DIA

11th European Forum for Qualified Person for Pharmacovigilance (QPPV)

4-5 October 2017 | The Crystal, London, UK

PROGRAMME COMMITTEE

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

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

Elspeth McIntosh
Director, Castle Pharmacovigilance Ltd., 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

OVERVIEW

This is the only forum designed for QPPVs by QPPVs, now in its 11th 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 11th 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

WHO WILL ATTEND?

- QPPVs
- Deputy QPPVs
- Pharmacovigilance Consultant
- Director Pharmacovigilance Oversight and Standards
- Drug Safety Manager
- Audits
- Drug Safety Leader
- Medical and Regulatory Affairs Experts
- Pharmacist
- Drug Safety Scientists

11th European Forum for QPPVs

DAY ONE I WEDNESDAY, 4 October

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 environment in which the pharmaceutical industry lives has seen dramatic changes in the past decade driven by changing legislation, heightened patient expectations on efficacy and safety and funding and access of medicines controlled by payers. This changed milieu has necessitated a confluence of pharmacovigilance, development and commercialisation of medicines to engage earlier and more transparently with regulators and payers:

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?
- Have regulators and Industry in particular the QPPV better oversight and insight to the use of medicines
- Have Patients and Healthcare providers received better and clearer information on the products they use?
- In the changed global environment have Industry achieved optimal organisational and functional models to continue successful delivery of new medicines and ensure safe and appropriate use and access of these
- Does Senior leadership in Industry support the role of the QPPV and the principle of single point oversight of the safety system?

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

This will be year three for this very popular session. Typically the session invites speakers who are leading discussions between industry trade associations and Regulatory Authorities on the key issues of the moment. The session provides insight into what are the hot topics under discussion, what progress has been made and what are the next steps. The session is of value to participants from both large and small companies alike as there is limited attendance possible at the public meetings with EMA so this is a fantastic opportunity to hear about these topics from individuals who are directly involved. The session consists of a series of short, concise presentations that cover the key messages. This session is always a crowd pleaser!

12:30 LUNCH

14:00 SESSION 3

HOT TOPICS – A REGULATORS' PERSPECTIVE

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

The activities in the Pharmacovigilance Risk Assessment Committee (PRAC) covers a wide range of procedures, and the level of experience has reached a high level of matureness more than 5 years after the 2012 EU pharmacovigilance legislation came into force. For the QPPV it is important to keep abreast with the PRAC activities, and the current session will provide valuable insight into the functioning of the PRAC. Which are the current hot topics the committee is dealing with? Who are the most important stakeholders and how does the PRAC cooperate with them? Answers to these and many more questions will be provided in this session.

Speakers:

Almath Spooner - Pharmacovigilance and Risk Management Lead, HPRA. Vice Chair, PRACHealth Products Regulatory Authority (HPRA)

15:30 COFFEE BREAK

16:00 SESSION 4

BREAK-OUT SESSIONS

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

17:30 END OF DAY ONE

Conference Venue

The Crystal
One Siemens Brothers Way
Royal Victoria Docks
London E16 1GB

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Email: info@thecrystal.org

11th European Forum for QPPVs

DAY TWO I THURSDAY, 5 OCTOBER

09:00 SESSION 5

INSIGHTS ON INSPECTIONS, AUDITS AND QUALITY MANAGEMENT

Session Chair:

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

The QPPV is important in directing the interpretation of pharmacovigilance legislation and guidance. QPPVs have considerable flexibility but the basis of the decision must be transparent and properly documented. QPPVs must be able to explain the rationale of why a process is set up in a certain way or whether further changes are required to produce a compliant process. Challenges for quality include obtaining cross-functional ownership of issues and ensuring that all root causes remained addressed by corrective and preventive action plans. This session will explore the different experiences of the MAHs systems that both inspectors and auditors have recently had, how their activities have been supported by the QPPV and how they might expect the MAH to approach human error, communications between departments and other options, apart from audit, that the MAH might use to assess quality.

Speakers:

Kiernan Trevett, MHRA Senior Pharmacovigilance Inspector, UK

Magnus Ysander, EU QPPV & Head Pharmacovigilance Excellence AstraZeneca AB

10:30 COFFEE BREAK

11:00 SESSION 6

EU QPPV OVERSIGHT OUTSIDE EU & ´QPPV REQUIREMENTS OUTSIDE EU´: HOW TO MARRY THESE UP

Session Chair:

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

Pharmacovigilance has evolved significantly over the past ten years in the EU, where the EU QPPV has a key role in the oversight of PV system for all medicinal products for which the company holds marketing authorisations.

The adoption of principles similar to those in the EU PV legislation is increasing in a significant number of ex-EU countries and regions (e.g. Arab league, EAEU league, Ukraine, Israel, Turkey, Cambodia, Malaysia, Ghana, Nigeria, Kenya, etc). The availability of a Pharmacovigilance Responsible Person is now mandatory in many of them in order to ensure PV system compliance.

This increasing complexity of regulatory requirements across the regions needs intense interactions between EUQPPV, ex-EUQPPVs and Local PV contacts.

Therefore, should the EUQPPV role be « globalized » to play the additional business critical role of “company PV policy holder”?

This session will provide updates on current regulatory and industry scenarios.

Pharmacovigilance System Master File

Willemijn Van Der Spuij - International Operations Lead & Pharmacovigilance Intelligence, Switzerland

QPPV Oversight Outside of the EU

Fanny Pruvot - EU Deputy QPPV - Director PV, France

Pharmacovigilance in the Rest of the World

12:30 LUNCH

13:30 SESSION 7

QPPV OVERSIGHT – CHANGE MANAGEMENT IN LINE WITH PHARMACOVIGILANCE SYSTEM UPDATES

Session Chair:

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

In November this year the EMA will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in line with the revised EU Pharmacovigilance legislation. This session will provide updates from several key EMA implementation leads together with an example of an MAHs planning for change. This will be followed by a panel discussion with key EMA speakers towards better enabling effective QPPV oversight of timely and effective internal implementation. Specific topics will include challenges for reporting (including ICSR downloads), processes for MAH signalling in EV and related access policy/data privacy questions.

15:30 COFFEE BREAK

16:00 SESSION 8

BREXIT

17:30 END OF THE CONFERENCE

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 Zsofia.Molnar@DIAglobal.org for a custom group rate.

REGISTRATION FORM | ID# 17104

11th Annual Forum for QPPVs | 4-5 October 2017 | London, UK

Early-bird discount and Advance rate

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird/Advance rate applies to industry members only.

Early bird discount: register by 12 July 2017 **€ 1'330.00** ❑

Advance rate: register by 23 August 2017 **€ 1'430.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'530.00 ❑	€ 1'685.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 765.00 ❑	€ 920.00 ❑

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.

*All fees are subject to the applicable VAT. 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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

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, Event ID#17104 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 made in writing and be received at the DIA Europe, Middle East and Africa 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

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 and Video 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.

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