

Advanced Workshop on QPPV Toolbox - Your Key to Success

12-13 November 2018
Mercure Lyon Charpennes Hotel, Lyon, France



OVERVIEW

The workshop is designed to include small group interaction and discussions, led by our expert instructor, and is based on suggestions from the QPPVs themselves. The workshop will allow you to be more efficient in solving the problems in your daily business, learn the right thinking processes to land at good results and hear from solutions from other in similar situations.

LEARNING OBJECTIVES

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

- Master the obligations of marketing authorization holder and QPPV – your responsibilities
- Prepare and go through the audits and inspections without major issues
- Navigate the changes in the QPPV role in a global commercial environment
- Achieve oversight of the PV system
- Set up a complete system: a QPPV Backup and delegating PV activities

KEY TOPICS

- PSMF oversight
- Quality management
- Vendor management
- Delivering a successful inspection
- QPPV in the global environment – European and international considerations

WHO WILL ATTEND

This workshop is intended for QPPVs who are already established in their role and would like to improve their daily practice.

FACULTY

- Shelley Gandhi**
Strategic Advisor, Pharmacovigilance and Drug Safety
NDA Group, United Kingdom

DAY 1

08:30 REGISTRATION

09:00 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 setup 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.

10:30 COFFEE BREAK

11:00 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.

12:30 LUNCH

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.

15:00 COFFEE BREAK

15:30 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.

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 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.

10:00 COFFEE BREAK

10:30 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, CCSL creation and maintenance and their implementation through SPC variations and awareness of regulatory safety queries with input where necessary.

12:00 LUNCH

13:00 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.

14:30 COFFEE BREAK

15:00 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.

16:30 END OF WORKSHOP

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

I Training Course Venue

MERCURE LYON CHARPENNES HOTEL

7 place Charles Hernu
69100 Lyon Villeurbanne, France
Tel: +33 4 72 44 46 46
Fax: +33 4 78 89 10 14
Email: H1625@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 139.00 from 11 to 14 Nov and EUR 159.00 from 14 to 16 Nov per standard room per night including breakfast and VAT, excl. EUR 1.65 City-Tax. If you would like to make a booking, please fill in the booking form available on the website and send it per email to H1625@accor.com with a reference "DIA".

The room rate is available until 15 October 2018 or until the room block is sold-out, whichever comes first.



HOW TO GET THERE

From train station Lyon Perrache: Take the metro line A, direction L.Bonnevay and exit at station Charpennes (7 stops).

From train station Lyon Part Dieu: Take the metro line B to the station Charpennes (2 stops).

From the airport Lyon ST EXUPERY: Take the shuttle "Satobus" to the train station TGV/Part Dieu and change there to the metro line B and exit at the station Charpennes (2 stops).

I 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 with 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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I Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 12 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12 credits.



I Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

REGISTRATION FORM

Advanced Workshop on QPPV Tool Box – Your Key to Success # 18547
12-13 November 2018 | Mercure Lyon Charpennes Hotel | Lyon, France



REGISTRATION FEES

Registration fee includes refreshment breaks, lunch and electronic access to training course material.

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	NON-MEMBER
INDUSTRY	€ 1'450.00 <input type="checkbox"/>	€ 1'605.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 <input type="checkbox"/>	€ 880.00 <input type="checkbox"/>

All registration fees are subject to applicable French VAT

Please enter your company's French VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.**

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click [here](#). If you want a membership, please indicate your preference below.

I would like to receive a one year complimentary DIA membership at no additional cost

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52**

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 [here](#).

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click [here](#). You agree that your personal data will be transferred to DIA in the US

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

Fax 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 #18547 as well as the invoice number to ensure correct allocation of your payment.

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