

## 7<sup>TH</sup> LATIN AMERICAN CONGRESS OF CLINICAL RESEARCH



### Harmonization and the Future of Drug Development in Latin America

November 10 - 12, 2010  
Maksoud Plaza Hotel - São Paulo - Brazil

## TUTORIAL 1

### 7<sup>th</sup> Latin American Congress of Clinical Research

**Date: November 10th, 2010**

**Tutorial Title: "Hands-on the Regulations for Clinical Trials in Latin America"**

**Director: Dr Silvia Zieher, INC Research**

**7:30-8:15: Registration**

**8:15-8:40: Introduction, *Silvia Zieher***

**8:40-10:00: Hands-on the Brazilian Regulations, *Anna Paula Más (PPD), Tania Nacamoto Nakada (Pfizer)***

**Regulatory Framework: main regulations & features**

**Timelines and steps: regulatory strategy**

**Preparing your submission to ECs. EC review process (CEP and CONEP).**

**Dossier content for protocol submission to ANVISA**

**Importation process in Brazil**

**Q&A**

**10:00-10:30 Break**

**10:30-11:45: Hands-on the Argentina Regulations, *Mónica Viard (BMS) and Carolina Diaz Rato (i3)***

**Regulatory Framework: main regulations & features**

**Timelines and steps: regulatory strategy**

**Preparing your submission to ECs. EC review processes**

**Preparing the protocol initial submission to ANMAT. ANMAT protocol review process**

Amendments and additional sites submissions  
Label requirements & Importation of supplies  
Progress reports to ANMAT  
Q&A

11:45-13:00: Hands-on the Mexican Regulation, *Teresa Gonzalez Pichardo (sanofi-aventis)*  
and *Hortencia Melgar (Kendle)*

Regulatory Framework: main regulations & features  
Timelines and steps: regulatory strategy  
Preparing your submission to ECs. EC review process  
Preparing your protocol submission to COFEPRIS.  
Amendments and additional sites submissions  
Label requirements & Importation of supplies  
Q&A

13:00-14:00 Lunch

14:00- 15:15 Hands-on the Regulations in Central America, Colombia & Venezuela *Yohana Granados (LATAM Clinical Trials)*

Summary of main regulations & features  
Q&A

15.15-15:50: Hands-on the Chilean Regulations , *Mafalda Gimenez (Quintiles)*

Regulatory Framework: main regulations & features  
Timelines and steps: regulatory strategy  
Preparing your submission to ECs. EC review process  
Preparing your submission to ISP. The ISP review process.  
Applying to the "Authorization for Use" at GICONA  
Q&A

15:50- 16:30: Hands-on the Peruvian Regulations , *Melissa Brosset (Gotuzzo & Asociados)*

Regulatory Framework: main regulations & features  
Timelines and steps: regulatory strategy  
Dossier content for submitting to ECs  
Dossier content for submitting to INS. The INS review process.  
Applying to the importation license in Peru: DIGEMID review process  
Q&A

16:30-16:45- Break

16:45-17:30: Informed consenting process and documentation : A regulatory and ethical perspective (review of main countries), *Maria Mateo (INC Research)*

17: 30- 18:00 Ethics Committees Composition and Functioning in LA. Assessing compliance.  
*Patricia Saidón (PAHO red PARF)*