

EU-RMP Creation

26-27 February 2018
Hotel Grand Majestic, Prague, Czech Republic

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 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,
Associate Director, Medical Writing,
Pharmlnvent, Czech Republic

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

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 END OF TRAINING COURSE

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.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

I Training Course Venue

HOTEL GRAND MAJESTIC PRAGUE

Truhlarova 16

110 00 Prague 1

Czech Republic

Tel: +420 211 159 100

E-mail: reception@hotel-grandmajestic.cz

DIA has blocked a limited number of hotel rooms at the rate of EUR 60.00 per superior (standard) room per night for single use including breakfast, wifi and VAT.

To book a hotel room please fill in the booking form available on DIA website www.DIAglobal.org/RMP and send it via email to reservation@hotel-grandmajestic.cz.

The room rate is available until 25 January 2018 or until the room block is sold-out, whichever comes first.



HOW TO GET THERE

From the airport take the Airport Express to Náměstí Republiky/Republic Square (travel time 35 min, price CZK 60).

From there turn into Truhlarova street. The hotel is located 200 m from the Republic Square.

I 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.



I 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.

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REGISTRATION FORM

EU-RMP Creation # 18563

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REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 1st day, 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 <input type="checkbox"/>	€ 1'395.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 <input type="checkbox"/>	€ 775.00 <input type="checkbox"/>

All registration fees are subject to applicable Czech VAT

Please enter your company's Czech 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.

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

I do not want complimentary membership

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.

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 #18563 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