DIA LEARNING

Pharmacovigilance Quality Management System

Virtual Live Training Course

22-25 September 2025 | 13:00-17:30 CEST

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 trainng 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 Assesment Worskhop
- Record Management, Documentation of QMS and data privacy regulation
- PV Inspections and Inspection Readiness
- Inspection Findings Response Workshop
- Root Cause Analysis Workshop

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION

13:30 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

14:05 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

15:00 BREAK

15:15 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

16:35 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

17:30 END OF DAY 1

DAY 2

13:00 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

14:25 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

15:15 BREAK

15:30 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

16:20 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

17:30 END OF DAY 2

DAY 3

13:00 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?

14:10 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

15:15 BREAK

15:30 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

16:20 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

17:30 END OF DAY 3

DAY 4

13:00 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

14:10 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

15:15 BREAK

15:30 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

16:25 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

17:15 SESSION 17

PHARMACOVIGILANCE QMS COURSE SUMMARY AND KEY POINTS

17:30 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.

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

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About DIA

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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

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.

SwAPP Swiss Association of Pharmaceutical Professionals

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 | # 25544
22-25 September 2025 | 13:00-17:30 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 28 Jul 2025	MEMBER valid from 29 Jul 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
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.

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

Payment by credit card or bank transfer is possible. Please tick your preferred option.

❑ **Credit card:** 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.

❑ **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 the **invoice number,** your name and company to ensure correct allocation of your payment. Payments must be net of all bank charges. Bank charges must be borne by the payer.

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.

If you have not received your confirmation within five working days, please contact 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