DIA Learning

Advanced Workshop on QPPV Toolbox - Your Key to Success

27-28 February 2017
Holiday Inn London Kensington Forum, London, United Kingdom



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

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NDA Group, United Kingdom

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

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 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.

10:30 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 timeliness 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 timeliness 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 to 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, 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, relationships 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

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REGISTRATION FORM

Advanced Workshop on QPPV Tool Box – Your Key to Success # 17546
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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

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Payment is due 30 days after registration and must be paid in full by commencement of the course.

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The DIA Europe, Middle East & Africa 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: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
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ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

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Attendee email required for course material access

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Date	Signature

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