Conference Overview

This conference will offer updates on global regulatory environments and how they impact the access of medicines and future research and development in the Latin American region. In-depth interactive discussion will highlight the Latin American region on the benefits, barriers, and direction of harmonization and regulatory trends will be evaluated across the lifecycle of the product.

Keynote Presentation

• Current Environment for Regulatory Authorities and Industry for Latin America

Sessions

• Harmonization Initiatives Throughout the Americas
• Current Status of Pan American Network for Drug Regulatory Harmonization (PANDRH): Overview and Working Group Updates
• Good Regulatory Practice (GRP): Ensuring Quality Throughout the Regulatory Process
• Collaborative Efforts on Inspections
• Collaborative Efforts on Pharmacovigilance
• Regulatory Updates from Latin American Countries
• Global Clinical Development: Opportunities in Latin America
• Biotechnology Paradigm in Latin America
• Promoting Faster Access by Globalizing Regulatory Processes

Learning Objectives

At the conclusion of this conference, participants should be able to:

• Define the global regulatory environment updates 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 groups to be integrated in the future

Simultaneous Translation will be available in English and Spanish.
TUESDAY • MAY 12
4:00-6:00 PM CONFERENCE PRE-REGISTRATION

WEDNESDAY • MAY 13
7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST
8:30-8:45 AM KEYNOTE PRESENTATION CURRENT ENVIRONMENT FOR REGULATORY AUTHORITIES AND INDUSTRY FOR LATIN AMERICA
8:45-9:15 AM CONFERENCE OVERVIEW
Justina A. Molzon, MS, Pharm, JD, CAPT. USPHS
Associate Director for International Programs
CDER, FDA
9:15-10:45 AM SESSION I
HARMONIZATION INITIATIVES THROUGHOUT THE AMERICAS
CHAIRPERSON
Justina A. Molzon, MS, Pharm, JD, CAPT. USPHS
Associate Director for International Programs
CDER, FDA
UPDATES: INTERNATIONAL CONFERENCE ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE
Mr. Mike Ward
Manager, International Programs Division
Health Canada

COMPLEXITIES AND ADVANTAGES FOR GLOBAL PRODUCT DEVELOPMENT
Dr. Richa Chandra
Development Team Head
Pfizer Inc.

UPDATES TO CLINICAL TRIAL RESEARCH REGULATIONS
Dr. Jesus M. Ruiz Rosillo
Medical Director
Boehringer Ingelheim Mexico

10:45-11:15 AM REFRESHMENT BREAK

11:15 AM-12:45 PM SESSION 2
CURRENT STATUS OF PAN AMERICAN NETWORK FOR DRUG REGULATORY HARMONIZATION (PANDRH): OVERVIEW AND WORKING GROUP UPDATES
SESSION CHAIRPERSON
To Be Confirmed
GOOD CLINICAL PRACTICE (GCP)
Dr. Maria Amparo Pascual
Director, National Center of Clinical Trials - CENCEC
Cuba

GOOD MANUFACTURER’S PRACTICE (GMP)
Mr. Rodolfo Mocchetto
Jefe Departamento de Inspectoría INAME
(Head of INAME Inspectorate), Argentina

BIOEQUIVALENCE
Justina A. Molzon, MS Pharm, JD, CAPT. USPHS
Associate Director for International Programs
CDER, FDA

12:45-1:45 PM LUNCHEON

1:45-3:30 PM SESSION 3
GOOD REGULATORY PRACTICE (GRP): ENSURING QUALITY THROUGHOUT THE REGULATORY PROCESS
SESSION CHAIRPERSON
Professor Stuart Walker
Vice President and Founder
Centre for Medicines Research International (CMR), UK

PERU
Dr. Sixto Sanchez
Gineco Obstetra, Epidémiólogo
Profesor de Post Grado, Universidad San Martín de Porres
Past General Director of Research and Technological Transfer, Instituto Nacional de Salud del Peru

VENEZUELA
Dr. Alessandra Poggi
Head of the Department of Clinical Evaluation of Protocols for Biological Products, Division of the National Control of Biological Products, Instituto Nacional de Higiene Rafael Rangel

COSTA RICA
Dr. Marcela Gonzalez Rodriguez
Regulator in Health
Ministry of Health
Costa Rica, Central America

MEXICO
To Be Confirmed

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.
3:30-4:00 PM  REFRESHMENT BREAK

4:00-5:00 PM  SESSION 4

IMPLEMENTATION OF DOCUMENT OF AMERICAS IN DIFFERENT COUNTRIES AND TRENDS IN THE DEVELOPMENT OF REGULATIONS
Dr. Patricia Saidon
Consultant

6:00-7:30 PM  NETWORKING RECEPTION

THURSDAY • MAY 14

7:30-8:30 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45 AM  KEYNOTE PRESENTATION

8:45-10:15 AM  SESSION 5

COLLABORATIVE EFFORTS ON INSPECTIONS
SESSION CHAIRPERSON
David LePay, MD, PhD
Senior Advisor for Clinical Science
Science/Health Coordination and International Programs
Office of the Commissioner, FDA

APIs
Justina A. Molzon, MS, Pharm, JD, CAPT. USPHS
Associate Director for International Programs
CDER, FDA

FDA’S REQUIREMENTS ON INSPECTIONS
David LePay, MD, PhD
Senior Advisor for Clinical Science
Science/Health Coordination and International Programs
Office of the Commissioner, FDA

INSPECTIONS IN LATIN AMERICA
Dr. Sixto Sanchez
Gineco Obstetra, Epidémiólogo
Profesor de Post Grado, Universidad San Martín de Porres
Past General Director of Research and Technological Transference, Instituto Nacional de Salud del Peru

10:15-10:45 AM  REFRESHMENT BREAK

10:45 AM-12:15 PM  SESSION 6

COLLABORATIVE EFFORTS ON PHARMACOVIGILANCE
SESSION CHAIRPERSON
Paul J. Seligman, MD, MPH
Associate Director, Safety Policy and Communication
CDER, FDA

SPEAKERS:
Dr. Miguel Angel Macia Martinez
Jefe de Servicio de Evaluacion de Riesgos
Division de Farmacoepidemiologia y Farmacovigilancia
Agencia Espanola de Medicamentos y Products Sanitarios

Liliana Michieletto
IMS-PVO Manager - Argentina & LatAm Region
Novartis Argentina S.A.

Additional Speakers have been invited

12:15-1:15 PM  LUNCHEON

1:15-2:45 PM  SESSION 7

REGULATORY UPDATES FROM LATIN AMERICAN COUNTRIES
SESSION CHAIRPERSON
Mark Paxton
Associate Vice President, International Regulatory Affairs
PhRMA, USA

GMP
A speaker from COFEPRIS has been invited

BIOEQUIVALENCE
A speaker from ANMAT has been invited

2:45-3:15 PM  REFRESHMENT BREAK

3:15-4:45 PM  SESSION 7 – CONTINUED

REGULATORY UPDATES FROM LATIN AMERICAN COUNTRIES
SESSION CHAIRPERSON:
Mark Paxton
Associate Vice President, International Regulatory Affairs
PhRMA, USA

PRE-SUBMISSION MEETINGS
A speaker from COFEPRIS has been invited

PHARMACOVIGILANCE
Quimica Maria del Carmen Becerril
Executive Director of Pharmacopoeia and Pharmacovigilance
Secretaria de Salud

FRIEDAY • MAY 15

7:30-8:30 AM  REGISTRATION AND CONTINENTAL BREAKFAST

8:30-10:00 AM  SESSION 8

GLOBAL CLINICAL DEVELOPMENT: OPPORTUNITIES IN LATIN AMERICA
SESSION CHAIRPERSON
Sergio Guerrero, MD
Director, OCA Hospital/Monterrey International Research Center, Mexico
SPEAKERS:
Dr. Ricardo Navarro
Clinical Research Director GCO
Janssen-Cilag, Mexico, Central America and Caribe

Dr. Alfonso Moguel
Regulatory Affairs Director
Schering-Plough Corporation

Dr. Diadelis Remirez Figueredo
Assistant Researcher, Center for State Quality Control of Drugs (CECMED), Cuba

10:00-10:30 AM  REFRESHMENT BREAK

10:30 AM-12:00 PM  SESSION 9
BIOTECHNOLOGY PARADIGM IN LATIN AMERICA
Dr. Diadelis Remirez Figueredo
Assistant Researcher, Center for State Quality Control of Drugs (CECMED), Cuba
Additional speakers have been invited

12:00-1:00 PM  LUNCHEON

1:00-3:00 PM  SESSION 10
PROMOTING FASTER ACCESS BY GLOBALIZING REGULATORY PROCESSES

Upcoming DIA Conferences and Training Courses

CONFERENCES
JUNE 21-25, 2009
45th DIA Annual Meeting
San Diego, CA

OCTOBER 5-7, 2009
3RD Annual Clinical Trial Disclosure Workshop
National Harbor, MD

OCTOBER 7-9, 2009
DIA/FDA/NCI/PhRMA Progression Free Survival Workshop
Bethesda, MD

OCTOBER 26-27, 2009
Measuring Study Endpoints in Multinational Clinical Trials: Outcomes Reported from the Viewpoint of the Clinician, Patient, and Caregiver
New Orleans, LA

OCTOBER 28-29, 2009
DIA/FDA/PhRMA Conference on Modeling and Simulation: Quantitative Approaches and Regulatory Sciences
Bethesda, MD

NOVEMBER 2-4, 2009
DIA’s 7th Annual Canadian Meeting “Time to Act”
The Westin Ottawa Hotel
Ottawa, Ontario, Canada

NOVEMBER 2-4, 2009
Regulatory Pathways for Global Vaccine Development – World Health Symposium: Updates from FDA, EMEA, Emerging Regions, NGO and Industry Perspectives
Bethesda, MD

TRAINING COURSES
MAY 13, 2009
Computer Systems Validation for the Non-computer Professional
Horsham, PA

MAY 14, 2009
Good Clinical Practices for the Clinical Research Professional
Horsham, PA

MAY 19-20, 2009
Introduction to Portfolio Management and Performance Metrics
Horsham, PA

MAY 20-22, 2009
Regulatory II: The CTD/NDA Phase
Baltimore, MD

MAY 21-22, 2009
Enterprise Resource Planning
Horsham, PA

AUGUST 3-7, 2009
Regulatory Affairs: Part I: The IND Phase & Part II: The CTD/NDA Phase
Boston, MA

AUGUST 17, 2009
Overview of Drug Development
Philadelphia, PA

AUGUST 18-19, 2009
Executing and Controlling Projects
Horsham, PA
**2nd LATIN AMERICAN REGULATORY CONFERENCE**

**May 13 – 15, 2009 / 13 al 15 de Mayo de 2009**

**Crowne Plaza Hotel de Mexico, Mexico City**

**HOTEL RESERVATION FORM / FORMA DE RESERVACIÓN DE HOTEL**

<p>| Name / Nombre: |</p>
<table>
<thead>
<tr>
<th>Family name /Apellido paterno</th>
<th>Name/Materno</th>
<th>Middle inicial/Nombre(s)</th>
</tr>
</thead>
</table>

<p>| Address / Dirección |</p>
<table>
<thead>
<tr>
<th>Street/Calle</th>
<th>No./No. Ext.</th>
<th>No. Int.</th>
<th>Distrito/Colonia</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Zip Code/Código Postal</th>
<th>City/Ciudad</th>
<th>State/Estado</th>
<th>Country/País</th>
<th>Telephone/Telef. Teléfono</th>
<th>Fax</th>
<th>Email</th>
</tr>
</thead>
</table>

**HOTEL RESERVATION/RESERVACIÓN DE HOTEL**

Mark with an X / Marque en el espacio correspondiente con una X

[CROWNE PLAZA HOTEL DE MEXICO]

- Single or double room / Habitación sencilla o doble USD $ 100.00
- Executive floor / Piso Ejecutivo USD $ 135.00

**NOTE: Rates do not include 15% vat + 2% I.S.H. / NOTA: Las tarifas son más 15% de IVA + 2% I.S.H.**

**Tips to Bell Boys and Maids are not included / No incluye propinas a Botones y Camaristas**

**Type of room /Tipo de habitación**

- (1 person-1 bed/1 persona-1 cama)
- (2 personas-1 bed/2 personas-1 cama)
- (2 personas-2 beds/2 personas-2 camas)

<table>
<thead>
<tr>
<th>Number of rooms /Número de habitaciones</th>
<th>Number of persons in the room /Número de personas en la habitación</th>
</tr>
</thead>
</table>

**Arrival date/Fecha de llegada**

**Departure date/Fecha de salida**

- **ONE NIGHT** deposit plus taxes is required to consider your reservation. The deposit will be credited to your account upon departure, or fill in the credit card information below, authorizing THE HOTEL to charge your credit card in case of No-Show. All payments must be in US Dlls or it’s equivalency in Mexican Pesos.
- Changes and cancellations: Up to 3 weeks before the arrival date all changes will be subject to availability
- Changes made one week before the arrival date will be made through B.P. Servimed. After that date all changes will be made directly in the hotel and will be subject to availability.
- Changes made between 3 WEEKS AND ONE WEEK prior to the arrival date which result in a reduction of nights staying will incur in a USD$50.00 charge.
- Changes in the arrival and departure dates less than one week prior to arrival which result in a reduction of nights staying will be considered as cancellations and will cause the total payment of one night which will be deducted from the initial deposit or will be charged to your credit card.
- Failure to check in at the hotel on your scheduled arrival day will result in forfeiture of your reservation and hotel deposit or credit card charge. The hotel will accommodate you on a space available basis.
- Early departure will result in the charge of one night’s room plus tax.
- All cancellations received between 4 WEEKS AND ONE WEEK PRIOR TO THE ARRIVAL DATE will forfeit in ONE NIGHT No-Show PLUS vat.
- When canceling your room reservation, please note the date and time of your call, with whom you spoke and make sure to obtain a cancellation number.
- Your credit card will merely be used as a guarantee in case of a No-Show. Except in case of cancellations, B.P. Servimed will not carry out any charges, as the charge will be made by the hotel upon arrival.

**METHOD OF PAYMENT/FORMA DE PAGO**

Mark with an X / Marque en el espacio correspondiente con una X

- Check payable to B.P. SERVIMED in the amount of /Cheque a nombre de B.P. Servimed, S.A. de C.V. por $ 

**Check No./Cheque No.**

**Bank/Banco**

- Credit charge in the amount of /Cargo a su tarjeta de crédito por $ 

**THE CREDIT CARD IS JUST USED AS A GUARANTEE IN CASE OF NO-SHOW / EL CARGO SERÁ HECHO POR EL HOTEL EN CASO DE NO SHOW.**

**Type of credit card /Emisor de la tarjeta:**

- Visa
- Master Card
- American Express

**Card number No. de tarjeta:**

**Valid from/Válido desde**

- Month/ mes
- Year/ año

**Expiry date/Válido hasta**

- Month/ mes
- Year/ año

**Security Code/ Código de Seguridad**

- Visa and M.C. a 3 digit number found in the back of the card
- American Express a 4 digit number found in the center right of your card
- Visa and M.C. los 3 últimos dígitos al reverso en el espacio de la firma
- American Express 4 dígitos que aparece a la derecha de la tarjeta

**Name of the card holder / Nombre como aparece en la tarjeta**

**Date/fecha/ Fecha de pago:**

**Signature of the cardholder/Firma del tarjetahabiente**

**Please print or type in your own handwriting:**

**B.P. SERVIMED, S.A. DE C.V.**

**Barranca del Muerto No. 520, Col. Alpes, 01010 México, D.F.**

**Tel: +52 (55) 9171-9570 / Fax: +52 (55) 5660-1903**

**E-mail: dia@servimed.com.mx / Web pages: http://www.servimed.com.mx/DIA09/indexi.htm / www.diahome.org**

**Crowne Plaza Hotel de Mexico, Mexico City**

**Arrival date/Fecha de llegada:**

**Departure date/Fecha de salida:**

**Valid from/Válido desde:**

**Expiry date/Válido hasta:**

**Security Code/ Código de Seguridad:**

**Name of the card holder / Nombre como aparece en la tarjeta:**

**Date/fecha:**

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**Crowne Plaza Hotel de Mexico, Mexico City**

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**Expiry date/Válido hasta:**

**Security Code/ Código de Seguridad:**

**Name of the card holder / Nombre como aparece en la tarjeta:**

**Date/fecha:**

**Signature of the cardholder/Firma del tarjetahabiente**

**Please print or type in your own handwriting:**
REGISTRATION FORM / FORMA DE REGISTRO

Degrees/Título:  
Dr.  
Mr.  
Ms.  
Job Title/Puesto:  

Name/Nombre:  
Family name / Apeildio paterno  
Name / materno  
Middle initial / nombre(s)  

Company/Compañía  
Address / Dirección:  
Street & number / Calle No. Ext. No. Int.  
District / Colonia  
Zip Code / Cód. Postal  
City / Ciudad  
State / Estado  
Country / País  
Area Code/Lada  
Teléfono  
Area Code/Lada  
Fax  
E-mail  

Name's receipt / Recibo a nombre de:  
(Only if it is different from the above name / Sólo en caso de ser a diferente nombre y para efectos fiscales)  
Address / Dirección:  
Street & number / Calle No. Ext. No. Int.  
District / Colonia  
Zip Code / Cód. Postal  
City / Ciudad  
State / Estado  
Country / País  
R.F.C.  

REGISTRATION FEES / CUOTAS DE INSCRIPCION  Please tick in the applicable space / Marque en el espacio correspondiente con una X

<table>
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<th>Category / Categoría</th>
<th>Before May 4, 2009/ Hasta Mayo 4 de 2009</th>
<th>On Site Registration/ Durante el Evento</th>
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</thead>
<tbody>
<tr>
<td>NON-LATIN AMERICAN INDUSTRY</td>
<td>$ 1,500.00 USD</td>
<td>$ 1,752.00 USD</td>
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<tr>
<td>LATIN AMERICAN INDUSTRY</td>
<td>$ 950.00 USD</td>
<td>$ 1,202.00 USD</td>
</tr>
<tr>
<td>NON-PROFIT ACADEMIA</td>
<td>$ 600.00 USD</td>
<td>$ 852.00 USD</td>
</tr>
<tr>
<td>FULL-TIME GOVERNMENT</td>
<td>$ 400.00 USD</td>
<td>$ 652.00 USD</td>
</tr>
</tbody>
</table>

CANCELLATION POLICY: On or before May 4, 2009
Administrative fee will be withheld from the refund amount: Industry = $200, Full-time Government and Non-profit = $100.
Cancellations must be in writing and be received by the cancellation date above. Cancellation notices should be emailed to dia@servimed.com.mx.
Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid.

Dietary requirements:  
Disability needs:  

PAYMENT FORM / FORMA DE PAGO  Please tick in the applicable space / Marque en el espacio correspondiente con una X

- Wire transfer to B.P. Servimed, S.A. de C.V.  
California Commerce Bank Account nbr 5946100101  
ABA 122233645  
2029 Century Park East No. 42 P.O. Box 90067  
Los Angeles, Ca. USA  

- Credit card charge / Cargo a su tarjeta de crédito por  
Charge will be made by / El cargo será hecho por B.P. Servimed, S.A. de C.V.  

Type of credit card / Emisor de la tarjeta:  
Visa  
Master Card  
American Express  

Card number / No. de tarjeta  
Valid from/Válido desde  
Expiration date/Válido hasta  
Security Code/Código de Seguridad  

Name of the card holder / Nombre como aparece en la tarjeta  

By this promissory note I bind myself to the order of the issuer of my credit card. This promissory note derives from the current agreement in regard to the utilization of the credit card entered into by and between the issuer and the credit cardholder and represents the warranties effected by the signer in regards to the credit which was granted. Both the restitution of the amount disposed likewise the interests beared by the aforecited amount so be fixed are estimated upon the form, terms and conditions agreed in the referred agreement. This promissory note shall only be negotiable through credit institutions.

Date / Fecha:  
Signature of the cardholder / FIRMA del tarjetahabiente  

Fill in this form and mail it immediately:  
Llene esta forma y envíe de inmediato a:

B.P. SERVIMED, S.A. DE C.V.  
Barranca del Muerto No. 520, Col. Alpes, 01010 México, D.F.  
Tels: + 52 (55) 9171-9570  
Fax: + 52 (55) 5660-1903  
E-mail: dia@servimed.com.mx  
Web pages: www.servimed.com.mx  
www.diahome.org