Hotel Casa Amsterdam

Nov 06, 2024 8:00 AM - Nov 07, 2024 6:00 PM

Eerste Ringdijkstraat 4, NL-1097 Amsterdam, Netherlands

Global Forum for Qualified Persons for Pharmacovigilance (QPPV)

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Early Bird ending in

57	05	58	10
DAYS	HOURS	MINUTES	SECONDS

Print Agenda

Day 1 Nov 05, 2024

9:00 AM — 1:00 PM

Pre-conference Tutorials: Introduction to the Role of QPPVs

Pre-Conference Tutorials: Globalisation of PSMF

Day 2 Nov 06, 2024

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 - Gazing into the Future of the QPPV Role

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Session Chair(s)

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.

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.

10:15 AM — 11:00 AM

Session 1: Exploring the New Horizons in Pharmacovigilance - New things QPPVs Should be Aware Of

As a QPPV, staying ahead of the rapid scientific and technological advancements in medicine is crucial. Join us for an enlightening session that offers an introductory exploration of two exciting topics shaping the future of pharmacovigilance: New Treatment Modalities and Digital Health Solutions. Gain foundational knowledge of the safety considerations associated with these cutting-edge innovations, understand their potential connections to pharmacovigilance, and discover how they could shape safety monitoring of patients and enhance risk minimization activities.

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD, Netherlands

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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.

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EU & UK QPPV & Head Pharmacovigilance Excellence
AstraZeneca, Sweden

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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.

Speaker(s)

Strategic and Operational Oversight by the Qualified Person for Pharmacovigilance (QPPV)

Antonio Corrado, PharmD

PV System Excellence and QPPV Support
BMS, Switzerland

11:50 AM — 1:20 PM

Session 2: Pharmacovigilance Updates & Collaboration Efforts From Around the Globe

This truly global session aims to provide insights into the latest developments in Pharmacovigilance. The session will take you on a journey around the world, starting with an exploration of PV requirements and experiences in Kazakhstan. We will then move on to the PV environment and collaborative efforts in Brazil. Next, we will focus on important PV developments in the Asia Pacific region. The session will highlight key aspects that impact the role of the QPPV. You will have the opportunity to engage directly with experts from the industry and regulatory agencies during the panel discussion.

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.

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.

1:20 PM — 2:20 PM

Lunch

2:20 PM — 3:00 PM

Networking (TBC)

3:00 PM — 3:20 PM

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Speaker(s)

Developing Influence as a QPPV Superpower

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.

3:20 PM — 3:50 PM

Coffee Break

3:50 PM — 5:20 PM

Session 3: How Do QPPVs Have Oversight Over Local Markets?

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.

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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.

Speaker(s)

Sina Schader, DrMed

Head of QPPV Office and EU QPPV
AbbVie, Germany

Sina is the Head of the QPPV Office & EU QPPV in the department Pharmacovigilance and Patient Safety and located in Germany. She has been with Abbvie 14 years. Prior to joining Abbvie, Sina studied veterinary medicine and wrote her PHD thesis in the Virology department, working group Immunology on bone marrow transplantation. In her free time, Sina loves spending time with her husband and two little girls and enjoys horse-riding.

Mette Stie Kallesoee

QPPV
Hansa Biopharma, Sweden

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Strategies for Overcoming Challenges Faced by Non-EU/UK Local QPPVs

Yoon Jeon (Jamey) Kim, MSc, RPh

Cluster Pharmacovigilance Lead for Latin America
MSD, Panama

Yoon Jeon (Jamey) Kim, the Director and North Cluster PV lead for Latin America at MSD, has 23 years of experience with the company. She provides strategic leadership for cluster countries (Colombia, Ecuador, Venezuela, Central America, and the Caribbean), with an extensive background in pharmacovigilance, regulatory affairs, and clinical trials. Additionally, she chairs the post-approval safety monitoring program review committee within the company. Previously, she held roles as Country PV lead and Regulatory Affairs manager at MSD Korea. She is a pharmacist with a master's degree in pharmaceutical technology and a bachelor's degree in pharmacy from Ewha Womans University in South Korea.

5:20 PM — 5:30 PM

Re-Cap Of The Day

5:30 PM — 6:00 PM

Networking Reception

Day 3 Nov 07, 2024

Session 4: AI: More Than One Year After The ChatGPT Boom, Where Are We Now In PV?

AI is here to stay, whilst it is still in its early days in terms of regulating its use, there is a huge opportunity to utilise it widely in PV processes starting with case processing and beyond. This year's session will provide most recent views on this topic from regulators, reflections from the industry on how this space can effectively be regulated, as well as serve as inspiration on how and when AI and automation can become a win for small/medium size companies.

Session Chair(s)

Gemma Jimenez Sese

Senior Director, Deputy EU QPPV
AstraZeneca, Spain

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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.

Speaker(s)

EMA On-going Activities on AI

Luis Pinhero

EMA. Before that, he worked in the PV Unit of the Faculty of Pharmacy of Lisbon for 8 years where he assisted in the teaching of Pharmacoepidemiology and Public health in undergraduate and postgraduate courses.

10:30 AM — 11:00 AM

Coffee Break

11:00 AM — 11:20 AM

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Speaker(s)

QPPV Gatekeeper Operating Model: Driving Efficient QPPV Oversight

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 5: Are Inspections a Necessary Distraction or a Welcome Opportunity for Improvement?

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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.

Angela Van Der Salm, PhD, MSc

Director PV, Managing partner

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12:50 PM — 1:50 PM

Lunch

1:50 PM — 2:30 PM

Networking (TBC)

2:30 PM — 2:50 PM

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Speaker(s)

Reference Safety Information for Registered Products in Clinical Trials

Anne Lappereau-Gallot, DrMed, MD

Sr Dir Deputy QPPV
ALEXION ASTRAZENECA RD, France

2:50 PM — 3:50 PM

Session 6: Hot Topics And Bitesized Updates

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

Qualified as a pharmacist in 1981 and started her career in hospital pharmacy. In 1983 she specialised in Drug Information Services and moved to Kuwait to set up and run the first National Drug Information Centre. On her return to the UK, Vicki spent the next four years in community pharmacy. In 1996 Vicki joined GlaxoWellcome and started her career in pharmacovigilance. In 2002 she moved to AstraZeneca UK Ltd

3:50 PM — 4:00 PM

Recap Of The Day And Closing Words