Course Overview

This is a basic overview course, intended for individuals who have limited experience in pharmacovigilance/drug safety monitoring. The focus will be on pharmacovigilance with traditional medicinal products, both investigational and marketed intended for human use in clinical trials, in post-marketing studies, and in the healthcare setting following product launch.

Who Will Attend - Beginner Level

Individuals with limited experience in the clinical safety/pharmacovigilance area. Those from the pharmaceutical industry, academia, regulatory authorities. Medical writers, marketing personnel, and those who need an overview of clinical safety and may interact with members of those departments.

Learning Objectives

At the conclusion of this course, the participants should be able to:
• Identify the history, the principles and regulatory framework for clinical safety/pharmacovigilance
• Discuss the basic definitions of terms used in day-to-day work
• Recognise EU, US and international safety surveillance regulatory requirements
• Describe the criteria and elements of expedited and periodic reporting of drug safety from phase I studies to post-marketing
• Demonstrate an awareness of risk management and pharmacoepidemiology

Key Topics

• Legal basis for safety reporting including a historical perspective
• Basic definitions and tools
• Data collection and processing in post-marketing phase
• Medical evaluation
• Safety reporting requirements in pre-marketing phase
• A workshop and practical exercises
• Safety reporting requirements in the post-marketing phase
• An introduction to risk communication
• Inspections in pharmacovigilance
• Introduction to risk management, epidemiological methods for signal detection and risk assessment

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 17.5 credits.
MONDAY | 16 MAY 2011

08:00  Registration

08:45  INTRODUCTION AND OVERVIEW

09:00  Session 1

LEGAL BASIS FOR SAFETY REPORTING INCLUDING A HISTORICAL PERSPECTIVE

The course starts with a concise overview of the history, the principles and the regulatory framework for pharmacovigilance. It includes an introduction to the mechanisms of international consensus building through the International Conference on Harmonisation (ICH) and Council for International Organization of Medical Sciences (CIOMS) working groups, as well as major trends in development of underlying technology and science.

Gaby Danan, Pharmacovigilance Expert, France

10:30  COFFEE BREAK

11:00  Session 2

BASIC PRINCIPLES, DEFINITIONS AND TOOLS

The second session features an introduction to safety data collected from clinical trials phases I to IV, definitions, reporting tools, adverse event processing and reporting requirements and how to collate the data for signal detection and safety monitoring.

Gaby Danan, Pharmacovigilance Expert, France

12:30  LUNCH

13:30  Session 3

POST-MARKETING SAFETY DATA (WITH AN INTRODUCTION TO MedDRA)

The third session (a) Explains the basics of data collection, processing, and reporting that pertain to Individual Case Safety Reports after a product is marketed; (b) Discusses the foundation for reporting aggregate safety data in the post-marketing phase; and (c) Describes the classification and analysis of medical concepts using MedDRA, the Medical Dictionary for Regulatory Activities.

William Gregory, Pfizer, USA

15:00  COFFEE BREAK

15:30  Session 4

MEDICAL EVALUATION OF ADVERSE EVENTS

The principles of the medical evaluation of single adverse event cases, things to consider and methods used.

Gaby Danan, Pharmacovigilance Expert, France

16:30  EXERCISES & CASE STUDIES

17:00  Session 5

AN INTRODUCTION TO RISK COMMUNICATION

Risk communication is a key tool for sharing the results of all the other laborious pharmacovigilance processes, a way of risk minimisation, a chance for improvement of benefit and risks of medicinal products. The session covers the major principles, communication channels and tools, communication planning, getting feedback, making adjustments, as well as organisational aspects of risk communication.

Gaby Danan, Pharmacovigilance Expert, France

17:30  DRINKS RECEPTION

18:30  END OF DAY ONE

TUESDAY | 17 MAY 2011

09:00  Session 5 (continued)

AN INTRODUCTION TO RISK COMMUNICATION - EXERCISES

Participants will be asked to draft a communication plan and a ‘Dear Healthcare Professional Letter’ in reaction to a major safety issue. The exercise will simulate the stress and emotions that are often involved in risk communication.

Gaby Danan, Pharmacovigilance Expert, France

10:00  Session 6

PRE-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

The sixth session describes and illustrates the basic requirements for clinical safety data reporting from interventional clinical trials, including Individual Case Safety Reports and aggregate reports.

Thomas R. Berry, FDA, USA
William Gregory, Pfizer, USA

10:30  COFFEE BREAK

11:00  Session 6 (continued)

PRE-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

Thomas R. Berry, FDA, USA
William Gregory, Pfizer, USA

12:00  EXERCISES AND CASE STUDIES

12:30  LUNCH

13:30  EXERCISES AND CASE STUDIES (continued)

14:30  Session 7

POST-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

The seventh session explains and illustrates the basic requirements for clinical safety data reporting in the post-marketing phase, including Individual Case Safety Reports and aggregate reports.

William Gregory, Pfizer, USA
Thomas R. Berry, FDA, USA

15:00  COFFEE BREAK

15:30  Session 7 (Continued)

POST-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

William Gregory, Pfizer, USA
Thomas R. Berry, FDA, USA

16:30  EXERCISES & CASE STUDIES

17:30  END OF DAY TWO
WEDNESDAY | 18 MAY 2011

09:00  Session 8

INSPECTIONS IN PHARMACOVIGILANCE

Panel Discussion on Audits and Preparations for Inspections, including Exercises and Case Studies

Thomas R. Berry, FDA, USA
Gaby Danan, Pharmacovigilance Expert, France
William Gregory, Pfizer, USA

10:30  COFFEE BREAK

11:00  Session 9

INTRODUCTION TO EPIDEMIOLOGICAL METHODS, SIGNAL DETECTION AND RISK ASSESSMENT

This session shows participants how to apply basic epidemiological approaches needed in pharmacovigilance for interpretation of the study designs and results. The participants will also learn the current methods of signal detection and risk assessment, the essential parts of all scientific and medical pharmacovigilance jobs.

Gaby Danan, Pharmacovigilance Expert, France

12:00  LUNCH

13:00  Session 10

RISK MANAGEMENT IN PHARMACOVIGILANCE

Since 2005, the risk management of medicinal product is an active part of pharmacovigilance, providing tools for further risk characterisation and intervention to improve benefit/risk of a medicine. The instructor will explain the background of risk management in Europe, guide the participants through the EU-RMP structure and logic, and share practical experience, dos, and don'ts in risk management planning.

Gaby Danan, Pharmacovigilance Expert, France

14:00  EXERCISES & CASE STUDIES

Quick EU-RMP drafting exercise will engage participants in a real life scenario to experience challenges and discuss possible solutions that will help them in their current and future pharmacovigilance career.

14:45  WRAP-UP AND SUMMARY

15:00  END OF TRAINING COURSE

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following Hotel:

Novotel Nice Centre Acropolis
8/10 Parvis de l’Europe
FR-06300 Nice - France


Tel (+33) 4 93 133093
Fax (+33) 4 93 130904

at the special rate of
EUR 106.20 for single occupancy
EUR 117.40 for double occupancy
including breakfast, service and VAT

To reserve a room, please fill in the booking form available on our website and fax it directly to the Novotel Nice at (+33) 4 93 130904.

IMPORTANT:
To be assured of accommodation registrants are recommended to complete their reservation form by 1 April 2011 latest.
CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date.

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Regrettably, if you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registered attendees.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT:

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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