

PHARMACOVIGILANCE AUDITS & INSPECTIONS MANAGEMENT

11th-12th September 2014 Budapest, Mercure Budapest Korona****

COURSE LEADER:

Graeme Ladds, Managing Director, Pharsafer, UK
Graeme has dedicated more than 21 years of expertise to drug safety issues. A visionary leader, Mr. Ladds is the chief executive officer and director of pharmacovigilance for PharSafer Associates Ltd.; a leading specialist company providing global clinical and post-marketing drug safety. Prior to forming PharSafer Associates Ltd, he was the head of global drug safety for a multinational pharmaceutical company. In his position, he is responsible for protecting patients, ensuring that processes are in place and data is documented properly. He reports to 80 countries around the world and addresses issues related to adverse reactions. Mr. Ladds has written a modular book on multinational pharmacovigilance, has written many articles on pharmacovigilance in peer-reviewed journals, and shares his industry knowledge through conducting numerous speaking engagements.

Mr. Ladds earned a Ph.D. in drug metabolism from the University of Hertfordshire and a Bachelor of Science in biochemistry and pharmacology from the University of Hertfordshire. He is affiliated with the Drug Information Association and Special Interest Group for Drug Safety.

BENEFITS OF ATTENDING

- **Understand** the Purpose and Requirements of Pharmacovigilance Audits
- **Discuss** the Scope and Content of the Audit Report
- **Prepare** your Audit Corrective Action Plans
- **Understand** the Conduct of a Regulatory Inspection
- **Learn** Practical Tips on how to Prepare for an Inspection
- **Discuss** Common Findings from Regulatory Inspections

WHO SHOULD ATTEND?

This MasterClass is relevant for those working in all areas of Drug Safety and PhV as Medical Information, Regulatory Affairs, QA and Compliance.

COURSE INTRODUCTION

This course will teach you how to prepare for an audit / inspection from the time of the receipt of the announcement to the conclusion of the audit or inspection.

Every pharmacovigilance function is subject of health authority inspections as well as audits by partners, internal auditors. There is a level of expectation from both the Regulators and Industry on understanding what is required as a responsible licence holder. Companies need to ensure that all products are managed properly in terms of the collection, assessment and reporting of adverse reactions. Serious safety issues can be identified early and acted quickly to protect patients.

The aim of this course is that through both a practical review of the purpose of internal audits to assess a companies current systems and understand potential pitfalls, there is also a review of the current regulatory attitudes and mechanisms for Inspections, the level of findings and penalties which are facing pharma companies – both big and small; innovator and generic and within the EU and globally

SESSION TOPICS:

- **The Audit Basics**
- **Quality Management**
- **The Legislation and Audits**
- **The Audit & Report**
- **Practical Exercise**
- **The Audit Cycle**
- **Introduction & History of PV Inspection**
- **Risk Based Inspections**
- **The Pharmacovigilance Inspection Cycle**
- **Practical Exercise**
- **Common Findings from Regulatory Inspections**
- **Final Discussion**

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09.00 Welcome & Introductions

The Audit Basics

- The purpose of an Audit
- Qualifications of the Auditor
- The Audit SOP & design
- The difference between Audits and Inspections

Quality Management

- Quality Planning
- Quality Systems
- Quality Cycles
- Quality Risk Assessments
- The Quality Risk Assessment

10.45 Coffee and refreshments

11.15 The Legislation and Audits

- The requirements to perform Company Audits
- In-house versus external audits
- What needs to be audited
- Which Departments need auditing for Safety

12.30 Lunch

13.30 The Audit & Report

- The Audit scope and conduct
- The Audit Report content
- The grading of Audit Reports
- Corrective Action Plans (Root Cause Analysis)
- Re-Audits

Practical Exercise

You will be provided with information concerning a Safety Department you have been asked to audit. The Safety Department in question is the Company Headquarters Safety Department based in the EU. You will be asked to devise an audit plan based upon any risk elements you have identified and will also set up what document requests they may make ahead of the audit.

15.15 Coffee and refreshments

15.35 Continuation of Practical Exercise

The Audit Cycle

- Audit Frequencies
- Routine and For Cause audits
- Audits and legislation changes
- Company versus Distributor audits
- Audits and Inspection findings

17.00 Close of the day

08.30 Opening day two

Introduction & History of PV Inspection

- Background
- Purpose
- Roles and responsibilities of the licence holder
- Conduct of Regulatory Inspections

Risk Based Inspections

- Defining Risk
- Routine and For Cause Inspections
- Triggers for an Inspection
- Who should attend the Inspection

10.30 Coffee and refreshments

11.00 The Pharmacovigilance Inspection Cycle

- Pre-Inspection Questionnaires
- Site visits & telephone audits
- Results and CAPAs
- Inspection follow up Questionnaires
- Follow up Inspections

Practical Exercise

You will be presented with a series of findings from a Regulatory Inspection. You will have to look at the findings and work out priorities, devise root cause analysis and provide detailed corrective actions

13.00 Lunch

14.00 Continuation of Practical Exercise

Common Findings from Regulatory Inspections

- Grades of findings
- How to grade findings in the same PV area
- Allied findings
- Variations in Major Authority Inspections

Final Discussion

15.30 Close of the meeting and farewell coffee

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REGISTRATION FORM

ORGANIZATION.....
VAT NUMBER

Compulsory for EU members

ADDRESS

CITY

COUNTRY

NAME.....
TITLE

JOB TITLE

EMAIL.....

PHONE

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PHONE

AUTHORIZATION

ACCEPTANCE OF TERMS AND CONDITIONS

NAME.....
DATE

MOBILE.....

SIGNATURE

Please sign it here

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