

BACK TO BASICS IN PHARMACOVIGILANCE

Solent Hotel, Whiteley, near Fareham

5 – 6 SEPTEMBER 2012

PROGRAMME – Wednesday 5 September 2012

- 0845 – 0915** **Registration for delegates**
- 0915 - 0930** **Welcome and introduction to the course**
- 0930 - 1045** **Definitions, History, Classifications of ADRs, Basic Principles of Pharmacovigilance [DSS 1, 3]**
Teaching objectives: To revise founding principles of pharmacovigilance. To make sure all course members are familiar with current ICH and regulatory basic definitions and be aware of change during interpretation both in the EU and USA. To provide an illustration of simple causality assessment, the principles behind current spontaneous reporting systems, and the logic behind pharmacovigilance planning (ICHE2E).
◊ *Definition of pharmacovigilance* ◊ *History of pharmacovigilance* ◊ *Operational definitions (serious, non-serious, expected, unexpected)* ◊ *Classification of ADRs* ◊ *Basic causality assessment* ◊ *Characteristics of different systems of reporting* ◊ *Strengths* ◊ *Weaknesses* ◊ *Definitions Medication errors, off-label, overdose, misuse*
- 1045 - 1100** **Coffee**
- 1100 - 1245** **Interactive session - History of pharmacovigilance [DSS 1]**
◊ *Case study: SSRIs / Coxibs / Praxolol*
- 1245 - 1345** **Lunch**
- 1345 - 1415** **Ethics and transparency in pharmacovigilance [DSS 1]**
Teaching objectives: To consider relevant ethical principles from an individual and societal point of view and outline the available ethical safeguards. To provide an understanding of main issues relating to transparency in pharmacovigilance i.e. availability of data and information about processes, and conflicts of interest.
- 1415 - 1500** **International collaboration in pharmacovigilance Part I [DSS 1,2, 3, 4]**
Teaching objectives: To achieve an understanding of the need for global pharmacovigilance and in particular for standardisation of collection and monitoring of data and the principles of risk benefit analysis.
◊ *Review of the structure of ICH and how guidelines are developed (ICHE2BM, ICH E2C (PSURs), ICH E6 (GCP), ICH E3 (reporting standards))* ◊ *CIOMS – outlines of: I, II and V (spontaneous reporting, CCSI, DCSI); IV (risk benefit assessment) and VI (clinical trials)* ◊ *Aggregate reports PSURs/DSURs* ◊ *PILs*
- 1500 - 1515** **Tea**
- 1515 - 1600** **International collaboration in pharmacovigilance Part II [DSS 1, 2, 3, 4]**
Teaching objectives: To achieve an understanding of the need for global pharmacovigilance and in particular for standardisation of collection and monitoring of data and the principles of risk benefit analysis.
◊ *Review of the structure of ICH and how guidelines are developed (ICHE2BM, ICH E2C (PSURs), ICH E6 (GCP), ICH E3 (reporting standards))* ◊ *CIOMS – outlines of: I, II and V (spontaneous reporting, CCSI, DCSI); IV (risk benefit assessment) and VI (clinical trials)* ◊ *Aggregate reports PSURs/DSURs* ◊ *PILs*

- 1600 - 1615** **Discussion**
- 1615 – 1645** **DSMBs - their history, structure, procedures, functions and possible roles [DSS 1, 4]**
Teaching objectives: To provide an insight into the function and challenges of DSMBs
- 1645 - 1800** **HMT/PMST/Postgraduate Students ONLY are requested to meet the assessor to discuss the pre-course assignment for this course**
- 1900** **Complimentary course dinner**

BACK TO BASICS IN PHARMACOVIGILANCE

Solent Hotel, Whiteley, near Fareham

5 – 6 SEPTEMBER 2012

PROGRAMME – Thursday 6 September 2012

0845 – 0900

Registration for delegates

0900 - 0945

Regulatory aspects of pharmacovigilance I [DSS 1, 2, 4]

Teaching objectives: To provide an understanding of the legal principles of pharmacovigilance through the enactment of EU and US legislation directly for pharmaceuticals.

◊ *Clinical trials Directive* ◊ *FDA (roles and responsibilities of therapeutic diagnoses, epidemiology group, Medwatch and AERS)* ◊ *FDA guidelines, points to consider and PDUFA III*

0945 - 1030

Regulatory aspects of pharmacovigilance - II [DSS 1, 2, 4]

Teaching objectives: To provide an understanding of the legal principles of pharmacovigilance and the enactment of European legislation directly for pharmaceuticals.

◊ *Legal basis of pharmacovigilance* ◊ *Roles of MHRA, CSM, EMA, CHMP, PhWP* ◊ *Relevant Guidelines*

1030 - 1045

Coffee

1045 - 1130

Pre-marketing safety monitoring and evaluation - I [DSS 1, 2, 3]

Teaching objectives: To achieve an understanding of the approach to developing the safety data base on which the risk benefit evaluation of a new medicinal product will be based.

◊ *Principles of risk benefit safety assessment within a clinical development plan* ◊ *Preclinical safety assessment* ◊ *Phase I* ◊ *Phase II* ◊ *Phase III*

1130 - 1215

Pre-marketing safety monitoring and evaluation - II [DSS 1, 2]

Teaching objectives: To achieve an understanding of the differences of pharmacovigilance reporting in clinical trials and especially pre-registration.

◊ *Clinical trials directive requirements* ◊ *US PDUFA III aspects of safety monitoring* ◊ *High mortality clinical trials* ◊ *DSMBs* ◊ *DCSIs and the concept of expectedness*

1215 - 1300

Practical aspects of signal detection [DSS 1, 3]

Teaching objectives: To understand how pharmaceutical companies approach signal detection and management, and the resources available to them.

▪ *Handling of signals in Pharmaceutical Companies* ▪ *Pre-licensing vs post-licensing issues* ▪ *Systems and software for detecting signals* ▪ *Regulatory interactions* ▪ *Interface between signals and risk-management strategies* ▪ *Coding systems for drug safety*

1300 - 1345

Lunch

1345 - 1515

Interactive session - Reporting adverse drug reactions [DSS 1, 2]

Teaching objectives: To give examples of the previous two sessions to reinforce the teaching principles.

1515 - 1530

Tea

1530 – 1615

New developments in pharmacovigilance [DSS 1, 3, 4, 8]

Teaching objectives:

◊ *New Methods for detection and prioritisation of signals derived from spontaneous ADR reports*
◊ *ICHE2E and Risk management planning* ◊ *Future directions* ◊

1615 – 1700

Impact of Adverse Drug Reactions [DSS 8]

Speaker: Prof Saad Shakir

Teaching objectives: To understand how patients, carers and the public understand risk benefit and perceive pharmacovigilance. To illustrate pharmaceutical obligations.

◊ *Informed consent* ◊ *PILs, provision of information* ◊ *When things go wrong* ◊ *Consumer groups* ◊ *Impact of media*

1700

Close of course