DIA LEARNING

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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

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 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)

12:30 SESSION 6

GROUP WORK I - SAFETY CONCERNS

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

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

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.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

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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.

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.

REGISTRATION FORM

EU RMP Creation | Virtual Live Training Course | # 26545
22-24 September 2026 | 09:00-13:30 CEST

DIA LEARNING

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 ❑	€ 1'400.00 ❑	€ 1'660.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 700.00 ❑	€ 960.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is 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.

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 METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

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:

http://www.diaglobal.org/EUterms

Date	Signature