DIA Learning

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

15-16 November 2017
Mercure Paris La Défense Grande Arche, Paris, France

OVERVIEW

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. It is necessary to take your laptop with you.

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.

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

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.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

FACULTY

Dr. Jan Petracek
CEO, PharmInvent and PrimeVigilance, Czech Republic

Dr. Zuzana Vinterova
Associate Director, Medical Writing, PharmInvent, Czech Republic

SPECIAL OFFER

Register for both EU-RMP Creation and Medical Writing of Periodic Safety Update Reports (PSUR/PBRER) training courses and save up to EUR 765! See registration form on the back for details.

DAY 1

12:30 REGISTRATION

13:15 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

Jan Petracek

13:30 SESSION 1

INTRODUCTION TO THE PSUR/PBRER

Jan Petracek

- 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

Zuzana Vinterova

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

15:00 COFFEE BREAK

15:30 SESSION 3

PLANNING PROCESS AND INTERDEPARTMENTAL RESPONSIBILITIES

Jan Petracek

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

16:00 SESSION 4

PSUR/PBRER PLANNING EXERCISE

Jan Petracek and Zuzana Vinterova

- Case study in planning process
- Team work and group discussion

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 SESSION 5

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

Zuzana Vinterova

- 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

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

Zuzana Vinterova

- 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

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

Zuzana Vinterova

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

12:00 LUNCH

13:00 SESSION 8

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

Zuzana Vinterova

- Integrated benefit-risk analysis
- Conclusions and actions
- Appendices

13:30 SESSION 9

QUALITY CONTROL AND REVIEW (WITH A CASE STUDY)

Zuzana Vinterova

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

14:00 TEST

Zuzana Vinterova

- Preparation for medical writing exercise

14:30 COFFEE BREAK

15:00 SESSION 10

EXERCISE IN MEDICAL WRITING OF CRITICAL PARTS

Zuzana Vinterova

- Case study in planning process
- Team work and group discussion

16:30 END OF TRAINING COURSE

Training Course Venue

Paris La Défense Grande Arche
17/20 Esplanade Ch. de Gaulle
- Rue des Trois Fontanot
92000 Nanterre/Paris, France

Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 180.00 per standard room per night including breakfast and VAT, excl. City-Tax.

If you would like to make a booking, please fill in the booking form available on the DIA website and send it per email to H1982@accor.com with a reference "DIA".

The room rate is available until 01 November 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet. Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect. The hotel is located right next to the train 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 EMEA@DIAglobal.org for a custom group rate.

REGISTRATION FORM

Medical Writing of Periodic Safety Update Reports (PSUR/PBRER) # 17556
15-16 November 2017 | Mercure Paris La Défense Grande Arche | Paris, France

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 2nd day of the course and training course material in electronic format. Please note that full amount must be received by DIA by commencement of the course to get the electronic access to course 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 ❑
I would like register for the ***EU-RMP Creation #17545 (14-15 November 2017) AND the Medical Writing of Periodic Safety Update Reports (PSUR/PBRER) #17556 (15-16 November 2017)*** courses to benefit from a combo discount.		
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
Join DIA now to qualify for the member rate	€ 155.00 ❑	

All registration fees are subject to applicable French VAT

Please enter your company's French VAT number: _____

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.

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

TERMS AND CONDITIONS

CANCELLATION POLICY

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.
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.

PHOTOGRAPHY AND VIDEO POLICY

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 # 17556 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