DIA Learning

Medical Writing of Periodic Safety Update Reports

Virtual Live Training Course

4-6 May 2021 14:00-18:00 CEST

OVERVIEW

Quality of Periodic Safety Update Reports (PSURs) and Periodic Benefit Risk Evaluation Reports (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.

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.

FACULTY

Sven Schirp
Head of Global Pharmacovigilance Writing
Boehringer Ingelheim Pharma
Germany

Jan Kolouch
Head of Pharmacovigilance and Clinical Safety
PVpharm
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

DAY 1

14:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

14:30 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

15:15 SESSION 2

GENERAL PRINCIPLES AND STRUCTURE OF THE PSUR/PBRER

Sven Schirp

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

16:00 BREAK

16:30 SESSION 3

PSUR/PBRER PLANNING EXERCISE

Jan Kolouch

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

17:00 SESSION 4

PLANNING PROCESS AND INTERDEPARTMENTAL RESPONSIBILITIES

Sven Schirp

- Project team
- Data collection

18:00 END OF DAY 1

DAY 2

14:00 SESSION 5

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)

15:00 SESSION 6

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

15:45 BREAK

16:15 SESSION 7

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

Jan Kolouch

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

17:30 QUESTIONS AND ANSWERS

18:00 END OF DAY 2

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.

DAY 3

14:00 SESSION 8

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

Jan Kolouch

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

14:30 SESSION 9

QUALITY CONTROL AND REVIEW (WITH A CASE STUDY)

Sven Schirp

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

15:00 PREPARATION FOR EXERCISE

15:30 BREAK

16:00 SESSION 10

EXERCISE IN MEDICAL WRITING OF CRITICAL PARTS

Sven Schirp

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

17:30 QUESTIONS AND ANSWERS

18:00 END OF VIRTUAL LIVE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company 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 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 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

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REGISTRATION FORM | Virtual Live Training Course

Medical Writing of PSUR #21556
4-6 May 2021 14:00-18:00 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 9 March 2021	MEMBER valid from 10 March 2021	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'115.00 ❑	€ 1'240.00 ❑	€ 1'425.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 ❑	€ 805.00 ❑
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 CET. **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. 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

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 #21556 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