

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

Event #10104

24-25 June 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

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the 4th European Forum for Qualified Person for Pharmacovigilance with 12 credits. The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom have accredited the 4th European Forum for Qualified Person for Pharmacovigilance with a maximum of 12 credits.

This conference was postponed from 21-22 April 2010, due to the volcanic activity in Iceland and the associated travel disruptions.

THURSDAY | 24 JUNE 2010

08:00 Registration and Welcome Coffee

09:00 Welcome and Update

09:15 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

Panelists 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

WHAT'S HOT

Session Chairperson:

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

Ana Hidalgo-Simon, Head of Signal Detection and Data Analysis, 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

12:30 Lunch

14:00 Session 3

QPPV POTENTIAL AREAS OF LIABILITY

Session Chairperson:

Christine Bendall, Consultant, Arnold & Porter Solicitors, UK

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
Henry Clinton-Davis, Partner, Arnold & Porter Solicitors, UK

Panel Discussion

Panelists include:

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

Open Session

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

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

Panel Discussion

17:30 Reception

18:30 End of Day 1

FRIDAY | 25 JUNE 2010

08:00 Welcome Coffee

08:30 Session 5

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?

Experience with Producing, Submitting and Updating the DDP

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

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.

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

10:00 Coffee Break

10:30 Session 6

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

Peter De Veene, Deputy EU QPPV, F. Hoffmann-La Roche Ltd.,
Switzerland

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

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

The Role of the QPPV in Business Alliances

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

Panel Discussion

12:00 Lunch

13:00 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?

The Role of QPPV in Implementation of EU-RMPs

Jan Petracek, Head of Risk Management, European Medicines Agency,
EU

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

14:30 Coffee Break

15:00 Session 8

QPPV INFLUENCE AND MODELS

Session Chairperson:

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

Panelists include:

- **Vicki Edwards**, Senior Director, European Pharmacovigilance, Abbott Laboratories, UK
- **Steve Douglas**, Director, SGD Consulting Ltd., UK
- **Elsbeth McIntosh**, Director and Consultant, Castle Pharmacovigilance Ltd., UK

Twitter, Facebook and Blogs - What every QP needs to know

Sharon Leighton, Sharon Leighton Consultancy Ltd., UK

16:30 Wrap up and End of Conference

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

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

at the special rate of:

£139 inclusive of breakfast, exclusive of VAT

To make your reservation please

Email: reservations.londonmet@hilton.com
Tel: + 44 207 616 6570

Please quote the booking reference: G D I A B

Important: Please complete your reservations by 11 May 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)
24-25 June 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.

Category	Member Fee FEE	Category	Non-Member Fee FEE
Industry	€ 1'365.00 <input type="checkbox"/>	Industry	€ 1'480.00 <input type="checkbox"/>
Charitable/Non-profit/Academia (Full-Time)	€ 1'024.00 <input type="checkbox"/>	Charitable/Non-profit/Academia (Full-Time)	€ 1'139.00 <input type="checkbox"/>
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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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 16 June 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.

Online www.diahome.org

Fax +41 61 225 51 52

Email diaeurope@diaeurope.org

Mail DIA European Office
Postfach, 4002 Basel, Switzerland