

## Advanced Workshop: QPPV Toolbox - Your Key to Success

Face-to-Face Training Course  
20-21 April 2027 | London, UK



### Overview

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**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

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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

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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

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

### Instructor

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**Shelley Gandhi**

Partner & PV trainer  
Eliquent Life Sciences, United Kingdom

## DAY 1

08:30 REGISTRATION AND WELCOME COFFEE

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09:00 INTRODUCTION

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09:30 SESSION 1

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### 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

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11:30 SESSION 2

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### 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

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14:00 SESSION 3

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### 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

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16:00 SESSION 4

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### 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

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18:00 WELCOME RECEPTION

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19:00 END OF DAY 1

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## DAY 2

08:30 SESSION 5

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### 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.

10:00 COFFEE BREAK

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10:30 SESSION 6

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### 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.

12:00 LUNCH BREAK

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13:00 SESSION 7

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### 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.

14:30 COFFEE BREAK

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15:00 SESSION 8

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### 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.

16:30 QUESTIONS AND ANSWERS

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17:00 END OF THE WORKSHOP

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*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](mailto:basel@diaglobal.org).

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



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## 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

### Hilton London Olympia

380 Kensington High Street London W14 8NL United Kingdom

Tel: +44 20 7603 3333

Email: [reservations.olympia@hilton.com](mailto:reservations.olympia@hilton.com)

Website: <https://www.hilton.com/en/hotels/lhrolhn-hilton-london-olympia/>

### Bedroom reservations

DIA has blocked a limited number of bedrooms for the course participants at the rate of GBP 148.48 per Classic Double room per night for single use. The rate includes VAT, free Wi-Fi and extensive breakfast.

Information on how to book will be available shortly.



## Continuing Education

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.



# REGISTRATION FORM

GPPV Toolbox # 27546

20-21 April 2027 | London, UK

## 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 23 Feb 2027	MEMBER valid from 24 Feb 2027	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'260.00 <input type="checkbox"/>	€ 1'400.00 <input type="checkbox"/>	€ 1'660.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 700.00 <input type="checkbox"/>	€ 960.00 <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.

## 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](mailto:Basel@DIAGlobal.org) **Mail:** DIA, KÜchengasse 16, 4051 Basel, Switzerland

**Web:** [www.diaglobal.org](https://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.

**If you have not received your confirmation within five working days, please contact [basel@diaglobal.org](mailto: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
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