DIA Learning

# EU-RMP Creation

28-29 November 2018
Holiday Inn London Kensington Forum hotel, London, UK

## OVERVIEW

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

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 Module V 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.**

**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 requirements of EU Good Pharmacovigilance Practice Module V
- Learn the best medical writing practices for EU-RMP and consistency check with other parts of the dossier
- Understand the project management challenges
- Deal with uncertainties and gaps in the data sets

Participants will complete two practical exercises - 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, and maintenance 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 professionals involved in preparation of the EU-RMP and working within the pharmaceutical industry, service providers, and research institutions.

## INSTRUCTOR

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

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

- Key concepts and terminology
- Essential principles for benefit-risk management

**09:15 SESSION 2**

### OBJECTIVES AND STRUCTURE OF THE EU-RMP

- 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**

### GROUP WORK - PROJECT MANAGEMENT

- Team work and group discussion

**11:15 SESSION 4**

### SOURCE DATA AND PLANNING PROCESS

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

**12:00 LUNCH**

**13:00 SESSION 5**

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

- 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**

### SAFETY SPECIFICATION MODULES SII-SVI

- Key findings from the nonclinical development
- Clinical development and populations not studied
- Post-marketing experience
- ATMP

**14:15 COFFEE BREAK**

**14:45 SESSION 7**

### IDENTIFIED/POTENTIAL RISKS AND SAFETY CONCERNS (MODULES SVII AND SVIII)

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

**16:15 SESSION 8**

### PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

- 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)

**16:45 NETWORKING RECEPTION**

**17:45 END OF DAY ONE**

## DAY 2

**08:00 SESSION 9**

### RISK MINIMISATION PLAN

- Routine risk minimisation measures
- Additional risk minimisation measures
- Evaluation of the effectiveness

**08:45 SESSION 10**

### SUMMARY OF THE EU-RMP AND ANNEXES

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

**09:30 SESSION 11**

### EXERCISE ON IDENTIFICATION OF SAFETY CONCERNS

**10:00 COFFEE BREAK**

**10:30 SESSION 12**

### GROUP WORK – WRITING EXERCISE

- Task 1: Key messages of the additional risk minimisation measures
- Task 2: Characterisation of risk

**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 9 CPD credits.

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

## Training 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.

## 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.

## 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.

Follow **@DrugInfoAssn**

# REGISTRATION FORM

**EU-RMP Creation # 18545**
**28-29 November 2018 | Holiday Inn London Kensington Forum hotel | London, UK**

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## REGISTRATION FEES

Registration fee includes refreshment breaks, lunches 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 #18545 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 |
|---|---|
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