DIA LEARNING

EU Risk Management Plan Creation

Virtual Live Training Course

21-23 September 2027 | 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
- 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
- RMPs outside of the EU
- EU-RMP for Generic Medicinal Products (and other “Article 10” Products)
- 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

Emil Andrei Cochino (invited)
Scientific Senior Specialist (Risk Management)
European Medicines Agency, Netherlands

Maria Escudeiro dos Santos (invited)
Risk Management Specialist
European Medicines Agency, Netherlands

Behija Hudina (invited)
Pharmacovigilance Assessor
Agency for Medicinal Products and Medical Devices, Croatia

Zeljana Margan Koletic
Director, Risk Management Strategy
Abbvie, Croatia

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

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

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

15:00 BREAK

15:15 SESSION 3

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)

17:00 SESSION 4

GROUP WORK I - SAFETY CONCERNS

Zeljana Margan Koletic and Emil Andrei Cochino

17:30 END OF DAY 1

DAY 2

13:00 SESSION 5

SOURCE DATA AND PLANNING PROCESS

Zeljana Margan Koletic

- Project plan
- Data sources (interdepartmental responsibilities)

13:30 SESSION 6

GROUP WORK II - PROJECT MANAGEMENT

Zeljana Margan Koletic, Maria Escudeiro dos Santos and Emil Andrei Cochino

14:15 BREAK

14:30 SESSION 7

PHARMACOVIGILANCE PLAN AND POST-AUTHORISATION EFFICACY STUDIES

Zeljana Margan Koletic

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

15:30 BREAK

15:45 SESSION 8

RISK MINIMISATION MEASURES

Behija Hudina

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

16:30 SESSION 9

GROUP WORK III - RISK MINIMISATION

Emil Andrei Cochino

17:30 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

13:00 SESSION 10

RMPS OUTSIDE OF THE EU

Zeljana Margan Koletic

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

13:30 SESSION 11

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

Behija Hudina

- Specifics of RMPs for generic medicinal products
- HaRP project

14:00 BREAK

14:15 SESSION 12

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

14:45 BREAK

15:00 Q&A

17:30 END OF THE TRAINING COURSE

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.

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.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact basel@diaglobal.org

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

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

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.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

REGISTRATION FORM

EU RMP Creation | Virtual Live Training Course | # 27545
21-23 September 2027 | 13:00-17:30 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 24 Aug 2027	MEMBER valid from 25 Aug 2027	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.

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.

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

© DIA 2026