DIA Learning

Medical Writing of Periodic Safety Update Reports (PSUR/PBRER)

29-30 November 2018
Holiday Inn London Kensington Forum hotel, London, UK

OVERVIEW

This course is part of the Benefit-Risk and Medical Writing week offering

Quality of PSURs and PBRERs became a major compliance issue globally, as the complexity of the documents increased hand in hand with unprecedented level of regulatory scrutiny and attention.

This practical training course will help industry professionals to keep up with the new demands. It introduces essential aspects of medical writing of aggregate safety reports (PSURs and PBRERs) in the context of current legal framework in the EU and globally.

Course participants will learn all they need to know about the requirements set out in the ICH E2C(R2) (plus Q&A) guideline on the PBRER, EU Good Pharmacovigilance Practices (GVP) - Module VII, as well as global acceptability and local variability in the requirements.

Course will demonstrate best practices in source data collection, about the essential role of quality checks (QC) during the whole process of report preparation, and about critical aspects of medical writing, including data editing and presentation.

A practical exercise involving key aspects of the medical writing process, based on real-life examples, will be included.

Participants will be provided with preparatory material to allow for maximum benefit from the team exercises onsite.

Participants are required to bring their laptops with them for this course.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Understand interpretation and application of the ICH E2C (R2) guideline, associated Q&A, and EU GVP Module VII standards and templates
- Learn how to overcome the most frequent challenges in getting the correct and complete source information performing effective quality checks, editing, table and graphical presentation, methodologies, and publication tips
- Understand important legal and regulatory context of PBRER, including local regulatory intelligence tips

Participants will complete two knowledge checks. The first will take part before the practical exercise from medical writing, focused on drafting the key parts of PSUR in groups based on real-life examples. The second one will be completed after the course end in an online platform, consisting of a standard multiple choice knowledge test.

WHO WILL ATTEND

This course is intended for the professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, regulatory, and medical writing positions. Professionals most likely to benefit from this training are newcomers to the medical writing and/or pharmacovigilance positions or writers/specialists with intermediate level of experience who wish to extend their professional skills in aggregate reports.

INSTRUCTOR

Dr. Zuzana Vinterova,
Director, Medical Writing
PrimeVigilance s.r.o., Czech Republic

KEY TOPICS

- PSUR: regulations, format and content of the document
- PBRER: regulations, format and content of the document
- Practical aspects of planning and medical writing related to aggregate reports

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

12:30 REGISTRATION

13:15 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30 SESSION 1

INTRODUCTION TO THE PSUR/PBRER

- Regulatory legal basis for the PSUR in the EU (GVP Module VII)
- ICH E2C(R2) guideline on safety reports among the ICH regions
- Terminology of aggregate reports

14:15 SESSION 2

GENERAL PRINCIPLES AND STRUCTURE OF THE PSUR/PBRER

- Scope of the documents
- Format and overview of contents
- Internal template for the PSUR/PBRER

15:00 COFFEE BREAK

15:30 SESSION 3

PSUR/PBRER PLANNING EXERCISE

- Team work and group discussion

16:00 SESSION 4

PSUR/PBRER PLANNING EXERCISE

- Project team
- Data collection (first QC within the process)

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 5

PSUR/PBRER SECTION-BY-SECTION (PART 1) – INTRODUCTORY SECTIONS

- Title page
- Executive summary
- Table of contents and other "lists"
- Introduction
- WWMAS
- Actions taken for safety reasons
- Changes to the RSI
- Exposure and use patterns (how to calculate patient exposure)

09:30 SESSION 6

PSUR/PBRER SECTION-BY-SECTION (PART 2) – PRESENTATION OF FINDINGS

- Data in summary tabulations
- Overview of findings from interventional/non-interventional clinical studies
- Other reports with impact on the PSUR/PBRER
- Non-clinical data
- Literature
- Late-breaking information

10:15 COFFEE BREAK

10:45 SESSION 7

PSUR/PBRER SECTION-BY-SECTION (PART 3) – DATA EVALUATION

- Overview of signals
- Signal and risk evaluation
- Benefit evaluation

12:00 LUNCH

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

13:00 SESSION 8

PSUR/PBRER SECTION-BY-SECTION (PART 4) – BENEFIT-RISK ANALYSIS

- Critical appraisal of presented data
- Conclusions and action
- Appendices

13:30 SESSION 9

QUALITY CONTROL AND REVIEW

- Scope of quality control of aggregate reports
- Responsibilities
- Examples from practice

14:00 EXERCISE

- Preparation for medical writing exercise

14:30 COFFEE BREAK

15:00 SESSION 10

MEDICAL WRITING EXERCISE

- Team work and group discussion

16:30 END OF TRAINING COURSE

Training Course Venue

COURSE VENUE

Holiday Inn London Kensington Forum

97 Cromwell Road

London, SW7 4DN

Tel: +44 871 942 9100

Email: reservations@hikensington.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 25 to 30 November 2018 at the rate of GBP 160.00 per standard double room for single use per night including full English breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA".

The room rate is available until 24 October 2018 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Heathrow Airport take the London Underground Victoria line and get off at Gloucester Road.

The hotel is located within 3 min walking distance from the station.

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 influencers 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-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

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Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 8.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

REGISTRATION FORM

Medical Writing of Periodic Safety Update Reports (PSUR/PBRER) # 18556
29-30 November 2018 | Holiday Inn London Kensington Forum hotel | London, UK

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 2nd day of the course and electronic access to training course material. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 ❑	€ 1'395.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 ❑	€ 775.00 ❑
Registration fees for all 3 courses (ID #18561): Benefit-Risk Management, EU-RMP Creation AND Medical Writing of Periodic Safety Update Reports (PSUR/PBRER)		
INDUSTRY	€ 3'320.00 ❑	€ 3'475.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 1'660.00 ❑	€ 1'815.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.**

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no additional cost**

The DIA 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: Basel@diaglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA 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.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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 office of any such substitutions as soon as possible.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. You agree that your personal data will be transferred to DIA in the US.

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

PAYMENT METHODS

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

Card N°

Exp. Date /

Cardholder's Name

❑ **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 #18556 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.**

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