

# Pharmacovigilance Quality Management System

## Virtual Live Training Course

24-27 February 2025 | 09:00-13:30 CET



### Overview

**This beginner to intermediate level virtual live training course will describe contemporary principles, practical approaches, and regulatory expectations for the Pharmacovigilance Quality Management System.**

The topics will cover organizational structure, responsibilities, processes and resources required for the Pharmacovigilance system and its quality system. The course employs a mixture of informative instructional sessions, real-world case studies, and hands-on interactive exercises where attendees can apply what they learn.

Participants will leave the course with an understanding of how elements of the Pharmacovigilance and Quality Management Systems fit together to achieve regulatory compliance.

A working knowledge of drug safety and Pharmacovigilance principles is necessary in order to gain maximum benefit from the course.

### Learning Objectives

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

- Describe how to design, develop, and manage a quality system related to your pharmacovigilance system
- Explain the components of the Pharmacovigilance Quality Manual
- Describe the process for the development and maintenance of the Pharmacovigilance System Master File
- Analyze how the pharmacovigilance quality system integrates with the pharmacovigilance system
- Discuss the development, maintenance, and quality oversight of pharmacovigilance SOPs and pharmacovigilance related documents, including Safety Management Plans and PV Agreements across clinical study programs and post-marketing
- Assess the effectiveness of the Quality Management System
- Explain Quality Risk Management Planning for risk-based audits of the Pharmacovigilance System and Quality System
- Define the scope of pharmacovigilance audits, including process audits, drug specific pharmacovigilance audits, and business partner pharmacovigilance audits
- Describe how to prepare for audits and inspections
- Practice preparing responses to a pharmacovigilance audit and inspection findings

### Who Will Attend

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

- Quality assurance and compliance of the pharmacovigilance system
- Pharmacovigilance auditing
- Drug safety and pharmacovigilance personnel responsible for compliance, pharmacovigilance agreements, and/or pharmacovigilance quality documents
- Pharmacovigilance activities at a pharmaceutical company or external service provider

Pharmacovigilance personnel who are considering the Pharmacovigilance Quality Management System field as a future career path would benefit from this course.

### Faculty

#### Wendy Huisman

Director  
Vigifit, Netherlands

#### Jose Ortiz

QPPV  
PVpharm, Spain

### Key Topics

- What is a Quality System
- How to set up a QMS
- Exercise on listing the key/critical PV activities
- Workshop on Gap Analysis of PV processes
- Overview and description of the PSMF and PV Quality Manual
- Risk Management Workshop
- Process Flow Workshop
- Safety Management Plans
- Exercise on SDEA agreements
- Commercial Activities and PV Obligations
- Exercise on KPIs/metrics
- Risk Assessment Workshop
- Record Management, Documentation of QMS and data privacy regulation
- PV Inspections and Inspection Readiness
- Inspection Findings Response Workshop
- Root Cause Analysis Workshop

# Schedule-At-A-Glance

## DAY 1

09:00 WELCOME AND INTRODUCTION

09:30 SESSION 1

### QUALITY AND THE QUALITY SYSTEM

*Jose Ortiz*

- What a Quality System is, its purpose, and what it typically includes
- Exercise: Each participant to write answers to four questions on the Quality System

10:05 SESSION 2

### QUALITY MANAGEMENT SYSTEM (QMS) OVERVIEW

*Wendy Huisman*

- Overview of the regulatory framework
- First steps in setting up a QMS, core principles applicable to all quality management standards, and the Quality Cycle

11:00 BREAK

11:15 SESSION 3

### THE PHARMACOVIGILANCE SYSTEM

*Jose Ortiz*

- Objectives, structures, and processes for the Pharmacovigilance System and how these interact
- Key pharmacovigilance activities/processes required per legal requirements and Pharmacovigilance System Element Ownership
- Exercise: List the key/critical PV activities

12:35 SESSION 4

### SYSTEMS, PROCESSES, QUALITY DOCUMENTS

*Wendy Huisman*

- Quality System SOPs versus Pharmacovigilance System SOPs
- Interactions of the Pharmacovigilance System with the Quality System and identifying potential gaps
- Gap Analysis of PV Processes Workshop

13:30 END OF DAY 1

## DAY 2

09:00 SESSION 5

### PHARMACOVIGILANCE SYSTEM MASTER FILE AND PHARMACOVIGILANCE QUALITY MANUAL

*Wendy Huisman*

- Overview and description of the Pharmacovigilance System Master File (PSMF) and the Pharmacovigilance Quality Manual
- Review requirements, content, and maintenance for these documents

10:25 SESSION 6

### RISK ASSESSMENT OF IDENTIFIED GAPS

*Jose Ortiz*

- Identifying potential risks and determining if they are critical based on impact
- Review common pharmacovigilance inspection findings from FDA and MHRA
- Risk Management Workshop

11:15 BREAK

11:30 SESSION 7

### PROCEDURES AND STANDARDS

*Wendy Huisman*

- Overview of a Quality Management Policy and its elements • Quality document hierarchy
- SOP hierarchy
- SOP components, regulatory requirements, and writing hints
- Process Flow Workshop

12:20 SESSION 8

### PHARMACOVIGILANCE IN THE STUDY AND CLINICAL TRIAL ENVIRONMENT

*Jose Ortiz*

- Review of study classification, causality assessments, expedited reporting, reference safety information and other areas subject to pharmacovigilance audits and inspections
- Pharmacovigilance-related clinical processes and crossfunctional SOPs
- Safety Management Plans, when they are required, and key elements to include

13:30 END OF DAY 2

## DAY 3

09:00 SESSION 9

### PHARMACOVIGILANCE AGREEMENTS (PVAS) AND PV PROVISIONS

*Jose Ortiz*

- Various relationships requiring a PVA (also known as Safety Data Exchange Agreement) or PV provisions and the types of contracts
- Development of PVAs across clinical study programs and post-marketing, including regulatory requirements, updating, quality oversight, operational aspects and best practices
- Exercise: Who is the functional owner of each agreement?

10:10 SESSION 10

### COMMERCIAL ACTIVITIES AND PV OBLIGATIONS

*Wendy Huisman*

- New and innovative ways that commercial gathers information on drugs and diseases to help guide future strategies such as patient support programs, mobile healthcare apps, and customer engagement/marketing programs
- Recommendations to ensure pharmacovigilance regulatory compliance due to the increased interaction with healthcare providers and patients

11:15 BREAK

11:30 SESSION 11

### COMPLIANCE MANAGEMENT AND MONITORING

*Jose Ortiz*

- Specific quality system procedures and processes that should be in place to ensure compliance with the various required pharmacovigilance activities
- Processes to monitor the performance and effectiveness of a Pharmacovigilance System and its Quality System
- Exercise: Using list of PV activities you prepared in Sessions 3, 4, & 9, identify where you could use KPIs/metrics

12:20 SESSION 12

### RISK-BASED AUDITING AND THE PHARMACOVIGILANCE AUDIT UNIVERSE

*Wendy Huisman*

- FDA and EMA requirements regarding Risk-Based Audits of the Pharmacovigilance System and Quality System
- Recommendations on the design of the pharmacovigilance audit strategy
- Identification of the pharmacovigilance processes and entities subject to pharmacovigilance audits (define the pharmacovigilance audit universe)
- Development of risk assessment methodology
- Implementation of the pharmacovigilance audit strategy plan
- Methods of quality oversight and management of third parties performing pharmacovigilance activities
- Risk Assessment Workshop

13:30 END OF DAY 3

## DAY 4

09:00 SESSION 13

### RECORD MANAGEMENT, DOCUMENTATION OF QMS AND DATA PRIVACY REGULATION

*Wendy Huisman*

- Requirements for information protection, classification, and management including computerized systems
- Data integrity, good documentation practices, maintenance of documents

10:10 SESSION 14

### PHARMACOVIGILANCE INSPECTIONS AND INSPECTION READINESS

*Jose Ortiz*

- The types and scopes of pharmacovigilance inspections
- The role of the PSMF in ensuring Marketing Authorization Holders and pharmacovigilance units remain inspection ready
- How to prepare for inspections and be inspection ready
- Checklists for planned and unplanned inspections, and tips on being the interviewee

11:15 BREAK

11:30 SESSION 15

### RESPONDING TO INSPECTION AND AUDIT FINDINGS

*Wendy Huisman*

- Preparation of responses to inspection and audit findings across commercial and research & development organizations
- Corrective and Preventive Action (CAPA) plans and effectiveness checks
- Responses accepted by regulators
- FDA Inspection Findings Response Workshop

12:25 SESSION 16

### CORRECTIVE AND PREVENTIVE ACTION (CAPA) PLAN

*Jose Ortiz*

- Conducting root cause analysis
- Preparing a CAPA Plan with the aim of correcting areas of noncompliance and determining how to prevent these issues from arising in the future
- Root Cause Analysis Workshop

13:15 SESSION 17

### PHARMACOVIGILANCE QMS COURSE SUMMARY AND KEY POINTS

13:30 END OF VIRTUAL LIVE TRAINING COURSE



## 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).

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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:  
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## Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 16.50 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

PV QMS | Virtual Live Training Course | # 25543  
24-27 February 2025 | 09:00-13:30 CET

# 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 30 Dec 2024	MEMBER valid from 31 Dec 2024	NON- MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 <input type="checkbox"/>	€ 1'580.00 <input type="checkbox"/>	€ 1'840.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 <input type="checkbox"/>	€ 1'050.00 <input type="checkbox"/>
A special discount is available for organisations which are listed in the <a href="#">EMA SME register</a> . 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](#).

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](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.

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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>.

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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

Company

Address

Postal Code

City

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Telephone Number

Attendee email required for course material access

## PAYMENT METHOD

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You will receive a payment link in the coming days to complete the payment.

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