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## Regulatory Strategies in Latin America: New Conquest for Pharmaceutical Companies for Timely Submissions and Project Start-ups

Event #10213 • February 17, 2010

11:00 AM-12:30 PM EST 9:00 AM-10:30 AM MST

10:00 AM-11:30 AM CST 8:00 AM-9:30 AM PST



### PRESENTERS

**Dr. Marlene Llopiz-Aviles**

Regional Director for Latin America  
Venn Life Sciences, Mexico

**Dr. Roberto Mendoza**

Regulatory Affairs Director  
Merck Serono

**Maria Eugenia Ruiz, QFB**

Regulatory Affairs Assistant Director  
Quintiles, Mexico

### WHO SHOULD ATTEND

Professionals involved in:

- Clinical operations/research and development
- Clinical studies/trials
- Outsourcing
- Clinical study recruitment
- Protocol design
- Regulatory affairs
- Site management
- Clinical safety and pharmacovigilance
- Good clinical practices
- Medical communications
- Medical writing
- Nonclinical laboratory safety assessment
- Pharmacoeconomics
- Health economics
- Outcomes research
- Statistics
- Professional development/Training
- Validation

#### Worldwide Headquarters

Drug Information Association, Inc.  
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#### Regional Offices

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Hear experts from the Latin American region discuss why the region is emerging as a hot spot for clinical trials and provide regulatory strategies you will need to follow in order to bring new therapeutic products to market.

Timely submissions and project start-ups are often difficult tasks due to the complexity of the necessary documentation required and delays in their delivery in each Latin American country versus differences with other continents. Careful selection is made of each Latin American country to participate in global trials dependent on the shortness and complexity or lack thereof of complications for study conduction and of course, patient, sites and investigator availability. This webinar will provide you with the necessary tools to help you comply with protocol and study needs and regulatory requirements.

### FEATURED TOPICS

- IRB/MoH submissions and approvals
- Regulatory requirement compliance follow through, translations, document review, and revision
- Ethics committee and Ministry of Health submissions and approvals
- Import/export detail license authorization processes
- Receipt of study supplies and customs strategies
- Drug storage site selection
- Distribution and destruction of expired or unused study drugs and supplies
- Pharmacovigilance reports
- Product registration, marketing, and sales authorizations

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The Importance of Latin America.**



## Technical Requirements for Audience Members

### Browser

Microsoft® Internet Explorer 5.2 or higher  
Netscape® Navigator 7

### Computer

166Mhz Pentium-based PC with Microsoft® Windows® 98,  
NT, ME, XP or 2000  
Sun JVM 1.4\* for Microsoft JVM (all versions supported by  
Microsoft Windows OS shown above)  
Sun SPARCstation with Solaris 8 or 9  
Audience: 64 MB RAM

*\*If you need to install Java Virtual Machine (JVM) on your  
system, please download it from the Sun Microsystems  
website.*

### Internet Connection Speed

56k or faster

### Display

800x600 pixel resolution or greater (1024x768 pixels  
recommended)

### Attendees using Macintosh OS

Microsoft IE 5.2  
Macintosh OS 10.2X

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## LEARNING OBJECTIVES

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

- ▶ Explain the evolving global climate for conducting clinical trials
- ▶ Outline the reasons for the significant increase in clinical trials being conducted in the Latin American region

**Disclosure Policy:** It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

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- Offering a multi-disciplinary neutral environment, respected globally for integrity and relevancy.

**CONTACT INFORMATION: Questions about this Webinar?** Contact Ellen Diegel at the DIA office in Horsham, PA by telephone +1.215.442.6158, fax +1.215.442.6199, or email [Ellen.Diegel@diahome.org](mailto:Ellen.Diegel@diahome.org).

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