DIA Learning

Advanced Workshop: QPPV Toolbox - Your Key to Success

18-19 November 2019
Hotel Berlin Mitte, Berlin, Germany

OVERVIEW

This 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 authorisation 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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 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.

10:00 COFFEE BREAK

10:30 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.

12:00 LUNCH

13:00 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.

14:30 COFFEE BREAK

15:00 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.

16:30 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, CCSI 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.

Training Course Venue

HOTEL BERLIN MITTE (MANAGED BY MELIA)
Chausseestrasse 33
10115 Berlin, Germany
Tel: +49 30 41 47 230
Email: hotel.berlin.mitte@melia.com

Participants are kindly requested to contact hotel directly for their best available rate.

HOW TO GET THERE

The closest U-Bahn station is "Naturkundemuseum" on line U6 Alt-Tegel - Alt-Mariendorf.
From Tegel Airport take the bus TXL128 towards Osloer Strasse, and get off at Kurt-Schumacher-Platz U-Bahn station.
Change there to U-Bahn line 6 towards Alt-Mariendorf and get off at Naturkundemuseum (8 stops).

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

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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.

SwAPP

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.