

# 4th European Forum for Qualified Person for Pharmacovigilance (QPPV)

Event #10104

21-22 April 2010

Hilton London Metropole, London, UK



## Programme Co-Chairs

### Vicki Edwards

Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

### Karen Pattenden

Senior Director, DSPH, Gilead Sciences International Ltd., UK

## Programme Committee

### Brian Edwards

Scientific Advisor Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

### Carmen Kreft-Jais

Chef de Département de Pharmacovigilance, Afssaps, France

### Graeme A. Ladds

Director, PharSafer Associates Ltd., UK

### Valerie Simmons

Lilly QPPV Executive, Global Patient Safety, Eli Lilly and Company Ltd., UK

### Anya Sookoo

Expert Inspector, GCP and Pharmacovigilance, MHRA, UK

### Deborah Szafir

Head of Safety Risk Management Strategy, Roche, France

### Margaret Walters

Director, EU Pharmacovigilance, Merck Sharp & Dohme Ltd., UK

## Overview

European legislation and guidelines such as Volume 9A require all marketing authorisation holders to have a Qualified Person for Pharmacovigilance (QPPV) with responsibility for establishing and maintaining all aspects of the company's global pharmacovigilance system. Although acknowledged to be a vital function, there is little practical guidance on how QPPV responsibilities should best be conducted, while maintaining compliance with regulatory requirements, particularly in complex or challenging situations. The jurisdiction of the QPPV stretches to wherever there is an active licence for a product authorised in the EU. Thus the role in many companies has a far reaching impact outside the EU or may extend to products licensed by one or more affiliates or subject to co-marketing agreements. During this meeting we will discuss and draw on experience of handling these situations in the current complex environment to help QPPVs perform their job more efficiently.

## Objectives

- Identify the role and expectations of the role in the context of the proposed new regulatory framework and updates to Volume 9a and transparency initiatives
- Look at upcoming areas of real challenge for the QPPV such as mergers, outsourcing and complex marketing situations
- Advance understanding of the legal aspects and associated liabilities for the QPPV
- Learn about regulatory and inspectorate expectations of the QPPV
- Share experiences to learn better how to fulfil and deal with the role of the QPPV

## Who Will Attend

- European Qualified Persons for Pharmacovigilance
- Deputy Qualified Persons
- Senior Pharmacovigilance Regulators and Inspectors
- CRO and Consultants providing QPPV Services
- National Responsible Persons for Pharmacovigilance

## WEDNESDAY | 21 APRIL 2010

08:00 Registration and Welcome Coffee

09:00 Session 1

### PERSPECTIVES ON EU LEGISLATIVE FRAMEWORK (TO INCLUDE THE UPDATED 9A IF APPLICABLE)

Session Chairperson:

**Vicki Edwards**, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

An oversight of what is new with specific emphasis on the role of the QPPV in any of the new changes presented. A useful insight and perspective of pharmacovigilance and the QPPV.

#### A Legal Update on the Proposed New Regulatory Framework

Maurits Lugard, Head of EU Life Sciences Regulatory Practice, Sidley Austin LLP, Belgium

#### Implications of the New Regulatory Framework

Carmen Kreft-Jais, Chef de Département de Pharmacovigilance, Afssaps, France

#### Panel Discussion

Panellists include:

- **Vicki Edwards**, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK
- **Carmen Kreft-Jais**, Chef de Département de Pharmacovigilance, Afssaps, France
- **Maurits Lugard**, Head of EU Life Sciences Regulatory Practice, Sidley Austin LLP, Belgium

10:30 Coffee Break

11:00 Session 2

### ACHIEVING QPPV OVERSIGHT IN THE MODERN BUSINESS ENVIRONMENT

Session Chairperson:

**Margaret Walters**, Director, EU Pharmacovigilance, Merck, Sharpe & Dohme Ltd., UK

With increasing trends to outsource or in-license products to maintain the strength of product portfolios, how does the QPPV maintain the oversight of the pharmacovigilance system in these different scenarios as required by the legislation?

#### Retaining Oversight of Outsourced Pharmacovigilance Activities

Deborah Szafir, Head of Safety Risk Management Strategy, Roche, France

#### The Role of the QPPV in Business Alliances

Valerie Simmons, Lilly QPPV Executive, Global Patient Safety, Eli Lilly and Company Ltd., UK

#### An Inspector's View of the Role of the QPPV in Interactions with other Companies

Anya Sookoo, Expert Inspector, GCP and Pharmacovigilance, MHRA, UK

#### Panel Discussion

12:30 Lunch

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

14:00 Session 3

### QPPV POTENTIAL AREAS OF LIABILITY

Session Chairperson to be confirmed

What are the possible areas of liability and how do we manage them?

#### Two Way Due Diligence for the Outsourcing of PV and the EU QPPV

Graeme A. Ladds, Director, PharSafer Associates Ltd., UK

#### QPPV Contracts

Christine Bendall, Consultant, Arnold & Porter Solicitors, UK

#### Panel Discussion

Panellists include:

- **Graeme A. Ladds**, Director, PharSafer Associates Ltd., UK
- **Jean-Paul Dutertre**, Pharmacovigilance Manager & Medical Information, EEA Qualified Person responsible for Pharmacovigilance, Orphan Europe, France
- **Christine Bendall**, Consultant, Arnold & Porter Solicitors, UK

15:30 Coffee Break

16:00 Session 4

### INTERFACES WITH THE QPPV

Session Chairperson:

**Graeme A. Ladds**, Director, PharSafer Associates Ltd., UK

There are many areas of the business that interface with the QPPV role. This session covers what these may be, what regulatory authority expectations are and provides some models of current practice

#### EU QPPV Non-Safety Interfaces

Guy Demol, Vice President Development, sanofi pasteur MSD, France

#### EU QPPV and Local Affiliate Oversight – A regulatory perspective

Anna Toth, Pharmacovigilance Assessor/Inspector, Medical Products Agency, Sweden

#### A Legal Perspective on Working with Pharmacovigilance and the QPPV

Industry representative invited

#### Panel Discussion

17:30 Reception

18:30 End of Day 1

## THURSDAY | 22 APRIL 2010

08:30 Welcome Coffee

09:00 Session 5

### WHAT'S HOT

Session Chairperson:

**Vicki Edwards**, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK

This session will discuss what is new in the field of pharmacovigilance and inspections, highlighting the potential impact on the QPPV role.

#### Pharmacovigilance and the QPPV: What's hot and what's not

Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

**Hot topics from Inspection**

Anya Sookoo, Expert Inspector, GCP and Pharmacovigilance, MHRA, UK

**New Technology, Social Networking Sites – Considerations for the QPPV**

Nassrin Payvandi, Director - Safety Evaluation & Risk Management, Global Clinical Safety & Pharmacovigilance, Glaxo SmithKline plc., UK

**Panel Discussion**

10:30 **Coffee Break**

11:00 **Session 6**

**THE ROLE OF THE QPPV IN MERGERS & ACQUISITIONS**

Session Chairperson:

**Karen Pattenden**, Senior Director, DSPH, Gilead Sciences International Ltd., UK

What are the responsibilities of the QPPV in complex marketing arrangements from an industry perspective?

**QPPV Preparations as you Approach Mergers and Acquisitions**

Bart Teeuw, Qualified Person for Pharmacovigilance & Site Head Global Pharmacovigilance - Schering-Plough, part of MSD, The Netherlands

**Best Practice in Mergers and Acquisitions – Oversight by the QPPV**

Maria Grazia Zurlo, Vice President, PV Strategy and Policy, EU Qualified Person for Pharmacovigilance, Pfizer Inc., Italy

**Panel Discussion**

12:30 **Lunch**

14:00 **Session 7**

**THE ROLE OF THE QPPV IN THE IMPLEMENTATION AND MANAGEMENT OF RISK MANAGEMENT PLANS AND IN TRANSPARENCY INITIATIVES**

Session Chairperson:

**Deborah Szafir**, Head of Safety Risk Management Strategy, Roche, France

What are the expectations beyond review and sign off of a Risk Management Plan – how does a QPPV ensure implementation and monitoring of minimisation activities? Does the QPPV have any role in, or is the role impacted by, transparency initiatives?

**Transparency Initiatives and the QPPV**

Government representative invited

**Challenges in Risk Management Planning and Implementation: The role of the QPPV**

Janet Hornbrey, EU Qualified Person For Risk Management & Pharmacovigilance, Merck, Sharp and Dohme Inc., Belgium

**Panel Discussion**

15:30 **Coffee Break**

16:00 **Session 8**

**QPPV INFLUENCE AND MODELS**

Session Chairperson:

**Brian Edwards**, Scientific Advisor, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

This session will be in the form of brief presentations and discussion on how QPPVs can exert influence within their respective companies, as well as sharing of experience across companies and organisations. It is anticipated that this will be an interactive session.

**How can a QPPV 'Influence' within their Company?****Panel Discussion**

Panellists include:

- **Brian Edwards**, Scientific Advisor, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK
- **Elsbeth McIntosh**, EU Qualified Person for Pharmacovigilance, Cambridge Laboratories Ltd., UK
- **Steve Douglas**, Director, SGD Consulting Ltd., UK

**QPPV Awareness: What's on twitters and blogs and why are they now being used by marketing?**

Sharon Leighton, Sharon Leighton Consultancy Ltd., UK

**Open Session**

17:15 **Wrap up and End of Conference**

If you have specific questions that you would like to ask the panellists please send them to [sandra.grass@diaeurope.org](mailto:sandra.grass@diaeurope.org)

**TRAVEL INFORMATION**

Edgware Road station, on the Bakerloo line and Circle line, is a five-minute walk to the hotel.

**London Heathrow**

Take the Heathrow Express rail link to Paddington station. The hotel is a five-minute walk from Paddington station or a short taxi ride.

**London Gatwick Airport**

Take the Gatwick Express train to Victoria station, change for the Circle line to Edgware Road station, which is 30 metres from the hotel entrance.

**London City Airport**

Take the DLR train to Canning town, change on to the Jubilee line to Baker Street and change on to the Bakerloo line to Edgware Road station. Alternatively travel one hour by car.

For more details please visit: [www.tfl.gov.uk](http://www.tfl.gov.uk)

**HOTEL INFORMATION**

The DIA has blocked a number of rooms at the:

**Hilton London Metropole**

225 Edgware Road  
London W2 1JU, UK  
[www.hiltonlondonmet.com](http://www.hiltonlondonmet.com)

**at the special rate of:**

£139 inclusive of breakfast, exclusive of VAT

**To make your reservation please**

Email: [reservations.londonmet@hilton.com](mailto:reservations.londonmet@hilton.com)

Tel: + 44 207 616 6570

Please quote the booking reference: GDIAA

**Important: Please complete your reservations by 19 February 2010****In case of cancellation:**

Cancellation of hotel room bookings must be made in writing directly to the hotel 7 days prior to the arrival date. Cancellations made at least 7 days prior to arrival will not incur any cancellation charges. Any cancellation made less than 7 days prior to arrival will be subject to the first night being charged at the full agreed rate. All no shows will be billed for the entire stay.

# REGISTRATION FORM

4th European Forum for Qualified Person for Pharmacovigilance (QPPV)  
21-22 April 2010 - Hilton London Metropole, London, UK

ID# 10104



If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

## Early-Bird rates available for Members: Deadline on or before 8 March 2010

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/academia/non-profit members**

Early-Bird Fee  
(on or before 8 March 2010)

FEE

Join DIA now to qualify for the Early-Bird Rate

€ 115.00

Early-Bird Industry

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Category	Member Fee (after 8 March 2010) FEE	Category	Non-Member Fee FEE
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Government (Full-Time)	€ 683.00 <input type="checkbox"/>	Government (Full-Time)	€ 798.00 <input type="checkbox"/>

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES\_\_\_ NO\_\_\_

**TOTAL AMOUNT DUE:**

€ \_\_\_\_\_

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

**STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT DIA FOR MORE INFORMATION.**

**10104DIAWEB**

## REGISTRANT

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

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## PAYMENT METHODS - Credit cards are our preferred payment method.

**Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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Card Number

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**Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:

**D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland**

**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." including your name, company, Meeting ID# 10104 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.**

**Persons under 18 are not allowed to attend DIA meetings.**

## CANCELLATION POLICY

**All cancellations must be in writing and received at the DIA office by 17:00 CET on 13 April 2010**

Cancellations received by the date above are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

### Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

## IMPORTANT:

**Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

## HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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**Fax** +41 61 225 51 52

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