DIA Learning

Risk Management Plan Creation

Best Practice in Medical Writing of the EU-RMP (GVP Module V)

Virtual Live Training Course

26-28 September 2023 09:00-13:00 CEST

OVERVIEW

This virtual live course is aimed at the practical aspects of the EU Risk Management Plan (EU-RMP) creation process. It will provide a detailed understanding of the GVP Module V (Rev. 2) and the Guidance on the format of the RMP 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.

LEARNING OBJECTIVES

At the conclusion of this virtual live course, participants will be able to:

- Follow requirements of the GVP Module V and Guidance on the format of the RMP
- Define the best medical writing practices for EU-RMP and consistency check with other parts of the dossier
- Identify the project management challenges

KEY TOPICS

- Background to the EU Risk Management
- Objectives and Structure of the EU-RMP
- RMP publication on EMA website – drafting early for post-opinion steps; Applicant/MAH requirements for publication
- Identification and Characterisation of Safety Concerns (Modules SVII and SVIII)
  - Group Work on Safety Concerns
- Risk Minimisation Measures
  - Group Work on Risk Minimisation
- Source Data and Planning Process
  - Group Work on Project Management
- Product and Disease/Condition Overviews
- Safety Specification Modules SII-SVI
- Pharmacovigilance Plan and Post-Authorisation Efficacy Studies
- RMPs outside of the EU
- Summary of the EU-RMP and Annexes
- EU-RMP for Generic Medicinal Products (and other “Article 10” Products)

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, as service providers, and/or research organisations.

FACULTY

Klaudija Marijanovic Barac
Senior Director, Teva Periodic Reports and Risk Management Centre (TPC), EU & UK QPPV Deputy
Teva
Croatia

Emil Andrei Cochino
Scientific Senior Specialist (Risk Management)
Advanced Therapies and Haematological Diseases Office
European Medicines Agency
Netherlands

Nuria Semis-Costa
Scientific Specialist (Risk Management)
Immune and Inflammatory Diseases/ Advanced Therapies Office
European Medicines Agency
Netherlands

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

09:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

09:15 SESSION 1

BACKGROUND TO THE EU RISK MANAGEMENT

Emil Andrei Cochino

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

09:30 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

Klaudija Marijanovic Barac and Emil Andrei Cochino

- Structure and content of the RMP
- EU-RMP versus Periodic Benefit-Risk Evaluation Report (PBRER)
- RMP updates

10:15 SESSION 3

CONSIDERATIONS ON PROTECTED PERSONAL DATA AND COMMERCIALLY CONFIDENTIAL INFORMATION DURING THE PREPARATION OF RMPS FOR PUBLICATION - CAPS WITH A NEW ACTIVE SUBSTANCE

Emil Andrei Cochino

- Protected Personal Data (PPD)
- Editorial/administrative notes
- Commercially Confidential Information (CCI)
- Assessment process updates – CCI/PPD deletion/anonymization
- Q&A and practical examples

11:00 BREAK

11:15 SESSION 4

IDENTIFICATION OF SAFETY CONCERNS (MODULES SVII AND SVIII)

Nuria Semis-Costa

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

12:15 SESSION 5

GROUP WORK I - SAFETY CONCERNS

Klaudija Marijanovic Barac and Nuria Semis-Costa

13:00 END OF DAY 1

DAY 2

09:00 SESSION 6

RISK MINIMISATION MEASURES

Nuria Semis-Costa

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

10:00 SESSION 7

GROUP WORK II - RISK MINIMISATION

Klaudija Marijanovic Barac and Nuria Semis-Costa

10:30 BREAK

10:45 SESSION 8

SOURCE DATA AND PLANNING PROCESS

Klaudija Marijanovic Barac

- Project plan
- Data sources (interdepartmental responsibilities)

11:15 SESSION 9

GROUP WORK III - PROJECT MANAGEMENT

Klaudija Marijanovic Barac, Nuria Semis-Costa and Emil Andrei Cochino

12:00 SESSION 10

PRODUCT AND DISEASE/CONDITION OVERVIEWS

Klaudija Marijanovic Barac

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

12:20 SESSION 11

SAFETY SPECIFICATION (MODULES SII-SVI)

Klaudija Marijanovic Barac

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

13:00 END OF DAY 2

DAY 3

09:00 SESSION 12

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Klaudija Marijanovic Barac and Emil Andrei Cochino

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

10:00 Q&A

10:30 SESSION 13

RMPS OUTSIDE OF THE EU

Klaudija Marijanovic Barac

- ICH founding members (Japan, United States)
- Canada, Australia, United Kingdom, Switzerland
- Other countries

11:00 COFFEE BREAK

11:15 SESSION 14

SUMMARY OF THE EU-RMP AND ANNEXES

Klaudija Marijanovic Barac

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

11:45 SESSION 15

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

Klaudija Marijanovic Barac

- Specifics of RMPs for generic medicinal products
- HaRP project

12:45 Q&A

13:00 END OF THE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same curse 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 industry (early-bird), 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 10 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Technical Requirements

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

For full system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

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REGISTRATION FORM | Virtual Live Training Course

EU-RMP Creation #23545
26-28 September 2023 09:00-13:00 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 1 August 2023	MEMBER valid from 2 August 2023	NON-MEMBER
INDUSTRY / REPRESENTATIVE	€ 1'115.00 ❑	€ 1'240.00 ❑	€ 1'475.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 620.00 ❑	€ 855.00 ❑
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 CE(S)T. **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.

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 #23545 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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