**ISoP 2009 Scientific Programme**

Venue: Centre des Congrès, Reims

**Wednesday, 7th October 2009**

**From 08.00**
- Registration

**09.00 - 09.45**
- **Welcome Opening Session**
  - Salle Clovis
  
  **N. Moore,** President of ISoP
  Université Victor Segalen, Bordeaux, France

  **T. Trenque,** Chairman, Local Committee
  Pharmacovigilance Regional Centre, Reims, France

  **J-P. Michelangeli,** Directeur Général CHU Reims
  France

  **J. Marimbert,** Directeur Général
  French Agency for the Safety of Health Products (AFSSaPS), Paris, France

**09.45 - 10.30**
- **Opening Plenary Lecture**
  - Salle Clovis

  **From Pharmacovigilance to Risk Management**
  
  **P. Arlett**
  Head of Sector Pharmacovigilance and Risk Management, European Medicines Agency (EMEA), UK

**10.30 - 11.00**
- Coffee-break / Poster viewing / Exhibition

**11.00 - 12h30**
- Parallel Sessions

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<tr>
<th>A. Pharmacovigilance challenges around the globe</th>
<th>B. Organ specific toxicity liver</th>
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Wednesday, 7th October 2009

A. Pharmacovigilance challenges around the globe

Co-Chairs:
P. Lechat
Director Evaluation of Drugs and Biologicals, AFSSaPS, France

R. Soulaymani
Director, Moroccan Pharmacovigilance Centre, Rabat, Morocco

11.00 - 11.20 Pharmacovigilance in India - the challenges and opportunities
P. Lalvani
Executive Director, O3i, RaPID Pharmacovigilance Program, Adjunct Professor of Practice, MIT-Zaragoza Program.

11.20 - 11.40 Harmonisation and consolidation of Pharmacovigilance and risk management systems in Latin America
A. Rosete
Head of Pharmacovigilance Institutional Center, Mexico

11.40 - 12.00 Pharmacovigilance in Africa - current state and future developments
A. Dodoo
Director, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, Accra, Ghana

12.00 - 12.20 From legislation to implementation: The challenge of taking regulation into day-to-day practice
R. Ferner
West Midlands Centre for Adverse Drug Reactions, City Hospital, Birmingham, UK

12.20 - 12.30 Discussion

B. Organ specific toxicity liver

Co-Chairs:
D. Larrey
Centre Hospitalier Universitaire, Montpellier, France

M. Avigan
Director Division of Pharmacovigilance, Center for Drug Evaluation and Research, FDA, USA

11.00 - 11.25 Drug-induced liver injury
D. Larrey
Centre Hospitalier Universitaire, Montpellier, France
Wednesday, 7th October 2009

11.25 - 11.50

**Drug-induced liver injury: Developments in the identification and characterization of risk**
M. Avigan
Director Division of Pharmacovigilance, Center for Drug Evaluation and Research, FDA, USA

11.50 - 12.05

**Hepatic adverse events associated with the use of herbal drugs in Norway (“the Fortodol case”)**
C.S. Nergård
RELIS Medicines Information Centres, Oslo, Norway

12.05 - 12.20

**Spontaneous reporting of hepatotoxicity: data from the Serbian Pharmacovigilance database**
M. Petronijevic
National Pharmacovigilance Centre, Medicines and Medical Devices Agency, Belgrade, Serbia

12.20 - 12.30

Discussion

12.30 - 13.15

Lunch / Poster viewing / Exhibition

13.15 - 14.00

ISoP General Assembly

14.00 - 15.30

Parallel Sessions

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<th>C. Risk Communication</th>
<th>D. New data sources and methods for signal detection and verification</th>
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**C. Risk Communication**

**Co-Chairs:**

G. Velo
University of Verona, Verona, Italy

A. Castot
Chef du Service de l'évaluation, de la surveillance du risque et de l'information sur le médicament, AFSSaPS, France

14.00 - 14.20

**Communication from regulatory authorities in the EU, current developments and challenges**
A. Castot
Chef du Service de l'évaluation, de la surveillance du risque et de l'information sur le médicament, AFSSaPS, France
Wednesday, 7th October 2009

14.20 - 14.40  Patients reporting of drug adverse reactions and cooperation with patient associations: a pilot study
H. Le Louet
Head Regional Pharmacovigilance Department, AP-HP, France

14.40 - 15.00  Risks of evidence based medicine and effective communication
M. Kouimtzi
Deputy Editor, British Medical Journal, UK

15.00 - 15.20  The media between alarmist headlines and confident declarations
F. Turone
Agency Zoe of Scientific Information, Milan, Italy

15.20 - 15.30  Discussion

D. New data sources and methods for signal detection and verification

Co-Chairs:
N. Norén
Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden

H. Fitt
Human Post-Authorisation Unit, European Medicines Agency (EMEA), UK

14.00 - 14.20  EMEA initiatives in the field of Pharmacoepidemiology: ENCePP and PROJECT
H. Fitt
Human Post-Authorisation Unit, European Medicines Agency (EMEA), UK

M. Lapeyre-Mestre
Centre Midi-Pyrénées de Pharmacovigilance, de Pharmacoépidémiologie, Toulouse, France

14.40 - 15.00  FDA's Sentinel Initiative
S. Iyasu
Director, Division of Epidemiology, Center for Drug Evaluation and Research, FDA, USA
### Wednesday, 7th October 2009

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| 15.00 - 15.20 | **A temporal association between prescriptions of antipsychotic drugs and pneumonia in electronic health records**  
|             | **K. Star**  
|             | Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden |
| 15.20 – 15.30 | **Discussion** |
| 15.30 - 16.15 | **Coffee-break / Poster viewing / Exhibition** |
| 16.15 - 17.45 | **Parallel Sessions** |
|              | **E. Pharmacovigilance and clinical trials**  
|              | **F. Improving the efficiency of Pharmacovigilance systems** |
|              | **Venue: Salle Clovis**  
|              | **Venue: Salle 1 & 2** |

### E. Pharmacovigilance and clinical trials

**Co-Chairs:**  
**S. Iyasu**  
Director, Division of Epidemiology, Center for Drug Evaluation and Research, FDA, USA  
**H. Le Louet**  
Head Regional Pharmacovigilance Department, AP-HP, France

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| 16.15 - 16.40 | **Post-approval clinical trials and meta-analysis in post-marketing safety surveillance and evaluation**  
|             | **S. Iyasu**  
|             | Director, Division of Epidemiology, Center for Drug Evaluation and Research, FDA, USA |
| 16.40 - 17.05 | **What information can provide Pharmacovigilance in non-commercial clinical trials to marketed drug safety profile?**  
|             | **H. Brocvielle**  
|             | Regional Pharmacovigilance Department, AP-HP, France |
| 17.05 - 17.30 | **Safety in clinical trials**  
|             | **A. Herpers**  
|             | EUQPPV, Boehringer Ingelheim Pharma, Germany |
| 17.30 - 17.45 | **Discussion** |
F. Improving the efficiency of Pharmacovigilance systems

Co-Chairs:
Y. Moride
Montreal University, Canada

S. Shakir
Director, Drug Safety Research Unit (DSRU), UK

16.15 - 16.35  Human factors affecting PSUR preparation
B. Edwards
Pharmacovigilance and Drug Safety, NDA regulatory Science Ltd, UK

G. Furlan
Corporate Drug Safety and Pharmacoepidemiology, Milan, Italy

16.35 - 16.55  A pharmaceutical collaborative initiative: an innovative approach to Risk mitigation strategies for a rare event: Progressive Multifocal Leukoencephalopathy
S. Banzet
F. Hoffmann-La Roche Ltd, Basel, Switzerland

16.55 - 17.15  Report processing and signal management at the Netherlands Pharmacovigilance Centre
E. Van Puijenbroek
Netherlands Pharmacovigilance Centre Lareb, Netherlands

17.15 - 17.25  How improve the reporting of Adverse Drug Reactions from hospitals: the performance of the French PharmacoMIP Network over a two-year period
H. Bagheri
Centre Midi-Pyrénées de Pharmacovigilance, de Pharmacopédiémiologie, Toulouse, France

P. Barrow
Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

17.30 - 17.45 Discussion

18.30  Welcome Reception
"Hôtel de Ville" (Reims Town Hall)

20.00  ISoP Executive Committee Meeting
Hôtel Continental
Thursday, 8th October 2009

09.00 - 10.30 Plenary session (Salle Clovis)

Regulatory initiatives with a global impact

Co-Chairs:
J. Raine
Director, Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

C. Kreft-Jaïs
Head of Pharmacovigilance Department, AFSSaPS, France

09.00 - 09.25 Regulatory Initiatives - when risk benefit balance is in question
J. Raine
Director, Vigilance and Risk Management of Medicines, Medicines and Healthcare products Regulatory Agency (MHRA), UK

09.25 - 09.50 Risk management initiatives - with a focus on HIV medicines
C. Kreft-Jaïs
Head of Pharmacovigilance Department, AFSSaPS, France

09.50 - 10.15 Risk minimisation and the challenge of biological medicines
S. Straus
Head of Pharmacovigilance Department at the Medicines Evaluation Board (MEB), Netherlands

10.15 - 10.30 Discussion

10.30 - 11h00 Coffee-break / Poster viewing / Exhibition

11.00 - 12.30 Plenary Session / Symposium Satellite

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<th>H. Satellite Symposium</th>
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<td>Prediction and prevention of ADRs</td>
<td>ISoP Swiss chapter</td>
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G. Plenary Session
Prediction and prevention of ADRs

Co-Chairs:
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<td>11.00 - 11.20</td>
<td>Pharmacogenomic biomarkers for prediction of drug induced hypersensitivity</td>
<td>A. Alfirevic</td>
<td>University of Liverpool, Department of Pharmacology and Therapeutics, UK</td>
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<td>11.20 - 11.35</td>
<td>Risk of oxatomide overdose in children in Italy</td>
<td>M. Venegoni</td>
<td>Italian Medicines Agency, Italy</td>
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<td>11.35 - 11.50</td>
<td>The relationship between baseline testing of serum electrolytes and creatinine and adverse outcomes in patients treated with antihypertensive drugs: an analysis using propensity score matching methods</td>
<td>S. McDowell</td>
<td>West Midlands Centre for Adverse Drug Reactions, City Hospital, Birmingham, UK</td>
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<tr>
<td>11.50 - 12.05</td>
<td>Pregnancy outcome in women exposed to atypical antipsychotics</td>
<td>T. Vial</td>
<td>Head Regional Pharmacovigilance Centre, Lyon, France</td>
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<tr>
<td>12.05 - 12.20</td>
<td>A prescription protocol to prevent intravenous immunoglobulin related serious adverse drug reaction</td>
<td>M. Grenouillet-Delacre</td>
<td>Université Victor Segalen, Bordeaux, France</td>
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<td>12.20 - 12.30</td>
<td>Discussion</td>
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Thursday, 8th October 2009

11.00 - 11.15  Evaluation of medication safety in medical in patients with three different prescription support solutions
               S. Russmann
               University Hospital Zurich, Zurich, Switzerland

11.15 - 11.30  Pharmacovigilance and drug consultation for health professionals: long-term experience at the Division of Clinical Pharmacology and Toxicology in Zurich, Switzerland
               M. Huber
               University Hospital Zurich, Zurich, Switzerland

11.30 - 11.45  Pharmacovigilance of over-the-counter products in community pharmacies: pilot study conducted in the canton of Zürich, Switzerland
               K. Hartmann
               Institute of Pharmaceutical Sciences, Zürich, Switzerland

11.45 - 12.00  Semantic interoperability and standardization enable an integrated evaluation of safety data"  
               J.W. van der Velden
               International Institute for the safety of Medicines, Basel, Switzerland

12.00 - 12.15  Drug interactions programs: clinician’s needs and program’s realities"
               E. Jaquenoud Sirot
               Klinik Königsfelden, Brugg, Switzerland

12.15 - 12.30  Discussion

12.30 - 13.15  Lunch

13.15 - 14.30  Poster Sessions

14.30 - 16.00  Parallel Sessions

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<th>I. Pharmacovigilance for vaccines</th>
<th>J. Undesirable psychiatric and behavioural effects of medications</th>
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I. Pharmacovigilance for vaccines

Co-Chairs:
Thursday, 8th October 2009

A. Dodoo
Director, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, Accra, Ghana

C. Pierfitte
Medical Governance Operations and Compliance, GlaxoSmithKline Biologicals, Brussels, Belgium

14.30 - 14.40  Post-marketing surveillance with new vaccine introduction - what have we learnt and what is working?
A. Bentsi-Enchill
WHO, Global Vaccine Safety group, Geneva, Switzerland

14.40 - 15.00  Adverse Events Following Immunization in the UMC adverse reaction database
J. Labadie
Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden

15.00 - 15.20  Managing Safety Signals Associated to Manufacturing in GlaxoSmithKline Biologicals
Z. Zeinoun
GlaxoSmithKline Biologicals, Belgium

15.20 - 15.35  Can rigorous vaccine safety studies be conducted in resource-poor countries during a pandemic?
A. Dodoo
Director, Centre for Tropical Clinical Pharmacology & Therapeutics, University of Ghana Medical School, Accra, Ghana

15.35 - 15.45  Pharmacovigilance study on diphtheria, tetanus and pertussis (dtp) based Combination vaccines (dtwp-hib and dtwp-hib-hepb) in asian indian paediatric population
M. Sharma
B.R. Nahata College of Pharmacy, Mandsaur, India

15.45 - 15.55  Haematological reactions by vaccines: data from the italian spontaneous reporting system
A Conforti
University of Verona, Italy

15.55 - 16.15  Discussion

J. Undesirable psychiatric and behavioural effects of medications

Co-Chairs:
K. Van Grootheest
Director, Netherlands Pharmacovigilance Centre Lareb, Netherlands

J-L. Montastruc
Université de Toulouse, Faculté de Médecine, Toulouse, France
Thursday, 8th October 2009

14.30 - 14.40 Introduction: psychiatric drugs in discussion
K. Van Grootheest
Director, Netherlands Pharmacovigilance Centre Lareb, Netherlands

14.40 - 15.00 Suicidality Issues Across Indications: Outcomes, Safety Evaluation, and Regulatory Concerns and Solutions
K. Posner
Columbia University/New York State Psychiatric Institute, USA

15.00 - 15.20 Drugs and violence
J-L. Montastruc
Université de Toulouse, Faculté de Médecine, Toulouse, France

15.20 - 15.35 Depressive episodes reported during a modified prescription event monitoring study for rimonabant
Y. Buggy
Research Fellow, Drug Safety Research Unit (DSRU), UK

15.35 - 15.50 Novel biomarkers of drug safety related to drug-induced neuropsychiatric adverse drug events including drug-induced suicidality
F. Allemand
Biocortech, France

15.50 - 16.00 Discussion

16.00 - 16.30 Coffee-break / Poster viewing / Exhibition

16.30 - 18.00 Parallel Sessions

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<th>K. Counterfeit Medicines</th>
<th>L. Hot topics (safety of biological products)</th>
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K. Counterfeit Medicines

Co-Chairs:
L. Alesso
Director Pharmacovigilance Center, Córdoba National University, Argentina

K. Hartigan-Go
The Zuellig Foundation, Manila, Philippines
**Thursday, 8th October 2009**

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| 16.30 - 16.50 | Combating counterfeit medicines  
L. Leclair  
Service National de Douane Judiciaire (Customs Directorate), Paris, France |
| 16.50 - 17.10 | The Pharmacovigilance of counterfeit medicines: Thai perspectives  
W. Suwankedawong  
Health Product Vigilance Centre, Thai FDA, Thailand |
| 17.10 - 17.30 | Anticounterfeiting - a constant challenge for legislators and industry  
T. Zimmer  
Chair Anticounterfeiting ad hoc group, European Federation of Pharmaceutical Industries and Association (EFPIA), Germany |
| 17.30 - 17.50 | Counterfeit medicines: a new kind of Russian Roulette  
M. Kaltenbach  
Faculté de Pharmacie, Université de Reims, France |
| 17.50 - 18.00 | Discussion |

**L. Hot Topics (Safety of biological products)**

*Co-chairs:*  
A. Pariente  
Université Victor Segalen, Bordeaux, France  
M.-C. Perault-Pochat  
Head Regional Pharmacovigilance Centre, Poitiers, France

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| 16.30 - 16.50 | New targets in rheumatoid arthritis  
P. Gillet  
Université de Nancy, France |
| 16.50 - 17.05 | Unravelling the safety profile of biologicals using post-marketing safety data  
T. Giezen  
Utrecht University, Netherlands |
| 17.05 - 17.20 | Challenges with continuity of pharmacovigilance systems during transfer of marketing authorizations and company mergers and buy-outs  
D. McCarthy  
Quintiles Ireland Ltd, Dublin, Ireland |
| 17.20 - 17.35 | Do adverse drug reaction reports differ between consumers and healthcare professionals?  
D. McLernon  
University of Aberdeen, UK |
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| 17.35 - 17.50 | Progressive multifocal leukoencephalopathy: a survey on HIV-negative patients with Non-Hodgkin’s lymphoma receiving rituximab  
M. Tuccori  
University of Pisa, Italy |
| 17.50 - 18.05 | The cardiovascular risk of sulfonylureas on newly diagnosed type II diabetes mellitus patients  
C-S. Gau  
Deputy Executive Director, Centre for Drug Evaluation, Taipei, Taiwan |
| 19.30 - Midnight | Gala dinner |
| 09.00 - 10.15 | Lecture + round table discussion  
Salle Clovis  
Ethical considerations in pharmacovigilance  
Co-Chairs:  
R. Edwards  
Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, Sweden  
L. Radoilska  
Faculty of Philosophy, University of Cambridge, UK |
| 10.15 - 10.45 | Coffee-break / Poster viewing / Exhibition |
| 10.45 – 12.00 | Plenary Sessions  
Salle Clovis  
Implications of personalised medicine |
Friday, 9th October 2009

**Co-Chairs:**

D. Singer  
University of Warwick, Clinical Pharmacology and Therapeutics, UK

U. Hagemann  
Head of Pharmacovigilance Department, Federal Institute for Drugs and Medical Devices, BfArM, Germany

10.45 - 11.15  **Virtual clinics as an approach to pharmacovigilance**  
D. Singer  
University of Warwick, Clinical Pharmacology and Therapeutics, UK

11.15 - 11.30  **Antitubercular drug induced hepatotoxicity and MDR1 C3435T polymorphism: a case control study**  
S. Chatterjee  
Department of Pharmacology, IPGMER, Kolkata, India

11.30 - 11.40  **Analysis of NAT2 Acetylation genotype and phenotype in children under isoniazid treatment in Argentine**  
M. Ponte  
Pharmacovigilance Unit, National University of Buenos Aires, Argentina

11.40 - 11.50  **Assessments of risk factors of bleeding due to oral anticoagulant treatment: a prospective study in patients with an INR > 5.5 admitted to the Amiens University Hospital**  
V. Gras  
Regional Pharmacovigilance Centre, Amiens, France

11.50 - 12.00  **Discussion**

12.00 - 12.45  **Bengt-Erik Wiholm Lecture**  
“Drug regulation: a decision under uncertainty. A tribute to Bengt-Erik Wiholm”  
B. Begaud  
Université Victor Segalen, Bordeaux, France

12.45 - 14.00  **Lunch**

14.00 - 15.30  **Poster Prize Awards**

**Presentation for ISoP 2010**  
A. Dodoo, Ghana

**Closing Ceremony of ISoP 2009**  
T. Trenque, France