International Society of Pharmacovigilance

Science and Regulation. Is this compatible?
Assessment and Management of Drug liver toxicity and copying with Audits and Inspections
Training Course, 2nd and 3rd February 2006, Sevilla

Venue: *the Hospital Virgen del Rocio*, Pabellon Docente, Avenida Manuel Siurot s/n 41013 Sevilla- Spain

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These two study-days, combining presentations from well-known experts in the field, panel discussion and questions among the group of delegates, will explore (during the first day) current debate and controversy in the area of liver toxicity, proposing models and patterns to avoid such an important medical condition caused by drug; and during the second day a whole dedicated panel will review the most update knowledge on Auditing and Inspection in pharmacovigilance: sharing best practices for shifting the quality in pharmacovigilance and Drug Safety.

Day 1: Thursday, 2 February

Chairpersons: *Paula Marquez Padorno and Giampaolo Velo*

Registration	8.30 - 9.00
Introduction How previous ISoP Training courses paved the way to this seminar and what we would like to achieve *Paula Marquez Padorno* *Giampaolo Velo, University of Verona*	9.00 - 9.15
Typology of hepatic ADRs *Jürgen Beckmann, University of Rostock*	9.15 – 10.00
Causality assessment with hepatic ADRs *Felix Stickel, University of Berne*	10.00 – 10.45
Coffee-break	10.45 - 11.15
Impact of drug induced hepatotoxicity in medical practice HepaTox: a Spanish Network *Mª Isabel Lucena, Hospital Virgen de la Victoria, Málaga*	11.15 - 12.00
A practical approach to one case of drug liver toxicity (I) *All attendees will work in separate groups to evaluate 3 to 5 different cases to be discussed* Discussion	12.00 - 13.30
Lunch	13.30 - 14.30
A practical approach to one case of drug liver toxicity (II): Lessons learnt	14.30 - 15.30
Genomic approaches to the prediction *of drug-induced hepatotoxicity* pharmacogenomics in hepatotoxicity: *Dangerous drug or susceptible patients* *Juan Ramon Castillo, Andaluz Centre of Pharmacovigilance* *NN*	15.30 - 16.30

Coffee-break 16.30 – 17.00

Detecting and assessing drug liver toxicity:
State of the art
Mechanisms of drug induced hepatotoxicity 17.00 – 18.00
Saad Shakir, DSRU

Discussion and
Close of Day 1 18.00 - 18.30
A short take-home-message of the first day
Paula Marquez Padorno

Day 2: Friday, 3 February

Chairpersons: Paula Marquez, Corinne Pierfitte, Amer Alghabban

Welcome to Day 2, Introduction 9.00 - 9.15
Paula Marquez
Juan Ramon Castillo, Andaluz Centre of Pharmacovigilance

Enlarging the concept of surveillance: 9.15 –10.00
- Haemo-Products Surveillance
- Medical Devices Surveillance
- Vaccine vigilance

Elisabeth Loupi, Sanofi Pasteur
Irene Rebollo. Alcon S.A
Rudolf Schosser, Baxter

Pharmacovigilance inspections:
State of Art (EU perspective) 10.00 - 10.45
Fergus Sweeney, EMEA

Coffee-break 10.45 - 11.15

Preparing for a pharmacovigilance inspection: 11.15 -12.45
A guide for survival
Practical approach
Amer Alghabban, Pharmaceutical Research Associates
Iain Cockburn, CCSL (Industry perspectives)

Lunch 13.00 - 14.30

How to survive a pharmacovigilance inspection 14.30 – 15.15
Vicki R Edwards, Abbott Laboratories

Coffee-break 15.15 - 15.45

One example of management of remediation plan
Corinne Pierfitte, GSK Biologicals 15.45 - 16.15

Discussion 16.15 - 17.00
and
Closing remarks