

## Global Pharmacovigilance System Master File

28 November 2024 | 13:00-17:00 CET



### Overview

Safety data related to a medicinal product authorised in the European Union is generated also in other regions, countries or continents around the globe. The European legislation stipulates that marketing authorization 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 and different options for the design and management of a global Pharmacovigilance System Master File.**

Participants are expected to have a firm understanding of the 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
- List the key components of Pharmacovigilance descriptions in selected countries/ regions and identify potential differences
- Differentiate and assess different structures for 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
- Sharing EU PSMF outside EU vs GDPR

### Who Will Attend

This virtual live training course is designed for professionals working 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

**Jose Alberto Ayala Ortiz**

CEO  
PVpharm  
Spain

## DAY 1

13:00 WELCOME AND INTRODUCTION

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13:30 SESSION 1

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### GLOBAL REGULATORY FRAMEWORK

*Marcela Fialova*

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

15:00 BREAK

15:30 SESSION 2

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### GLOBAL PSMF

*Marcela Fialova*

- Points for consideration when designing a global PSMF
- Possible options for design of a global PSMF
- The relationship between global & regional & local PSMF
- How to share the EU PSMF outside of the EU from a GDPR perspective

17:00 END OF THE TRAINING COURSE

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## 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](mailto:basel@diaglobal.org).

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



## Customized Professional Development for Your Team

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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

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 3 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

Global PSMF Virtual Live Training Course # 24555  
28 November 2024 | 13:00-17:00 CET

## 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 3 Oct 2024	MEMBER valid from 4 Oct 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 450.00 <input type="checkbox"/>	€ 500.00 <input type="checkbox"/>	€ 760.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 250.00 <input type="checkbox"/>	€ 510.00 <input type="checkbox"/>

A special discount is available for organisations which are listed in the EMA SME register: <https://fmapps.ema.europa.eu/SME/>. 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.**

### DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at [DIAGlobal.org/Membership](https://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](https://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](mailto:Basel@DIAGlobal.org) **Mail:** DIA, KÜchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAGlobal.org](https://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.**

### 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>.

## 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](mailto: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
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