



**8<sup>th</sup> International Society of  
Pharmacovigilance Annual Meeting**

**“Strategies for developing Pharmacovigilance”**  
5<sup>th</sup> to 8<sup>th</sup> October 2008

Sheraton Hotel & Convention Center  
Buenos Aires - Argentina

[www.isop2008.org](http://www.isop2008.org)

## Institutional Sponsorships

**Asociación Médica Argentina (AMA)**  
Argentine Medical Association (AMA)

**Facultad de Ciencias Médicas, Universidad Nacional de Córdoba**  
Faculty of Medicine, Córdoba National University

**Facultad de Farmacia, Universidad Nacional de Buenos Aires**  
Faculty of Pharmacy, Buenos Aires University

**Ministerio de Relaciones Exteriores y Culto**  
Argentine Ministry of Foreign Affairs

**Ministerio de Salud de la Nación**  
Argentine Ministry of Health

**Ministerio de Salud de la Provincia de Córdoba**  
Provincial Ministry of Health, Córdoba

**Organización Panamericana de la Salud (OPS/OMS)**  
Pan American Health Organization (PAHO / WHO)

**Secretaría General de la Presidencia de la Nación Argentina**  
Argentine Presidency

**Secretaría de Turismo de la Nación**  
National Secretary of Tourism

**Venue**  
Sheraton Hotel & Convention Center  
San Martín 1225/1275 - Buenos Aires - Argentina - Zip: 1104 - Phone: (54)(11) 43189000

## Welcome

Dear Colleagues,

On behalf of the ISoP Executive Committee and the Argentinian Society of Pharmacovigilance as Local Organizer, we are deeply honored to welcome you to the 8<sup>th</sup> International Society of Pharmacovigilance Annual Meeting, the first ISoP Meeting in the American continent.

We now have the opportunity to participate in one of the most important annual international pharmacovigilance meetings and to learn from a scientific programme supported by an panel of the most acknowledged experts in drug safety and Pharmacovigilance.

"Strategies for developing Pharmacovigilance", the title of this Meeting, strives to involve both the developed as well as the developing world, because Pharmacovigilance needs to evolve and to expand accordingly with pharmacotherapy development, drug production and medicines use in every country, region and economic and political setting. With this Meeting, we aim to contribute to build bridges between developed and developing countries in the field of drug safety, and to contribute to harmonization worldwide.

For this ISoP 2008 Meeting, the differences in organization, complexity and effectiveness of Pharmacovigilance in different countries have been considered: we have included sessions devoted to enhancing Methodology and others aiming to improve the efficacy of systems preventing counterfeit and substandard medicines. The need to enhance Pharmacovigilance in pregnant women, children and older people is also stressed. Different approaches for Pharmacovigilance in vaccines and a Round Table discussion on strategies of Risk Management, from a regulatory perspective, take care of two global main topics in Pharmacovigilance.

The session "Harmonization in Pharmacovigilance" aims to make consistent Pharmacovigilance approaches both in developed and developing world. The need for surveillance of a relatively new group of medicines is the basis for the session for biological products and advanced therapies. The crucial role of communication in Pharmacovigilance is also approached from different views and focuses on public and media communication.

The complex process of marketing authorization and its impact on patient safety is tackled in three plenary lectures dealing with benefit/risk balance, off-label use and the non commercial sponsorship of clinical investigations.

Both the ISoP's lecture about Education and Training and "Lessons learned from the development of Pharmacovigilance in Spain" aim to contribute to a better and sounder knowledge of Pharmacovigilance, mainly in Latin-American countries.

We sincerely acknowledge the privilege of hosting this conference here, in Buenos Aires, Argentina, and we hope that in the future the ISoP's stars will continue to enlighten the Latin part of the American continent.

**Dr. Luis Alesso**  
Chairman, Local Organizing Committee

**Prof. Nicholas Moore**  
International Society of Pharmacovigilance  
President



---

PRE-CONFERENCE COURSES



# Sunday

5<sup>th</sup> October - 09.00 h. to 18.00 h.

## Pre-Conference Course I Pharmacovigilance: from Fundamental Basis to Practice

Venue: Golden Horn conference room

### Chairpersons

*Luis Alesso*, Córdoba National University, Argentina  
*Ronald Meyboom*, Uppsala Monitoring Centre, Sweden

### Faculty

*Carmen Kreft-Jais*, AFSSAPS, France  
*Marie Lindquist*, Uppsala Monitoring Centre, Sweden  
*Nicholas Moore*, Department of Pharmacology, University of Bordeaux, France  
*Ronald Meyboom*, Uppsala Monitoring Centre, Sweden  
*Jan-Willem van der Velden*, Pharmanet, Switzerland

### Programme

08.30	Welcome-registration		
09.00	Registration Desk, Foyer of Catalinas and Golden Horn conference rooms		
-----			
09.00	Introduction	13.15	Sandwich Lunch (Golden Horn conference rooms)
09.10	<i>Luis Alesso</i>	14.15	Pharmacovigilance from industry perspective
09.10	Objectives of the course	14.45	<i>Jan-Willem van der Velden</i>
09.20	<i>Ronald Meyboom</i>	14.45	The WHO Database and the UMC
09.20	Historical Background	15.30	<i>Marie Lindquist</i>
09.50	<i>Marie Lindquist</i>	15.30	Pharmacoepidemiology in Pharmacovigilance
09.50	Fundamental Concepts: the state of the art	16.20	<i>Nicholas Moore</i>
10.45	<i>Nicholas Moore</i>	16.20	Coffee break (Foyer of Catalinas and Golden Horn conference rooms)
10.45	Coffee break (Foyer of Catalinas and Golden Horn conference rooms)	16.50	Risk/Benefit evaluation: Basis and consequences
11.15	11.15	17.50	<i>Carmen Kreft-Jais</i>
12.00	Basis for causality assessment	17.50	Closure
12.00	<i>Ronald Meyboom</i>	18.00	<i>ANMAT representative</i>
12.30	Case reports in Pharmacovigilance		
12.30	<i>Nicholas Moore</i>		
12.30	Effectiveness failure in Pharmacovigilance		
13.15	<i>Ronald Meyboom</i>		

18.30 - 20.00 **Welcome Reception**  
San Telmo Conference Room, Sheraton Buenos Aires Hotel & Convention Center

## Pre-Conference Course II Drug-related Risk Management

Venue: Catalinas Conference Room

### Chair:

*Xavier Kurz*  
Scientific Administrator, Risk Management Team, Sector Pharmacovigilance and Safety & Efficacy of Medicines, European Medicines Agency (EMA), London

### Faculty:

*Robert Ball*, Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, USA

*Gerald J. Dal Pan*, Director, Office of Drug Safety, Center for Drug Evaluation and Research (CDER), FDA  
*Murilo Freitas-Dias*, Head of Pharmacovigilance, Brazilian Health Surveillance Agency - ANVISA, Brazil  
*Xavier Kurz*, EMA, London  
*Aparna Mohan*, Senior Director of Pharmacovigilance Analytics, Benefit Risk Management, Johnson and Johnson  
*Analia Pérez*, Head of Medicines Evaluation Department, National Administration for Food, Drug and Medical Technology (ANMAT), Argentina

### Programme

08.30	Welcome- registration		
09.00	Registration Desk, Foyer of Catalinas and Golden Horn conference rooms		
-----			
09.00	Introduction-Objective of the course	13.00	Lunch (San Telmo conference room, ground floor)
09.10	<i>Analia Pérez</i>	14.00	Risk management from an Industry perspective
09.10	Why do we need risk management ?	14.40	<i>Aparna Mohan</i>
10.00	<i>Robert Ball</i>	14.40	Risk mitigation and its measurement
10.00	Concept and components of risk management	15.30	<i>Gerald Dal Pan</i>
10.45	<i>Xavier Kurz</i>	15.30	How to prepare a risk management plan/strategy ?
10.00	Coffee break (Foyer of Catalinas and Golden Horn conference rooms)	16.20	<i>Aparna Mohan</i>
10.45	10.45	16.20	Coffee break (Foyer of Catalinas and Golden Horn conference rooms)
11.15	Risk management in the United-States: the REMS	16.50	Improvements and future developments
11.45	<i>Gerald Dal Pan</i>	17.30	<i>Xavier Kurz</i>
11.45	Risk management in Europe: the EU-RMP	17.30	Perspectives for risk management in Latin-America
12.15	the REMS	18.00	<i>Murilo Freitas-Dias</i>
12.15	<i>Xavier Kurz</i>	18.00	Closure
12.15	Risk management in Latin America		
13.00	<i>Murilo Freitas-Dias</i>		

18.30 - 20.00 **Welcome Reception**  
San Telmo conference room, Sheraton Buenos Aires Hotel & Convention Center



---

SCIENTIFIC PROGRAMME



# Monday

6<sup>th</sup> October - 09.00 h. to 17.50 h.

From 08.00 **Registration**  
Foyer of the Libertador conference room

09.00 - 10.40 **Plenary Sessions Morning**

- 09.00 - 09.15 **Opening of the 8<sup>th</sup> Annual ISoP Meeting**  
*Nicholas Moore*  
President of International Society of Pharmacovigilance (ISoP)  
*Luis Alesso*  
President of Argentinian Society of Pharmacovigilance (SAFV), Chairman of the Local Organizing Committee
- 
- 09.15 - 09.30 **Opening address**  
*Lic. Graciela Ocaña*  
Argentine Minister of Health
- 
- 09.30 - 10.20 **Keynote lecture**  
**Early Licensing versus Greater Safety? Where's the Balance?**  
*Michael Rawlins*  
Chairman of National Institute for Health and Clinical Excellence (NICE), United Kingdom
- 
- 10.20 - 10.40 **ISoP's presentation:**  
**ISoP's comprehensive modular pharmacovigilance curriculum: the result of worldwide interdisciplinary teamwork**  
*Jürgen Beckmann*  
Former Director Drug National Agency, Germany

10.40 - 11.10 Coffee-break and poster viewing

# Monday

6<sup>th</sup> October - 09.00 h. to 17.50 h.

# Monday

6<sup>th</sup> October - 09.00 h. to 17.50 h.

## 11.10 - 12.40 Parallel Sessions Morning

### Libertador A

#### 1. Reports of Lack of Effectiveness

Chairpersons  
*Pedro Lipszyc*  
*Thierry Trenque*

11.10 - 11.30	<b>1.a</b> Keynote presentation: Medicaments interchangeability: are all the drugs alike? <i>Pedro Lipszyc</i>
11.30 - 11.50	<b>1.b</b> Drugs associated with ineffectiveness as adverse drug reaction <i>Sander Borgsteede</i>
11.50 - 12.10	<b>1.c</b> Programme of Bioequivalence in Argentina <i>Ricardo Bolaños</i>
12.10 - 12.30	<b>1.d</b> Cholinesterase inhibitors in demented patients: impact of treatment non-persistence on institutionalization or death <i>Yola Moride</i>
12.30 - 12.40	<b>Discussion</b>

### Libertador B

#### 2. Pharmacogenetics and Drug Interactions in Pharmacovigilance

Chairpersons:  
*Eveline Jaquenoud-Sirot*  
*Paula Márquez*

11.10 - 11.30	<b>2.a</b> Keynote presentation: Drug plasma levels and ADRs <i>Eveline Jaquenoud-Sirot</i>
11.30 - 11.50	<b>2.b</b> Genetic polymorphisms and risk of ADRs in NSAID and SSRI users <i>Adolfo Figueiras</i>
11.50 - 12.10	<b>2.c</b> Association of cardiovascular drugs and NOS1AP with QT prolongation <i>Charlotte van Noord</i>
12.10 - 12.30	<b>2.d</b> Genotyping in the TDM laboratory – necessary for Pharmacovigilance <i>Astrid Hader</i>
12.30 - 12.40	<b>Discussion</b>

12.40 - 14.00 Lunch (San Telmo Room)

## 14.00 - 15.30 Parallel Sessions Afternoon

### Libertador A

#### 3. Pharmacovigilance in Hospitals

Chairpersons  
*Jan-Willem van der Velden*  
*Raquel Herrera Comoglio*

14.00 - 14.20	<b>3.a</b> Keynote presentation: Off-label use in psychiatric inpatients - Data from the AMSP Study Group <i>Anastasios Konstantinidis</i>
14.20 - 14.40	<b>3.b</b> Profile of Drugs Related to Adverse Events at Brazilian University Hospitals <i>Adriano Max. Moreira-Reis</i>
14.40 - 15.00	<b>3.c</b> Pharmacovigilance within the Internal Medicine Division of Argerich Hospital <i>Marcelo L. Ponte</i>
15.00 - 15.20	<b>3.d</b> Admissions by bleeding or high INR caused by drugs in a Private Non-profit Hospital, Montevideo, Uruguay <i>Ismael Olmos</i>
15.20 - 15.30	<b>Discussion</b>

15.30 - 16.00 Coffee-break and poster viewing

### Libertador B

#### 4. Methodology in Pharmacovigilance I

Chairpersons  
*Saad Shakir*  
*Nicholas Moore*

14.00 - 14.20	<b>4.a</b> Keynote presentation: The role of prescription event monitoring in the risk management of medicines <i>Saad Shakir</i>
14.20 - 14.40	<b>4.b</b> Analysis of a depletion of susceptibles effect in the risk of MI and diclofenac: a field case referent study with the PGRx Information System <i>Lamia Bensouda-Grimaldi</i>
14.40 - 15.00	<b>4.c</b> The monitoring of serum electrolytes and creatinine in patients treated with antihypertensive drugs: a retrospective analysis in UK general practice <i>Jamie Coleman</i>
15.00 - 15.20	<b>4.d</b> MedDRA as a standard: approach to version updates and primary SOC allocation <i>Tomás Moraleta</i>
15.20 - 15.30	<b>Discussion</b>

# Monday

6<sup>th</sup> October - 09.00 h. to 17.50 h.

## 16.00 - 17.50 Parallel Sessions Afternoon

### Libertador A

#### 5. Counterfeit Medicines and Illegitimate Drugs

Chairpersons

*Luis Alesso*

*María José Sánchez*

### Libertador B

#### 6. Intensive Pharmacovigilance Programmes

Chairpersons

*Eugène van Puijenbroek*

*Deirdre McCarthy*

16.00 16.20	<b>5.a</b> Keynote presentation: Counterfeit and illegitimate medicine: a view from the Americas <i>José Luis Castro</i>	16.00 16.20	<b>6.a</b> Keynote presentation: Web-based intensive monitoring, a new method for active surveillance of drugs <i>Eugène van Puijenbroek</i>
16.20 16.40	<b>5.b</b> Argentine Programme of Detection of Illegitimate Medicines <i>María José Sánchez</i>	16.20 16.40	<b>6.b</b> Novel approach for intensive Pharmacovigilance Studies application to Hepatitis C treatment in Mexican patients <i>Ricardo Jiménez-Méndez</i>
16.40 17.00	<b>5.c</b> Administrative traceability requirements in medicines purchasing <i>Rodolfo Rodríguez</i>	16.40 17.00	<b>6.c</b> Monitoring of haematological safety of Leponex (Clozapine). Results of 14 years. <i>Mónica Fuentes-Vargas</i>
17.00 17.20	<b>5.d</b> Industry commitment in the battle against fraud and medicines counterfeiting <i>Miguel Maito</i>	17.00 17.20	<b>6.d</b> Priority groups identification for the development of intensified pharmacovigilance in Bogotá <i>Rosa Ángela Caro Rojas</i>
17.20 17.40	<b>5.e</b> Combating Drug Counterfeiting: the Nigerian Experience <i>Dora Akunyili</i>	17.20 17.40	<b>6.e</b> Safety profile of modanafil used in GP in England: a modified PEM study <i>Saad Shakir</i>
17.40 17.50	<b>Discussion</b>	17.40 17.50	<b>Discussion</b>

# Tuesday

7<sup>th</sup> October - 09.00 h. to 17.50 h.

## From 08.00 Registration

## 09.00 - 12.40 Parallel Sessions Morning

### Libertador A

#### 7. Pharmacovigilance in Special populations

Chairpersons

*Geral Dal Pan*

*Anthony Wong*

### Libertador B

#### 8. Harmonization in regulatory aspects of Pharmacovigilance: How do you do it?

Chairpersons:

*Ulrich Hagemann*

*Ricardo Bolaños*

09.00 09.20	<b>7.a</b> Keynote presentation: Pediatric Pharmacovigilance - New FDA and EMEA Requirements and new WHO Focus: Impact on Pharmaceutical Industry and other Stakeholders <i>Klaus Rose</i>	09.00 09.20	<b>8.a</b> Keynote Presentation: Global markets - global patient safety - global harmonization in Pharmacovigilance? <i>Ulrich Hagemann</i>
09.20 09.40	<b>7.b</b> Identifying and Evaluating Teratogenic risks of Drugs in Humans <i>Myla Moretti</i>	09.20 09.40	<b>8.b</b> Thalidomide: review of the 10 year Intensive Pharmacovigilance Program in Argentina <i>Inés Bignone</i>
09.40 10.00	<b>7.c</b> Only few Serious Adverse Drug Reactions are due to drugs of Beers' list of inappropriate medications for the elderly <i>Marietta Rottenkolber</i>	09.40 10.00	<b>8.c</b> Epidemiologic Vigilance of Thalidomide syndrome in Brazil: old drug with new applications <i>Lavinia Schuler-Faccini</i>
10.00 10.20	<b>7.d</b> Psychotropic drug used for Attention-deficit/hyperactivity disorder (ADHD) in Italian children and adolescent population <i>Pietro Panei</i>	10.00 10.20	<b>8.d</b> Thalidomide's come back: Implementing Safe Use in the EU <i>Carmen Kreft-Jais</i>
10.20 10.40	<b>7.e</b> Adverse Drug Reactions with Donepezil: Analysis of the French Pharmacovigilance Database <i>Hervé Le Louët</i>	10.20 10.40	<b>8.e</b> Pharmacovigilance and the Pan American Network for the Drug Regulatory Harmonization <i>José Luis Castro</i>
	<b>Discussion</b>		<b>Discussion</b>

10.40 - 11.10 Coffee-break and poster viewing

# Tuesday

7<sup>th</sup> October - 09.00 h. to 17.50 h.

# Tuesday

7<sup>th</sup> October - 09.00 h. to 17.50 h.

## 11.10 - 12.40 Parallel Sessions Morning

### Libertador A

#### 9. Vaccine Pharmacovigilance

Chairpersons:

*Murilo Freitas-Dias*

*Corinne Pierfitte*

### Libertador B

#### 10. Methodology in Pharmacovigilance II

Chairpersons:

*Marie Lindquist*

*Anders Sundström*

11.10 11.30	<b>9.a</b> Keynote Presentation: Conduct of Pharmacovigilance of vaccines- why is it different from pharmacovigilance of other medicinal products <i>Brigitte Keller-Stanislawski</i>	11.10 11.30	<b>10.a</b> Keynote presentation: Signal management: Can you see the wood for the trees? <i>Eugène van Puijenbroek</i>
11.30 11.50	<b>9.b</b> Brazilian Vaccine Safety Monitoring System <i>Murilo Freitas-Dias</i>	11.30 11.50	<b>10.b</b> Risk Validation against internal and external Data Source <i>Peter Schulz</i>
11.50 12.10	<b>9.c</b> Post-authorization Safety Surveillance of a new pentavalent vaccine within a National Childhood Vaccination Program in Central America <i>Katharina Hartmann</i>	11.50 12.10	<b>10.c</b> Data mining on health record databases for detecting adverse reactions: which events to monitor? <i>Gianluca Trifirò</i>
12.10 12.30	<b>9.d</b> Vaccine Pharmacovigilance: are we asking the right questions? <i>Robert Ball</i>	12.10 12.30	<b>10.d</b> Creating Pharmacovigilance Quality Assurance <i>Tyler Cochran</i>
12.30 12.40	<b>Discussion</b>	12.30 12.40	<b>Discussion</b>

12.40 - 14.00 Lunch (San Telmo conference room)

13.15  
14.00 ISO P General Assembly (Libertador A)

## 14.00 - 15.30 Plenary Sessions Afternoon (Libertador A /B)

14.00  
14.45 **Keynote lecture:**  
**Monitoring adverse events in an off-label use setting**  
*Gerald Dal Pan*  
Director of Center for Drug Evaluation and Research (CDER), Food and Drug Administration, USA

14.45  
15.30 **Keynote presentation:**  
**Lessons learned from the development of pharmacovigilance in Spain**  
*Joan Ramon Laporte*  
Director of Catalan Institut of Pharmacology Foundation (FICF), Spain

15.30 - 16.00 Coffee-break and poster viewing

## 16.00 - 17.50 Plenary sessions afternoon (Libertador A/B)

16.00  
16.20 **Pharmacovigilance and clinical trials: experience of the first European non commercial sponsor**  
*Hervé Le Louët*  
Head Pharmacovigilance Regional Centre Creteil, France

16.20  
17.50 **Round table discussion: Customising Risk Management: Global or local?**  
Chairperson  
*Joan-Ramon Laporte*

**Tailoring Emerging Vaccine Safety infrastructures: Recent advances in Monitoring Vaccine Safety**  
*Nelson Arboleda*  
Centers for Disease Control and Prevention (CDC), USA  
Round table with:  
- *Xavier Kurz*  
- *Chalbi Belkahia*  
- *Dora Akunyili*  
- *Joan-Ramon Laporte*  
- *Nelson Arboleda*  
- *Latin America Regulatory Agencies*

# Wednesday

8<sup>th</sup> October - 09.00 h. to 17.30 h.

From 08.00 Registration Foyer Libertador Room

09.00 - 12.40 Parallel Sessions Morning

## Libertador A

### 11. Estimating AE/ADR seriousness, causality and frequency as the basis of risk assessment

Chairpersons  
*Jürgen Beckmann*  
*Ronald Meyboom*

09.00 - 09.20	<b>11.a</b> Keynote Presentation: Sense and non-sense in case-causality assessment <i>Ronald Meyboom</i>
09.20 - 09.40	<b>11.b</b> Ventricular arrhythmia and sudden unexpected death and domperidone <i>Charlotte van Noord</i>
09.40 - 10.00	<b>11.c</b> Hospital admissions due to severe adverse drug reactions: EMIR, a nationwide study <i>Ghada Miremont-Salamé</i>
10.00 - 10.20	<b>11.d</b> Patients starting anti-obesity drugs carry higher psychiatric and cardiovascular baseline risk <i>Marjolein Willemen</i>
10.20 - 10.40	<b>11.e</b> Allergic reactions to oral drugs: a case/non case study from an Italian spontaneous reports database (GIF) <i>Francesco Salvo</i>

#### Discussion

## Libertador B

### 12. Pharmacovigilance in Biologicals and Advanced Therapies

Chairpersons  
*Xavier Kurz*  
*Michael Rawlins*

09.00 - 09.20	<b>12.a</b> Keynote lecture: EMEA guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products <i>Brigitte Keller-Stanislawski</i>
09.20 - 09.40	<b>12.b</b> Anti Rheumatic Treatment in Sweden (ARTIS): Clinicians, Academia and Regulators in collaboration for the pharmacovigilance of biologics, including TNF-blocking drugs <i>Anders Sundström</i>
09.40 - 10.00	<b>12.c</b> Psychiatric disorders with anti-TNF alpha treatment: an adverse drug reaction to keep in mind <i>Ghada Miremont-Salamé</i>
10.00 - 10.20	<b>12.d</b> Pharmacovigilance characteristic and activities within the first cohort of EU Risk Management Plans (RMPs): small molecules vs. biologicals <i>Thijs Giezen</i>
10.20 - 10.40	<b>12.e</b> Pharmacovigilance for Biological Medicinal Products: the Market Authorisation Holder's Experience <i>Marianne Gerber</i>

#### Discussion

10.40 - 11.10 Coffee-break and poster viewing

# Wednesday

8<sup>th</sup> October - 09.00 h. to 17.30 h.

11.10 - 12.40 Parallel Sessions Morning

## Libertador A

### 13. Developments in Global Pharmacovigilance and Implementation in a Regional Setting

Chairpersons  
*Ralph Edwards*  
*Luis Alesso*

11.10 - 11.30	<b>13.a</b> Analysis of Drug Adverse Reaction Relief applications in Taiwan from 1999-2007 <i>Churn-Shiouh Gau</i>
11.30 - 11.50	<b>13.b</b> Pharmacovigilance and Patient Safety: Results of the German Net of Regional Pharmacovigilance Centers <i>Sven Schmiedl</i>
11.50 - 12.10	<b>13.c</b> Development of guideline and macro flow for Brazilian system of Pharmacovigilance: basis for decentralization <i>Milena Bittencourt</i>
12.10 - 12.30	<b>13.d</b> Current processes and challenges in Pharmacovigilance in Latin America <i>Sandra Abrahao</i>
12.30 - 12.40	<b>Discussion</b>

12.40 - 14.00 Lunch (San Telmo Room)

## Libertador B

### 14. Communication in Pharmacovigilance

Chairpersons  
*Giampaolo Velo*  
*Brian Edwards*

11.10 - 11.30	<b>14.a</b> Keynote Presentation: Pharmacovigilance Communication to the Public: A Process Calling for Leadership <i>Priya Bahri</i>
11.30 - 11.50	<b>14.b</b> Clinical trials: patient's safety and AE's accurate media communication <i>Miguel Tregnaghi</i>
11.50 - 12.10	<b>14.c</b> Adverse Events communication: the role of MD specialised in Pharmaceutical Medicine <i>Héctor Arenoso</i>
12.10 - 12.30	<b>14.d</b> Information or promotion? <i>Giampaolo Velo</i>
12.30 - 12.40	<b>Discussion</b>

# Wednesday

8<sup>th</sup> October - 09.00 h. to 17.30 h.

# Wednesday

8<sup>th</sup> October - 09.00 h. to 17.30 h.

## 14.00 - 15.30 Parallel Sessions Afternoon

### Libertador A

#### Workshop: Widening Pharmacovigilance's scope: Consumer reporting

Chairpersons

*John McEwen*

*Syed Rizwanuddin Ahmad*

Do Consumer Reports of Adverse Drug Reactions Add Value or Noise to Postmarketing Safety Surveillance?

14.00 - 14.15 FDA Experience with Consumer Reports  
*Syed Rizwanuddin Ahmad*

14.15 - 14.30 The Adverse Medicine Events (AME) Line: Australian experience with consumer pharmacovigilance  
*John McEwen*

14.30 - 14.45 Consumers and health care professionals differences in reporting trend: a register-based study of Danish adverse drug reactions reports (2004- 2006)  
*Lise Aagaard*

14.45 - 15.00 10 years of experiences with consumer reporting to KILEN - a Swedish consumer organization  
*Lina Westin*

15.00 - 15.30 **Discussion**

### Libertador B

#### Workshop: Pharmacovigilance in Herbal medicines

Chairpersons

*Deborah Shaw*

*Chalbi Belkahia*

14.00 - 14.15 Keynote presentation: Myths and misinformation: cautionary herbal tales  
*Deborah Shaw*

14.15 - 14.30 Acute hypersensitivity reactions to Andrographis Paniculata containing products, as reported in international Pharmacovigilance  
*Ronald Meyboom*

14.30 - 14.45 Ethnopharmacovigilance: special considerations and examples from Brazil  
*Eliana Rodrigues*

14.45 - 15.00 International Assessment of Herbal Medicines Pharmacovigilance  
*Souad Skalli*

15.00 - 15.30 **Discussion**

## 16.00- 17.50 Plenary Sessions Afternoon (Libertador A/B)

16.00 - Bengt-Erik Wiholm Lecture

16.45 - Beje Wiholm: putting the pieces together  
*Ralph Edwards*  
Director of the Uppsala Monitoring Centre, Sweden

16.45 - 17.50 **Closure**

16.45 - 17.00 **Presentation for ISoP 2009**

17.00 - 17.15 **Poster Prize Awards**

17.15 - 17.30 **Closing Ceremony of ISoP 2008**



---

SPEAKERS AND CHAIRPERSONS



- A**
- Lise Aagaard** Pharm PhD MSc, PhD, BEcon,  
Consumer Safety Division, Danish Medicines Agency; Faculty  
of Pharmaceutical Sciences, Institute of Pharmacology and  
Pharmacotherapy, Copenhagen, Denmark
- Sandra Abrahao** MD, PhD  
Medical Director Bayer SA, Brazil
- Syed Rizwanuddin Ahmad**, MD, MPH, FISPE  
Food and Drug Administration, USA
- Dora Akunyili** MD, PhD  
Director, NAFDAC, Drug Agency for Food and Drug  
Administration and Control, Nigeria
- Luis Alesso** MD  
Director Pharmacovigilance Center, Public Health School,  
School of Medicine, Córdoba National University;  
Head of AProSS Drug Department, Córdoba Provincial  
Administration Health Insurance, Córdoba,  
Chairman of the Local Scientific Committee, Argentina
- Nelson Arboleda** MD, MPH  
Senior Medical Epidemiologist Immunization Safety Office  
(ISO) Office of the Chief Science Officer  
Centers for Disease Control and Prevention (CDC), USA
- Héctor Arenoso** MD  
Director of Speciality of Pharmaceutical Medicine, School  
of Medicine, Buenos Aires University; Argentine Society of  
Pharmaceutical Medicine, Argentina
- B**
- Priya Bahri** MD, PhD  
European Medicines Evaluation Agency, United Kingdom
- Robert Ball** MD, MPH, ScM  
Director, Office of Biostatistics and Epidemiology, Center for  
Biologics Evaluation and Research (CBER), Food and Drug  
Administration, USA
- Jürgen Beckmann** MD  
Former Director Drug National Agency, Germany
- Inés Bignone** MD  
Head Pharmacovigilance Department, National Administration  
of Food, Drug and Medical Technology (ANMAT), Argentina
- Milena Oliveira Bittencourt**  
Pharmacovigilance Office (GFARM), Brazilian Health  
Surveillance Agency, (ANVISA), Brazil
- Ricardo Bolaños** MD, PhD  
Head Studies and Projects Department, National  
Administration of Food, Drug and Medical Technology  
(ANMAT), Argentina
- Sanders Borgsteede** PharmD  
Netherlands Pharmacovigilance Centre Lareb,  
's-Hertogenbosch, The Netherlands
- C**
- Deirdre McCarthy** MD  
Associate Director, Pharmacovigilance, Quintiles Ireland,  
Dublin, Ireland
- Rosa Caro Rojas** Pharm  
Health District Secretariat, Bogotá D.C. Colombia

- José Luis Castro** MD  
Pan American Health Organization, World Health Organization,  
Argentina
- Tyler Cochran** MD  
Global Clinical Safety and Pharmacovigilance Quality  
Assurance Department, UCB, USA
- Jamie Coleman** MBChB, MRCP(UK)  
Department of Clinical Pharmacology, University of  
Birmingham, United Kingdom
- D**
- Gerald Dal Pan** MD, PhD  
Director of Center for Drug Evaluation and Research (CDER),  
Food and Drug Administration, USA
- E**
- Ralph Edwards** MB, ChB, FRCP (Lond) FRACP  
Director, WHO Programme for International Drug Monitoring,  
the Uppsala Monitoring Centre, Uppsala, Sweden
- Brian Edwards** BSc, MD, MRCP  
Director, Pharmacovigilance and Drug Safety, NDA Regulatory  
Science Ltd, United Kingdom
- F**
- Adolfo Figueiras** Pharm PhD MPH MPE  
Prof. Preventive Medicine and Public Health, Santiago de  
Compostela University, Spain
- Mónica Fuentes-Vargas**, MD  
Department of Pharmacovigilance, Novartis Pharmaceuticals,  
Mexico
- Murilo Freitas Dias**, Pharm, MSc Pharmacology  
Head of Pharmacovigilance, Brazilian Health Surveillance  
Agency - ANVISA, Brazil
- G**
- Churn-Shiouh Gau** PhD  
Deputy Executive Director Centre for Drug Evaluation, Taiwan
- Marianne Gerber** MD,  
Drug Safety Product Specialist, Drug Safety and Risk  
Management, F. Hoffmann-La Roche Ltd, Switzerland
- Thijs Giezen** PharmD  
Utrecht Institute for Pharmaceutical Sciences (UIPS), Division  
of Pharmacoepidemiology and Pharmacotherapy, Utrecht;  
Medicines Evaluation Board, The Hague, The Netherlands
- Lamia Bensouda-Grimaldi** PharmD, MSc  
InsERM U657 and Laser, Paris, France
- H**
- Astrid Hader**  
Clinical Pharmacology, Department of Psychiatry,  
Psychosomatic, and Psychotherapy, University of Regensburg,  
Germany
- Ulrich Hagemann** PhD  
Head of Pharmacovigilance Department, Federal Institute for  
Drugs and Medical Devices - BfArM, Germany
- Katharina Hartmann** MScPharm  
Senior Lecturer Pharmaceutical Sciences, Swiss Federal  
Institute of Technology ETHZ, Zürich, Switzerland

**J** **Raquel Herrera Comoglio MD**  
Co-Director Pharmacovigilance center, Public Health School, School of Medicine, Córdoba National University, Argentina

**J** **Eveline Jaquenoud-Sirot MSc**  
Psychiatric Clinic Königsfelden, Switzerland

**J** **Ricardo Jiménez-Méndez MD, MSc**  
Section of Pharmacology Center for Research and Advanced Studies of The National Polytechnical Institute, Mexico

**K** **Brigitte Keller-Stanislawski MD PhD**  
Paul Ehrlich Institute, Germany

**K** **Anastasios Konstantinidis MD**  
Division of Biological Psychiatry, Dpt. of Psychiatry and Psychotherapy Medical University Vienna, Austria

**K** **Carmen Kreft-Jais MD**  
Chef du Département de Pharmacovigilance, AFSSAPS, Drug National Agency, France

**K** **Xavier Kurz MD, PhD**  
Principal Scientific Administrator, Pharmacovigilance and Post-Authorisation Safety and Efficacy of Medicines, European Medicines Agency (EMA), United Kingdom

**L** **Joan-Ramon Laporte MD, PhD**  
Director Catalan Institut of Pharmacology Foundation (FICF), Spain

**L** **Hervé Le Louët MD, PhD**  
Head Pharmacovigilance Regional Centre Creteil, France

**L** **Marie Lindquist**  
Deputy Director, the Uppsala Monitoring Centre, Uppsala, Sweden

**L** **Pedro Lipszyc MD**  
Head Pharmacology chair, School of Medicine, Buenos Aires University, Head of Internal Medical Department, Diego E. Thompson University Hospital, Buenos Aires, Argentina

**M** **Miguel Maito MBA**  
International Trade and Health Regulations Manager, Cilfa, Argentine Chamber of Pharmaceutical Laboratories, Argentina

**M** **Paula Márquez MD, PhD**  
Ministry of Health, Spain

**M** **John McEwen PSM, MBBS, MSc, MPS**  
Visiting Lecturer, Discipline of Pharmacy, University of Canberra, Australia

**M** **Ronald Meyboom MD, PhD**  
Uppsala Monitoring Centre, Sweden

**M** **Ghada Miremont-Salamé MD**  
Centre Régional de Pharmacovigilance; Inserm U 675; Université de Bordeaux; CHU Bordeaux; France

**M** **Aparna Mohan MD, PhD**  
Senior Director, Pharmacovigilance Analytics, Benefit Risk

Management, Johnson and Johnson, USA

**N** **Nicholas Moore MD, PhD, FRCP (Edin) FISPE**  
University Victor Segalen, Bordeaux, France and President of ISoP

**N** **Tomás Moraleda MD**  
MSSO (Maintenance Service and Support Organization for MedDRA) Spain

**N** **Myla Moretti MD, PhD**  
Assistant Director of the Motherisk Program, Toronto's Hospital for Sick Children, Toronto, Canada

**N** **Yola Moride PhD FISPE**  
Associate Professor, Faculty of Pharmacy, Université de Montréal, Canada

**N** **President of the International Society for Pharmacoepidemiology (ISPE)**

**O** **Charlotte van Noord MD**  
Erasmus MC, Dutch Medicines Evaluation Board, The Netherlands

**O** **Ismael Olmos Pharm,**  
Pharmacovigilance Unit Asociación Española Primera de Socorros Mutuos. Montevideo, Uruguay

**P** **Pietro Panei**  
Department of Drug Research and Evaluation, Italian National Institute of Health, Italy

**P** **Analia Pérez MD, PhD**  
Head of Medicines Evaluation Department, National Administration for Food, Drug and Medical Technology (ANMAT), Argentina

**P** **Corinne Pierfitte MD**  
Director, Medical Governance, GlaxoSmithKline Biologicals, Rixensart, Belgium

**P** **Marcelo Luis Ponte MD**  
Pharmacovigilance Unit, Pharmacology Chair, School of Medicine, National University of Buenos Aires, Argentina

**P** **Eugène van Puijenbroek MD, PhD**  
Head Scientific Department, Netherlands Pharmacovigilance Centre, 's-Hertogenbosch, The Netherlands

**R** **Michael Rawlins MD, PhD**  
Chairman of National Institute for Health and Clinical Excellence (NICE), United Kingdom

**R** **Adriano M. Moreira Reis MD**  
University of São Paulo at Ribeirão Preto, College of Nursing, Federal University of Minas Gerais, School of Pharmacy, Brazil

**R** **Eliana Rodrigues Biol Ph D**  
Preventive Medicine Department, Sao Paulo Federal University, Brazil

**R** **Rodolfo Rodriguez MD**  
Director of Córdoba Provincial Administration Health

Insurance (AProSS), Córdoba, Argentina

**S** **Klaus Rose MD, MS**  
Head of Pediatrics, Pharmaceutical Division Hoffmann La Roche, Switzerland

**S** **Marietta Rottenkolber Dipl. Stat.**  
Institute for Medical Informatic, Biometry and Epidemiology, Ludwig-Maximilians-Universitaet Munich, Germany

**S** **Francesco Salvo MD**  
Department of Clinical Experimental Medicine and Pharmacology, University of Messina, Italy

**S** **María José Sánchez Pharm**  
Head of National Programme of Detection of Illegitimate Medicines, INaMe, National Administration of Food, Drug and Medical Technology (ANMAT), Argentina

**S** **Martin Seoane MD**  
Sub-director of Drug Evaluation Department, National Administration of Food, Drug and Medical Technology (ANMAT), Argentina

**S** **Saad Shakir MB, ChB, LRCP&S, FRCP, FFPM, FISPE, MRCP**  
Director of Drug Safety Research Unit (DSRU), United Kingdom

**S** **Deborah Shaw MD, PhD**  
Guy's & St Thomas' NHS Foundation Trust, United Kingdom

**S** **Sven Schmiedl MD**  
HELIOS Klinikum Wuppertal, University Witten/Herdecke, Germany

**S** **Lavinia Schuler-Faccini MD, PhD**  
Rio Grande do Sul Federal University, Brazil

**S** **Peter Schulz MD**  
International Institute for the Safety of Medicines Ltd, Switzerland

**S** **Soud Skalli MD, PhD**  
Moroccan Pharmacovigilance Centre, Rabat, Morocco

**S** **Anders Sundström BA**  
Statistician and Pharmacoepidemiologist, Karolinska Institute, Sweden

**T** **Miguel W. Tregnaghi MD**  
President of Latin-American Pediatric Infectology Society's Clinical Investigation Committee; President of Centro de Desarrollo de Proyectos Avanzados (CEDEPAP), Córdoba, Argentina

**T** **Thierry Trenque MD, PhD**  
Pharmamacovigilance Regional Centre Reims, France

**T** **Gianluca Trifirò MD**  
IRCCS Centro Neurolesi "Bonino-Pulejo", Messina, Department of Clinical and Experimental Medicine and Pharmacology, Pharmacology Unit, University of Messina, Messina – Italy

**V** **Jan-Willem van der Velden MD**  
Sr. Vice President, Global Safety and Pharmacovigilance, Pharmed, Switzerland

**V** **Giampaolo Velo MD**  
University of Verona, Italy

**W** **Marjolein Willemsen PharmD**  
Utrecht Institute for Pharmaceutical Sciences (UIPS), Faculty of Science, Utrecht, The Netherlands, Medicines Evaluation Board, The Hague, The Netherlands

**W** **Anthony Wong MD, PhD**  
Ceatox, Sao Paulo, Brazil

