

EU Risk Management Plan Creation

Virtual Live Training Course

16-18 September 2025 | 13:00-17:30 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 training 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
- Product and Disease/Condition Overviews
- Safety Specification Modules SII-SVI
- Identification and Characterisation of Safety Concerns (Modules SVII and SVIII)
 - Group Work on Safety Concerns
- Source Data and Planning Process
 - Group Work on Project Management
- Pharmacovigilance Plan and Post-Authorisation Efficacy Studies
- RMPs outside of the EU
- Summary of the EU-RMP and Annexes
- Risk Minimisation Measures
 - Group Work on Risk Minimisation
- EU-RMP for Generic Medicinal Products (and other "Article 10" Products)
- Publication of EU RMPs
- Preview of the GVP V Rev 3 and RMP Template Rev 3

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
Teva, Croatia

Emil Andrei Cochino

Scientific Senior Specialist (Risk Management)
European Medicines Agency, Netherlands

Maria Escudeiro dos Santos

Risk Management Specialist
European Medicines Agency, Netherlands

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:15 SESSION 1

BACKGROUND TO THE EU RISK MANAGEMENT

Emil Andrei Cochino and Maria Escudeiro dos Santos

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

14:00 SESSION 2

OBJECTIVES AND STRUCTURE OF THE EU-RMP

Emil Andrei Cochino and Maria Escudeiro dos Santos

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

14:45 BREAK

15:00 SESSION 3

PRODUCT AND DISEASE/CONDITION OVERVIEWS

Klaudija Marijanovic Barac and Emil Andrei Cochino

- 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

15:30 SESSION 4

SAFETY SPECIFICATION (MODULES SII-SVI)

Klaudija Marijanovic Barac and Maria Escudeiro dos Santos

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

16:00 SESSION 5

IDENTIFICATION AND CHARACTERISATION OF SAFETY

CONCERNS (MODULES SVII AND SVIII)

Emil Andrei Cochino

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

16:30 SESSION 6

GROUP WORK I - SAFETY CONCERNS

Klaudija Marijanovic Barac and Emil Andrei Cochino

17:00 Q&A

17:30 END OF DAY 1

DAY 2

13:00 SESSION 7

SOURCE DATA AND PLANNING PROCESS

Klaudija Marijanovic Barac

- Project plan
- Data sources (interdepartmental responsibilities)

13:30 SESSION 8

GROUP WORK II - PROJECT MANAGEMENT

Klaudija Marijanovic Barac, Emil Andrei Cochino and Maria Escudeiro dos Santos

14:15 BREAK

14:30 SESSION 9

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Klaudija Marijanovic Barac and Maria Escudeiro dos Santos

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

15:30 SESSION 10

RISK MINIMISATION MEASURES

Klaudija Marijanovic Barac and Emil Andrei Cochino

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

16:15 SESSION 11

GROUP WORK III - RISK MINIMISATION

Klaudija Marijanovic Barac and Emil Andrei Cochino

17:00 SESSION 12

SUMMARY OF THE EU-RMP AND ANNEXES

Emil Andrei Cochino

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

17:30 END OF DAY 2

DAY 3

13:00 Q&A

14:00 SESSION 13

RMPS OUTSIDE OF THE EU

Klaudija Marijanovic Barac

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

14:30 BREAK

14:45 SESSION 14

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

Klaudija Marijanovic Barac

- Specifics of RMPs for generic medicinal products
- HaRP project

15:45 SESSION 15

PUBLICATION OF EU RMPS

Klaudija Marijanovic Barac and Emil Andrei Cochino

- Procedural guidance
- Protected Personal Data (PPD)
- Commercially Confidential Information (CCI)
- Drafting of the RMP
- Redaction of the RMP
- Q&A and practical examples

16:15 SESSION 16

PREVIEW OF THE GVP V REV 3 AND RMP TEMPLATE REV 3

Emil Andrei Cochino

- ATMP focus
- Main changes proposed
- Timelines for consultation and publication
- Future legislative requirements

16:45 Q&A

17:30 END OF THE TRAINING COURSE



Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

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.

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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.



Technical Requirements

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

For further information on system requirements, please visit the website: <https://www.diaglobal.org/General/System-Requirements>



Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 10 credits.



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.

REGISTRATION FORM

EU RMP Creation | Virtual Live Training Course | # 25545
16-18 September 2025 | 13:00-17:30 CEST

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **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 22 Jul 2025	MEMBER valid from 23 Jul 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'215.00 <input type="checkbox"/>	€ 1'350.00 <input type="checkbox"/>	€ 1'610.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 675.00 <input type="checkbox"/>	€ 935.00 <input type="checkbox"/>

A special discount is available for organisations which are listed in the [EMA SME register](#).
Number of discounted seats are limited.

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.

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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

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

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.

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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 the **invoice number**, your name and company to ensure correct allocation of your payment. Payments must be net of all bank charges. Bank charges must be borne by the payer.

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By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

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Date	Signature
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