DIA Learning

EU-RMP Creation

14-15 November 2017
Mercure Paris La Défense Grande Arche, Paris, France

OVERVIEW

This course is aimed at the practical aspects of the EU-RMP creation process. We will demonstrate the various uses of the EU-RMP within the lifecycle of medicinal products, medical writing process and RMP management process associated with the daily RMP job. It will provide a detailed understanding of the GVP Modules V and XVI with all potential implications for the marketing authorisation holders.

The participants will learn the best practice in medical writing of the EU-RMP. The solutions will be demonstrated in practical exercises included throughout the course.

Participants will be provided with preparatory material to facilitate their learning process at the group 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 requirements of EU Good Pharmacovigilance Practice Module V and XVI
- Learn the best medical writing practices for EU-RMP and consistency check with other parts of the dossier
- Understand the project management challenges and budget implications of EU-RMP
- Deal with uncertainties and gaps in the data sets
- Respond to regulatory authority requests effectively

Participants will complete two knowledge checks - project management exercise in writing the EU-RMP and writing exercise of the critical parts of the EU-RMP. They will obtain an individual feedback to ensure learning objectives are attained.

KEY TOPICS

The course will teach the EU-RMP creation skills, including the project management, medical writing, design, associated tactical and strategic decisions, publication, maintenance, and submission of the document.

WHO WILL ATTEND

This course is intended for the professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, regulatory and medical affairs or similar positions, who are involved in the medicinal product lifecycle. This course would be especially beneficial for junior and medium level experience medical writers working within the pharmaceutical industry, service providers, and research institutions.

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.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

08:45 SESSION 1

INTRODUCTION TO BENEFIT-RISK MANAGEMENT

Jan Petracek

- Key concepts and terminology
- Essential principles for benefit-risk management
- Roles and responsibilities, regulatory expectations

09:30 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

Zuzana Vinterova

- Overview of the GVP - Module V
- Guidance on the template of the EU-RMP
- Requirements based on the MAA/MAH legal basis

10:00 COFFEE BREAK

10:30 SESSION 3

SOURCE DATA AND PLANNING PROCESS

Jan Petracek

- Project team
- Internal template of the EU-RMP
- Data collection (interdepartmental responsibilities)
- Other documentation (safety documents, CTD)

11:00 SESSION 4

GROUP WORK - PROJECT MANAGEMENT

Jan Petracek and Zuzana Vinterova

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

12:00 LUNCH

13:00 SESSION 5

CREATION OF THE EU-RMP – PRODUCT AND DISEASE/ CONDITION OVERVIEWS

Jan Petracek

- Product overview
- Indication(s) and target population(s)
- Epidemiology of the disease/condition
- Risk factors, comorbidities
- Natural history of the disease, main treatment options

13:30 SESSION 6

CREATION OF THE EU-RMP – SAFETY SPECIFICATION MODULES SII-SVI

Zuzana Vinterova

- Key findings from the nonclinical development
- Clinical development and populations not studied
- Post-marketing experience
- ATMP-specific sections for safety specification

14:15 COFFEE BREAK

14:45 SESSION 7

CREATION OF THE EU-RMP – IDENTIFIED/POTENTIAL RISKS AND SAFETY CONCERNS (MODULES SVII AND SVIII)

Jan Petracek

- Identification of important identified/potential risks
- Characterisation of identified and potential risks (ATMP versus non-ATMP version)
- Safety concerns

15:45 SESSION 8

CREATION OF THE EU-RMP – PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Zuzana Vinterova

- Routine pharmacovigilance activities
- Additional pharmacovigilance activities
- Post-authorisation safety studies (PASS) and GVP – Module VIII
- Imposed, specific obligation, required or stated pharmacovigilance activity
- Post-authorisation efficacy studies (PAES)

16:30 NETWORKING RECEPTION

17:30 END OF DAY ONE

DAY 2

08:00 SESSION 9

CREATION OF THE EU-RMP – RISK MINIMISATION PLAN

Jan Petracek

- GVP – Module XVI
- Routine risk minimisation measures
- Additional risk minimisation measures
- Evaluation of the effectiveness
- Implications for marketing authorisation holders

09:00 SESSION 10

CREATION OF THE EU-RMP - SUMMARY OF THE EU-RMP AND ANNEXES

Zuzana Vinterova

- Summary of the RMP
- Annexes to the EU-RMP

09:30 TEST

Jan Petracek and Zuzana Vinterova

- Basis for the medical writing exercise

10:00 COFFEE BREAK

10:30 SESSION 11

GROUP WORK – KEY PARTS OF EU RMP (WRITING EXERCISE)

Jan Petracek and Zuzana Vinterova

- Team work and group discussion

12:00 LUNCH & END OF TRAINING COURSE

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 8.75 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 8.75 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

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.

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

EU-RMP Creation # 17545
14-15 November 2017 | Mercure Paris La Défense Grande Arche | Paris, France

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunches 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 # 17545 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