DIA LEARNING

Global Pharmacovigilance System Master File

Virtual Live Training Course

10 June 2027 | 09:00-13:00 CEST



Overview

Safety data related to a medicinal product authorised in the European Union are generated also in other regions, countries and continents around the globe. The European legislation stipulates that marketing authorisation holders are required to maintain a pharmacovigilance system and make global safety information available. The Pharmacovigilance System Master File (PSMF) is expected to present information on the pharmacovigilance system applied at global, regional and local levels.

During the course we will explore the current global regulatory framework for the description of pharmacovigilance systems and different options for the design, implementation and management of a global Pharmacovigilance System Master File.

The course includes practical exercises on governance model selection, PSMF contributors and sources, update timelines, and a scalable PSMF tracker.

Participants are expected to have a firm understanding of GVP Module II – Pharmacovigilance system master file.

Learning Objectives

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

- Describe the global regulatory framework for description of pharmacovigilance systems and understand that local requirements and formats differ
- Differentiate and assess governance models and structural options for a global PSMF
- Outline the processes needed to implement and maintain a global PSMF

Key Topics

- PV system
- Regulatory requirements for PV system description
- Relation between EU and non-EU PSMF
- Global, regional and local PSMF and related procedures
- Design, implementation and maintenance of the global PSMF
- Potential audit and inspection findings related to the PSMF

Who Will Attend

This course is designed for professionals involved in:

- Design and management of global PV system
- Preparation and maintenance of PSMF
- Global and local PV functions
- QPPVs
- Regulatory affairs
- Quality assurance

Faculty

Marcela Fialova
COO
iVigee Services
Czech Republic

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

09:00 WELCOME AND INTRODUCTION

09:30 SESSION 1

GLOBAL REGULATORY FRAMEWORK

Marcela Fialova

- The global regulatory framework for description of pharmacovigilance systems
- The expected components of the PV system description
- Relation between EU and non-EU PSMF
- Common points and differences

11:00 BREAK

11:30 SESSION 2

GLOBAL PSMF

Marcela Fialova

- Points for consideration when designing a global PSMF, including governance models
- Possible options for the structure and content of a global PSMF
- The relationship between global, regional and local PSMF
- Implementation and maintenance of the global PSMF, including potential audit and inspection findings

13:00 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.*

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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

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

Global PSMF | Virtual Live Training Course | # 27554
10 June 2027 | 09:00-13:00 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 13 May 2027	MEMBER valid from 14 May 2027	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 360.00 ❑	€ 400.00 ❑	€ 660.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 200.00 ❑	€ 460.00 ❑
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.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

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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**

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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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.

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Privacy Policy

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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

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Attendee email required for course material access

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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.

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These are available from the office or online by clicking:

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Date	Signature

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