DIA Learning

EU-RMP Creation
Virtual Live Training Course

13 May 2020 08:30-16:45 CEST
14 May 2020 08:00-12:00 CEST

OVERVIEW

This Virtual Live 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 during the virtual live course.

LEARNING OBJECTIVES

At the conclusion of this virtual live 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 virtual live 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

Zuzana Vinterova,
Strategic Advisor, Medical Writing
PrimeVigilance s.r.o., Czech Republic

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

08:45 SESSION 1

BACKGROUND TO THE EU RISK MANAGEMENT

- Terminology
- History of RMP in the EU
- Legal framework in the EU

09:30 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

- Overview of the GVP modules relevant to risk management
- Structure and content of the RMP
- EU-RMP versus Periodic Benefit-Risk Evaluation Report (PBRER)

10:15 BREAK

10:45 SESSION 3

SOURCE DATA AND PLANNING PROCESS

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

11:15 SESSION 4

EU-RMP FOR GENERIC MEDICINAL PRODUCTS (AND OTHER 'ARTCILE 10' PRODUCTS)

- Risk-proportionality principle
- HaRP project
- Specifics of RMPs for generic medicinal products

12:00 BREAK

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

14:15 BREAK

14:45 SESSION 7

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

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

15:45 SESSION 8

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

- Routine pharmacovigilance activities
- Additional pharmacovigilance activities
- Post-authorisation efficacy studies (PAES)

16:45 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 of risk minimisation measures

08:45 SESSION 10

SUMMARY OF THE EU-RMP AND ANNEXES

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

09:00 SESSION 11

MONITORING OF EU-RMP QUALITY

- Feedback from the EMA on quality of submitted RMPs

09:30 SESSION 12

GROUP WORK I - PRACTICAL EXERCISE

- Task 1

10:30 BREAK

11:00 SESSION 13

GROUP WORK II – PRACTICAL EXERCISE

- Plagiarism quiz
- Task 2

12:00 END OF VIRTUAL LIVE TRAINING COURSE

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

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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.

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

System 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, 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).

REGISTRATION FORM | Virtual Live Training Course

EU-RMP Creation #20545
13 May 2020 08:30-16:45 (CEST) 14 May 2020 08:00-12:00 (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	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'240.00 ❑	€ 1'395.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 ❑	€ 775.00 ❑
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 #20545 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