SECOND COURSE
MEDICAL ADRs: FROM FIRST CASE TO REGULATORY ACTION

6 -8 May 2014
Hotel NH Nacional, Madrid

Course Overview

The assessment, management and investigation of potential ADRs identified through single case reports require a basic understanding of clinical medicine and pharmacology.

The course focuses on acquiring and using the knowledge of mechanisms, clinical features, diagnosis and the clinical investigation and management of major ADRs to correctly identify, classify, investigate, assess causality, conduct appropriate studies to establish causality and act accordingly. (This is NOT a course about case processing or regulations).

The course will also help to assess the probability that a drug may have played a role in the occurrence of an adverse event.

The medical approach presented during this training course is based on the experience and expertise of a facility of European clinicians and pharmacovigilance experts involved with adverse drug reactions and experience of the EMA.

Learning Objectives

At the conclusion of this training course participants should be able to:

- Understand the mechanisms, clinical patterns, and clinical investigation and management of serious ADRs in major organ systems.
- Understand the practical usefulness of EIDOS/DoTS compared with the type A-E system to assess ADRs for evaluating, classifying and assessing causality of individual ADRs - from its inventor.
- Feel confident about interpreting cases through practice with clinical case histories and feedback.
- Learn from past ADRs how to investigate and manage ADRs from first case report to regulatory actions.

Who Should Attend

People working in Pharmacovigilance, Epidemiologists working in safety, Medical Affairs, Investigators and all healthcare professionals involved in the monitoring and assessment of pre- and post-marketed adverse drug reactions. Certificates of Attendance will be distributed at the end of the course.

Language

English

Organiser

OXON Epidemiology, Madrid & London

6th May 2014 - Day 1:

09.15 – 09.30	**Welcome and Introduction**
09.30 – 10.30	**Keynote Lecture: Classifying adverse drug reactions - relevance to pharmacovigilance** ***Professor Jeffrey Aronson**, Reader in Clinical Pharmacology, Oxford University & a past Editor-in-Chief of the British Journal of Clinical Pharmacology*
10.30 – 11.30	**Immune basis of drug hypersensitivity** ***Dr. Carlos Blanco**, Head, Department of Allergy, University Hospital La Princesa, Madrid*
11.30 – 11.45	**Coffee**
11.45 – 12.45	**Dermatological ADRs** *Speaker to be confirmed*
12.45 – 13.45	**Haematological ADRs** *Speaker to be confirmed*
13.45 – 14.30	**Lunch**
14.30 – 15.30	**Hepatic ADRs** ***Professor Raúl J. Andrade Bellido**, Head, Department of Hepatology, University Hospital Virgen de La Victoria, Málaga*
15.30 – 16.30	**Cardiac ADRs** ***Professor Jeffrey Aronson**, Reader in Clinical Pharmacology, Oxford University & Honorary Consultant Physician, John Radcliffe Hospital, Oxford*
16.30 – 17.30	**Practical interactive session with case histories**
17.30 – 17.45	**Review of Day 1**

7th May 2014 - Day 2:

9.15 – 10.15	**Keynote Lecture: Diagnosis and management of ADRs** ***Professor Ralph Edwards**, Former Director of the WHO Monitoring Centre, Uppsala & Past President, International Society of Pharmacovigilance*
10.15 – 10.45	**Reporting ADRs in observational studies of 'real world' clinical practice** ***Marta Mariño Negron**, Pharmacovigilance Director at OXON, Madrid & Former Head of PV, Schering Plough, Spain, 1985-2010*
10.45 – 11.45	**ADR databases** ***Dr. Nawab Qizilbash**, Head of OXON & Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene and Tropical Medicine*
11.45 – 12.00	**Coffee**
12.00 – 13.00	**Neuro-psychiatric ADRs** ***Dr. Jesús López Arrieta**, Head of Geriatrics, University Hospital La Paz-Cantoblanco, Madrid*
13.00 – 14.00	**Vaccine-related ADRs** *Speaker to be confirmed*
14.00 – 14.45	**Lunch**
14.45 – 15.45	**Gastrointestinal ADRs** ***Professor Agustín Albillos**, Professor of Gastroenterology, University of Alcalá, Madrid*
15.45 – 16.45	**Practical interactive session with case histories**
16.45 – 17.00	**Review of Day 2**

8th May 2014 - Day 3:

9.15 – 10.15	**Post-marketing risk management** ***Professor Jeffrey Aronson**, Reader in Clinical Pharmacology, Oxford University & President Emeritus, British Pharmacological Society*
10.15 – 11.15	**Study Designs to Assess Causality Following ADR Reports** ***Dr. Nawab Qizilbash**, Head of OXON & Honorary Senior Lecturer in Pharmacoepidemiology, London School of Hygiene and Tropical Medicine*
11.15 – 11.30	**Coffee**
11.30 – 12.30	**Benefit-Risk Assessment** ***Andy Maguire**, Director of Epidemiology, OXON, London & Pharmacoepidemiology Department, Alcala University, Madrid*
12.30 – 13.30	**Renal ADRs** ***Dr. José Luño Fernández**, Head, Department of Nephrology, University Hospital Gregorio Marañón, Madrid*
13.30 – 14.15	**Lunch**
14.15 – 15.15	**Ophthalmological ADRs** **Dr. Francisco J Muñoz Negrete**, *Head, Department of Ophthalmology Hospital Ramón y Cajal, Madrid*
15.15 – 16.15	**ADRs in Pregnancy** **Dr. Javier Plaza Arranz**, *Head, Department of Gynecology & Obstetrics, Fundación Jiménez Díaz, Madrid*
16.15 – 17.15	**Practical interactive session with case histories**
17.15 – 17.30	**Review of Course**