DIA Learning

Pharmacovigilance System Master File

Virtual Live Training Course

16-17 April 2024 09:00-13:00 CEST

OVERVIEW

This virtual live training course covers essential concepts and guidance about the Pharmacovigilance System Master File (PSMF).

This key document describes the company's pharmacovigilance system, supporting, and documenting its compliance with the requirements laid down in the EU legislation and is the first document requested by a Competent Authority in preparation of a pharmacovigilance inspection.

The entire course is in line with the guidelines on EU Good Pharmacovigilance Practices GVP Module II – Pharmacovigilance System Master File (rev. 2), Commission Implementing Regulation (EU) No. 520/2012, and relevant EMA guidelines.

Participants benefit from hands-on expertise on best practices shared by trainers with extensive experience regarding PSMF including the EU-QPPV perspective.

Ample time is set aside for Q&A and interactive discussions.

LEARNING OBJECTIVES

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

- Identify the structure, sections, and annexes of the PSMF
- Recognize the importance of the PSMF in the Pharmacovigilance system of a pharmaceutical company
- Evaluate the interaction between Regulatory Affairs, Pharmacovigilance, and other departments with regards to the maintenance of the PSMF
- Apply the essential concepts and principles of the GVP Module II – Pharmacovigilance System Master File (rev. 2)
- Prepare and manage this document in their own organisation
- Assess the regulatory expectations for this important document, common inspection findings and gaps
- List quality performance indicators for monitoring timely submissions of ICSRs, PSURs and safety variations

Learning objectives will be achieved using a combination of trainer presentations, trainer-led plenary discussions, and case studies.

KEY TOPICS

- GVP Module II – Pharmacovigilance System Master File (rev. 2) guidance
- Creation, maintenance, and management of the PSMF
- Practical exercise on drafting a PSMF
- The PSMF as a quality document
- Regulatory expectations for the PSMF, including UK PSMF
- Practical exercise on PSMF after an inspection

WHO WILL ATTEND

This virtual live training course is designed for professionals working in:

- Pharmacovigilance (including EU QPPVs)
- Drug Safety and Risk Management
- Pharmacovigilance Consultancies and Service Providers
- Quality and Compliance

FACULTY

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Czech Republic

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

DAY 1

09:00 WELCOME AND INTRODUCTION

09:30 SESSION 1

GVP MODULE II – PHARMACOVIGILANCE SYSTEM MASTER FILE (REV. 2) GUIDANCE

Jose Ortiz

- Objectives, location and registration
- Responsibilities
- Information to be contained, sections
- Annex

11:00 COFFEE BREAK

11:15 SESSION 2

CREATION, MAINTENANCE, AND MANAGEMENT OF THE PSMF

Jose Ortiz

- Processes and workflows
- Interaction with other departments
- Change control, log book, versions and archiving

12:30 SESSION 3

PRACTICAL EXERCISE ON DRAFTING A PSMF

Jose Ortiz

13:00 END OF DAY 1

DAY 2

09:00 SESSION 4

THE PSMF AS A QUALITY DOCUMENT

Jose Ortiz

- The PSMF in the QMS
- Audits, inspections

10:30 COFFEE BREAK

10:45 SESSION 5

REGULATORY EXPECTATIONS FOR THE PSMF

Jose Ortiz and Zoe Hamill

- Regulatory expectations
- Globalization
- UK PSMF

12:30 SESSION 6

PRACTICAL EXERCISE ON PSMF AFTER AN INSPECTION

Jose Ortiz

13:00 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 industry (early-bird), 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.

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

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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 6 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

REGISTRATION FORM

PSMF Virtual Live Training Course # 24533
16-17 April 2024 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 20 Feb 2024	MEMBER valid from 21 Feb 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 900.00 ❑	€ 1'000.00 ❑	€ 1'260.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 500.00 ❑	€ 760.00 ❑
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.

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 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 #24533 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