DIA
Global Forum for Qualified Persons for Pharmacovigilance (QPPV)

6-8 October 2020
Virtual Conference

PROGRAMME CO-CHAIRS

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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 14th year and still going strong.

The QPPV Forum focuses on international QPs' role and gives a high-level approach to the discussed topics and 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 thirteen meetings, plus many years of QPPV and Regulator interaction at this Forum. Moreover, we are looking forward to receiving information and discuss pragmatic approaches on the modern technology and how this will impact the QPPV Role.

This year we will be focusing more on scanning the horizon and check the opportunities and considerations for QPPV role regarding AI, with the hope to demystify AI for QPPV.

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 14th 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 changing role of QPPVs
- Modern Technology and AI in Pharmacovigilance: opportunities and considerations for QPPVs
- Business Partners Oversight
- Inspections and Audits
- The QPPV Role in Manufacturing and Quality Issues
- Signal Management
- Measuring Effectiveness of aRMM

Target Audience

- 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 OCTOBER | 13:00-17:00

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 Chairs:

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

Separate Registration Required

WORKSHOP AGENDA

12:45	LOG IN AND CONNECT
13:00	WHAT DOES IT MEAN TO BE A QPPV?
	Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
13:45	BREAK
13:50	QPPV LEGAL ISSUES
	Anna Pavlou, Counsel, Sidley Austin LLP
14:20	THE 'SMALL PHARMA' QPPV
	Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd
14:40	BREAK
15:00	QPPV OVERSIGHT AND THE VIEW FROM 'BIG PHARMA'
	Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca
15:20	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
16:30	PANEL DISCUSSION
17:00	END OF WORKSHOP

Disclosure Policy

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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 that has its Global Center in Washington, DC, USA and the Europe, Middle East and Africa office in Basel, Switzerland. DIA has additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China. For more information, visit www.DIAglobal.org or call DIA EMEA: +41 61 225 51 51.

DAY ONE | TUESDAY, 6 OCTOBER 2020

08:45 LOG-IN AND CONNECT

09:00 WELCOME WORDS AND KEYNOTE

Georgy Genov, Head of Pharmacovigilance, European Medicines Agency

09:45 SESSION 1

ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Session Chairs:
Doris Stenver, Independent Pharmacovigilance Adviser, Unique Advice
Nicolas Tsiakkas, Scientific Director/EU QPPV, Medwork

Artificial Intelligence in Pharmacovigilance is an area where the degree of confusion is proportionate to the number of published information and advertisement of AI products that will offer "holistic and integrated SaaS solution that covers everything". The aim of this presentation will be to demystify AI, explain what automation solutions are and, present the current status of developments in this field, their chances of making it to PV practice and the experience and position of the regulatory authorities. QPPVs will receive adequate input that will help them, among others, decide whether it is time to seriously deal with AI or just keep watching until a viable solution is in sight.

Regulators' perspective – Legal framework
Phil Tregunno, Group Manager, Vigilance, Intelligence and Research Group, Medicines and Healthcare Products Regulatory Agency (MHRA)

Industry Perspective
Marco Anelli, Data, Information, Knowledge & Intelligence Group Leader, Productlife Group – Keypharma
Salvatore G. Cicirello, Senior Director - Safety Science & PASS – WWPS, Celgene

Panel discussion with Q&A

11:15 BREAK

11:30 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 1)

INTRODUCING THE CONCEPT & SPEAKERS

Angela van der Salm, Director Pharmacovigilance, Managing Partner, DADA Consultancy B.V.
Magnus Ysander, EU QPPV and Head Risk Management & Pharmacovigilance Excellence, AstraZeneca R&D

11:45 SESSION 2

BUSINESS PARTNERS OVERSIGHT

Session Chairs:
Shahinaz Badr, Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey
Gemma Jiménez, Head of Drug Safety, EU QPPV, Almirall, Spain

NO SIZE FITS ALL: Mergers, acquisitions, joint ventures, Co-marketing, Co-Promotion or just distribution deals, are different business models for which QPPV is expected to have oversight whether in EU or outside EU regardless whether you are from a big or small company. This session will cover key aspects regarding business partners, from due diligence activities, establishment the appropriate PV agreements or KPIs to how to maximise PSMF use.

Examples of two of big pharma, different corporate restructuring, and the impact on the oversight starting with the due diligence and structuring of the SDEA
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb

Outsourcing and extended role of the EU QPPV which may not involve the integration of other PV systems into the company's PV system but oversight as it is a different PV system: Small pharma example
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

Challenges Met to Keep the Oversight in Terms of Legislations Changes
Shahinaz Badr, Regional Pharmacovigilance Manager, NewBridge Pharmaceuticals, Africa, Middle East, and Turkey
Gemma Jiménez, Head of Drug Safety, EU QPPV, Almirall Spain

Challenges met in the PSMF, PSSF or different PSMFs involved, and how far can we go with auditing
Dionne Usher, Associate Director, Office of the EU QPPV, Merck Sharp & Dohme Limited

Panel discussion with Q&A

13:15 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 2)

PV SYSTEM OVERSIGHT

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

What to measure and how to use these metrics. Measuring standard compliance but also quality of output. The importance of defining responsibility for metrics. Big company perspective.

13:30 NETWORKING SESSION

14:30 END OF DAY 1

DAY TWO | WEDNESDAY, 7 OCTOBER 2020

08:45 LOG-IN AND CONNECT

09:00 SESSION 3

INSPECTIONS AND AUDITS

Session Chairs:
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb
Kiernan Trevett, Expert Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA)

Audits and inspections play an important role in pharmacovigilance activities. Managing multiple audits and inspections brings new challenges for stakeholders. This session will explore different inspectors' perspectives on inspection topics and trends and will include industry experiences related to managing inspections from different authorities. In addition the session will look at different approaches to risk assessments for audit planning and how to handle and manage multiple audit requests. An interactive part to the session will allow the audience to share their experiences and engage with regulators and industry experts.

Audit risk-assessment process
Rebecca Webb, Pharmacovigilance Quality Assurance, AbbVie

Regulators' Perspective
Amal M. Arafah, Pharmacovigilance Systems Inspector, National Pharmacovigilance Center, SFDA, Saudi Arabia
Pieter Grotenhuis, Senior Inspector Pharmacovigilance, Healthcare and Youth Inspectorate

Industry perspective on differences between inspections from various authorities (FDA, Europe, Japan)
Joanne Webbe, Executive Director, Gilead Sciences International

Panel discussion with Q&A

10:30 BREAK

10:45 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 3)

DELEGATION OF QPPV RESPONSIBILITIES

Wendy Huisman, Director, Vigifit

Different options to manage QPPV delegation of PV responsibilities – Any pharma perspective.

11:00 SESSION 4

THE QPPV ROLE IN MANUFACTURING AND QUALITY ISSUES

Session Chairs:
Elspeth McIntosh, Director, Castle Pharmacovigilance Limited
Katarzyna Swiderek, Acting Manager, Safety Evaluation Risk Management (SERM), GlaxoSmithKline

The PV Quality system is an integral part of the PV system, but QPPVs also need to have an understanding of wider quality issues and of safety considerations from other disciplines. As innovative products have entered mainstream use, regulations become increasingly more complex, and expectations for PV become greater and more stringent, we provide an overview of some of the quality and GMP topics that should be considered as part of the QPPV oversight.

Quality oversight and interactions with GMP
Monika Pietrek, Managing Director and Senior Consultant, Pietrek Associates GmbH

The QPPV Perspective
Jens-Ulrich Stegmann, Senior Vice President, Head Clinical Safety and Pharmacovigilance and EU QPPV, GSK

Signal detection
Suzie Seabroke, Leading Senior Pharmacoepidemiologist, MHRA

Health Hazard Evaluation
Ruth Luther, Pharmacovigilance Excellence Expert, AstraZeneca

Panel discussion with Q&A

12:30 BREAK

12:45 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 4)

VISIBILITY OF THE QPPV FOR INTERNAL/EXTERNAL STAKEHOLDERS

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

How to make sure everyone in your organization understands the role, responsibilities and importance of the QPPV (and knows when to involve him/her). Generic and CRO QPPV perspective.

DAY TWO | WEDNESDAY, 7 OCTOBER 2020

13:00 SESSION 5

SIGNAL MANAGEMENT

Session Chairs:
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Peter De Veene, QPPV, Alexion Pharmaceuticals
Mette Stockner, Senior Pharmacovigilance Director, Savara ApS

In the last few years, signal management requirements have become more international and at the same time more complex. Regulatory authorities across the world have introduced regulations covering signal management varying from information sharing to specific local signal detection requirements. At the same time, a number of initiatives in Europe and the US have changed the way we are managing data and how these data can be used either in the signal detection process as well as the evaluation of signals. This session will provide some practical examples of different data sources and how they can be used. And we will learn how we can cope with the additional local requirements without compromising the global processes.

Local Signal Detection requirements and their impact on the global signal detection process
Jean Kilgour-Christie, Deputy EU-QPPV, Novartis Pharma AG

eRMR: Dummy Guide
Jose Alberto Ayala Ortiz, QPPV, PVpharm

Sentinel use for signal detection
Carla Rodriguez-Watson, Scientific Director, IMEDS

Panel discussion with Q&A

14:30 NETWORKING SESSION

15:30 END OF DAY 2

DAY THREE | THURSDAY, 8 OCTOBER 2020

08:45 LOG-IN AND CONNECT

09:00 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 5)

SIGNAL DETECTION

Jose Alberto Ayala Ortiz, QPPV, PVpharm

How to make use of EVDAS data for signaling on generic products. Generic company perspective.

09:15 SESSION 6

RISK MINIMISATION MEASURES

Session Chairs:
Peter De Veene, QPPV, Alexion Pharmaceuticals
Maarten Lagendijk, Director, Deputy EU QPPV, MSD

One of the critical PV processes is establishing, assessing and implementing risk management systems and evaluating the effectiveness of risk minimization. Module XVI of the EMA GVP guidelines is completely dedicated to risk minimization measures and provides guidance on measuring the effectiveness of risk minimization measures both at the level of implementation of the activities but also at patient level (outcome indicators). However, this part of the guidelines still raises many questions. This session will explore the expectations of the regulators towards the measurement of effectiveness but also on when to stop activities. In addition, we will focus on the tracking of additional risk minimisation activities at a global level with examples from our industry colleagues.

Update on GVP XVI
Nuria Semis-Costa, Scientific Officer, European Medicines Agency (EMA)

Effectiveness of educational materials
Inge Zomerdijk, Pharmacovigilance Assessor, Medicines Evaluation Board (MEB)

Tracking additional risk minimisation activities outside the EEA: can you extrapolate from the EU?
Jane Feron, Risk Management Director, AstraZeneca

Panel discussion with Q&A

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10:45 BREAK

11:00 QPPV TALKS – INSPIRATIONAL STORYTELLING (PART 6)

LITERATURE REPORT CAUSALITY ASSESSMENT CONSIDERATIONS

Nicolas Tsiakkas, Scientific Director/EU QPPV, Medwork

When do we consider that a literature case report passes the causality threshold? How to assess whether the author intended to report a relationship? Any pharma perspective.

11:15 SESSION 7

HOT TOPICS IN PHARMACOVIGILANCE

Session Chairs:
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Kiernan Trevett, Expert Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA)

This will be year six 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 ongoing Hot-Topics (ICH E2D, E19, EMA industry platform meeting areas for discussion)
Guy Demol, EU QPPV, MSD Europe Inc

Impact of COVID-19 on Pharmacovigilance: Industry Perspective
Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie

Impact of COVID-19 on Pharmacovigilance: Regulator Perspective
Kiernan Trevett, Expert Pharmacovigilance Inspector, Medicines and Healthcare products Regulatory Agency (MHRA)

Panel discussion with Q&A

12:45 CLOSING REMARKS

Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie
Willemijn Van Der Spuij, Regional Director, PV Intelligence & International Operations, Bristol-Myers Squibb

13:00 END OF THE CONFERENCE

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