7th European Forum for Qualified Person for Pharmacovigilance (QPPV)

Event #13104
17-18 April 2013
Hotel Holiday Inn Bloomsbury, London, UK
16 April 2013 - Pre-Conference Workshop

Programme Co-Chairs
Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

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

Programme Committee
Barbara De Bernardi
Qualified Person Deputy, Pfizer Italy, Italy

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

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

Maarten A.C. Lagendijk
Pharmacovigilance Coordinator, Pharmacovigilance Department, Medicines Evaluation Board (MEB), the Netherlands

Elspeth McIntosh
Director, Castle Pharmacovigilance Limited, UK

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

Overview
In an ever changing regulatory environment it is vital to remain abreast of any changes likely to impact on the QPPV’s essential role. Such changes may arise from updates to European requirements or those of the regulatory authorities outside of the EEA (e.g. FDA) or from cross-regional initiatives such as ICH. The 2013 meeting aims to inform QPPVs about any challenges relating to the ongoing release of the new PV legislation by the EMA and provide recommendations on incorporating those changes into the daily life of the QPPV.

Objectives
• To explore early experience and challenges of implementation of the new Pharmacovigilance legislation
• To identify and understand the specific impact of the changes on the QPPV role
• To address issues arising for QPPVs in working with partners
• To provide some practical guidance on how to work with the new Pharmacovigilance System Master File
• To determine if the QPPV now needs new skills
• To understand the role of the QPPV in the world of ongoing benefit/risk evaluation

Who Will Attend
• EEA Qualified Persons for Pharmacovigilance
• Deputy Qualified Persons for Pharmacovigilance
• Senior Pharmacovigilance Regulators and Inspectors
• CRO and Consultants providing QPPV Services
• National Responsible Persons for Pharmacovigilance
• Quality Management
• Heads of Pharmacovigilance

About DIA
DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

EU QPPV
Pre-Conference Workshop
Tuesday, 16 April 2013
13:00 - 18:00
Register for only € 300

www.diahome.org
EU QPPV PRE-CONFERENCE WORKSHOP

As a result of positive feedback from previous years we are repeating this informative workshop. It is intended for those EU QPPVs who are new to the role, those who support the QPPV and those who are thinking of taking on a QPPV role. The workshop will focus on providing an understanding of the QPPV role, the practical issues facing QPPVs in a range of company sizes and types, what skills and knowledge you need for the role, and legal considerations for QPPVs.

REGISTRATION AND WELCOME COFFEE

Welcome and Introduction
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

The Impact of the 2012 Legislation on the QPPV Role – Key Changes and New Responsibilities (including local QPs/RPs)
Deirdre McCarthy, Director, Customer Delivery Europe, Lifecycle Safety & Infrastructure Management, Quintiles, Ireland

Key Definitions and Terms in the QPPV World
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

The QPPV role - panel discussion, hints and tips, different ways of working, training etc.
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd., UK
Deirdre McCarthy, Director, Customer Delivery Europe, Lifecycle Safety & Infrastructure Management, Quintiles, Ireland
Janet Hormbrey, Executive Director, EU QPPV, For Risk Management & Pharmacovigilance, Merck Sharp & Dohme Inc., Belgium

REGISTRATION AND WELCOME COFFEE

08:00 WELCOME AND WELCOME COFFEE

Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd, UK
Jytte Lyngvig, European Director, Dia Europe, Switzerland

08:45 WELCOME AND INTRODUCTION

09:00 Session 1

REFLECTIONS ON THE NEW LEGISLATION; IS IT MEETING THE OBJECTIVES?

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

The focus of this year’s conference is implementation of the new EU pharmacovigilance legislation and on its impact on the EU QPPV. The opening session will hear views from stakeholders, industry and patients on whether the new safety legislation is achieving its objectives.

Are Patients Better Protected? – A industry view
Thomas Loenngren, Strategic Advisor, NDA Group, UK

Was the Pain Worth the Gain?
Barry Arnold, EU Qualified Person for Pharmacovigilance, AstraZeneca, UK

And what do patients think?
David H.-U. Haerry, European Aids Treatment Group (EATG), Belgium

Panel Discussion

10:30 COFFEE BREAK

11:00 Session 2

PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE AND THE QPPV

Session Chairperson:
Maarten A.C. Lagendijk, Pharmacovigilance Coordinator, Pharmacovigilance Department, Medicines Evaluation Board (MEB), the Netherlands

With the new legislation, pharmacovigilance in the EU saw many changes. Among other things a new committee was created, the Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC deals with all aspects of the risk management of medicinal products, including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, the design and evaluation of post-authorisation safety studies and pharmacovigilance audits. This session will focus on the role and responsibilities of the PRAC, those of the QPPV and will handle the interaction and communication between them. In addition, the session will also focus specifically on one of the new tasks of the PRAC under the new legislation: the detection and management of safety signals.

In this session the experience of PRAC so far will be discussed, and the expectations of this Committee in the ever changing pharmacovigilance environment. The experience of industry will also be shared, accompanied by practical examples, to highlight the challenges that are faced by industry in general and people in pharmacovigilance in particular. Finally, it will also provide insight into the process surrounding signal management: from data collection and the signal detection process to the methodology used and the communication of the outcome.

PRAC: Experiences to date
Almath Spooner, Vigilance Assessment Manager, Irish Medicines Board, Ireland
Signal Detection under the New Legislation
Anja Van Haren, EudraVigilance Coordinator, Medicines Evaluation Board, the Netherlands

PRAC/Industry Communication Challenges
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland

Panel Discussion

12:30 LUNCH BREAK

14:00 Session 3
EU LEGISLATION IMPACT ON GLOBAL REQUIREMENTS & QPPV OVERSIGHT
Session Chairperson:
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

For a QPPV working in company with EU authorised products marketed internationally, there are interesting challenges with global implementation of the new EU standards arising out of the latest legislation. This session will examine how a QPPV can practically have oversight and influence the quality of global processes impacting EU authorised products. Topics to discuss include adverse event management, risk management, post-marketing study conduct, differing regulatory interpretations of ICH, use of technology and affiliate training and performance. Speakers will give a first-hand account of their experiences with advice about how to cope.

Personal Perspectives on Practicality of Being a QPPV in a Global System
Sue Rees, Head of Pharmacovigilance & Medical Information and EU QPPV, Eisai Europe Limited, UK
Anne-Ruth Van Troostenburg de Bruyn, QPPV, Takeda R & D (Europe) Ltd, UK

Benefit/Risk for the PBRER of Mature Products - Is this a waste of our time or an opportunity?
Anne-Ruth van Troostenburg de Bruyn, QPPV, EBD London, UK

Risk Management: Company standards versus local requirements
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

15:30 COFFEE BREAK

16:00 Session 4
CONTRACTS AND AGREEMENTS: HOW CAN THE QPPV ACHIEVE OVERSIGHT?
Session Chair:
Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK

There is clearly an increasing focus at inspection on QPPV oversight of contracts and agreements. Now more than ever it is essential to ensure mutual understanding, update and implementation to comply with new requirements and expectations i.e. with respect to training, reconciliation, data collection (i.e. from social media), awareness of PSPs, access to applicable PSMFs etc. This session will seek to aid awareness of potential pitfalls and explore future possibilities.

License Partner Oversight - Towards a comprehensive approach
Philip J. Weatherill, Vice President Global Pharmacovigilance, Ipsen Biopharm Ltd, UK

Challenges with Updtaing Agreements through Product Lifecycles and with Changing Expectations
Gro Laier, Deputy QPPV, Novo Nordisk A/S, Denmark

Auditing for Compliance and/or Sharing PSMF and Inspection Data – The future?
Pam Bones, Head, GRQ-PV Audit, Allergan, UK

THURSDAY | 18 APRIL 2013

08:00 WELCOME COFFEE

08:30 INTRODUCTION TO DAY 2
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

08:45 Session 5
FROM SAFETY SIGNAL TO B/R ASSESSMENT: IMPACTS ON PSURS/ PBRERS AND RMPs
Session Chairperson:
Barbara De Bernardi, Qualified Person Deputy, Pfizer Italy, Italy

New European Legislation: Is it time for a new era of safety science? Requirements for many pharmacovigilance activities have been significantly amended. What is its impact, especially on PSURs / PBRERs, RMPs and PASSs? What are the difficulties associated with its implementation? What are the experiences gained and the lessons learned until now?

Information presented in the different sections will be enriched by a final interactive discussion.

Signal Management
• Signal detection, validation/evaluation
• Risk determination for New EU-RMPs
Craig Hartford, VP, Safety Surv & Risk Management, Worldwide Safety Strategy, W R&D, Pfizer Ltd, UK

From PSURs to PBRERs
• Focus on special challenges (e.g. off label use, effectiveness, transparency)
• PRAC Interactions/experiences
Valerie E. Simmons, EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd, UK

PASS and ENCePP Register
Susana Perez-Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions, Spain

Discussion

10:45 COFFEE BREAK

11:15 Session 6
NEW SKILLS FOR THE QPPV
Session Chair:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

The new pharmacovigilance legislation poses new challenges for, and requires new skills from, QPPVs. This session will increase awareness of some key issues which may be new to QPPVs.

Technical Challenges – What’s next for EVMPD and E2B
Adrian Maynier, PV Business Systems Specialist, Genzyme, the Netherlands
External Communications – New skills and challenges arising from increased transparency
Peter Coë, Executive Director, Tudor-Reilly, UK

12:30  LUNCH BREAK

13:30  Session 7

ARE THERE DIFFERENT EXPECTATIONS OF THE QPPV AT INSPECTIONS UNDER THE NEW LEGISLATION?
Session Chairperson:
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

This session will explore early inspection experiences following implementation of the new legislation. It will look at whether or not the approach to inspection has changed and if there are different expectations of the QPPV. It will identify any common findings noted by inspectors.

My First PV Inspection under the New Legislation
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK

Inspection under the New Legislation – How is the industry doing?
Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK

14:30  COFFEE BREAK

15:00  Session 8

PSMF – CREATION, MAINTENANCE AND QPPV INVOLVEMENT
Session Chairperson:
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland

This session will look at the challenges for the industry in implementation of the PSMF requirements. It will look at different company approaches and provide practical guidance on how to establish and maintain a PSMF and explore if and how QPPVs are using it as a tool for system oversight. Delegates will be invited to complete a questionnaire on Day 1 on their experience with compilation and use of the PSMF. The session will consist of a brief overview to set the scene and will then open into a panel discussion and Q&A driven by the results of the questionnaire.

Setting the Scene – The need for a PSMF
Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Pharmaceuticals Europe B.V., the Netherlands

Questionnaire Feedback and Panel Discussion
Peter de Veene, EU QPPV, F. Hoffmann-La Roche Ltd, Switzerland
Anya Sookoo, Expert Inspector, GCP & Pharmacovigilance, MHRA, UK
Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Wendy Huisman, EU Qualified Person for Pharmacovigilance, Teva Pharmaceuticals Europe B.V., the Netherlands

Closing Remarks
Vicki Edwards, QPPV and Head of Affiliate Vigilance Excellence, Global Pharmacovigilance and Global Medical Services, AbbVie, UK
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

17:00  WRAP UP AND END OF CONFERENCE
ATTENDEE DETAILS  
Please complete in block capital letters or attach 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  

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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 #13104 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.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date  Signature

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

Email diaeurope@diaeurope.org  Tel. +41 61 225 51 51  Fax +41 61 225 51 52  Web www.diaeurope.org  Mail DIA Europe, Postfach, 4002 Basel, Switzerland  © DIA 2013

Cancellation Policy  
All cancellations must be made in writing and be received at the DIA Europe office five working days 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  
• Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

Fees  

<table>
<thead>
<tr>
<th>Industry</th>
<th>Member</th>
<th>Non-Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>€ 1365.00</td>
<td></td>
<td>€ 1480.00</td>
</tr>
<tr>
<td>€ 683.00</td>
<td></td>
<td>€ 798.00</td>
</tr>
<tr>
<td>Join DIA now to qualify for the member rate</td>
<td></td>
<td>€ 115.00</td>
</tr>
</tbody>
</table>

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 availability – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and meeting material.

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

TOTAL AMOUNT DUE: ___

PRE-CONFERENCE WORKSHOP  
I wish to attend the EU QPPV Pre-Conference Workshop 16 April 2013  
€ 300.00  

REGISTRATION FORM  
7th European Forum for Qualified Person for Pharmacovigilance (QPPV)  
17–18 April 2013  
Hotel Holiday Inn Bloomsbury, London, UK  
ID #13104