

Advanced Workshop: QPPV Toolbox - Your Key to Success

Face-to-Face Training Course
4-5 June 2025 | Amsterdam, NL



Overview

The face-to-face workshop is designed to maximise interaction and discussions within small groups, based on suggestions from people in QPPV roles and led by our expert instructor.

The workshop discussions will enable you to address and solve problems in your daily business more efficiently.

You will learn how to adopt the right mindset and the right thinking processes to deliver positive results while learning from the experience of your peers in similar situations.

Learning Objectives

At the conclusion of this workshop, participants will be able to:

- Identify the requirements for marketing authorisation holder and QPPV
- Discuss how to prepare for and conduct the audits and inspections
- Navigate the changes in the QPPV role within a global commercial environment
- Identify elements of the pharmacovigilance system
- Describe components of a complete pharmacovigilance system: including a QPPV back-up and delegating pharmacovigilance activities

Key Topics

This workshop is aimed at QPPVs who are already established in their role and seek to further improve their daily practice.

- Systems accountability
- Regulatory confidence in the quality of the PSMF
- Oversight of the Case Management process
- Policies for medication errors, misuse and lack of effect
- Quality, accuracy, completeness and timelines of PSURs/PBRERs, RMPs and design of RMMs
- Oversight of PASS processes
- Safety Governance processes
- Interface with RA: Best team-working practices
- Investigator-initiated research, market research and patient support programmes
- QPPV inspection and audit readiness

Who Will Attend

This workshop is aimed at QPPVs who are already established in their role and seek to further improve their daily practice.

Instructor

Shelley Gandhi

Partner & PV trainer
Eliquent Life Sciences, United Kingdom

DAY 1

08:30 REGISTRATION AND WELCOME COFFEE

09:00 INTRODUCTION

09:30 SESSION 1

DEFINING THE SCOPE OF SYSTEM AND RELATIONSHIPS: GETTING ORGANISED

This session covers systems accountability, how relationships with the MAH and the wider company should be set up and documented. This includes techniques such as delegation, deputisation and good practices for personal job descriptions, training and contracts. The QPPV is expected to maintain regulatory confidence in the quality of the PSMF.

11:00 COFFEE BREAK

11:30 SESSION 2

ENSURING GOOD CASE QUALITY

This session will describe how the QPPV can demonstrate oversight of the case management process from end to end, influence case quality, causality assessment and timelines of expedited reporting including safety database validations and updates and consequences of any technical changes within this environment. The interface with product quality complaints will be examined as the QPPV would be expected to guide policies for medication errors, misuse and lack of effect.

13:00 LUNCH BREAK

13:30 SESSION 3

PERIODIC REPORTS AND RISK MANAGEMENT PLANS

This session will describe how the QPPV can assure and demonstrate the quality, accuracy, completeness and timelines of PSURs/PBRERs, risk management plans and design of risk minimisation measures.

15:30 COFFEE BREAK

16:00 SESSION 4

POST-AUTHORISATION SAFETY STUDIES AND COMMITMENTS AS PART OF THE LIFECYCLE REQUIRING AND INTERFACE WITH CLINICAL TEAMS

This session will discuss how the QPPV can assure and demonstrate oversight of PASS processes in accordance with regulatory requirements with production of PASS reports of adequate quality and completeness in a timely manner. The QPPV needs to be aware of post-authorisation clinical trials, non-interventional studies and future development plans for the product.

17:30 QUESTIONS AND ANSWERS

18:00 WELCOME RECEPTION

19:00 END OF DAY 1

DAY 2

09:00 SESSION 5

SIGNAL DETECTION AND BENEFIT-RISK ASSESSMENT

This session will discuss how the QPPV can supervise and be involved in establishing the safety governance processes for signal detection and benefit-risk assessment, be responsible for the adequacy of documentation describing these processes and their tracking and assure compliance. The QPPV is expected to explain best signal detection practices, the rationale for different methodologies and choice of sources for signal detection and how validation should occur.

10:30 COFFEE BREAK

11:00 SESSION 6

INTERFACE WITH REGULATORY AFFAIRS: LABELLING, VARIATIONS AND RESPONDING TO SAFETY REQUESTS

This session will discuss best team-working practices to ensure QPPV involvement in labelling decisions, CCSI creation and maintenance and their implementation through SPC variations and awareness of regulatory safety queries with input where necessary.

12:30 LUNCH BREAK

13:30 SESSION 7

INTERFACE WITH COMMERCIAL AND LEGAL GROUPS

This session will cover best practices about liaising with commercial teams concerning investigator-initiated research, market research and patient support programmes. In addition, relationship with legal group is important concerning agreements with partners to ensure adequate pharmacovigilance obligations are in place and that the QPPV is consulted early when future partnerships or product acquisitions are planned.

15:00 COFFEE BREAK

15:30 SESSION 8

INTERFACE WITH THE QUALITY ASSURANCE GROUP

This session will input into how the QPPV should be aware of the PV audit schedule and subsequent processes for CAPAs. Influencing the wider quality management system within a Company is one of the main ways of successfully fulfilling the role of QPPV. This includes ensuring all staff receive appropriate PV training and are competent for their PV roles and responsibilities. This final session will also cover QPPV Inspection/Audit Readiness.

17:00 QUESTIONS AND ANSWERS

17:30 END OF THE WORKSHOP

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.



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 (excludes government/academia/non-profit). 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.*



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
- Cost Effectiveness

Or explore [eLearning](#) to allow self-paced learning.

For more information please contact 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.

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.



Venue Information

Mercure Hotel Amsterdam City

Joan Muyskenweg 10, 1096 CJ Amsterdam, The Netherlands

Tel: +31 20 721 917

Email: H1244@accor.com

Website: <https://www.mercureamsterdamcity.com/>

Bedroom reservations

DIA has blocked a limited number of hotel bedrooms for the course participants from 3rd to 5th June 2025 at the rate of EUR 239.00 per standard/classic double room for single use per night including breakfast, excluding taxes and city-tax. In order to book a hotel bedroom, please fill out the booking form that is available on the DIA website and send it by email to Diego.Fort@accor.com.

The room rate is available until 4th April 2025 or until the room block is sold-out, whichever comes first.



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 12 credits.



REGISTRATION FORM

QPPV Toolbox # 25546
4-5 June 2025 | Amsterdam, NL

REGISTRATION FEES

Registration fee includes admission to the course, refreshment breaks and lunches, and 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 Apr 2025	MEMBER valid from 9 Apr 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 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://www.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://www.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

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.

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