9th European Forum for Qualified Person for Pharmacovigilance (QPPV)

13-14 October 2015
Pre-Conference Workshop on 12 October 2015
Millennium Gloucester Hotel, London, UK

PROGRAMME CO-CHAIRS:

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

Vicki Edwards
EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, 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
Executive Director, Clinical Safety and Pharmacovigilance, Daiichi Sankyo Pharma, UK

Shelley Gandhi
Director, Pharmacovigilance and Drug Safety at NDA Group AB, UK

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 12 credits for pharmaceutical medicine. All participants are eligible for these credits.

OVERVIEW

This is the only forum designed for QPPVs by QPPVs, now in its 9th 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 eight meetings.

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 9th 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

- EU QPPVs and Deputies (present or aspiring), regardless of company size
- Pharmacovigilance Regulators and Inspectors
- CRO and Consultants providing QPPV Services
- National Responsible Persons for Pharmacovigilance
- Quality Management Personnel
- Heads of Pharmacovigilance
- Other stakeholders supporting the EU QPPV

FINAL PROGRAMME

DIA DEVELOP INNOVATE ADVANCE

Half Day Pre-Conference Workshop

Monday 12 October | 13:00–17:30

'Introduction to the role of QPPVs'

As a result of feedback from previous years we are repeating this workshop aimed at 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. It can also act as a 'sanity check' for those who feel they need it! The session will focus on providing an understanding of 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 audits and inspections.

12:00 **Registration and Welcome Coffee**

13:00 **Workshop**

Workshop Co-Chairs:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Shelley Gandhi, Director, Pharmacovigilance and Drug Safety at NDA Group AB

What does it mean to be a QPPV
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

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

QPPV Challenges - Panel Discussion

Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

Chris Foreman, Director, Legal Affairs, Nordic Region, Merck Sharp & Dohme (Europe) Inc, UK

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd, UK

15:15 **Refreshment Break**

What do we Mean by QPPV Backup?
Shelley Gandhi, Director, Pharmacovigilance and Drug Safety, NDA Group, UK

Sourcing a QPPV
Barry Mulchrone, Director, Customer Delivery Europe, Customer Safety Services, Lifecycle Safety, Quintiles Ltd, Ireland

QPPV and QA/Audit/Inspection
Noha Kassem, Senior Director, Medicines Quality Organisation – International, Eli Lilly, UK

Panel Discussion

Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd, UK

Margaret Walters, Director & Deputy EU Qualified Person for Pharmacovigilance, Merck Sharp & Dohme Ltd, UK

Shelley Gandhi, Director, Pharmacovigilance and Drug Safety, NDA Group, UK

Barry Mulchrone, Director, Customer Delivery Europe, Customer Safety Services, Lifecycle Safety, Quintiles Ltd, Ireland

Noha Kassem, Senior Director, Medicines Quality Organisation – International, Eli Lilly, UK

Separate registration required

DAY ONE | TUESDAY, 13 OCTOBER 2015

08:00 **Registration and Welcome Coffee**

09:00 **Session 1**

KEY NOTE

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. This session will ask key regulators the following questions:

- Has the implementation been achievable, practical and complete?
- 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 health care 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 are responsible?

Update on Three Years of Operation of the New EU Pharmacovigilance System
Peter Arlett, Head of Pharmacovigilance Department, Inspections & Human Medicines PV Division, European Medicines Agency, European Union

SCOPE: Standards of Collaboration to Operate Pharmacovigilance in Europe
Mick Foy, Group Manager, Vigilance Intelligence and Research Group, MHRA, UK

Industry Perspective – Building on 3 Years of EU Pharmacovigilance Legislation
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., presentation by Elizabeth Swain, Director, Pharmacovigilance Advocacy and Policy, GlaxoSmithKline, UK

10:30 **Refreshment Break**

11:00 **Session 2**

HOT TOPICS

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

Since implementation of the new legislation the pharmacovigilance committees of the industry trade associations have been raising topics for discussion with the EMA and Member States where there are areas of uncertainty and clarification is required. Typically it is the larger pharmaceutical companies who are members of these trade associations and for companies who are not members it is difficult to know what the areas of interest under discussion are. This session will share the key topics of interest and progress made to date.

Post-Authorisation Safety Studies/Post-Authorisation Efficacy Studies/Off Label use
Emma Du Four, Senior Director, Regulatory Policy and Intelligence, Abbvie, UK

Patient Support Programmes
Sue Rees, QPPV, Executive Director Global Safety, Amgen Ltd, UK

Risk Management Definitions and Approaches
Maria Grazia Zurlo, Vice President, Pharmacovigilance Policy and Strategy, Pfizer, Italy

Periodic Safety Update Reports
Jean Kilgour-Christie, Director, Deputy EU QPPV, Takeda, UK

Risk Management Plans for Generics, Problems, Proposals and Progress
John Barber, QPPV and Director, Dr. Reddy's Laboratories (UK) Ltd, UK

12:30 **Lunch**

14:00 **Session 3**

HEAR FROM THE REGULATORS – CURRENT EXPERIENCES

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

Three years after the creation of the Pharmacovigilance Risk Assessment Committee (PRAC) a lot of experience has been gained with the new procedures put in place to strengthen public health. In order to fulfil their obligations QPPVs must keep abreast with developments in the PRAC. This session will take stock of PRAC achievements to date and will also focus on the important link between this committee and the CHMP/CMD(h). Furthermore the session will provide regulatory insight regarding the handling of the periodic safety update reports, a tool which has become of increasing importance, forming the basis for frequent benefit-risk assessments of medicinal products. The session will also include an update on the continued work with optimising risk minimisation measures and methods suitable for measuring their effectiveness.

PRAC Activities Overview and Collaboration Between PRAC and CHMP (Scientific Committee) / CMDh (Regulatory Committee)
June Raine, PRAC Chair, Director, Vigilance and Risk Management of Medicines Division, MHRA, UK

PSUR Concept as a Benefit-Risk Tool – Practical Aspects
Jolanta Gulbinovic, PRAC Member, Chief Expert, State Medicines Control Agency, Lithuania

Measurement of Effectiveness of Risk Minimisation Measures
Jean-Michel Dogne, PRAC Member, Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) and Professor, University of Namur, Belgium

15:30 **Refreshment Break**

16:00 **Session 4**

QPPVs AND RMMs EVALUATION STUDIES. WHAT IS OUT THERE?

Session Co-chairs:
Susana Perez-Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions
Winrich Rauschning, QPPV, Biolitec Pharma, Germany

Ten years have passed since the development of the Model of Excellence in pharmacovigilance, and three years since the publication of EMA GVP Guidelines. The number of Post-Approval Safety Studies (PASS) has increased dramatically specially those focused on the evaluation of the effectiveness of risk minimisation measures. These Risk Minimisation Evaluation Effectiveness Studies (RMEES) can be extremely complex to conduct, have less history in implementation and methodology than other types of PASS. The session will focus on RMEES from the EU QPPVs perspective and discuss value, expectations, state of the art knowledge, experience and lessons learnt. Regulatory expectations, key concepts on designs and methods, data collection and available data sources will be reviewed. The session will include opportunity for questions and answers.

How We Got Here and What Does the Future Hold? A Regulatory Perspective
June Raine, PRAC Chair, Director, Vigilance and Risk Management of Medicines Division, MHRA, UK

Making It Happen (I): Study Types and Data Sources. A Research Centre Perspective
Susana Perez-Gutthann, Vice President, Global Head Epidemiology, RTI Health Solutions, Spain

Making It Happen (II): Challenges and Opportunities. Where Is the Role of the QPPV? An Industry Perspective
Lesley Wise, Senior Director Global PV Risk Management, Takeda, UK

17:30 **Networking Reception**

18:30 **End of Day One**

DAY TWO | WEDNESDAY, 14 OCTOBER 2015

09:00 **Session 5**

SIGNALLING: DEALING WITH THE TRAFFIC JAM

Session Chair:
Shelley Gandhi, Director, Pharmacovigilance and Drug Safety at NDA Group AB, UK

Signal management is a key function in a pharmacovigilance quality management system. Thus a QPPV would be expected to show scientific direction and leadership around defining requirements and methodologies for worldwide sources of evidence. Concepts such as signal validation and causality assessment need to be addressed. New data sources such as big data and social media and technologies are being developed or have arrived. In particular, QPPVs need to think what will be the impact of examining EudraVigilance and other regulatory databases and what should this process look like for their company. By combining traditional and new processes, QPPVs can keep their signalling processes relevant to maintain an adequate benefit-risk balance.

Signal Management in the EU - Key Principles and Process Optimisation
Georgy Genov, Head of Signal Management, European Medicines Agency (EMA), European Union

Signal Management – A QPPV's Temperature Check
Sue Rees, QPPV, Executive Director Global Safety, Amgen Ltd, UK

Signal Management – An SME Perspective
Winrich Rauschning, QPPV, Biolitec Pharma, Germany

10:30 **Refreshment Break**

11:00 **Session 6**

QPPV OVERSIGHT - PV SYSTEM UPDATES

Session Chair:
Margaret Walters, Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK

The EMA has several major deliverables scheduled throughout 2015/2016 to support various business activities of the revised pharmacovigilance legislation. This session will provide updates followed by a panel discussion with several key EMA speakers towards better enabling effective QPPV oversight of timely and effective internal implementation.

Medical Literature Monitoring
Tom Paternoster-Howe, Scientific Administrator, European Medicines Agency, European Union

EudraVigilance
Francois Domergue, Scientific Administrator, European Medicines Agency, European Union

Article 57 Database of Medicinal Products
Ilaria Del Seppia, Scientific Administrator, Data Standardisation and Analytics Department, European Medicines Agency, European Union

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

Open Discussion on Implementation Challenges:
Speakers and Attendees

12:30 **Lunch**

14:00 **Session 7**

REFERENCE SAFETY INFORMATION (RSI): TRANSLATION OF PV ACTIVITIES RESULTS INTO "THE" ROUTINE RISK MANAGEMENT TOOL

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

Labelling is a legal requirement within the EU and a pillar among risk management tools. The RSI should properly communicate the efficacy and safety characteristics of a medicinal product, thus allowing HCPs and patients to appropriately select and use them. The continuous and timely maintenance of the RSI safety content, as the creation of processes and procedures related to its management, are MAH's responsibilities subjects to Health Authorities' evaluation – of which the EU QPPV's knowledge is often checked at inspection. This session will review the main concepts associated with the description, selection and maintenance of an RSI and will address practical challenges associated with these activities. Any potential differences deriving from features of the various medicinal products (e.g. type of chemical entity category, registration status etc) will be discussed.

Reference Safety Information (RSI): Translation of PV Activities Into 'The' Routine Risk Management Tool: Innovator Company Viewpoint
Anne Kehely, Medical Fellow, Global Patient Safety, Eli Lilly & Company Ltd., UK

Selection and Maintenance of RSI – Issues in the Generics Sector
John Barber, QPPV and Director, Dr. Reddy's Laboratories (UK) Ltd, UK

Reference Safety Information (RSI): Translation of PV Activities Into 'the' Routine Risk Management Tool: A Health Authority
Doris Stenver, Chief Medical Officer, Danish Medicines Agency, Denmark

15:30 **Refreshment Break**

16:00 **Session 8**

ASK THE PANEL: QUESTIONS FROM THE PRE-CONFERENCE SURVEY

Session Co-Chairs:
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK
Peter De Veene, Executive Director, Clinical Safety and Pharmacovigilance, Daiichi Sankyo Pharma, UK

As the QPPV's role has become busier and busier, we acknowledge that we cannot cover everything that we would all like in one meeting. In order to help us to address your needs, we have created a session that will be guided by topics and questions that we have received from attendees before and during the conference. Our expert panel will select key topics and provide guidance and practical advice to help QPPVs. In addition, this session will look to explore the role of the EU QPPVs and that of the National PV Responsible Person(s) – together with inspectors' expectations and experience with respect to interactions between these roles.

Common MHRA GPvP Inspection Findings
Mandeep Rai, GCP Inspector, MHRA, UK

EEA Local 'QPPVs' versus EU QPPV – Requirements and MAH Inspection Experiences
Michelle Grimes, Global Safety Regional Lead Europe, Middle East and Africa, Merck Sharp & Dohme Ltd, UK

Panelists:

Sue Rees, QPPV, Executive Director Global Safety, Amgen Ltd, UK

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

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

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK

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

Winrich Rauschning, QPPV, Biolitec Pharma, Germany

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

Shelley Gandhi, Director - Pharmacovigilance and Drug Safety at NDA Group AB, UK

17:30 **End of Conference**

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link:

https://www.surveymonkey.com/s/15104

PRESENTATION ACCESS

As a benefit of registration, presentations are available on the DIA website. Please sign in to DIA Website and choose "My Presentations" within "My account", where you will be able to download all presentations that have been submitted by speakers.

Note: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use the Login Reminder.
After logging in to the website, you will see presentation PDFs from all the DIA offerings you have attended in the past 6 months. Simply choose the presentation you would like to view or download.

Please note that if a presentation is not available on the website, it is because:

- The presenter has not supplied us with a presentation file
- There was no slide presentation planned by the speaker
- The speaker did not agree to share it with other participants
- You have not yet paid the registration fee

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be e-mailed to all attendees after they have filled in the evaluation. Please note certification requires full attendance to the event.

For more information please contact DIA EMEA Contact Center on EMEA@DIAglobal.org or call +41 61 225 51 51.