Hotel Casa Amsterdam

Nov 19, 2025 8:30 AM - Nov 20, 2025 4:00 PM

Eerste Ringdijkstraat 4, NL-1097 Amsterdam, Netherlands

Global Forum for Qualified Persons for Pharmacovigilance (QPPV)

This Forum continues to be the ONLY conference designed by QPPVs, for QPPVs - uniting leaders, subject matter experts, and peers in a dedicated setting for open exchange, practical learning, and professional growth.

Print Agenda

Day 1 Nov 18, 2025

9:00 AM — 1:30 PM

Pre-Conference Tutorial: Introduction to the Role of QPPVs

3:00 PM — 7:00 PM

Pre-Conference Tutorial: Globalisation of PSMF

Day 2 Nov 19, 2025

8:30 AM — 9:00 AM

Registration and Welcome Coffee

9:00 AM — 9:15 AM

Welcome and Introduction to the QPPV Forum

Session Chair(s)

Claudia Ferreira

Scientific Programs Manager
DIA, Switzerland

9:15 AM — 10:00 AM

Keynote: A Day in the Life of (Several) QPPVs

This year's keynote session will explore 'A Day in the Life of (Several) QPPVs'. This session will be in the style of a 'chat show' and QPPVs from organisations of different sizes will be invited to share real life experiences in the form of anecdotes and conversations on diverse topics such as stakeholder management, crisis management, oversight, and day-to-day activities like signal management and risk mitigation. The session will be facilitated by Sue Rees who will act as host. This informal and (hopefully) entertaining but also insightful and informative session is a great way to start the conference.

Session Chair(s)

Sue Rees, MS

Director
Sue Rees Consultancy Ltd, United Kingdom

Sue is a former EU QPPV and established expert in pharmacovigilance in Europe, with over 30 years' pharmaceutical industry experience across a number of organisations including GSK,

AstraZeneca and Amgen and served on the EFPIA PV Expert Group for 10 years. As an independent consultant, Sue now shares her knowledge and expertise with organisations through interim leadership, consultancy projects and training. Sue holds a BSc (Hons) in Biochemistry and MSc in Immunology and is a Senior Lecturer at the University of Hertfordshire for the post graduate Pharmacovigilance Master's degree course.

Speaker(s)

Fabian Heisig

Head Global Drug Safety & QPPV, Chief Medical Officer
Grünenthal Gmbh, Germany

Fabian Heisig is leading the Global Drug Safety Department at Grünenthal since 2018 and was appointed as EU QPPV and UK QPPV. In addition, he is deputizing the Chief Medical Officer. He started his career at Grünenthal in 2007 and had various roles incl. leadership responsibilities in case processing, benefit risk management and clinical safety. He has expertise in the pre-marketing area as well as in the post-marketing area. He is a member of EFPIA Pharmacovigilance Expert group.

Mette Kallesøe, PharmD, MPharm, MS

Head of Pharmacovigilance, QPPV
Hansa Biopharma, Denmark

Raphael Van Eemeren

EU QPPV Senior Director, Global Patient Safety
Amgen AB, Sweden

Monica Tomas Morales, PharmD

Chief Executive Officer
PHARMYA, France

10:00 AM — 11:00 AM

Session 1: Effectiveness of RMMs: Challenges and Opportunities

This session will delve into the challenges and opportunities around effectiveness of Risk Minimisation Measures, with a focus on evolving regulatory expectations and practical methodologies. We will explore updates to GVP Module XVI, examine commonly used approaches such as drug utilisation studies and PASS studies, and reflect on lessons learned

from industry and academic experience, including impact studies conducted per PRAC requests. Discussion will also address the real-world impact of RMMs in clinical practice, the objectives we aim to achieve, and the challenges posed by personal data protection and other regulatory requirements. Join us as we unpack the complexities of evaluating RMM effectiveness and work toward improving patient safety outcomes.

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

Maarten Lagendijk is the deputy QPPV at MSD since 2019 and is based in the Netherlands. Maarten has over 20 years of experience in pharmacovigilance. He has previously worked for the Medicines Evaluation Board in different pharmacovigilance related roles as well as a national expert at the European Medicines Agency. Maarten has been involved with DIA for many years and is part of the programme committee for the Global QPPV Forum since 2020.

Katarzyna Okrojek-Swiderek, MPharm, RPh

Scientific 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.

Speaker(s)

Setting the Scene: RWE for effectiveness measures in RMMs

Liana Martirosyan

PRAC Member and PRAC Vice-Chair
Medicines Evaluation Board (MEB), Netherlands

Dr Liana Martirosyan is a medical doctor with an MPH and a PhD in pharmacoepidemiology. She represents the Netherlands at the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and serves as its Vice-Chair. Liana joined the Medicines Evaluation Board (MEB) in 2012, where she worked as a pharmacovigilance assessor before becoming a PRAC member. Her special interests include interventions in clinical practice to minimise drug safety risks and the evaluation of the effectiveness of additional risk minimisation measures.

Updates to Module XVI: Challenges of Effectiveness Measurement

Mark Perrott, PhD

Managing Partner
Axian Consulting Ltd., United Kingdom

Mark is a founder and managing partner at Axian Consulting, where he focuses on improving benefit-risk balance and outcomes for patients through improving communication and adding value using digital approaches. He has a >20 year pharma career which has included industry (Wellcome, GW, GSK and AZ) and consultancy roles (WCI, Foresight, PopeWoodhead, Huron and now is a founder and managing partner of Axian Consulting). He is now focusing on the opportunities presented by improved benefit-risk management approaches to enhance risk management decision-making in development and on adding value to the interactions of industry and customers to maximise B-R balance and improve outcomes in REMS and aRMM programmes.

11:00 AM — 11:30 AM

Coffee Break

11:30 AM — 1:00 PM

Session 2: Oversight Session – Building Blocks of a Compliant PV System

This session focusses on several areas that feed into QPPV (office) oversight of the operational aspects of the PV system. As a popular recurring topic, this year we are looking at it from a different angle, peeling off the multiple layers that compose a PV system. We start at the PV department, then look at neighboring functions (Marketing/Regulatory/ClinOps/Quality/etc), and then at all the outsourced activities. Who keeps oversight on what (e.g. what if the service provider further subcontracts specific activities to another third party)? When is who informed?

Session Chair(s)

Ilaria Grisoni, MSc

Executive Director, Head of International QPPV Office, EEA QPPV
Jazz Pharmaceuticals, Italy

Angela Van Der Salm, PhD, MSc

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

Angela has almost 20 years experience in PV with 15 years of functioning as a (deputy) QPPV. She provides customized pharmacovigilance support, including QPPV provision & responsibility for the clients pharmacovigilance systems. After her PhD in 2005, she started her career in pharmacovigilance & 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 Medication Errors, & she recently obtained a MSc in Clinical Epidemiology.

Speaker(s)

How does the QPPV have oversight over the Local QPPV?

Rory Littlebury

Head of PVSO and QPPV Office
GlaxoSmithKline (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.

How does the QPPV ensure oversight of neighboring functions?

Lene Holdrup, MSc

Senior Director, QPPV
Ferring Pharmaceuticals A/S, Denmark

How does the QPPV ensure oversight of insourced activities (outsourced to a subcontractor)?

Ana Pedro Jesuíno

Director, Local QPPV Network - Global Head
IQVIA, Portugal

Marketed Product Safety Ass. Director at IQVIA, with more than 10 years pharmacovigilance experience, including both CRO and Pharmaceutical industries. Oversight of Local QPPV Global Network.

1:00 PM — 2:00 PM

Lunch

2:00 PM — 2:40 PM

QPPV Open Mic Sessions

2:40 PM — 2:45 PM

Move to Main Room

2:45 PM — 3:00 PM

QPPV Talks – Inspirational Storytelling (I)

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.

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

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Willemijn van der Spuij, MSc

Executive Director Europe | International - Patient Safety
Bristol Myers Squibb, Switzerland

Willemijn is the Executive Director Europe in the WorldWide Patient Safety Organisation in Bristol Myers Squibb. She is responsible for Patient Safety in the European region, including the Balkans, Baltics and distributor markets. Prior to this role she was responsible for the European markets, PV Intelligence & International Operations including the PSMF as well as Training and Outsourcing activities. Willemijn holds a Nursing Degree from the Netherlands, a BA (Hons) in Sociology from Goldsmiths college, University of London, UK and an MSc in Pharmacovigilance from the University of Hertfordshire, UK. Willemijn is co-chair of the EFPIA Pharmacovigilance Expert Working Group and Chair of the EFPIA International Pharmacovigilance Group.

Speaker(s)

Business decisions impacting the local QPPV

Elena Colombo

Director, PV System Governance & Intelligence Lead, Deputy EEA QPPV
Jazz Pharmaceuticals , Italy

3:00 PM — 3:30 PM

Session 3 – Part I: Update on International Activities and Collaboration - Focus on Africa

Session Overview: This year's session will focus on international cooperation and joint collaboration between national and regional regulators, as well as international organizations. As examples we will look at the role of the Bill & Melinda Gates Foundation in advancing patient safety in Africa, hear updates on the development of the African Medicines Agency and learn more about the development of the QPPV role in an individual African country.

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.

Shahinaz Badr, PharmD

Pharmacovigilance Consultant and PVQA Auditor - EMEA
Independent Consultant, United Arab Emirates

Shahinaz, a pharmacist with over 20 years in pharmacy and the pharmaceutical industry, is a Pharmacovigilance Consultant and Lead Auditor across the EMEA region. She began as a clinical pharmacist at Cairo University Medical School and advanced to an internal auditor role. Transitioning to the pharmaceutical industry, she worked in Regulatory Affairs before specializing in Pharmacovigilance as a regional QPPV and later as a PVQA Lead Auditor. Shahinaz is active in the ISOP Special Interest Group, contributing to global pharmacovigilance certifications, and frequently speaks at international conferences on patient and drug safety

Speaker(s)

African Union Smart Safety Surveillance (AU-3S) Programme Overview

Deirdre McCarthy, MSc

Pharmacovigilance Lead, Regulatory System Strengthening
Gates Foundation, United States

Deirdre is a Senior Program Officer and Pharmacovigilance Lead at the Gates Foundation, overseeing grants that support the African Union's first continental safety surveillance platform for the African Medicines Agency. With over 20 years of PV experience across regulatory, industry, and non-profit sectors in the EU, US, and Latin America, she

brings a global perspective to post-marketing safety, compliance, and global health. She has lectured at Tufts University and is a Fellow of the International Society of Pharmacovigilance (ISoP).

3:30 PM — 4:00 PM

Coffee Break

4:00 PM — 5:00 PM

Session 3 – Part II: Update on International Activities and Collaboration – Focus on Africa

This year's session will focus on international cooperation and joint collaboration between national and regional regulators, as well as international organizations. As examples we will look at the role of the Bill & Melinda Gates Foundation in advancing patient safety in Africa, hear updates on the development of the African Medicines Agency and learn more about the development of the QPPV role in an individual African country.

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Speaker(s)

Updates on the African Medicines Agency

Chimwemwe Chamdimba

Principal Programme Officer-African Medicines Regulatory Harmonisation Program
African Union Development Agency-NEPAD, South Africa

Chimwemwe Chamdimba leads the African Medicines Regulatory Harmonization (AMRH) Initiative at AUDA-NEPAD, overseeing the programme and supporting the operationalisation of the African Medicines Agency (AMA). A health policy specialist, she drives regulatory reforms that strengthen systems, align with procurement, and boost local manufacturing. She has contributed to key AU policy frameworks, including the Model Law on Medical Product Regulation, the AMA Treaty, the AU Health Strategy, the Private Sector Engagement Framework, and STISA-2024.

EFDA: Ethiopia's Initiative on Training QPPVs

Demeke Amare

Pharmacovigilance and Clinical Trial expert
Ethiopian Food and Drug Authority (EFDA), Ethiopia

Mr. Demeke Amare is a Pharmacist and Regulatory Affairs expert with over 14 years' experience in pharmacovigilance, clinical trials, quality control, and regulatory inspections (GMP, GCP, GLP, GVP). He currently serves as a Medicine Safety and Post-Marketing Surveillance Expert at the Ethiopian Food and Drug Authority (EFDA). Demeke holds a Master's in Clinical Trials and has held several senior roles at EFDA, including QPPV focal point. He has contributed to key regulatory initiatives with WHO, AUDA-NEPAD, and others, and has participated in international forums across Africa, Asia, Europe, and the Middle East.

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Pharmacovigilance Lead, Regulatory System Strengthening
Gates Foundation, United States

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5:00 PM — 5:15 PM

QPPV Talks – Inspirational Storytelling (II)

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Willemijn van der Spuij, MSc

Executive Director Europe | International - Patient Safety
Bristol Myers Squibb, Switzerland

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Speaker(s)

QPPV - LSO network

Geraldine Peyrard-Levy

Director, PV System Oversight
Johnson & Johnson Innovative Medicine, France

5:15 PM — 5:30 PM

Re-Cap of the Day

5:30 PM — 7:00 PM

Networking Reception

Day 3 Nov 20, 2025

8:30 AM — 10:00 AM

Session 4: Tech It or Leave It? PV Innovation in Practice

This session is dedicated to the use of advanced technologies including AI in Pharmacovigilance and will look at its use in pharma as well as how regulators use it. We will explore how these advance technologies are transforming the way we monitor and ensure the safety of medicines, from streamlining case processing to identifying safety signals more efficiently. We will also discuss particularly how AI systems are inspected and validated to meet regulatory standards, how regulators use AI, and consider the important question: as advanced cognitive technologies such as AI becomes more integrated into our daily work, do we all need to become experts on this topic? Join us to continue diving into the opportunities, challenges, present and future of advanced technologies in pharmacovigilance with a focus on the role of the QPPV.

Session Chair(s)

Gemma Jimenez Sese

Senior Director, Deputy EU QPPV
AstraZeneca, Spain

Gemma Jiménez Sesé currently holds the position of Deputy EU and UKQPPV at Astrazeneca, based in Barcelona, Spain. Previously, she served as the EUQPPV at Almirall. With over 20 years of experience in pharmacovigilance, she has taken on roles with increasing responsibility. In pharmacovigilance, she has been involved in a broad scope of activities, encompassing safety in clinical development and support for marketed medicinal products, including small molecules and biologics. Beyond safety, she has led projects in late-phase development and product life-cycle management. Additionally, she is a member of the Program Committee for the DIA QPPV Forum

Willemijn van der Spuij, MSc

Executive Director Europe | International - Patient Safety
Bristol Myers Squibb, Switzerland

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Speaker(s)

Where Is Technology Making a Difference in Pharmacovigilance Today?

Jan Cleerbout, MD

Senior Director, deputy EU QPPV
Johnson & Johnson, Belgium

Medical Doctor with substantial Industry experience in global Drug Safety & Pharmacovigilance. Values a lifecycle integrated benefit-risk management approach, transparency, diversity, building cross-functional relationships and putting patients first. After a career at UCB Pharma and GSK Vaccines, joined Janssen Pharmaceuticals in 2016 as a Medical Safety Officer before joining the Office of the QPPV in 2019. Currently the Janssen deputy EU QPPV and Head of the PV System Oversight team.

Is QPPV the one to be the expert in tech, automation and AI?

Jean-Marie Heim

Vice-President, Head of EU QPPV Office, Takeda EU/EEA QPPV
Takeda, Belgium

Indy Ahluwalia

Senior Managing Consultant
ELIQUENT Life Sciences, United Kingdom

Indy Ahluwalia is a PV professional who has been in the industry for 15 years. Working in different aspects Indy first started out as a Drug Safety Associate, then moved to the technology side. He has previously worked for Eisai, Amgen, Gilead and Perficient he then moved to work in software companies My Meds and Me and then PVAI. He know works for management consulting firm Eliquent Life Sciences.

How technology is being inspected? Lessons learnt from first experiences.

Christine Prendergast

GCP/PV Inspection Manager
Health Products Regulatory Authority (HPRA), Ireland

Christine is the Good Clinical Practice and Pharmacovigilance Inspection Manager at the HPRA. She has 8 years' experience at the HPRA, holding positions within the Human Products Monitoring department as a Pharmacovigilance Assessor and within the Compliance department as a GCP/PV Inspector and GCP/PV Inspection Manager. Christine is the Irish member of the EMA Pharmacovigilance Inspectors Working Group (IWG) and Irish alternate member of the EMA GCP IWG. She is also an active member of the Pharmaceutical Inspection Co-operation Scheme (PIC/s) GVP Expert Circle - Artificial Intelligence and Machine Learning Working Group. Prior to joining the HPRA, Christine worked in industry where she gained experience in Pharmacovigilance

10:00 AM — 10:30 AM

Coffee Break

10:30 AM — 10:45 AM

QPPV Talks – Inspirational Storytelling (III)

Session Overview: 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.

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DADA Consultancy B.V., Netherlands

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Speaker(s)

Practical Implementation of a Local AI Tool - SofIA Platform (Insud Pharma)

Jorgen Matz, MSc

Head of Global Clinical Quality & Pharmacovigilance
InsudPharma Group, Spain

10:45 AM — 12:15 PM

Session 5: Inspections Session - Will the Future of Inspections be more Connected?

This session will explore the evolving landscape of pharmacovigilance inspections. Insights and key metrics will be shared, highlighting common observations, followed by a panel discussion of experts — including representatives from the European Medicines Agency, EU member state inspectors, and industry professionals— who will discuss the future of inspections and the opportunities for collaborations between health authorities. Topics will include inspection processes and standardisation, sharing information globally, and how emerging authorities can leverage established practices.

Session Chair(s)

Claire Longman, MSc

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

Claire is the Expert Pharmacovigilance Inspector at the MHRA. She has 10 years experience at the MHRA holding various positions within the MHRA Compliance Teams. Claire has led multiple high profile inspections as well as given a variety of presentations and talks at numerous events in the UK and overseas. In Claire's current role as the Expert Inspector, she is responsible for developing the strategy of the GPvP Compliance Team and aligning this with other GxPs across the MHRA. Prior to joining the MHRA Claire worked in Industry where she gained experience in a number of aspects of Pharmacovigilance and Medical Information.

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

Maarten Lagendijk is the deputy QPPV at MSD since 2019 and is based in the Netherlands. Maarten has over 20 years of experience in pharmacovigilance. He has previously worked for the Medicines Evaluation Board in different pharmacovigilance related roles as well as a national expert at the European Medicines Agency. Maarten has been involved with DIA for many years and is part of the programme committee for the Global QPPV Forum since 2020.

Speaker(s)

EMA Inspection Updates: Trends and Common Findings

Peter Twomey, MA, MPharm

Head of Inspections
European Medicines Agency, Netherlands

Peter Twomey is the Head of Inspections at EMA, which supports the supervision of GxP practices, market surveillance, quality defects and recalls and harmonisation of standards in the inspections area. He is the current Regulatory Chair of the Expert Working Group drafting the revision of ICH GCP E6 (revision 3) and Chair of the GCP Inspectors' Working Group. He previously held inspection and management positions at the Irish Health Products Regulatory Authority (HPRA) and UK-MHRA, and positions in pharmacovigilance, medical affairs and good distribution practice in industry. He holds a BSc and Masters degrees in pharmacy, and two Bachelor of Laws degrees.

Inspector from a Member State: Metrics and Findings

Christine Prendergast

GCP/PV Inspection Manager
Health Products Regulatory Authority (HPRA), Ireland

Christine is the Good Clinical Practice and Pharmacovigilance Inspection Manager at the HPRA. She has 8 years' experience at the HPRA, holding positions within the Human Products Monitoring department as a Pharmacovigilance Assessor and within the Compliance department as a GCP/PV Inspector and GCP/PV Inspection Manager. Christine is the Irish member of the EMA Pharmacovigilance Inspectors Working Group (IWG) and Irish alternate member of the EMA GCP IWG. She is also an active member of the Pharmaceutical Inspection Co-operation Scheme (PIC/s) GVP Expert Circle - Artificial Intelligence and Machine Learning Working Group. Prior to joining the HPRA, Christine worked in industry where she gained experience in Pharmacovigilance

Panel Discussion: Future of Inspections and Opportunities for Collaborations between Health Authorities

Carrie Scott

Head, Global PV Compliance and Policy, Pharmacovigilance & Patient Safety
Abbvie, Portugal

Responsibility to lead the strategic positioning & direction of Pharmacovigilance (PV) quality & compliance across AbbVie's global PV QMS. Act as an expert in critical assessment & interpretation of PV compliance regulations, and consequential internal PV policy and process determination. Previously worked at the UK's MHRA, holding a variety of positions, including PV Inspectorate Operations Manager & Senior PV Inspector, and other roles in the Enforcement and Post-Licensing Divisions. Took a lead role in the publication of the MHRA's Good Pharmacovigilance Practice Guide and also contributed to the development of the EU Good Vigilance Practice modules. Carrie has also held other PV Compliance and Quality Assurance roles in the Industry.

Norleen Mohamed Ali

Head of Pharmacovigilance Section, Center for Compliance & Quality Control
National Pharmaceutical Regulatory Agency (NPRA), Malaysia

12:15 PM — 1:15 PM

Lunch

1:15 PM — 1:55 PM

QPPV OPEN MIC Session

1:55 PM — 2:00 PM

Move to Main Room

2:00 PM — 2:15 PM

QPPV Talks – Inspirational Storytelling (IV)

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

Angela has almost 20 years experience in PV with 15 years of functioning as a (deputy) QPPV. She provides customized pharmacovigilance support, including QPPV provision & responsibility for the clients pharmacovigilance systems. After her PhD in 2005, she started her career in pharmacovigilance & 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 Medication Errors, & she recently obtained a MSc in Clinical Epidemiology.

Willemijn van der Spuij, MSc

Executive Director Europe | International - Patient Safety
Bristol Myers Squibb, Switzerland

Willemijn is the Executive Director Europe in the WorldWide Patient Safety Organisation in Bristol Myers Squibb. She is responsible for Patient Safety in the European region, including the Balkans, Baltics and distributor markets. Prior to this role she was responsible for the European markets, PV Intelligence & International Operations including the PSMF as well as Training and Outsourcing activities. Willemijn holds a Nursing Degree from the Netherlands, a BA (Hons) in Sociology from Goldsmiths college, University of London, UK and an MSc in Pharmacovigilance from the University of Hertfordshire, UK. Willemijn is co-chair of the EFPIA Pharmacovigilance Expert Working Group and Chair of the EFPIA International Pharmacovigilance Group.

Speaker(s)

EU QPPV On-Boarding: Guide for a pleasant Cruise around the World

Jean-Marie Heim

Vice-President, Head of EU QPPV Office, Takeda EU/EEA QPPV
Takeda, Belgium

2:15 PM — 3:45 PM

Session 6: Hot Topics - The Rapid-Fire Rundown

Session Overview: The Hot Topics session provides insights in the very latest on discussions in specific Safety areas of interest. 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.

Session Chair(s)

Vicki Edwards, RPh

Vice President, Pharmacovigilance Excellence and International QPPV
Abbvie, United Kingdom

Vicki, a qualified pharmacist, began her career in hospital pharmacy and later specialized in Drug Information Services, setting up Kuwait's first National Drug Information Centre. After returning to the UK and spending four years in community pharmacy, she transitioned to pharmacovigilance, joining Abbott as EU QPPV in 2005. She stepped down as AbbVie EU QPPV in 2018 due to Brexit. Now, as Head of PV Excellence and International QPPV, Vicki oversees the QPPV Office, Global Safety Compliance, and Risk Management. She is passionate about pharmacovigilance and developing teams.

Speaker(s)

Update on E2D

Raphael Van Eemeren

EU QPPV Senior Director, Global Patient Safety
Amgen AB, Sweden

UK Updates: Decentralized Manufacturing, CTR 2026 and UK MDR PMS

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.

Follow Up Initiative

Peter De Veene, MD

QPPV
MSD Belgium, Belgium

Peter got his medical degree from the Catholic University of Leuven in Belgium and until the end of 2003, Peter practised as a General Practitioner in the UK. In 2004, he joined Roche as a drug safety physician in the local organisation. Taking up roles with increasing responsibility, Peter was appointed Qualified Person for Pharmacovigilance for Roche in 2011. He left Roche at the end of 2014 to take a role at Daichii Sankyo and moved on to be the Head of Global Drug Safety & QPPV for Grunenthal. Peter has extensive experience in pre-approval and post-marketing pharmacovigilance.

Privacy and Patient Safety Update

Jason Burns

Data Protection Officer (EU/EEA, UK and Switzerland)
Bristol Myers Squibb, Ireland

Data Masking Guideline

Raphael Van Eemeren

EU QPPV Senior Director, Global Patient Safety
Amgen AB, Sweden

AI in PV Updates

Andreia Dinis

Associate Director, Safety Compliance Intelligence & Policy
AbbVie, Portugal

Module XVI: Best Practices

Peter De Veene, MD

QPPV
MSD Belgium, Belgium

Peter got his medical degree from the Catholic University of Leuven in Belgium and until the end of 2003, Peter practised as a General Practitioner in the UK. In 2004, he joined Roche as a drug safety physician in the local organisation. Taking up roles with increasing responsibility, Peter was appointed Qualified Person for Pharmacovigilance for Roche in 2011. He left Roche at the end of 2014 to take a role at Daichii Sankyo and moved on

to be the Head of Global Drug Safety & QPPV for Grunenthal. Peter has extensive experience in pre-approval and post-marketing pharmacovigilance.

3:45 PM — 4:00 PM

Re-Cap of the Day and Closing Words

Session Chair(s)

Claudia Ferreira

Scientific Programs Manager
DIA, Switzerland

4:00 PM — 4:00 PM

End of the DIA QPPV Forum and Farewell Coffee