

# Global Pharmacovigilance System Master File

## Virtual Live Training Course

4 November 2022 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

After the completion of this virtual live training course, participants will be able to:

- Describe the global regulatory framework for description of Pharmacovigilance systems
- Understand 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

- Overview of key components of the Pharmacovigilance system
- Global Regulatory Requirements for Pharmacovigilance System Description
- Relation between EU and non-EU PSMF
- Points to consider with regard to design of a Global, Regional & Local PSMF and related procedures
- GDPR considerations with regard to sharing EU PSMF outside of the European Union

### 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
- or similar positions within the industry



### FACULTY

#### Marcela Fialova

- COO
- iVigee Services
- Czech Republic

#### Jose Alberto Ayala Ortiz

- CEO
- PVpharm
- Spain

## DAY 1

### 13:00 WELCOME AND INTRODUCTION

### 13:30 SESSION 1

#### 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 COFFEE BREAK

### 15:30 SESSION 2

#### 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

## Group Discounts

**Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!**

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/ academia.

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).

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.

## Technical Requirements

To test your system compatibility, please click on the link: <https://diaglobal.zoom.us/test>

### Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

### Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

### Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

### Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

### Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

## 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.



## 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
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For more information please contact [tereza.krucka@diaglobal.org](mailto:tereza.krucka@diaglobal.org)

# REGISTRATION FORM

Global PSMF Virtual Live Training Course # 22554  
4 November 2022 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 9 Sep 2022	MEMBER valid from 10 Sep 2022	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 360.00 <input type="checkbox"/>	€ 400.00 <input type="checkbox"/>	€ 585.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 200.00 <input type="checkbox"/>	€ 385.00 <input type="checkbox"/>

A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

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 CET. 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](http://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 METHODS

**Credit cards:** Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my  VISA  MC  AMEX

Card N°

Exp. Date

Cardholder's Name

**Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #22554 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date	Signature
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