DIA Learning

Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing

12-13 December 2017
Four Points by Sheraton Bur Dubai, Dubai, United Arab Emirates

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.

LEARNING OBJECTIVES

At the conclusion of this course, participants will 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 with confidence
- Understand international and regional safety surveillance requirements
- Describe the criteria and elements of expedited and periodic reporting of drug safety from phase I studies to post-marketing

KEY TOPICS

- Global and regional guidelines in place
- Basics for methods for data collection and processing
- Safety reporting requirements in pre- and post-marketing phases
- Inspections in pharmacovigilance

WHO WILL ATTEND

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.

FACULTY

Jan Petracek
Director of Pharmacovigilance, PharmInvent, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:45 INTRODUCTION AND OVERVIEW

09:00 SESSION 1

HISTORY AND LEGAL BASIS FOR SAFETY REPORTING AND BASIC PRINCIPLES, DEFINITIONS AND TOOLS

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.

The second part 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.

11:00 COFFEE BREAK

11:30 SESSION 2

POST-MARKETING SAFETY DATA

The 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.

13:00 LUNCH

14:00 SESSION 3

MEDICAL EVALUATION OF ADVERSE EVENTS

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

15:00 EXERCISES & CASE STUDIES

15:30 COFFEE BREAK

16:00 SESSION 4

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.

17:30 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.

18:30 END OF DAY ONE & NETWORKING

DAY 2

09:00 SESSION 5

PRE-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

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

10:30 COFFEE BREAK

11:00 EXERCISES AND CASE STUDIES

12:30 LUNCH

13:30 SESSION 6

POST-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

The 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.

15:00 COFFEE BREAK

15:30 EXERCISES AND CASE STUDIES

16:00 SESSION 7

INSPECTIONS IN PHARMACOVIGILANCE

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

17:30 END OF THE COURSE

Training Course Venue

Four Points by Sheraton Bur Dubai
Khalid Bin Walid Street
Bur Dubai P.O. Box 33196
Dubai
United Arab Emirates

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About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and infl uencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profi t organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offi ces in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Continuing Education

DIA meetings and trainings are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available

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

SwAPP Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

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REGISTRATION FORM

Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing # 16551
12-13 December 2016 | Four Points by Sheraton Bur Dubai | Dubai, United Arab Emirates

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

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All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
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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 office of any such substitutions as soon as possible.

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.** :+41 61 225 51 51 **Fax:** +41 61 225 51 52

Email: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

Attendee email required for course material access

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Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID # 16551 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature