DIA Learning

Medical Writing of Periodic Safety Update Reports

Virtual Live Training Course

9-11 April 2024 09:00-13:00 CEST

OVERVIEW

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 /PBRERs) for medicinal products in the context of current legal framework at the European and Global level.

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

This course will demonstrate best practices in source data collection, the essential role of quality checks (QC) during the process of report preparation, and the critical aspects of medical writing, including data selection and presentation. Practical exercises involving key aspects of safety medical writing, based on real-life examples, will be included.

LEARNING OBJECTIVES

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

- Explain the ICH E2C (R2) guideline, including the associated Q&A
- Evaluate the EU GVP Module VII standards and templates
- Discuss strategies to overcome the most frequent challenges in managing a team of authors and data considerations in a PSUR
- Recognize important legal and regulatory context of PBRER, including local regulatory intelligence tips
- List key principles of safety medical writing

KEY TOPICS

- Introduction to the PSUR/PBRER, general principles and structure
- Planning process and interdepartmental responsibilities
- Writing of PSUR/PBRER:
  - Introductory sections
  - Presentation of findings
  - Data evaluation
  - Benefit-Risk analysis
  - Critical parts
- Practical exercises on:
  - PSUR writing
  - PSUR planning process
  - Medical writing

WHO WILL ATTEND

This course is intended for 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 clinical medical writing experience who wish to extend their professional skills in aggregate reports.

FACULTY

Sven Schirp
Head of Global Pharmacovigilance Writing
Boehringer Ingelheim Pharma
Germany

Jan Kolouch
CEO, Strategic PV Advisor
NextPV Services
Czech Republic

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

09:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

09:30 SESSION 1

INTRODUCTION TO THE PSUR/PBRER

Sven Schirp

- Regulatory legal basis for the PSUR in the EU (GVP Module VII)
- ICH E2C(R2) guideline on safety reports among the ICH regions
- Key differences of a PSUR for generics compared to originator and possible regulatory aspects
- The PSUR in the product lifecycle

10:15 SESSION 2

GENERAL PRINCIPLES AND STRUCTURE OF THE PSUR/PBRER

Jan Kolouch

- Scope of the documents
- Format and overview of contents

11:00 BREAK

11:30 SESSION 3

PLANNING PROCESS AND INTERDEPARTMENTAL RESPONSIBILITIES

Jan Kolouch

- Project team
- Data collection

12:00 SESSION 4

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

Sven Schirp

- 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)

13:00 END OF DAY 1

DAY 2

09:00 SESSION 5

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

Sven Schirp

- 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

10:00 SESSION 6

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

Jan Kolouch

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

11:00 BREAK

11:30 SESSION 7

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

Jan Kolouch

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

12:15 SESSION 8

EXERCISE IN MEDICAL WRITING OF CRITICAL PARTS

Sven Schirp

- Case study in PSUR writing
- Case study in planning process
- Teamwork and group discussion

13:00 END OF DAY 2

DAY 3

09:00 SESSION 9

MEDICAL WRITING OF PERIODIC REPORTS

Sven Schirp

- General considerations
- Writing PSURs vs writing Clinical Study Reports
- Examples from practice

10:30 BREAK

11:00 SESSION 9 CONTINUED

TARGETED WRITING EXERCISES WITH FEEDBACK DISCUSSION, SUMMARY, AND DO'S AND DON'TS

Sven Schirp and Jan Kolouch

12:30 QUESTIONS AND ANSWERS

13:00 END OF VIRTUAL LIVE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary 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 does not apply to the already discounted fees for industry (early-bird), government or charitable nonprofit/academia.

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 via email to basel@diaglobal.org.

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9.5 credits.

Technical Requirements

To test your system compatibility, please click on the link:

https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:

https://www.diaglobal.org/General/System-Requirements

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REGISTRATION FORM | Virtual Live Training Course

Medical Writing of PSUR/PBRER #24556
9-11 April 2024 09:00-13:00 CEST

DIA Learning

REGISTRATION FEES

Registration fee includes admission to the full virtual live course, electronic access to training course material, access to course recordings. **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 EARLY-BIRD valid until 13 Feb 2024	MEMBER valid from 14 Feb 2024	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

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 https://www.diaglobal.org/General/Photography-Policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/About-Us/Privacy-Policy.

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

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 #24556 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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