European Forum for Qualified Person for Pharmacovigilance (QPPV)

10-11 October 2018
(Pre-conference Workshops on 9 October)
Renaissance London Heathrow Hotel, Heathrow, London, UK

PROGRAMME CO-CHAIRS

Elspeth McIntosh
Director, Castle Pharmacovigilance Limited

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

PROGRAMME COMMITTEE

Vicki Edwards
Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

Doris Stenver
Chief Medical Officer, Danish Medicines Agency

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

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

Winrich Rauschning
QPPV, BioLitec Pharma

Barbara De Bernardi
EU QPPV Deputy, and Head of EU Safety Office, Pfizer Italia S.r.l.

Peter De Veene
QPPV, Alexion Pharmaceuticals

Magnus Ysander
EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca R&D

Angela van der Salm
Director Pharmacovigilance, Managing Partner, DADA Consultancy B.V.

Overview

This is still the only forum designed for QPPVs by QPPVs, now in its 12th year and still going strong. This Forum continues to identify key trends requiring QPPV awareness, input and oversight. This year's objectives, as shown below, build on past successes and have been shaped by valuable feedback provided by participants of the past eleven meetings, plus many years of QPPV and Regulator interaction at 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 12th QPPV Forum continues this successful approach.

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 continually evolving regulatory framework
- Examine current areas of real challenge

PRE-CONFERENCE WORKSHOPS | TUESDAY, 9 OCTOBER

HALF-DAY WORKSHOPS, 12:00 - 17:30
Limited Places Available

WORKSHOP 1: INTRODUCTION TO THE ROLE OF QPPVS
Meeting Room: Blackfriars

As a result of feedback from previous years we are repeating this workshop aimed at those EU QPPVs who are new to the role, need to refresh on the role, those who support the QPPV and those who are thinking of taking on a QPPV role. It may also be of interest to any QPPV who wish to refresh their knowledge. The session will focus on providing an understanding of, and update on, the QPPV role, legal considerations for QPPVs and the practical issues facing QPPVs in a range of company sizes and types.

Workshop Chairs:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca

WORKSHOP AGENDA

12:00 Registration (**Arora Lobby**) and Lunch (**Market Garden Restaurant**)

13:00 **What does it mean to be a QPPV?**
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd.

13:45 **QPPV Legal Issues**
Chris Foreman, Director, Legal Affairs, Mid-Europe II Region, Merck Sharp & Dohme (Europe) Inc., Nordic Region

14:15 **The 'Small Pharma' QPPV**
Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd.

14:45 COFFEE BREAK (ARORA LOBBY)

15:15 **QPPV oversight and the view from 'Big Pharma'**
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca

15:45 **Practical Issue for QPPVs: Presentations to highlight the QPPV role in**
- Business partner management and Outsourcing
- Quality oversight and processes and Inspection
- Pharmacovigilance System Master File (PSMF)

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca

16:45 **Panel Discussion**

17:30 Close out

Seperate Registration Required

WORKSHOP 2: THE PSMF: WHERE ARE WE TODAY AND WHERE DO WE WANT TO GO?
Meeting Room: Tower

The purpose of this tutorial is to share knowledge and come up with some best practices between participants so that delegates leave the session better equipped and with an informal network of colleagues to tap into for working on the PSMF outside the EU.

Workshop Chairs:
Dionne Usher, Senior Specialist, EU QPPV Office, MSD
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca
Willemijn Van Der Spuij, Director International Operations & PV Excellence, Bristol-Myers Squibb

Learning Objectives:
- Exploring the current PSMF requirements and challenges across the world and discuss practical solutions to simplify work.
- Discuss and understand feedback received on existing PSMFs, sharing of strategies and processes.
- Encourage participants to work towards an approach that ensures compliance, good quality, simplification to deliver what is needed whilst eliminating duplication wherever possible

Audience: PV/Industry experts involved in PSMF coordination and/or maintenance.

Level: PV audience; beginners and advanced, trying to better understand the PSMF landscape and requirements around the globe

WORKSHOP AGENDA

12:00 Registration (**Arora Lobby**) and Lunch (**Market Garden Restaurant**)

13:00 Introduction and Welcome

13:00 **PSMF: Where we are Today: Legislative Update - sharing of information from Industry Group and DIA meeting**

14:00 **Audit and Inspections. Feedback on PSMFs EU/ex EU**
Dionne Usher, Senior Specialist, EU QPPV Office, MSD

14:45 COFFEE BREAK (ARORA LOBBY)

15:00 **Building your PSMF (EU vs ex-EU)**
Maria Wishart, Deputy EU Qualified Person for Pharmacovigilance, AstraZeneca

15:45 **The Ideal Global PSMF; the Future**
Willemijn Van Der Spuij, Director International Operations & PV Excellence, Bristol-Myers Squibb

16:30 **Workshop feedback and Q&A**

17:00 Close out

Seperate Registration Required

CONFERENCE | DAY ONE | WEDNESDAY, 10 OCTOBER

Meeting Room: Westminster

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

KEY NOTES: CHANGE IS IN THE AIR

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

The oversight of how drugs benefit and expose patients to risk is changing dramatically, driven by legislation, new therapies, unprecedented access to information and new unexpected challenges. A QPPV has to understand these forces, think creatively and be adaptable, to ensure industry manages their medicines and protects patients whilst ensuring optimal access and benefit to treatment.

Approaching Change as an Opportunity
Heather Bewers, Director, Change is an Opportunity Limited

Pharmacovigilance in the next 5 years, The Industry Vision
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

Managing Sudden Change - Experience with a Cyber Attack
Janet Hormbrey, Head Global Pharmacovigilance, Merck & Co, Inc.

10:40 COFFEE BREAK (WESTMINSTER LOBBY)

11:10 SESSION 2

HOT TOPICS – INDUSTRY PERSPECTIVES, WHAT DO I NEED TO KNOW?

Session Chair:
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

This will be year four 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!

Update on collection of safety data from PSPs
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd.

Update on EV new functionalities
Margaret Walters, Deputy EU QPPV, Merck Sharp & Dohme Ltd.

Update on RSI
Willemijn Van Der Spuij, Director International Operations & PV Excellence, Bristol-Myers Squibb

Country level signal notification requirements
Willemijn Van Der Spuij, Director International Operations & PV Excellence, Bristol-Myers Squibb

EV Signalling Metrics
Valerie E. Simmons, EU QPPV, Global Patient Safety, Eli Lilly and Company Ltd.

12:40 LUNCH (MARKET GARDEN RESTAURANT)

14:00 SESSION 3

HOT TOPICS – A REGULATOR'S PERSPECTIVE? DO YOU KNOW WHAT WE ARE DOING?

Session Chair:
Maarten Lagendijk, Pharmacovigilance Coordinator, Medicines Evaluation Board (MEB)
Menno Van Der Elst, PRAC member, Medicines Evaluation Board (MEB)

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.

Disclosure Policy

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An update from the Pharmacovigilance Risk Assessment Committee (PRAC)
Doris Stenver, Chief Medical Officer, PRAC member, Danish Medicines Agency
Menno Van Der Elst, Alternate PRAC member, Medicines Evaluation Board (MEB)
Anja van Haren, EudraVigilance Coordinator, Pharmacovigilance, Medicines Evaluation Board (MEB)

15:30 COFFEE BREAK (WESTMINSTER LOBBY)

16:00 SESSION 4

ARE WE MANAGING THE RIGHT RISK IN THE RIGHT WAY?
Session Chair:
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca

One and a half year since the significant GVP V revision, experiences from both regulators and industry are shared and reflected on. Has the new wave of RMPs worked as expected? What are the remaining challenges and how can they be approached? What is the next evolution in risk management?

Jane Feron, Pharmacovigilance and Regulatory Compliance, GRAPSQA, AstraZeneca
Randip Kahlon, Implementation Lead - Global Safety Risk Management, BMS

17:30 END OF THE DAY

18:30 DINNER (WATERLOO SUITE)

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No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with the presentation. Updated versions of the slides will be made available shortly after the conference.

Certificate of Attendance

A Certificate of Attendance will be sent electronically fter the conference . Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.

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://bit.ly/2y6KQzW

Conference Venue

Renaissance London Heathrow Hotel
Bath Road
Hounslow, TW6 2AQ
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SwAPP Swiss Association of Pharmaceutical Professionals

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

DAY TWO | THURSDAY, 11 OCTOBER 2018

Meeting Room: Westminster

08:00 WELCOME COFFEE (WESTMINSTER LOBBY)

08:30 SESSION 5

ARE WE LOOKING AT THE RIGHT THING IN THE RIGHT PLACE? - EUDRAVIGILANCE SIGNALING EXPERIENCE

Session Chair:
Peter De Veene, QPPV, Alexion Pharmaceuticals
Winrich Rauschning, QPPV, BioLitec Pharma

In October 2018 signaling in EV will have been mandatory for about 7 months. Experts from EMA, large and small pharma will review their experience and discuss points like: Are we looking at the right thing? Are we identifying signals in a timely manner? How complementary is this approach to established sources and methods?

Speakers:

Alternative Data sources for Signal Detection
Phil Tregunno, Interim Group Manager, Vigilance, Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA)

Feedback to Signaling in Eudravigilance – Big Pharma Perspective
Yusuf Tanrikulu, Deputy EU QPPV, F-Hoffmann-La Roche AG

Eudravigilance Signal Experience – Small Pharma Perspective
Christina Alma Strom Moller, Head DSP and EU-QPPV, Swedish Orphan Biovitrum AB

10:00 COFFEE BREAK (WESTMINSTER LOBBY)

10:30 SESSION 6

AM I COMPLIANT ENOUGH?

Session Chair:
Angela van der Salm, Director Pharmacovigilance, DADA Consultancy B.V.
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

The actions required to demonstrate compliance may vary depending on company size, products and complexity of processes. This session will look at challenges and potential solutions for small/medium sized companies across a range of activities which affect QPPV oversight.

International Infrastructure Challenges (Small vs Large Company)
Peter De Veene, QPPV, Alexion Pharmaceuticals

Small Pharma Challenges and Outsourcing
Angela van der Salm, Director Pharmacovigilance, DADA Consultancy B.V.

Challenges in Compliance and Audits
Martijn van de Leur, Deputy QPPV, Vifor Pharma

Challenges in Computer System Validation
David Stokes, Director and Principal Consultant, Convalido

Panel Discussion with Q&A

12:00 LUNCH (MARKET GARDEN RESTAURANT)

13:00 SESSION 7

ARE YOU COMPLIANT ENOUGH? - AUDITS, INSPECTIONS AND QMS

Session Chairs:
Barbara De Bernardi, EU QPPV Deputy, and Head of EU Safety Office, Pfizer Italia S.r.l.
Helen Powell, Principal Consultant, NDA Regulatory Science Ltd.

The QPPV role includes oversight over the functioning of the PV system in all relevant aspects to ensure effective compliance with applicable EU legislation is maintained. However, distilling out what is truly required out from the 'nice to have' or from subjective interpretations is key to avoid allocation of valuable resources without real gain. This session will focus on current challenges with compliance interpretation and implementation from the perspectives of inspectors, companies and auditors

Joanna Harper, Expert Inspector, GPvP, Medicines and Healthcare products Regulatory Agency (MHRA)

Helen Powell, Principal Consultant, NDA Regulatory Science Ltd.

Panel Discussion with Q&A
Margaret Walters, Deputy EU QPPV, Merck Sharp & Dohme Ltd.

14:30 COFFEE BREAK (WESTMINSTER LOBBY)

15:00 SESSION 8

AM I IMPACTED BY BREXIT?

Session Chair:
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd.

This session will address some of the uncertainty surrounding the QPPV role and Brexit. What are practical implications of Brexit for UK based QPPVs? What is the impact for MAHs if QPPV moves and the team remains UK based? What is the legal situation concerning the definition 'reside and operate in the EU? Does this mean meeting rules for residency rather than just 'work out of'? Will there be an impact on the deputy QPPV (or 'back-up')? These questions and more we'll try and answer in what promises to be a lively discussion.

Speakers:
Mick Foy, Head of Pharmacovigilance Strategy, Vigilance Intelligence and Research Group, Medicines and Healthcare products Regulatory Agency (MHRA)

Turning Confusing Political Scenarios into Workable Plans

Tim Sarson, Partner, Life Sciences Lead for Brexit, KPMG
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

16:30 END OF CONFERENCE

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