing Surveillance and Quality Control Monitoring
- Regulatory Concerns: Health Systems and Security of the Supply Chain
- Current Regulations of Biologics and Biosimilars
- Emerging Topics

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

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PROGRAM

REGISTRATION | **TUESDAY, MAY 14, 2013**

4:00-6:00 PM **CONFERENCE REGISTRATION**

AGENDA

Theme

Pharma-Co-Vergence: the act of achieving pharmaceutical regulatory convergence through stakeholder's collaboration

DAY 1 | **WEDNESDAY, MAY 15, 2013**

7:00-8:30 AM **CONFERENCE REGISTRATION**

8:30-9:00 AM **WELCOME AND OPENING COMMENTS**

PROGRAM CO-CHAIR/SESSION CHAIR

Mr. Mike Ward
Manager, International Programs Division
Health Canada, Canada

Words on Pharmacovergence

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

Sergio Guerrero, MD
President/CEO, Accelerium Clinical Research, México
Chair, DIA Advisory Council for Latin America

Claudia Vaca, MD
Advisor on Medicines
Ministry of Health and Social Protection, Government of Colombia

9:00-9:30 AM **KEY NOTE SPEAKER**

SESSION PRESENTER

Colombia Representative

Claudia Vaca, MD
Advisor on Medicines
Ministry of Health and Social Protection, Government of Colombia

9:30-10:00 AM **COFFEE BREAK**

10:00-11:50 AM **SESSION 1**

Updates on Regional and Global Convergence

This panel session will provide an update on the current harmonization/convergence activities to promote awareness: PAHO-Lead PANDRH, East African Community, Consortium of HC, SwissMedic, TGA and H.S.A., APEC Regulatory Harmonization Steering Committee, Generic Drugs Forum, among others.

PROGRAM CO-CHAIR/SESSION CHAIR

Mr. Mike Ward
Manager, International Programs Division
Health Canada, Canada

SESSION PRESENTERS

Regulatory Convergence

Mr. Mike Ward
Manager, International Programs Division
Health Canada, Canada

Colombian Perspective

Claudia Vaca, MD
Advisor on Medicines
Ministry of Health and Social Protection, Government of Colombia

Chilean Perspective

Ms. Elizabeth Armstrong González
Head, Instituto de Salud Publica de Chile (ISPCH)
Agencia Nacional de Medicamentos (ANAMED), Chile

PAHO Perspective

Jose Daniel Peña Ruz, QF
Regional Advisor, Medicines and Health Technologies PAHO/WHO
Pan American Health Organization (PAHO)/World Health Organization (WHO)
Santiago, Chile

WHO Perspective

Lembit Rago, MD - via Skype
Coordinator for Quality and Safety of Medicines
World Health Organization (WHO), Geneva, Switzerland

Industry Perspective

Diana Valencia, MD
President
Asociación Para el Avance de La Investigación Clínica
AVANZAR
Colombia

11:50-12:20 PM **QUESTION AND ANSWER FOR SESSION 1**

12:20-1:30 PM **LUNCH**

1:30-2:30 PM **SESSION 2**

Latin American Agencies Profiles by CIRS: Number of Reviewers, Inspectors, Timeliness, Predictability and Quality of a Full Review

SESSION PRESENTER

Larry Liberti, MS, RPh, RAC
Director
CIRS - Centre for Innovation in Regulatory Science,
USA & United Kingdom

2:30-3:30 PM SESSION 3

Case Study: Challenges faced by Regulators in the Adoption of Internationally Recognized Technical Guidance Documents and Standards

Session Presenters

Jose Daniel Peña Ruz, QF
Regional Advisor, Medicines and Health Technologies PAHO/WHO
Pan American Health Organization (PAHO)
World Health Organization (WHO)
Santiago, Chile

Industry Perspective

Ms. Claudia Prieto
Regulatory Affairs, Pfizer Inc., Colombia

3:30-3:45 PM COFFEE BREAK

3:45-5:00 PM SESSION 4

Risk Based Approach to Inspections

Session Chair

Maria Guazzaroni Jacobs, PhD
Director, Quality and
Regulatory Policy (QRP)
Pfizer Inc., US

Session Presenters

Rafael Nevarez Nieves, MSc
Office of International Programs, FDA - Latin American Region, Mexico

Ms. Laura Gomes Castanheira
Manager of Research and Clinical Trials
COPEM/ANVISA, Brazil

Industry Perspective

Mr. Mauricio Gantiva
Quality Manager, Pfizer Inc., Colombia

5:00-6:00 PM SESSION 5

Integrity of the Supply Chain: Serialization, Counterfeits and Disposal of Expired Drugs

Session Presenters

Jésica Carino, Pharm
Fiscalizadora, Programa Nacional de Control de Mercado de Medicamentos y Productos Médicos ANMAT, Argentina

APEC Roadmap on Supply Chain Integrity

Rafael Nevarez Nieves, MSc
Office of International Programs, FDA - Latin American Region
Mexico

6:00 PM ADJOURN

6:00-7:30 PM CONFERENCE RECEPTION

DAY 2 | THURSDAY, MAY 16, 2013

9:00-10:00 AM SESSION 6

Transparency of Review Process

Session Chair

Jose Daniel Peña Ruz, QF
Regional Advisor, Medicines and Health Technologies PAHO/WHO
Pan American Health Organization (PAHO)
World Health Organization (WHO)
Santiago, Chile

Session Presenters

Mr. Mike Ward
Manager, International Programs Division
Health Canada, Canada

Larry Liberti, MS, RPh, RAC
Director,
CIRS - Centre for Innovation in Regulatory Science,
USA & United Kingdom

10:00-11:00 AM SESSION 7

Health Technology Assessment

Session Presenter

Mr. Alexandre Lemgruber (via video conference)
Regional Advisor, Health Technologies
Pan American Health Organization

11:00-11:15 AM COFFEE BREAK

11:15 AM-12:00 PM SESSION 8

Implementation of e-Submissions

Session Presenters

Overview in Latin America

Industry Perspective

Ines Elvira Ordóñez, MD
Medical Director, Asociación de Laboratorios Farmacéuticos de Investigación – AFIDRO, Colombia

Cesar Masache, MD
Head, National System on Pharmacotherapy & Pharmacovigilance
Ministry of Public Health, Ecuador

Areli Cerón Sánchez, MSc
Dictaminador Especializado--Ensayos Clinicos
Comision de Autorizacion Sanitaria
Comision Federal para la Proteccion Contra Riesgos Sanitarios (COFEPRIS) Mexico

12:00-1:00 PM SESSION 9

Pharmacovigilance

Session Chair

Claudia Vaca, MD
Advisor on Medicines
Ministry of Health and Social Protection, Government of Colombia

Session Presenters

Colombian Pharmaceutical Policy and Pharmacovigilance

Claudia Vaca, MD
Advisor on Medicines
Minsitry of Health and Social Protection, Government of Colombia

Guatemalan Perspective

Lilly Gordillo, MSc
Pharmacovigilance,
Ministerio de Salud,
Guatemala

1:00-1:15 PM QUESTION AND ANSWER FOR SESSION 9

1:15-2:00 PM LUNCH

2:00-3:00 PM SESSION 10

Biosimilar Products/Generics and Bioequivalence

Session Presenters

Hans Vasquez, MD
Clinical Review Coordinator
Dirección General de Medicamentos Insumos y Drogas (DIGEMID)
Ministerio de Salud, Perú

Ms. Laura Gomes Castanheira
Manager of Research and Clinical Trials
COPEM/ANVISA, Brazil

Ines Bignone, MD
Director, Drugs Evaluation
ANMAT, Argentina

3:00-4:00 PM SESSION 11

Panel on Clinical Studies and Bioethics

Panel Presenters

Cesar Masache, MD
Head, National System on Pharmacotherapy & Pharmacovigilance
Ministry of Public Health, Ecuador

Nazly Cuevas Melendez, MD
Medicines for Human Use Department, Clinical Trials Division Spanish Agency Medicine and Sanitary Products (AEMPS)
Government of Spain

Areli Cerón Sánchez, MSc
Dictaminador Especializado--Ensayos Clínicos
Comisión de Autorización Sanitaria
Comisión Federal para la Protección Contra Riesgos Sanitarios (COFEPRIS) Mexico

4:00-4:15 PM COFFEE BREAK

4:15-4:45 PM SESSION 12

"Miracle" Drugs and Pharmaceutical Products Bordering Dietary Supplements

Session Presenter

Rafael Nevarez Nieves, MSc
Office of International Programs, FDA - Latin American Region
Mexico

4:45-5:45 PM SESSION 13

Special Planning Session for the 6th DIA Latin American Regulatory Conference (LARC)

Organizing Committee: Brainstorming Session for the entire audience.

Moderators

Mr. Mike Ward
Manager, International Programs Division
Health Canada, Canada

Sergio Guerrero, MD
President/CEO, Accelerium Clinical Research, Mexico
Chair, DIA Advisory Council for Latin America

Alejandro Bermudez-Del Villar, MA
DIA Latin America and Global Program Development

5:45-6:00 PM CLOSING REMARKS AND CONFERENCE ADJOURNED

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Register online or fax this page to +1.215.442.6199

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Latin American Regulatory Conference (LARC) 2013: "Pharma-Co-Vergence"**

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The most convenient airport is El Dorado International Airport (BOG) in Bogotá and attendees should make airline reservations as early as possible. *El aeropuerto cercano más conveniente es el Aeropuerto Internacional El Dorado (BOG) en Bogotá. Se les exhorta a hacer sus planes de viaje lo más pronto posible.* The Radisson Royal Bogotá Hotel is holding a block of rooms at the reduced rate below until **April 9, 2013**, for DIA attendees. Room availability at this rate is guaranteed only until this date or until the block is filled. *El Hotel Radisson Royal Bogotá ha bloqueado un grupo de habitaciones y preparado un paquete especial para los asistentes de la Conferencia. Este precio sólo se le puede garantizar mientras haya disponibilidad o hasta antes del día* ***9 de abril del 2013****.*

Single $197+ Double $197+
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CANCELLATION POLICY: On or before APRIL 26, 2013
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Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable./ *Es Posible transferir el registro a otro colega, excepto el pago por membresía, que no es transferible.*
Please notify DIA of any such substitutions as soon as possible./*Favor de notificar a DIA de cualquier cambio con suficiente anticipación.*

DIA reserves the right to alter the venue, if necessary./*DIA se reserva el derecho de cambiar el lugar del evento si es necesario.*

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