Mercure Amsterdam City Hotel

Nov 08, 2023 8:30 AM - Nov 09, 2023 5:15 PM

Joan Muyskenweg 10, 1096 CJ Amsterdam, Netherlands

Global Forum for Qualified Persons for Pharmacovigilance (QPPV)

This Forum provides valuable insights into the most pressing issues QPPVs are facing today. This event has limited capacity, register early!

CONTACT US

Send Email

+41 61 225 51 51

Print Agenda

Day 1 Nov 07, 2023

9:00 AM — 1:30 PM

Pre-conference Workshop 1: Introduction to the Role of QPPVs

3:00 PM — 7:00 PM

Pre-conference Workshop 2: Globalisation of PSMF

Day 2 Nov 08, 2023

8:30 AM — 9:00 AM

Registration And Welcome Coffee

9:00 AM — 9:15 AM

Welcome And Introduction To The QPPV Forum

9:15 AM — 10:15 AM

Keynote Presentation

Keynote Presentation

Session Chair(s)

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Switzerland

Responsible for Pharmacovigilance activities in the EU and Balkans, as well as PV Intelligence and Operational activities within the International PV organization. As part of the Operational activities she holds responsibility for the PSMF. She previously served as Intelligence and Training expert in PV as part of the Quality Standards and Training Group in Bristol Myers Squibb and managed PV projects. Willemijn is a member of the EFPIA Pharmacovigilance Expert Working Group and the International Pharmacovigilance Group where she chairs the CIS and Balkan sub-teams. She started her career in Quintiles, followed by Aventis where she was involved in GCP activities.

Speaker(s)

Advancing Pharmacovigilance: Gene Therapies, Registries, Real World Evidence, and Patient Voices

Sabine Straus, MD, PhD, MSc

PRAC Chair, Staff Member
Medicines Evaluation Board (MEB), Netherlands

Dr. Sabine Straus has been with the Medicines Evaluation Board (MEB) in the Netherlands since 1997, where she started as an Assessor Pharmacovigilance. Prior to working at the MEB she held different positions in the pharmaceutical industry, her last job as Medical Director at Searle Monsanto in the Netherlands. As of July 2012 she is the Dutch member in the Pharmacovigilance Risk Assessment Committee (PRAC). In addition to her work at the MEB she holds a position as associate professor at the Erasmus Medical Center, department of Medical Informatics in Rotterdam. Her main research focus is on additional risk minimisation, pregnancy prevention programs, biologicals, signal detection and signal management.

10:15 AM — 11:00 AM

Major Pharmacovigilance Decisions: The Trend in the Evidence Used And Measuring their Impact

Speaker(s)

Considerations about Benefits-Risks Linked to the Patient Voice

Saad Shakir, DrMed, MD, FFPM, FISPE, FRCP

Director
Drug Safety Research Unit, United Kingdom

Saad Shakir is a pharmacoepidemiologist and drug safety physician. He has worked in the fields of pharmacovigilance, pharmacoepidemiology and risk management for 30 years, initially at the UK Regulatory Authority, then the international pharmaceutical industry and as the Director of the Drug Safety Research Unit (DSRU) in Southampton. The DSRU is a service provider and associate department of the University of Portsmouth. At the DSRU Saad leads a research team with an active programme for monitoring and studying the safety of medicines in populations. He has led many important drug safety studies and has worked and advised on many drug safety issues including product withdrawals, major restrictions and important safety hazards.

11:00 AM — 11:30 AM

Coffee Break

11:30 AM — 11:50 AM

QPPV Talks - Inspirational Storytelling

The QPPV Talks are designed to inspire participants through practical storytelling. Experienced QPPVs will share their real-life challenges and offer practical solutions in brief talks, followed by a live Q&A session. The talks cover a range of themes that are of general interest, providing valuable insights and advice to attendees. Join us for a session packed with real-world examples and practical advice from seasoned QPPVs.

Session Chair(s)

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner
DADA Consultancy B.V., Netherlands

Angela has over 15 years of experience in PV with more than a decade of functioning as a QPPV. She provides customized pharmacovigilance support, including QPPV provision and responsibility for the clients pharmacovigilance systems. After completing her PhD in 2005, she started her career in pharmacovigilance and in 2008, she joined Organon to gain experience in PV during the different mergers taking place at that time. In 2010, she joined DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management, and she recently obtained a MSc in Epidemiology.

Magnus Ysander, MD

EU & UK QPPV & Head Pharmacovigilance Excellence
AstraZeneca, Sweden

Magnus Ysander is the EU and UK QPPV for the AstraZeneca group of companies since 2015 and is based in Gothenburg, Sweden. He joined the company in 2002 and have had several specialist, oversight and line managerial roles within the AstraZeneca pharmacovigilance organisation. Magnus is a MD and has previously worked as a certified Orthopedic Surgeon. He is a member of EFPIA Pharmacovigilance Expert Group and the Program Committee for the DIA QPPV Forum.

Speaker(s)

Harmonised Evaluation of PRAC PSUR Assessment Reports to Support QPPV Quality Oversight and Feed Continuous Improvement

Ruth Luther, MPharm, RPh

Director, Pharmacovigilance Excellence
Astrazeneca UK Ltd, United Kingdom

Ruth is a registered pharmacist who joined AstraZeneca in 1999 after completing her pre-registration training in hospital pharmacy. After several years working in a number of formulation development and regulatory CMC roles, she joined the Pharmacovigilance department in 2007. Ruth worked in the Safety Surveillance Group before moving

on to become the process owner for a number of Pharmacovigilance processes including Safety Surveillance and Risk Management. Currently Ruth is a Pharmacovigilance Excellence Expert where, since 2017, her main responsibilities include support to the EU QPPV on process related matters and leading continuous improvement projects relevant to the content quality of key Pharmacovigilance deliverables.

11:50 AM — 1:10 PM

Session 1: AI And Digitalization

Artificial intelligence and digital activities are creating quite a buzz in a range of different professions, but what does it mean for QPPVs? In this session we will try to give you an overview of regulatory developments, help you understand what QPPVs need to know to enable oversight of new activities and provide ideas for managing compliance, with presenters from a range of backgrounds. We also invite you to discuss with us where technological developments could take PV and the QPPV role in the future.

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

Maarten Lagendijk is currently Deputy EU QPPV at MSD. Previously he has held different positions in pharmacovigilance at the Medicines Evaluation Board (MEB), the Dutch Regulatory Authority, with increasing responsibilities. With over 15 years of experience in pharmacovigilance, Maarten has a good understanding of all different aspects of safety and risk evaluation of medicines in a broad range of therapeutic areas, most notably in oncology and hematology, as well as in immunology and pulmonology. Through the years he has also focused on developments around risk communication and additional risk minimisation, as well as the evolution of risk management and efforts to streamline and harmonise risk management plans.

Elspeth McIntosh, MBA, RN

Director
Castle Pharmacovigilance Ltd, United Kingdom

Elspeth McIntosh began her career in the pharmaceutical industry in 1993, initially working in clinical research, before moving into Pharmacovigilance. She has extensive experience of all aspects of pharmacovigilance and has been a small company QPPV since 1999, dealing with innovative, generic and biotech/biological products. Elspeth set up Castle Pharmacovigilance in 2009 and post Brexit she is a UK QPPV and UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

Speaker(s)

MHRA / Regulatory Perspective

Sarah Vaughan

Head of Vigilance Operations
Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom

Sarah has worked in pharmacovigilance at the MHRA for the past 15 years, her current role is the Head of Vigilance Operations, responsible for adverse incident collection & signal management for medicines and medical devices. Sarah is currently leading on the development and transformation of the Agency's vigilance systems for all medicinal product types.

Digital Solutions – What the QPPV Needs to Know

James Whitehead, MBA, MSc

Senior Director, Device & Digital Safety
AstraZeneca, United Kingdom

James Whitehead is the Senior Director, Device & Digital Safety at AstraZeneca working within Global Patient Safety, having started his career with AZ as a Pharmacovigilance Scientist in Oncology. Since graduating with a BSc in Psychology from the University of Leicester, James has held positions at CROs, Pharmaceutical Companies and Consulting Practises with a focus on Signal and Risk Management. That passion for Signal and Risk Management culminated in a MSc in Pharmacovigilance from the University of Hertfordshire, James is now a Visiting Lecturer on the course. Recently, James studied for an MBA and focused this project on innovation and digital transformation within Patient Safety.

Control of Digital Activities – Validation, Compliance Monitoring, Audit and Inspection of and using Digital/AI tools

Barbara Bovy

Quality Auditing and Center of Excellence, Quality Assurance
UCB, Belgium

Barbara has worked in Quality at UCB for the past 5 years. Her current role is Head of Early & Development Solutions Quality Auditing and Center of Excellence. Prior to her current position, she was EU QPPV in Mithra Pharmaceuticals. Barbara studied epidemiology, public health, social sciences and business management. She holds a PHD in Pharmacovigilance and wrote her thesis on signals and whistleblowers in health and pharma sector.

1:10 PM — 2:45 PM

Lunch And Learn (Sign-up required, spaces limited)

Come and be part of our first-ever lunch and learn session! Enjoy a casual conversation during lunchtime about key topics covered throughout the day. Bring your meal to the table, engage with fellow participants, and converse with both session chairs and other attendees to share solutions, ideas, and insights. Plus, take this opportunity to foster new connections and contribute to the vibrant learning community we're building together.

(This event has limited spaces available and needs pre-registration)

Table 1: Medicine Shortages

Helen Fiddes, Head of Country Pharmacovigilance, UK and Ireland, Pharmacovigilance, BMS

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

Table 2: Keynote Discussion

Willemijn van der Spuij, Exec. Director Europe WorldWide Patient Safety, Bristol-Myers Squibb

Sabine Strauss, PRAC Chair, Staff Member, Medicines Evaluation Board (MEB)

Table 3 and 4: AI and Digitalization:

Maarten Lagendijk, Director, Deputy EU QPPV, MSD

James Whitehead, Patient Safety Medical Device Lead, Astrazeneca

Session Chair(s)

Helen Fiddes

Head of Country Pharmacovigilance, UK and Ireland
United Kingdom

Helen Fiddes, Head of Patient Safety, UK and Ireland at Bristol-Myers Squibb, based in Uxbridge, United Kingdom. Managing a team of nearly thirty Pharmacovigilance professionals, working on a diverse portfolio including three Pregnancy Prevention Programmes for thalidomide and its derivatives. Been in the industry and pharmacovigilance for over 20 years. Prior to that community pharmacy, after graduating from the University of Strathclyde, in Glasgow.

Elspeth McIntosh, MBA, RN

Director
Castle Pharmacovigilance Ltd, United Kingdom

Elspeth McIntosh began her career in the pharmaceutical industry in 1993, initially working in clinical research, before moving into Pharmacovigilance. She has extensive experience of all aspects of pharmacovigilance and has been a small company QPPV since 1999, dealing with innovative, generic and biotech/biological products. Elspeth set up Castle Pharmacovigilance in 2009 and post Brexit she is a UK QPPV and UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Switzerland

Responsible for Pharmacovigilance activities in the EU and Balkans, as well as PV Intelligence and Operational activities within the International PV organization. As part of the Operational activities she holds responsibility for the PSMF. She previously served as Intelligence and Training expert in PV as part of the Quality Standards and Training Group in Bristol Myers Squibb and managed PV projects. Willemijn is a member of the EFPIA Pharmacovigilance Expert Working Group and the International Pharmacovigilance Group where she chairs the CIS and Balkan sub-teams. She started her career in Quintiles, followed by Aventis where she was involved in GCP activities.

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

Maarten Lagendijk is currently Deputy EU QPPV at MSD. Previously he has held different positions in pharmacovigilance at the Medicines Evaluation Board (MEB), the Dutch Regulatory Authority, with increasing responsibilities. With over 15 years of experience in pharmacovigilance, Maarten has a good understanding of all different aspects of safety and risk evaluation of medicines in a broad range of therapeutic areas, most notably in oncology and hematology, as well as in immunology and pulmonology. Through the years he has also focused on developments around risk communication and additional risk minimisation, as well as the evolution of risk management and efforts to streamline and harmonise risk management plans.

James Whitehead, MBA, MSc

Senior Director, Device & Digital Safety
AstraZeneca, United Kingdom

James Whitehead is the Senior Director, Device & Digital Safety at AstraZeneca working within Global Patient Safety, having started his career with AZ as a Pharmacovigilance Scientist in Oncology. Since graduating with a BSc in Psychology from the University of Leicester, James has held positions at CROs, Pharmaceutical Companies and Consulting Practises with a focus on Signal and Risk Management. That passion for Signal and Risk Management culminated in a MSc in Pharmacovigilance from the University of Hertfordshire, James is now a Visiting Lecturer on the course. Recently, James studied for an MBA and focused this project on innovation and digital transformation within Patient Safety.

Sabine Straus, MD, PhD, MSc

PRAC Chair, Staff Member
Medicines Evaluation Board (MEB), Netherlands

Dr. Sabine Straus has been with the Medicines Evaluation Board (MEB) in the Netherlands since 1997, where she started as an Assessor Pharmacovigilance. Prior to working at the MEB she held different positions in the pharmaceutical industry, her last job as Medical Director at Searle Monsanto in the Netherlands. As of July 2012 she is the Dutch member in the Pharmacovigilance Risk Assessment Committee (PRAC). In addition to her work at the MEB she holds a position as associate professor at the Erasmus Medical Center, department of Medical Informatics in Rotterdam. Her main research focus is on additional risk minimisation, pregnancy prevention programs, biologicals, signal detection and signal management.

2:45 PM — 4:20 PM

Session 2: QPPV Oversight - Deep Dive In Business Partners

One of the main responsibilities of the QPPV is to ensure that the PV system under their responsibility is functioning as it should. QPPV oversight is therefore a recurrent topic in the QPPV Forum to share new insights and systems for ensuring this, especially relevant in the globalisation of PV systems and increased complexity with shared responsibilities between multiple business partners. This year, we dive deeper into oversight strategies for PV vendors and licensing partners, including key performance indicators and other measures outside of periodic audits.

Session Chair(s)

Katarzyna Swiderek, MPharm, RPh

Director, Safety Evaluation Risk Management (SERM)
GlaxoSmithKline, Poland

Katarzyna qualified as a pharmacist and joined GlaxoSmithKline in 2017 as the Safety Evaluation Risk Management Scientist in a central team supporting established products. She is responsible for a broad range of pharmacovigilance activities, such as the global signal detection, preparation of periodic safety reports, RMPs and safety input to queries from regulatory agencies. Katarzyna has been extensively involved in associative work throughout her whole pharmacy studies, up to the European level when she was the President of the European Pharmaceutical Students' Association (EPSA), representing 160 000 European pharmacy students and young professionals.

Kiernan Trevett, MSc

Principal Quality Lead, PDQ Quality Assurance Process GVP
Roche, United States

Kiernan joined Roche as a Principal Quality Lead focussing on pharmacovigilance quality assurance strategies. Previously, she worked as a GPvP Inspector at the MHRA for 10 years, with her most recent role being Expert GPvP Inspector. She contributed to the development of the EU GVP, had a role in the training of GPvP Inspectors in other EU Member States and contributed significantly to the MHRA's preparedness work in relation to the UK's withdrawal from the EU. Before joining the MHRA, Kiernan worked as a certified Quality Assurance auditor for a central laboratory that provided services for Phase I-III pharmaceutical clinical trials. Kiernan has a Master of Biomedical Sciences degree from the University of Southampton.

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner
DADA Consultancy B.V., Netherlands

Angela has over 15 years of experience in PV with more than a decade of functioning as a QPPV. She provides customized pharmacovigilance support, including QPPV provision and responsibility

for the clients pharmacovigilance systems. After completing her PhD in 2005, she started her career in pharmacovigilance and in 2008, she joined Organon to gain experience in PV during the different mergers taking place at that time. In 2010, she joined DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management, and she recently obtained a MSc in Epidemiology.

Speaker(s)

Oversight from a CRO Point of View

Caroline Fitzsimons

Associate Director, Local QPPV Network Oversight
IQVIA, Ireland

Caroline has 25+ years of experience in the pharma industry. She started her career in clinical research, in Data Management and subsequently as a Clinical Research Associate and (CRA) and a Clinical Team Lead working across a number of therapeutic areas. She embarked her pharmacovigilance (PV) career in 2010, where she worked as a local QPPV managing the local PV system & Quality Complaints. Since re-joining IQVIA in 2015 she has performed various PV roles, including heading the Global PV Agreements services with a team of 15 managing >2000 agreements, as Quality Manager supporting Regulatory Inspections and deviation/process improvement strategies, as PSMF Coordinator and more recently within the Local QPPV team as Lead and Line Manager.

QPPV Oversight where Non-EU License Partner is GSDB Holder

Yusuf Tanrikulu

Deutschland, Germany

Yusuf is the Deputy EU QPPV for Roche since 2018 and is based in Grenzach-Wyhlen in Germany. He has been with multiple international pharma companies in his career, spending more than a decade in pharmacovigilance. With a background in Bioinformatics, he had previously helped multiple organisations to set up their statistical signal detection and management systems, and gained experience in early drug development as well..

PV System Oversight as a Process

Rory Littlebury

Safety Governance Director
GSK, United Kingdom

Rory has over ten years' experience working at the MHRA, and two years working at GSK in Safety Governance. Rory's experience includes engagement with a variety of stakeholders, from multi-national pharma companies to healthcare professionals and patients, giving a well-rounded view of the difficulties and challenges faced by those in, or affected by, the regulations of pharmaceuticals.

4:20 PM — 4:50 PM

Coffee Break

4:50 PM — 5:10 PM

QPPV Talk - Inspirational Storytelling

The QPPV Talks are designed to inspire participants through practical storytelling. Experienced QPPVs will share their real-life challenges and offer practical solutions in brief talks, followed by a live Q&A session. The talks cover a range of themes that are of general interest, providing valuable insights and advice to attendees. Join us for a session packed with real-world examples and practical advice from seasoned QPPVs.

Session Chair(s)

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner
DADA Consultancy B.V., Netherlands

Angela has over 15 years of experience in PV with more than a decade of functioning as a QPPV. She provides customized pharmacovigilance support, including QPPV provision and responsibility for the clients pharmacovigilance systems. After completing her PhD in 2005, she started her career in pharmacovigilance and in 2008, she joined Organon to gain experience in PV during the different mergers taking place at that time. In 2010, she joined DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management, and she recently obtained a MSc in Epidemiology.

Magnus Ysander, MD

EU & UK QPPV & Head Pharmacovigilance Excellence
AstraZeneca, Sweden

Magnus Ysander is the EU and UK QPPV for the AstraZeneca group of companies since 2015 and is based in Gothenburg, Sweden. He joined the company in 2002 and have had several specialist, oversight and line managerial roles within the AstraZeneca pharmacovigilance organisation. Magnus is a MD and has previously worked as a certified Orthopedic Surgeon. He is a member of EFPIA Pharmacovigilance Expert Group and the Program Committee for the DIA QPPV Forum.

Speaker(s)

Role of QPPV in a referral - Challenges/how to influence as a QPPV

Sina Schader, DrMed

EU and UK QPPV
AbbVie, Germany

Sina is the EU QPPV in the department Pharmacovigilance and Patient Safety and located in Germany. She has been with Abbvie 11 years, before her current position, she was Head of the German PV, Medical Information and Medical Quality department and national QPPV in Germany. Prior to joining Abbvie, Sina studied veterinary medicine and wrote her PHD thesis in the Virology department, working group Immunology on bone marrow transplantation. Post Brexit she is also the UK QPPV for Abbvie.

Role of QPPV in a referral - Challenges/how to influence as a QPPV

Koen Van Der Heijden, MSc

QPPV
Menarini Stemline, Netherlands

Koen has over 15 years of experience in pharmacovigilance and more than 9 years as QPPV. Since summer 2021 he is the EU and UK QPPV for Galapagos, where he joined to help finalize the pharmacovigilance system in light of an upcoming transfer of a Market Authorisation. Prior to Galapagos he worked 10 years for Medtronic BioPharma, a small pharma entity in the medical device company Medtronic. Within this company he build up the pharmacovigilance system for the first pharma product of Medtronic. He has a Master in Biomedical Sciences, with a main focus on epidemiology and pathobiology.

5:10 PM — 5:30 PM

Re-cap of the Day

5:30 PM — 6:30 PM

End Of Day One - Networking Drinks Reception

Day 3 Nov 09, 2023

8:30 AM — 9:00 AM

Welcome Coffee

9:00 AM — 10:30 AM

Session 3: International PV

PV regulatory requirements keep growing year after year and GVP regulations are being expanded across the globe with slightly different local flavours. What is the impact of the new local requirements for the international QPPVs and companies PV system? How can we keep up with the new extended network of local QPPVs? Africa is moving fast, will the QPPV role be impacted by the current activity of the African Medical Agency? Last but not least, data privacy is a topic of growing interest - European QPPVs have actually been approached to ensure compliance in PV activities on this regard... Do we as QPPVs know enough?

Session Chair(s)

Shahinaz Badr

Pharmacovigilance Consultant and PVQA Auditor - EMEA
Pharma Quality Europe, United Arab Emirates

Pharmacist with >20 years' experience in pharmacy & pharmaceutical business, started as clinical pharmacist in Cairo Univ. Med-School Teaching Hospital integrating with top HCPs of different specialties where safety monitoring is an integral part of clinical practice. Using her expertise, she joined the pharmaceutical industry working in RA & regional positions before focusing on Pharmacovigilance. Actively working in PV Reg-Intel in a role enabling her to interact with industry colleagues and Competent Authority PV departments. Contributed to several international initiatives and partnerships to support patient safety & improve drug safety monitoring. She's an active ISOP member collaborating in the initiation of the Global PV Certificate.

Gemma Jimenez Sese

Senior Director, Deputy EU QPPV
AstraZeneca, Spain

Gemma Jimenez Sese is the EUQPPV for Almirall since 2011 and is based in Barcelona, Spain. Pharmacist by education, after a short period in hospital research moved to pharma industry working in UK and Spain, first in regulatory affairs and for the last 15 years in pharmacovigilance taking up roles with increasing responsibility. In PV she has been involved in a broad scope of activities, from safety in development to marketed medicinal products support, from small mollecules to biologics. Passionate about science and strong believer in our mission of putting always the patient first.

Speaker(s)

Management of a Local QPPV Network - a PV System that can Accommodate Local Regulation Challenges

Ilaria Grisoni, MSc

Executive Director, Head of EU/International PV & Global Risk Management and EEA
Gentium Srl, A Jazz Pharmaceuticals Company, Italy

China GVP Update – From a QPPV Perspective

Marylene Zhan, MBA

Senior consultant
Accestra Consulting Company, China

Marylene Zhan, a senior consultant at Accestra Consulting, brings extensive expertise in pharmacovigilance and regulatory affairs. Holding a Master's Degree from Zhongnan University of Economics and Law, she excels as a bilingual and bicultural consultant, specializing in China regulatory compliance and pharmacovigilance (RA/PV). With deep insights into Chinese Pharmaceutical regulations and market access, Marylene aids international pharma companies in entering China market. Her adept communication fosters strong client relationships, ensuring top-notch services aligned with business goals.

Deep Dive in Africa: Harmonization of Legislation

Chimwemwe Chamdimba

African Medicines Regulation Harmonization Programme Head
African Union Development Agency-NEPAD, South Africa

Chimwemwe Chamdimba heads the African Medicines Regulatory Harmonization Initiative at AUDA-NEPAD. She manages the AMRH Programme, supports AMA operationalization, and drives policy reforms connecting regulatory strengthening to local medical product manufacturing. A health policy expert, she leads reforms, harmonization, and partner coordination, contributing to vital continental policies including the AU Model Law on Medical Product Regulation; the Treaty for the establishment of the African Medicines Agency (AMA); and the AU Private Sector Engagement in Health Framework.

Eudravigilance and Data Privacy

Raphael Van Eemeren

EU QPPV Director, Global Patient Safety
Amgen AB, Sweden

11:00 AM — 11:20 AM

QPPV Talks - Inspirational Storytelling

The QPPV Talks are designed to inspire participants through practical storytelling. Experienced QPPVs will share their real-life challenges and offer practical solutions in brief talks, followed by a live Q&A session. The talks cover a range of themes that are of general interest, providing valuable insights and advice to attendees. Join us for a session packed with real-world examples and practical advice from seasoned QPPVs.

Session Chair(s)

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner
DADA Consultancy B.V., Netherlands

Angela has over 15 years of experience in PV with more than a decade of functioning as a QPPV. She provides customized pharmacovigilance support, including QPPV provision and responsibility for the clients pharmacovigilance systems. After completing her PhD in 2005, she started her career in pharmacovigilance and in 2008, she joined Organon to gain experience in PV during the different mergers taking place at that time. In 2010, she joined DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management, and she recently obtained a MSc in Epidemiology.

Magnus Ysander, MD

EU & UK QPPV & Head Pharmacovigilance Excellence
AstraZeneca, Sweden

Magnus Ysander is the EU and UK QPPV for the AstraZeneca group of companies since 2015 and is based in Gothenburg, Sweden. He joined the company in 2002 and have had several specialist, oversight and line managerial roles within the AstraZeneca pharmacovigilance organisation. Magnus is a MD and has previously worked as a certified Orthopedic Surgeon. He is a member of EFPIA Pharmacovigilance Expert Group and the Program Committee for the DIA QPPV Forum.

Speaker(s)

Assessing Pharmacovigilance Competency of PV organisation to support QPPV Oversight of staff PV knowledge and comply with GVP

Jessica Mårlind Würtele, PhD, MSc

Director, Patient Safety Excellence
Astrazeneca, Sweden

Jessica is the Director of Patient Safety Excellence and an expert PV advisor in the AstraZeneca QPPV Office. She has been with the company for 8 years, including heading the global PV audit team. Jessica previously worked at Biogen in Switzerland as the Swiss QP and held several roles within Medical Affairs. She has thorough experience across multiple GxP areas both from a global and local perspective. Jessica holds a PhD in Immuno-oncology from the Swiss Federal Institute of Technology in Zurich.

11:20 AM — 12:50 PM

Session 4: Inspections - Expectations And Interactions

This session will address both a regulatory perspective and an industry perspective on inspections. The audience will learn about inspection findings and trends and in addition, also hear what it means to manage inspections in multiple countries and how to handle different expectations. The future of inspections will also be addressed to give the audience a broad insight into various aspects of inspections.

Session Chair(s)

Claire Longman, MSc

Expert Pharmacovigilance Inspector
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

I am a Senior GPvP Inspector at the MHRA. I have over 5 years experience as an Inspector in Pharmacovigilance and have recently taken on the role as Head of the Good Clinical Practice Compliance Team within the MHRA. Prior to joining the MHRA I worked in Industry where I held various roles within Pharmacovigilance and Medical Information.

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Switzerland

Responsible for Pharmacovigilance activities in the EU and Balkans, as well as PV Intelligence and Operational activities within the International PV organization. As part of the Operational activities she holds responsibility for the PSMF. She previously served as Intelligence and Training expert in PV as part of the Quality Standards and Training Group in Bristol Myers Squibb and managed PV projects. Willemijn is a member of the EFPIA Pharmacovigilance Expert Working Group and the International Pharmacovigilance Group where she chairs the CIS and Balkan sub-teams. She started her career in Quintiles, followed by Aventis where she was involved in GCP activities.

Speaker(s)

International Collaboration: PV collaboration between Ghana, MHRA & MEB

Adela Ashie

Principal Regulatory Officer
Food and Drugs Authority- Ghana, Ghana

Adela Ashie is a pharmacist with over 15 years of experience in Pharmacovigilance. She holds a master's in international health (MPH IH) from the University of Nottingham, United Kingdom and is currently Head of the Vigilance Unit under the Safety Monitoring Department of the Food and Drugs Authority-Ghana. Adela is involved in

the strengthening of the pharmacovigilance system in Ghana through education of stakeholders including healthcare professionals and the general public. Adela's recent works have been in assisting pharmaceutical companies in Ghana to establish efficient Pharmacovigilance systems through the training of Qualified Persons for Pharmacovigilance and the conduct of Good Pharmacovigilance Practice Inspections since 2016.

Industry Experiences with Inspections - More countries with less experience

Pat Harding

Senior Advisor, Medicines Quality Organisation – International,
Eli Lilly and Company, United Kingdom

Pat Hawthorne works in the International Medicines Quality Organisation and is based at Eli Lilly in the UK. Primary responsibilities are leading the processes around the maintenance the EU PSMF and localised PSMFs and shaping affiliate vigilance.

Managing the Perfect Deviation – Regulatory and Industry Perspective

Lauren Kelly

Associate Director, PV Inspection Readiness & Deviation Management
Bristol-Myers Squibb, Ireland

Lauren has nearly 10 years' experience working in the pharmaceutical industry in a variety of quality and compliance roles. She has worked in BMS for the last 4 years just recently taking the position of Associate Director, PV Inspection Readiness & Deviation Mgmt. which will involve leading the inspection readiness, audit CAPA and Deviation management teams within the PV Compliance function of BMS. Prior to this change, she worked in the same team supporting multiple inspections globally, audit CAPA management and execution of the inspection readiness program. Prior to BMS, she worked in the PV and country organisation quality auditing departments in both Pfizer and AbbVie.

12:50 PM — 2:50 PM

Lunch And Learn

Come and be part of our first-ever lunch and learn session! Enjoy a casual conversation during lunchtime about key topics covered throughout the day. Bring your meal to the table, engage with fellow participants, and converse with both session chairs and other attendees to share solutions, ideas, and insights. Plus, take this opportunity to foster new connections and contribute to the vibrant learning community we're building together.

(This event has limited spaces available and needs pre-registration)

Table 1: QPPV Oversight

Katarzyna Swiderek Angela van der Salm

Table 2: Interpretation of Regulations

Shahinaz Badr

Table 3: Inspections

Claire Longman

Willemijn van der Spuij

Session Chair(s)

Katarzyna Swiderek, MPharm, RPh

Director, Safety Evaluation Risk Management (SERM)
GlaxoSmithKline, Poland

Katarzyna qualified as a pharmacist and joined GlaxoSmithKline in 2017 as the Safety Evaluation Risk Management Scientist in a central team supporting established products. She is responsible for a broad range of pharmacovigilance activities, such as the global signal detection, preparation of periodic safety reports, RMPs and safety input to queries from regulatory agencies. Katarzyna has been extensively involved in associative work throughout her whole pharmacy studies, up to the European level when she was the President of the European Pharmaceutical Students' Association (EPSA), representing 160 000 European pharmacy students and young professionals.

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner
DADA Consultancy B.V., Netherlands

Angela has over 15 years of experience in PV with more than a decade of functioning as a QPPV. She provides customized pharmacovigilance support, including QPPV provision and responsibility for the clients pharmacovigilance systems. After completing her PhD in 2005, she started her career in pharmacovigilance and in 2008, she joined Organon to gain experience in PV during the different mergers taking place at that time. In 2010, she joined DADA Consultancy to start up a department of PV consultants to take on global and local responsibilities from clients in need of PV support. Her personal interests lie with Compliance management and auditing, as well as Risk Management, and she recently obtained a MSc in Epidemiology.

Shahinaz Badr

Pharmacovigilance Consultant and PVQA Auditor - EMEA
Pharma Quality Europe, United Arab Emirates

Pharmacist with >20 years' experience in pharmacy & pharmaceutical business, started as clinical pharmacist in Cairo Univ. Med-School Teaching Hospital integrating with top HCPs of different specialties where safety monitoring is an integral part of clinical practice. Using her expertise, she joined the pharmaceutical industry working in RA & regional positions before focusing on Pharmacovigilance. Actively working in PV Reg-Intel in a role enabling her to interact with industry colleagues and Competent Authority PV departments. Contributed to several international initiatives and partnerships to support patient safety & improve drug safety monitoring. She's an active ISOP member collaborating in the initiation of the Global PV Certificate.

Claire Longman, MSc

Expert Pharmacovigilance Inspector
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

I am a Senior GPvP Inspector at the MHRA. I have over 5 years experience as an Inspector in Pharmacovigilance and have recently taken on the role as Head of the Good Clinical Practice Compliance Team within the MHRA. Prior to joining the MHRA I worked in Industry where I held various roles within Pharmacovigilance and Medical Information.

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Switzerland

Responsible for Pharmacovigilance activities in the EU and Balkans, as well as PV Intelligence and Operational activities within the International PV organization. As part of the Operational activities she holds responsibility for the PSMF. She previously served as Intelligence and Training expert in PV as part of the Quality Standards and Training Group in Bristol Myers Squibb and managed PV projects. Willemijn is a member of the EFPIA Pharmacovigilance Expert Working Group and the International Pharmacovigilance Group where she chairs the CIS and Balkan sub-teams. She started her career in Quintiles, followed by Aventis where she was involved in GCP activities.

2:50 PM — 3:50 PM

Session 5: Hot Topics - Bitesize Updates

The Hot Topics session provides insights in the very latest on discussions in specific Safety areas of interest. Experts will address the latest on topics that are being discussed by the Industry Trade Association (EFPIA - should we be more global?) ?and Regulatory Authorities and will therefore give the audience an insight in the key topics of the moment. The expert speakers that lead these discussions will share information on these key topics, the issues at hand, the progress that is being made and what the audience can expect on these topics for the future. The topics will be of interest to a broad audience and will be of specific value to participants that are not able to attend Industry Association meetings or public meetings with EMA due to limited attendance possibilities.

These are some of the topics that we will cover:

- Transitioning in Transparency

- Risk Management Plans

- EMA Publication of full Periodic PSURs

Signal Detection (Monitoring EVDAS Pilot)
Environmental Risk Assessment (Pharma Legislation)

This session offers a great opportunity to hear about these topics from experts in the field. The audience can expect different exciting presentations that will please the crowd.

Session Chair(s)

Elspeth McIntosh, MBA, RN

Director
Castle Pharmacovigilance Ltd, United Kingdom

Elspeth McIntosh began her career in the pharmaceutical industry in 1993, initially working in clinical research, before moving into Pharmacovigilance. She has extensive experience of all aspects of pharmacovigilance and has been a small company QPPV since 1999, dealing with innovative, generic and biotech/biological products. Elspeth set up Castle Pharmacovigilance in 2009 and post Brexit she is a UK QPPV and UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

Speaker(s)

Windsor Framework – Catch Up

Helen Fiddes

Head of Country Pharmacovigilance, UK and Ireland
United Kingdom

Helen Fiddes, Head of Patient Safety, UK and Ireland at Bristol-Myers Squibb, based in Uxbridge, United Kingdom. Managing a team of nearly thirty Pharmacovigilance professionals, working on a diverse portfolio including three Pregnancy Prevention Programmes for thalidomide and its derivatives. Been in the industry and pharmacovigilance for over 20 years. Prior to that community pharmacy, after graduating from the University of Strathclyde, in Glasgow.

ICH E2D Updates

Michelle Grimes, MSc

Head, International Pharmacovigilance. GCS&PV
MSD, United Kingdom

Michelle is leading the International Pharmacovigilance organization at MSD. She has 25+ years of experience in the pharma industry and worked in clinical research and consulting prior to moving into pharmacovigilance (PV). Since joining MSD in 2002 she has performed various roles within PV including an EUQPPV support function, as well as prior regional operations roles in Asia Pacific and EMEA. Michelle has accountability for PV activities ex-US which consists of approx. 205 markets managed from 56 locations across the globe. Michelle is a part of the Global Clinical Safety and Pharmacovigilance Leadership Team, and works closely with HQ colleagues in the US. She is based in Europe.

PVEG taskforce - 'Non-Fixed-Dose Combination'

Magnus Ysander, MD

EU & UK QPPV & Head Pharmacovigilance Excellence
AstraZeneca, Sweden

Magnus Ysander is the EU and UK QPPV for the AstraZeneca group of companies since 2015 and is based in Gothenburg, Sweden. He joined the company in 2002 and have had several specialist, oversight and line managerial roles within the AstraZeneca pharmacovigilance organisation. Magnus is a MD and has previously worked as a certified Orthopedic Surgeon. He is a member of EFPIA Pharmacovigilance Expert Group and the Program Committee for the DIA QPPV Forum.

Electronic Products Information Pilot and the New Pharma Legislation

Koen Nauwelaerts, PharmD, PhD, MBA

Regulatory Policy and Innovation Lead
Bayer AG, Belgium

Koen Nauwelaerts holds a Master's degree in Pharmacy from Leuven University, Belgium and a PhD in Drug Development from the same university. Further he obtained an MBA degree from Vlerick Business School and completed the technology immersion program at MIT. Koen is currently working at Bayer as RA Policy and Innovation Lead. He joined Bayer as head of regulatory affairs and quality for the Belgium/Luxemburg region and previously has been active within MSD and Medicines for Europe in different roles in Regulatory Affairs and Quality. Within his current role as RA Policy and Innovation Lead, Koen leads the internal global e-labeling initiatives at Bayer and is vice-chair of the Inter Association TaskForce (IATF) for ePI.

3:30 PM — 4:00 PM

Coffee Break

3:50 PM — 4:10 PM

Recap of the Day And Closing Words