DIA

Global Forum for Qualified Persons for Pharmacovigilance (QPPV)

Networking your path to success among a world-class community

6-7 November 2019 | Holiday Inn Amsterdam Arena Towers
Amsterdam, The Netherlands
5 November: Pre-Conference Tutorials

Programme Committee

Programme Co-Chairs

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
Peter De Veene, QPPV, Alexion Pharmaceuticals

Shahinaz Badr
Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey

Vicki Edwards
Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

Mette Stockner
Senior Pharmacovigilance Director, Savara

Gemma Jiménez
Head of drug safety, EU QPPV, Almirall Spain

Doris Stenver
Independent Pharmacovigilance Adviser, Unique Advice

Katarzyna Świderek
Safety Evaluation Risk Management (SERM) Senior Scientist, GlaxoSmithKline

Nicolas Tsiakkas
Scientific Director/EU QPPV, Medwork Greece

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

Willemijn Van Der Spuij
Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb

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

Overview

In a changing and expanding world, this is still the only forum designed for QPPVs by QPPVs, now in its 13th year and still going strong.

In 2019 the forum is expanding to a global approach on the topics, programme committee composition and programme content. In addition, its location moves to Amsterdam to be in line with the new EMA office.

This Forum continues to identify key trends requiring QPPV awareness, input and oversight. This year's objectives are built on past successes and have been shaped by valuable feedback provided by participants of the past twelve meetings, plus many years of QPPV and Regulator interaction at this Forum. Moreover, we are looking forward to receive information on the globalization of the QPPV role.

Over time, one of the key successes of the Forum has been the ability to secure the 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. The 13th 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 the QPPV
- Network with colleagues and meet regulators
- Learn from and share experience and ideas with like-minded QPPVs in a neutral environment
- Better understand regulatory and inspectorate expectations globally
- Examine current challenges and share potential solutions

Key Topics

- The future of pharmacovigilance in the globalisation environment
- Global perspective on inspection and audits
- QPPV oversight and data integrity
- Signalling and risk management
- Communication channels for QPPVs
- EU/Ex-EU QPPV interactions and challenges

Who Will Attend

- Global QPPVs/ Deputies
- Regulators
- Pharmacovigilance Consultants
- Directors of Pharmacovigilance Oversight and Standards
- Drug Safety Managers/Leaders
- Auditors
- Medical and Regulatory Affairs Experts
- Aspiring PV Specialists/QPPVs

WORKSHOP 1: INTRODUCTION TO THE ROLE OF QPPVS

5 NOVEMBER | 12:00-17:30

Limited Places Available.

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 Instructors:

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited, UK
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca
Anna Pavlou, Counsel, Sidley Austin LLP

Separate Registration Required

WORKSHOP AGENDA

12:00 REGISTRATION

13:00 WHAT DOES IT MEAN TO BE A QPPV?

Elspeth McIntosh

13:45 QPPV LEGAL ISSUES

Anna Pavlou

14:15 THE 'SMALL PHARMA' QPPV

Elspeth McIntosh

14:45 COFFEE BREAK

15:15 QPPVS OVERSIGHT AND THE VIEW FROM 'BIG PHARMA'

Magnus Ysander

15:45 PRACTICAL ISSUE FOR QPPVS: PRESENTATIONS TO HIGH LIGHT THE QPPV ROLE IN:

- Business partner management and Outsourcing
- Quality oversight and processes and Inspection
- Pharmacovigilance System Master File (PSMF)

Elspeth McIntosh and Magnus Ysander

16:45 PANEL DISCUSSION

17:30 END OF WORKSHOP

WORKSHOP 2: THE PSMF IN 2019 - GENERAL DEVELOPMENTS IN - AND OUTSIDE EUROPE: WHERE ARE WE HEADING?

5 NOVEMBER | 10:00-15:30

Limited Places Available.

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:

Clare Lavery, Pharmacovigilance Excellence Principal, AstraZeneca, UK
Dionne Usher, Associate Director, Office for the EU QPPV, MSD, UK
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb, Switzerland

Learning Objectives:

- Exploring the current PSMF landscape.
- Sharing of experiences 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.

Separate Registration Required

WORKSHOP AGENDA

Potentially some pre-meeting research by delegates (if they are not directly involved in the PSMF)

10:00 REGISTRATION

10:30 INTRODUCTION AND WELCOME

10:40 THE CURRENT PSMF LANDSCAPE (LEGISLATIVE UPDATES AND RECENT LEARNINGS)

11:30 WORKSHOP I

AUDIT AND INSPECTIONS. FEEDBACK ON PSMFS AND LESSONS LEARNED

12:15 COFFEE BREAK

13:15 WORKSHOP II

BUILDING YOUR PSMF TO ALLOW GLOBAL USE (GLOBAL, EU AND REST OF WORLD) – LISTING PROS AND CONS OF EACH APPROACH WITH EXAMPLE OF SPECIFIC AREAS WHERE THERE ARE QUESTIONS (E.G. DO YOU LIST VENDOR SOPS AND CONTENTS OF NON-EU PSMFS)

14:15 WORKSHOP III

PSMF PROCESS AND OVERSIGHT FOR QPPVS

15:00 WORKSHOP FEEDBACK

15:30 END OF WORKHSOP

DAY ONE | WEDNESDAY, 6 NOVEMBER 2019

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

FUTURE OF PHARMACOVIGILANCE – IMPACT OF GLOBALISATION

Session Chair:
Doris Stenver, Independent Pharmacovigilance Adviser, Unique Advice

In this session key EU regulators will provide an update of current activities at the level of EMA and PRAC, 8 months after re-location to the Netherlands and 7 years after the creation of the PRAC. How far is EMA with regard to regaining the momentum in further developing pharmacovigilance, after years with need for strict prioritization to safeguard the core business? How does increasing globalization impact the Agency´s strategies? Which are the major achievements of the PRAC? And how does the future look like in a PRAC perspective? This session will also include an update on the WHO Pharmacovigilance System and activities to strengthen pharmacovigilance in low and middle income countries, linkages with the WHO global benchmarking activities and institutional development plans for regulatory agencies.

Data and Evidence to Support Benefit Risk Decisions
Peter Arlett, Head of Pharmacovigilance and Epidemiology Department, European Medicines Agency (EMA)

Future of PRAC
Sabine Straus, Chair, Pharmacovigilance Risk Assessment Committee (PRAC)

Pharmacovigilance Systems Strengthening – WHO Perspective
Shanthi Pal, Group Lead, Medicines Safety, Safety & Vigilance, World Health Organization (WHO)

Panel discussion with Q&A

10:30 COFFEE BREAK

11:00 SESSION 2

HOT TOPICS FOR QPPV OVERSIGHT

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

This will be year five 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!

ICH E2D
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd

ICH E19
Guy Demol, AVP Drug Safety, MSD Europe

EFPIA updates related to PV (RWE)
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

International Groups Achievements
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb

Updates on Medical Device Regulation & Risk Management Plan.
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca R&D

RSI
Judith Weigel, Pharmacist, Pharmacovigilance/ Interface Regulatory Affairs, VFA Research-Based Pharmaceutical Companies

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 3

GLOBAL PERSPECTIVE: INSPECTION & AUDITS

Session Chairs:
Mette Stockner, Senior Pharmacovigilance Director, Savara ApS
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb

The Quality system is becoming an integrated part of the PV system. Audits and inspections play a major role in a quality system and PV inspections are a common sight in many markets today, both in and outside the EU. This brings new challenges for industry in terms of managing multiple inspections and findings and underlines the overall goal of supporting solid and accurate PV systems.

What are the challenges for industry when it comes to multiple PV inspections, what are inspectors' experiences and how are our findings exchanged? This session will focus on inspections, with a session on local inspections, a session on the PV Inspectorate Working Group and the experience of a Saudi Inspection. Throughout the presentations some general thoughts on how findings are discussed and shared will be provided. Sharing the learnings from inspections will benefit PV systems and strengthen collaboration and dialogue with inspectors. In addition, it may enable QPPVs to focus their efforts and collaborations on certain areas of their PV system.

Inspectors' experiences
Kiernan Trevett, Senior Pharmacovigilance Inspector, Enforcement and Standards, Medicines and Healthcare products Regulatory Agency (MHRA)
Line Michan, Medicines Inspector, Danish Medicines Agency (DKMA)

Arab League GVP Inspection – Pharma Perspective
Marouane Ek Kabaili, Cluster Safety Lead North Africa & Middle East, Pfizer, Morocco

Panel discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 4

QPPV OVERSIGHT AND DATA INTEGRITY

Session Chairs:
Katarzyna Świderek, Safety Evaluation Risk Management (SERM) Senior Scientist, GlaxoSmithKline
Angela van der Salm, Director Pharmacovigilance, Managing Partner, DADA Consultancy B.V.

In this session, we are investigating the QPPV oversight role when it comes to data rather than processes. How reliable are the data listings that end up in your PSMF? What tools can you use to appropriately monitor your risk minimisation and pharmacovigilance activities? And how to cope with the requirements posed by the General Data Privacy Regulation with regards to the processing of personal data?

GDPR
Christopher Foreman, Senior Director, Legal Affairs, Nordic Sub-Region, Merck Sharp & Dohme (Europe) Inc.

PSMF Listings
Wendy Huisman, Director, Vigifit

Tracking and Implementation of PASS and of Risk Minimization Measures (RMM)
Joanne Emmott, Deputy QPPV, MSD, UK

Panel discussion with Q&A

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY TWO | THURSDAY, 7 NOVEMBER 2019

08:00 WELCOME COFFEE

09:00 SESSION 5

SIGNAL DETECTION AND RISK MANAGEMENT: WHAT´S NEXT?

Session Chairs:
Gemma Jiménez, Head of drug safety, EU QPPV, Almirall Spain
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca R&D

Signal detection and risk management have been continuously evolving in recent years. In the EU there are new requirements for signal detection in EVDAS and steps towards more strict definitions of risk. At the same time emerging legislation from global markets bring new obligations for signal notification and risk management plans. What have we learnt from the signal pilot? How can we ensure consistency of risk definitions internationally? Finally, are we communicating signals and risks appropriately with the patient in mind?

Signaling Pilot EVDAS
Achint Kumar Gupta, EU QPPV - Safety & Benefit-Risk Management, Biogen

Globalization of the RMP
Frederic Bouder, Professor in Risk Management SEROS, University of Stavanger

Communication of Identified Signals
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca R&D

Panel discussion with Q&A

10:30 COFFEE BREAK

DAY TWO | THURSDAY, 7 NOVEMBER 2019

11:00 SESSION 6

COMMUNICATION CHANNELS FOR QPPVS

Session Chairs:
Peter De Veene, QPPV, Alexion Pharmaceuticals
Nicolas Tsiakkas, Scientific Director/EU QPPV, Medwork Greece

Access to timely information is critical for the EU QPPV to fulfil their role of providing patients and prescribers with the most relevant data. This happens in collaboration with internal and external stakeholders. Currently the QPPV has access to several data sources and at the same time the QPPV receives regular communications from the EMA (signals, QPPV Update) and other competent authorities. This session will explore the different communication channels the EU QPPV has access to and to assist the discussion, attendees and QPPVs will be asked to fill in a survey covering the different types of communications.

Feedback from the Communication Channels Survey
Zurab Koberidze, Director Pharmacovigilance, FGK Pharmacovigilance GmbH

Incoming communications from regulators and how they are being assessed and distributed internally by the QPPV office
Naomi Morris, Head QPPV Compliance Office, Pfizer, Italy

Communication on Safety Information: Regional and Local Case Study
Nicolas Tsiakkas, Scientific Director/EU QPPV, Medwork Greece

Panel discussion with Q&A

12:30 LUNCH

14:00 SESSION 7

EU/EX-EU QPPV INTERACTIONS AND CHALLENGES

Session Chairs:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
Shahinaz Badr, Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey

As more territories adopt a QPPV role based on the EU responsibilities, EU QPPVs need to know how these local requirements are being implemented and how this effects the EU functions. By looking at the requirements for a couple of the more established ex-EU QPPV roles, we will describe some of the ways that EU QPPVs can influence, support and interact with their other colleagues, and introduce some of the local challenges which can, and do, have an impact on the EU PV systems and data.

UK QPPV: Brexit Updates
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

Proliferation of QPPVs: what you need to know?

Middle-East QPPV
Shahinaz Badr, Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey

Euroasia QPPV
Olga Ermishina, Pharmacovigilance Country Head, Qualified Person for Pharmacovigilance in EAEU, Bayer Russia

Interfaces with EU QPPVs
Gabrielle Amselem, Deputy QPPV, Alexion

Regional Challenges
- Pediatric PV guideline
- Orphan drugs
- Counterfeit Medicines
- Drug-Device Combination with the different approaches of drug safety between medicines, and medical devices and how the scope of the QPPV role is altered accordingly.

Panel discussion with Q&A

16:00 END OF THE CONFERENCE

16:00 OPTIONAL: INFORMAL NETWORKING

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

SwAPP Swiss Association of Pharmaceutical Professionals

Venue

Holiday Inn Amsterdam
Arena Towers, Amsterdam,
The Netherlands

WIFI Access

Username: **M&E**
Password: **meetingandevent**

EVALUATION

We value your feedback on the content and organisation of this conference. Please complete the electronic survey after the conference

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on the DIA website.

To access presentations, go to www.diaglobal.org and click on Sign in at the very top. Once you have successfully logged in, click on the event page, then Resources on the left.

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 to all attendees electronically after 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.

About DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA: +41 61 225 51 51.