

EU Risk Management Plan Creation

Virtual Live Training Course

22-24 September 2026 | 09:00-13:30 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
- Risk Minimisation Measures
 - Group Work on Risk Minimisation
- Summary of the EU-RMP and Annexes
- RMPs outside of the EU
- 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

HALMED speaker invited

Princial coordinator for new safety issues
Agency for Medicinal Products and Medical Devices of Croatia

Schedule-At-A-Glance

DAY 1

09:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

09:15 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

10:00 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

10:45 BREAK

11:00 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

11:30 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

12:00 SESSION 5

IDENTIFICATION AND CHARACTERISATION OF SAFETY CONCERN (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)

12:30 SESSION 6

GROUP WORK I - SAFETY CONCERN

Klaudija Marijanovic Barac and Emil Andrei Cochino

13:00 Q&A

13:30 END OF DAY 1

DAY 2

09:00 SESSION 7

SOURCE DATA AND PLANNING PROCESS

Klaudija Marijanovic Barac

- Project plan
- Data sources (interdepartmental responsibilities)

09:30 SESSION 8

GROUP WORK II - PROJECT MANAGEMENT

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

10:15 BREAK

10:30 SESSION 9

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Klaudija Marijanovic Barac and HALMED speaker invited

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

11:30 SESSION 10

RISK MINIMISATION MEASURES

Klaudija Marijanovic Barac and HALMED speaker invited

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

12:15 SESSION 11

GROUP WORK III - RISK MINIMISATION

Klaudija Marijanovic Barac, Emil Andrei Cochino and HALMED speaker invited

13:00 SESSION 12

SUMMARY OF THE EU-RMP AND ANNEXES

Emil Andrei Cochino and HALMED speaker invited

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

13:30 END OF DAY 2

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.

DAY 3

09:00 Q&A

10:00 SESSION 13

RMPS OUTSIDE OF THE EU

Klaudija Marijanovic Barac

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

10:30 BREAK

10:45 SESSION 14

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

Klaudija Marijanovic Barac and HALMED speaker invited

- Specifics of RMPs for generic medicinal products
- HaRP project

11:45 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

12:15 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

12:45 Q&A

13:30 END OF THE TRAINING COURSE

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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.



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Continuing Education

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PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.



REGISTRATION FORM

EU RMP Creation | Virtual Live Training Course | # 26545
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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 25 Aug 2026	MEMBER valid from 26 Aug 2026	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'260.00 <input type="checkbox"/>	€ 1'400.00 <input type="checkbox"/>	€ 1'660.00 <input type="checkbox"/>
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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

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Telephone Number

Attendee email required for course material access

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