DIA Learning

QPPV Toolbox: Your Key to Success

Advanced Virtual Live Workshop

23-26 November 2020 09:00-13:00 CET

OVERVIEW

The 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 course, participants will be able to:

- Master the obligations of marketing authorisation holder and QPPV – your responsibilities
- Prepare for and conduct the audits and inspections without major issues
- Navigate the changes in the QPPV role within a global commercial environment
- Gain oversight of the pharmacovigilance system
- Establish a complete system: a QPPV back-up and delegating pharmacovigilance activities

KEY TOPICS

- PSMF oversight
- Quality management
- Vendor management
- Successful inspection delivery
- QPPV in the global environment – European and international considerations

WHO WILL ATTEND

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

FACULTY

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PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

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 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 END OF DAY 1

DAY 2

09:00 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.

10:30 BREAK

11:00 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.

12:30 QUESTIONS AND ANSWERS

13:00 END OF DAY 2

DAY 3

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 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 QUESTIONS AND ANSWERS

13:00 END OF DAY 3

DAY 4

09:00 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.

10:30 BREAK

11:00 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.

12:30 QUESTIONS AND ANSWERS

13:00 END OF WORKSHOP

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

800x600 pixel resolution or greater (1024x768 pixels recommended).

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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.

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 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

Plan Your Team's Professional Development

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

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For more information please contact Basel@diaglobal.org.

REGISTRATION FORM

QPPV Tool Box: Your Key to Success # 20546

23-26 November 2020 09:00-13:00 CET

DIA Learning

REGISTRATION FEES

Registration fee includes full access to virtual course 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	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
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.

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 CET. **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. 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

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

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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 #20546 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