10th European Forum for Qualified Person for Pharmacovigilance (QPPV)

5-6 October 2016 (Pre-Conference on 4th October)
The Crystal, London, UK

PROGRAMME CHAIRS

Vicki Edwards
EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, UK

Margaret Walters
Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK

PROGRAMME COMMITTEE

Elspeth McIntosh
Director, Castle Pharmacovigilance Limited, UK

Doris Stenver
Chief Medical Officer, Danish Medicines Agency, Denmark

Michael Richardson
International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Brian Edwards
Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Winrich Rauschning
QPPV, BioLitec Pharma, Germany

Barbara De Bernardi
EU QPPV Deputy, Pfizer Italia S.r.l.,Italy

Peter De Veene
Head Global Drug Safety & QPPV, Grünenthal, Germany

COMMITTEE LIAISON ON TRAINING FOR QPPVS:

Shelley Gandhi
Strategic Advisor, Pharmacovigilance and Drug Safety at NDA Group AB

OVERVIEW

This is the only forum designed for QPPVs by QPPVs, now in its 10th year and ever growing. This year's objectives, as shown below, build on past successes and have been shaped by valuable feedback provided by participants of the past nine meeting, plus will celebrate a decade of QPPV and Regulator interaction through this Forum.

Over time, one of the key successes of the Forum has been the ability to secure continuing support and involvement of key regulators. Sessions have been open and interactive with attendees appreciating opportunities to raise challenging issues in an informal environment. This 10th QPPV Forum aims to continue to attract such key speakers and encourage open debate

OBJECTIVES

- Hear the latest updates and hot topics relating to the role of the QPPV
- Explore long term PV visions, future directions of the 'PV world', and potential impact on the role of QPPV
- Network with colleagues and meet regulators
- Learn from and share experience and ideas with like-minded QPPVs in a neutral environment
- Take away practical hints and tips
- Better understand regulatory and inspectorate expectations of the QPPV
- Identify the expanded expectations of the role in the context of the new regulatory framework and transparency initiatives
- Examine current areas of real challenge

NEW IN 2016!

A Gala Dinner will be held on Wednesday evening, 5 October at the Crown Plaza Docklands

ADVANCE PROGRAMME

DIA DEVELOP INNOVATE ADVANCE

10th European Forum for Qualified Person for Pharmacovigilance (QPPV)

HALF DAY PRE-CONFERENCE WORKSHOP 4TH OCTOBER | 13:00–17:30

'INTRODUCTION TO THE ROLE OF QPPVS'

Limited places available.

As a result of feedback from previous years we are repeating this workshop aimed at those EU QPPVs who are new to the role, need to refresh on the role, those who support the QPPV and those who are thinking of taking on a QPPV role. The session will focus on providing an understanding of and update on the QPPV role and the support required, the practical issues facing QPPVs in a range of company sizes and types, legal considerations for QPPVs and expectations of the QPPV in audit and inspection.

Workshop Chair:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

12:00 Registration and coffee

13:00 **What does it mean to be a QPPV?**
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

QPPV Legal Issues
Chris Foreman, Senior Director, Legal Affairs, Nordic Region, Merck Sharp & Dohme (Europe) Inc., Belgium

QPPV Challenges - Panel Discussion,
Session speakers
Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd., UK

15:15 Refreshment Break

QPPV Backup and required skills/training:
Maria Wishart, Deputy QPPV, AstraZeneca, UK
Jefferson Guillon, Pharmacovigilance Manager & EEA QPPV, Alliance Pharma plc and, Alliance Pharmaceuticals Ltd, UK

QPPV and QA/Audit/Inspection
Janet Scott, Senior Consultant (Pharmacovigilance), Xendo-Vigilex, UK

Panel Discussion
Session speakers
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK
Margaret Walters, Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd., UK
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK
Peter De Veene, Head Global Drug Safety & QPPV, Grünenthal

Separate registration required

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

Conference Venue

The Crystal
1 Siemens Brothers Way,
Royal Victoria Dock
London, E16 1GB
United Kingdom

Gala Dinner Venue

Crowne Plaza London - Docklands
Royal Victoria Dock
Western Gateway
London, E16 1AL
United Kingdom

Accommodation

Holiday Inn Express – London Royal Docks
1 Silvertown Way
London, E16 1EA
United Kingdom

DIA has blocked a limited number of hotel rooms for the participants from 4 to 6 October 2016 at the rate of GBP 185.00 per single room per night including VAT, breakfast and free wifi.

In order to book a hotel room, please contact reservations department at reservations@hiexroyaldocks.co.uk using reference "DIA Europe". The room rate is available until 20 August 2016 or until the room block is sold-out, whichever comes first. Please refer to the hotel for cancellation policy.

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members — regulators, researchers, industry professionals, advocates and patients — join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

DAY ONE | WEDNESDAY, 5 OCTOBER 2016

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

KEY NOTES

Session Chair: **Michael Richardson**, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

The EU PV legislation, which came with clearly defined objectives, has been in force since 2012. Additional to this PRAC and the EMA have clarified and evolved multiple projects. This session will ask key regulators and Industry the following questions:

- Have the deliverables of transparency, simplification and enhanced evaluation of benefit risk been achieved?
- Are the regulators gaining better oversight and insight to the use of medicines within Europe and have Patients and Healthcare providers received better and clearer information on the products they use?
- Are industry and regulators better able to collaborate and communicate in the oversight of the use of medicines and does the QPPV have greater oversight of the safety of the products for which they have responsibility?
- How is the global environment requiring a single point oversight of the system changing the QP role organisationally to maintain consistent safety oversight?

10:30 COFFEE BREAK

11:00 SESSION 2

HOT TOPICS FOR QPPV OVERSIGHT

Session Chair: **Vicki Edwards**, EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, UK

Post the new legislation implementation we are still in a time of change whereby new GVPs and guidance documents are released and existing documents are updated. The industry continues to engage with the Regulators to provide feedback on the changes and new requirements on practical implications and opportunities for clarifications and potential improvements. Not all companies are represented on the various trade associations that form the main forum for ongoing discussion with Regulators and so this session will share the topics of interest currently under discussion.

- Topics of interest that the EFPIA and other industry trade associations are actively discussing with the Regulators for example PSPs, Off-label use, PASS and PAES, signal detection
- Speakers will be from the working groups engaged in specific topics
- New issues and progress of ongoing issues will be presented

Speakers will be identified closer to the event to ensure timeliness of the topics.

12:30 LUNCH

14:00 SESSION 3

HOT TOPICS – A REGULATORS' PERSPECTIVE

Session Chair: **Doris Stenver**, Chief Medical Officer, Danish Medicines Agency, Denmark

Following completion of the implementation of the 2012 pharmacovigilance legislation, PRAC has engaged in further development of a wide range of areas. For the QPPV it is important to keep abreast with these developments. Among the ongoing activities is the development of the conduct of pharmacovigilance in relation to biologicals. The PRAC is also involved to an increasing extent in the scientific advice process, risk management planning for high risk products and in the development of the PAES concept. Finally, this session will highlight how PRAC utilizes real world evidence as a basis for their decisions.

Brigitte Keller-Stanislawski, Head, Pharmacovigilance, Paul-Ehrlich-Institut, Germany

Margarida Guimaraes, Pharmacovigilance Assessor and Project Manager, Infarmed, Portugal

15:30 COFFEE BREAK

16:00 SESSION 4

RISK MANAGEMENT MEASURES (RMMS)

Session Chair: **Barbara De Bernardi**, EU QPPV Deputy, Pfizer Italia S.r.l., Italy

Session Co-Chair: **Winrich Rauschning,** QPPV, BioLitec Pharma, Germany

Approaches to risk management and evaluation have been evolving extensively over the last few years. This session will review the current practices and the interplay of the various tools and associated aggregate reports (risk minimisation tools/surveys, RMM effectiveness measurement/surveys, Risk Management Plans, Periodic Safety Update Reports, Development Safety Update Reports, etc.) with a focus on changes in guidelines and future trends.

Emil Cochino, Scientific Officer, Anti-infectives and Vaccines, SRM Department, EMA, UK

George Pajovich, Head of Safety Risk Research, Pfizer Inc., USA

Anne-Ruth van Troostenburg de Bruyn, EU QPPV & Sen Director, Drug Safety & Public Health, Gilead Sciences International, UK

17:30 END OF DAY ONE

19:30 GALA DINNER AT CROWNE PLAZA DOCKLANDS

DAY TWO | THURSDAY, 6 OCTOBER 2016

09:00 SESSION 5

INSIGHTS ON INSPECTIONS, AUDITS AND QUALITY MANAGEMENT: WHAT'S IT ALL ABOUT?

Session Chair: **Peter De Veene**, Head Global Drug Safety & QPPV, Grünenthal, Germany

A robust Quality Management System is the foundation for a well-functioning PV system. This session will explore how latest developments in inspections and audits impact the QPPV role and what tools a QPPV can use to measure system performance. The auditing landscape is becoming more and more complex, as many companies are involved in several licensing relationships with many vendors providing services to multiple MAH´s. So how can the QPPV survive this auditing frenzy?

KPIs and Metrics as tool for the QPPV
Monika Pietrek, Managing Director & Senior Consultant, Pietrek Associates GmbH, Germany

Switching from Regulatory Authority to Industry: a new Perspective?
Rebecca Webb, Senior Manager - PV Auditor, Abbvie, UK

Challenges of Partner Audits
Andrew Moore, Head QPPV and Alliance Office, Grünenthal, Germany

10:30 COFFEE BREAK

11:00 SESSION 6

HOW HAS SYSTEM TRANSPARENCY CONTRIBUTED TO SAFER MEDICINES AND WHAT IS THE PLACE OF THE QPPV IN MAINTAINING PROGRESS?

Session Chair: **Brian Edwards**, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Transparency depends on better communication which itself is a key pharmacovigilance activity but have the legislative intentions been fulfilled? Success may be reflected in the level of public reassurance in the face of major safety concerns. This session will discuss the role of the QPPV is ensuring robust risk communication and overseeing systematic contact with patients. If PV oversight by the QPPV is meant to stretch across the lifecycle back to first into man, we shall examine what this means in reality and how this relates to better engagement of patients.

The QPPV's role in transparency and communication with patients: matching the ideal state with reality
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen, UK
Anne-Ruth van Troostenburg de Bruyn, EU QPPV & Sen Director, Drug Safety & Public Health, Gilead Sciences International, UK

What do patients expect of the QPPV concerning transparency and communication?
Francois Houyez, Treatment Information and Access Director Health Policy adviser, EURORDIS, Belgium

12:30 LUNCH

13:30 SESSION 7

QPPV OVERSIGHT – CHANGE MANAGEMENT IN LINE WITH PHARMACOVIGILANCE SYSTEM UPDATES

Session Chairs: **Margaret Walters**, Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK
Peter Arlett, Head of the Pharmacovigilance Department, European Medicines Agency, United Kingdom

New EU Pharmacovigilance legislation has been operational since July 2012. The legislation foresees various information systems to enhance pharmacovigilance. These systems contribute to public health through optimisation of the safe and effective use of medicines.

This session will provide an overview of the important progress made and will focus at providing the marketing authorisation holders (MAHs) with information to help prepare for business change.

Medical Literature Monitoring
Tom Paternoster-Howe, Scientific Administrator, Monitoring and Incident Management, PhV, European Medicines Agency, European Union

EudraVigilance
Francois Domergue, European Medicines Agency, European Union

Article 57 Database of Medicinal Products
EMA speaker invited

PSUR Repository
Irene Rager, Head of Service E, Procedure Management Department, European Medicines Agency, European Union

Open Discussion on Implementation Challenges: Speakers and Attendees

15:45 END OF CONFERENCE

16:15 DISCUSSION GROUP: BREXIT AND ITS IMPACT

17:30 CLOSING OF THE DISCUSSION

REGISTRATION FORM

10th European Forum for Qualified Person for Pharmacovigilance (QPPV) | ID#16104
5-6 October 2016 | The Crystal, London, UK

DIA DEVELOP INNOVATE ADVANCE

Early-bird discount available for members: Register by 23 August 2016

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'330.00** ❑

CATEGORY (AFTER 23 AUGUST 2016)	Member	Non-Member
Industry	€ 1'530.00 ❑	€ 1'685.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 815.00 ❑	€ 970.00 ❑
Optional Pre-Conference Workshop | 4 October 2016 | 13:00-17:30		
I wish to attend the Pre-Conference Workshop - Introduction to the Role of the QPPVs	€ 400.00 ❑	

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

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

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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Country

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Fax

Email

Please provide your European VAT number

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#16104 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 Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature

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DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be in writing and received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA 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 EMEA office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email emea@DIAglobal.org
Tel. +41 61 225 51 51
Fax +41 61 225 51 52
Web www.DIAglobal.org
Mail DIA EMEA, Kuechengasse 16, 4051 Basel, Switzerland