Mercure Amsterdam City Hotel

May 29, 2024 8:00 AM - May 30, 2024 4:30 PM

Joan Muyskenweg 10, 1096 CJ Amsterdam, Netherlands

Pharmacovigilance Strategies Workshop

Collaborate and Innovate for Patient-Centric Safety.

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Print Agenda

Day 1 May 29, 2024

8:00 AM — 8:45 AM

Registration And Welcome Coffee

8:45 AM — 9:00 AM

Welcome And Introduction To The Workshop

9:00 AM — 10:30 AM

Session 1: Navigating The Regulatory Landscape In Pharmacovigilance

The regulatory landscape is a changing environment with new or updated requirements and the emergence of highly regulated countries. Safety intelligence is key to adapt the safety governance and allowing full compliance of Pharmacovigilance processes to these international regulations. This session will provide guidance on recent important updates and comings changes and will give you the opportunity to exchange with representatives from pharmaceutical industry and regulators on these challenges.

Session Chair(s)

Francoise Sillan, MD

EU1 UK QPPV
Ipsen, France

Françoise is a medical doctor as background, working in Pharmacovigilance for more than 30 years in big Pharmaceutical companies with different managerial roles, interactions with Health Authorities, and coordination of international networks of Pharmacovigilance. She has spent 15 Years on Vaccine Pharmacovigilance where she contributed to the development of standards definitions and methods through CIOMS WHO working groups on vaccine safety. Within the EFPIA Pharmacovigilance expert group, she analysed the influence of EU pharmacovigilance regulations outside Europe and of non EU regulations on the EUQPPV role.

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.

Speaker(s)

Updates on the ICH E2D

Anja Van Haren, MSc

Eudravigilance coordinator
Medicines Evaluation Board (MEB), Netherlands

Anja van Haren holds a Master in Health Policy and Management from the Erasmus University in Rotterdam. Her career at the Medicines Evaluation Board (MEB) in the Netherlands started in 1998 as a Pharmacovigilance assessor. Since 2004 she has been responsible for technical and procedural aspects of expedited Adverse Drug Reaction

reporting in pharmacovigilance. In her current position at the MEB as EudraVigilance Coordinator the focus of her work is on ADR reports, signal detection and signal management. Anja is co-chair of the EudraVigilance Expert Working Group, co-chair of the Pharmacovigilance Business Team and representative of the EU in the ICH E2B(R3) and ICH E2D(R1) Expert Working Groups.

General Updates on GVP for Risk Minimisation Evaluation Methods

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.

New Guidance on AI In PV: General Overview

Jens-Ulrich Stegmann, MD, RN

Senior Vice President, Head Clinical Safety and Pharmacovigilance and EU QPPV
GSK , Belgium

A trained registered nurse with an M.D degree in nursing from the University of Essen Germany and a PhD in Physiology from Christian-Albrechts University in Kiel Germany, Jens worked as an anaesthesiologist and emergency doctor at the University of Dusseldorf. At Grünenthal he contributed to the development of several acting analgesics as clinical lead before moving into Safety in 2008.He joined GSK Vaccines in 2012 as Head of Safety Evaluation and Risk Management in Safety and was appointed Deputy EU-QPPV before becoming Head of Clinical Safety and Pharmacovigilance for the business unit. In 2019, he took on the role as EU-QPPV for GSK and ViiV Healthcare and later became Head Clinical Safety and Pharmacovigilance for GSK in 2020.

10:30 AM — 11:00 AM

Coffee Break

11:00 AM — 12:30 PM

Session 2: Best Practices In Compliance

A Marketing Authorisation Holder in EU should have a Pharmacovigilance System and a Quality Management System (QMS). The QMS can be solely for PV, however generally is for all GxP functions within the company. Compliance is an important part of this.

The goals of audits and inspections are regulatory compliance monitoring and improvement. Among the numerous challenges there are the complexity of local regulations, complexity of Pharmacovigilance organization with numerous partnerships and subcontracting of activities to external vendors.

This session will give an overview on these challenges and (cross GxP) practical examples derived from audits and inspections and how the development of new technologies can support the preparation to successful Pharmacovigilance inspections.

Session Chair(s)

Francoise Sillan, MD

EU1 UK QPPV
Ipsen, France

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Wendy Huisman, PharmD

Director
Vigifit, Netherlands

Over the past 25 years Wendy has been dedicated to pharmacovigilance. She has broad experience as EU QPPV for generic and innovative products in complex companies. She also has wealth of experience in lobbying and networking in trade associations/working groups. In her current role, Wendy provides pharmacovigilance support to Pharmaceutical Industry and SMEs (startups). She enjoys setting up the PV system and supports in the development of the PSMF with associated documents. Since 2020 Wendy is a trained professional in Transactional Analysis (TA). TA is a theory of human personality and social behavior. TA gives a wealth of options to work with challenges and changes in organisational and personal development.

Speaker(s)

Risk Based Approach To Audit And Inspection (Company Perspective)

Kristel Van De Voorde, MPharm

Senior Director, Pharmacovigilance QA

GSK, Belgium

Kristel Van de Voorde is a pharmacist and has more than 25 years of experience in the quality area covering GCP,GVP and interfaces in R&D with GLP and GMP. Currently, Kristel is the global head of the quality function for pharmacovigilance at GSK. Her main responsibilities are to oversee the strategy and execution of the audit schedule related to pharmacovigilance, manage health authority inspections and support building a strong Quality Management System aiming for proactive risk identification.

Oversight: Striking the Right Balance with Vendors

Jean Kilgour-Christie, BSN, MSc

Deputy EU QPPV Head, UK QPPV
Sandoz International GmbH, Germany

My background is one of a Nursing degree and Masters in Clinical Pharmacology. I have been in the Pharmaceutical Industry for almost 30 years. Most spent in Pharmacovigilance in all areas, globally and locally. I spent some time as Director Regulatory Operations. My career has been spent mainly in Big Pharma although I have covered most therapeutic areas including generics, biosimilars, innovators etc. I have been a deputy QPPV for 8 years and most recently in Novartis since 2018. I have experience in different external committees and industry partnerships.

12:30 PM — 2:00 PM

Lunch

2:00 PM — 3:30 PM

Session 3: Ethical Discussions In Pharmacovigilance

At first sight, pharmacovigilance activities and its legislation seem black and white – at least that is what Industry and inspectors agree to disagree on. There are however different shades of grey and that is where dilemma's come in. This session will not focus on changes in the legislation. Instead, we would like to get into the ethical dilemma's that arise in the grey zone; between the boundaries of the legislation / providing medicinal products / providing APIs on one hand and patient needs and patient safety on the other hand.

"Is it preferable to do nothing or to take action even if the outcome is disruptive to current regulations?"

This session aims to take the audience on a reflective journey outside of the 'regulatory comfort zone' in which we often operate and instead stimulates participants to think and discuss safety activities at a different level.

Session Chair(s)

Wendy Huisman, PharmD

Director
Vigifit, Netherlands

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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)

Introduction on Ethics: How to Deal with Ethical Dilemmas?

Wim Pinxten

Professor of Medical Ethics
Hasselt University, Belgium

Automating Extemporaneous API Preparations for Custom Dosage Manufacturing at the Primary Care

Arian Khoshchin

CCO
DOSER, Netherlands

As a Biopharmaceutical Scientist and Business Developer, Arian bring a unique blend of scientific expertise and entrepreneurial spirit to the table. With an MSc in Biopharmaceutical Sciences and Indiustrial Pharmacy from Leiden University and over 8 years of experience in pharmaceutical innovation, R&D, and technology, he has a track record novel market development.

Contributing Panelist

Lina Mourad

Hospital Pharmacist, Production,
Catharina Ziekenhuis, Netherlands

Lina van Hout has more than 20 years experience at several production sites in hospital pharmacies. Currently she works at the Catharina Pharmacy Production Unit, which manufactures medicines that pharmaceutical industry cannot or will not make.

3:30 PM — 4:00 PM

Coffee Break

4:00 PM — 6:00 PM

Session 4: Think Tank - Building Pharmacovigilance Regulations/GVP: A Collaborative Workshop

In 2010, the journey to author the Good Pharmacovigilance Modules in the EU began, and two years later, they were released. Since then, the EMA and partners have maintained them and supported their evolvement whilst many authorities have replicated their content. But what if we had a blank page, how would you define GVP? Knowing what we know now, what approach would you take?

This collaboration session will dive into four topical areas and where you will be guided through one, designing an alternative through the lens of a Marketing Authorisation Holder or a Regulator.

- *Handling the patient experience*
- *Overseeing compliance of the pharmacovigilance system*
- *Combination products ~ Devices & digital health combined with medicinal products*
- *Minisimsing and mitigating product risks*

Session Chair(s)

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.

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6:00 PM — 6:30 PM

Highlights Of The Day

6:30 PM — 7:30 PM

Networking Activity (Drinks)

Day 2 May 30, 2024

9:00 AM — 10:00 AM

Session 5: RWE And Data Insights

The sources that inform pharmacovigilance actions continues to expand. One broad source is Real-World Data (RWD), which is data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. It becomes Real-World Evidence (RWE) when analysed and utilised as clinical evidence about a medical product's usage and potential benefits or risks. RWE compliments the data collected from other sources like clinical studies to enable the generation of a more holistic picture. To quote the EMA, "In pharmacovigilance, it has become

mainstay to use routinely collected data about a patient's health status or the delivery of healthcare from a variety of sources other than traditional clinical trials to support decision-making"

This session will focus on the insight that pharmacovigilance can derive from the growing sources of data before diving into case studies on the utilisation of RWD and RWE.

Session Chair(s)

Esther De Vries, MS, MSc

Pharmacovigilance Assessor
CBG-MEB, Netherlands

Esther de Vries is a pharmacovigilance assessor at the Dutch national agency (MEB), while finishing her PhD at the University Medical Center Groningen in the Netherlands. Her PhD centres around the Direct Healthcare Professional Communication (DHPC) in the hospital setting in the Netherlands. In addition to these activities, she is involved in digitalising the DHPC in the Netherlands.

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.

Speaker(s)

DARWIN Project - Data Analysis and Real World Interrogation Network

Andrej Segec, MPharm, MS

Scientific administrator
European Medicines Agency, Netherlands

Andrej Segec is a pharmacist by training (Comenius University, Bratislava, Slovakia) with an MSc in Epidemiology (London School of Hygiene and Tropical Medicine, London, UK). He has worked for the European Medicines Agency since 2008, in pharmacovigilance/signal management, monitoring of the EMA pharmacovigilance system, in surveillance and epidemiology, as committee manager for the operations of the Pharmacovigilance Risk Assessment Committee (PRAC) and as a risk management specialist for anti-infective therapies and vaccines during the COVID-19 pandemic.Currently, Andrej's focus is on the generation and use of RWE in regulatory decision making and the establishment of the DARWIN EU®.

Registry Holder

Lutz Nährlich

Departement of Pediatrics
Justus-Liebig-University Giessen, Germany

Lutz Naehrlich is a pediatric pulmonologist and works as a consultant Departement of Pediatrics, Justus-Liebig-University Giessen, Germany. His research focus are the iagnosis and epidemiology of Cystic Fibrosis. He is the medical lead of the German CF Registry and the Pharmacovigilance Study manager of the European Cystic Fibrosis Society Patient registry.

With additional participation of:

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.

10:00 AM — 10:30 AM

Coffee Break

10:30 AM — 12:00 PM

Session 6: Patient Registries: Medicines With Limited Safety Data

During the application of a new drug, not all safety information is always available. Special populations might be missing from the clinical trials and long-term safety data is still being collected. There may be some safety concerns that require further characterization in the clinical setting. Especially for rare diseases knowledge gaps concerning the safety of a drug can occur, as clinical trials are more of a challenge due to limited patients. Registries are a way to solve some of these challenging knowledge caps especially for rare chronic diseases or innovative medicinal products.

This session will explore patient registries, discuss some of the challenges faced and potential solutions from the perspective of the regulators, industry and the patient. There will also be a unique opportunity for delegates to ask the panel questions during the question-and-answer session.

Session Chair(s)

Esther De Vries, MS, MSc

Pharmacovigilance Assessor
CBG-MEB, Netherlands

Esther de Vries is a pharmacovigilance assessor at the Dutch national agency (MEB), while finishing her PhD at the University Medical Center Groningen in the Netherlands. Her PhD centres around the Direct Healthcare Professional Communication (DHPC) in the hospital setting in the Netherlands. In addition to these activities, she is involved in digitalising the DHPC in the Netherlands.

Shahin Kauser

Leading Senior Scientific Assessor
MHRA, United Kingdom

Shahin Kauser also has a Certificate in Pharmacoepidemiology & Pharmacovigilance from the London School of Hygiene and Tropical Medicine. Shahin is a Leading Senior Scientific Assessor and joined the MHRA Agency (former MCA) in 2001. She has extensive experience of the 'life-cycle' of pharmacovigilance both nationally and in Europe. Her current portfolio includes monitoring the post-marketing safety of medicines in various therapeutic areas including blood disorders, multiple myeloma and malignant melanoma. Shahin has expertise in assessing benefit/risk, PSURs, safety Variations and risk management plans, additional risk minimisation measures and assessing their effectiveness.

Speaker(s)

Rare Disease Registries: A Must For Regulatory Decision-Making

Carla Jonker, MS

Senior Regulatory Project Leader
Medicines Evaluation Board (MEB), Netherlands

Carla Jonker has obtained a master's degree in biomedical sciences at the University of Leiden. Currently she combines her position as Senior Regulatory Project Leader at the Medicine Evaluation Board in the Netherlands with her work as National Expert in the Real World Evidence department within the Data Analytics and Methodology Task Force at the European Medicine Agency. She has over 20 years' experience, both in industry in different positions and at the Medicine Evaluation Board. Her work experience includes multiple topics related to the benefit-risk assessment of medicinal products and a PhD research at the University of Utrecht to investigate the value of rare disease registries for regulatory decision-making.

Patient Registries - Industry Perspective

Elodie Aubrun, PharmD, MPH, MSc

Group Head Quantitative Safety and Epidemiology
Novartis, Switzerland

Elodie Aubrun is Group Head of Quantitative Safety and Epidemiology (QSE) at Novartis since August 2018, specializing in pre- and post-marketing epidemiology and safety strategy for products in Respiratory, Global Health, and Immunology. Previously, she was Associate Director of Epidemiology and Outcome Research at IQVIA. A member of ISPE and CIOMS working group XIII on Real World Evidence, Elodie has 16 years of experience in pharmacoepidemiology across pharma companies and contract research organizations. She holds a PharmD, MSc, and MPH from University Paris XI, France.

Patient Registries: Limited but Extensive

Domenique Zomer, PhD

PhD, Manager Research and Quality of Care, Coordinator Dutch CF Registry
Dutch CF Foundation, Executive Committee Member ECFS Patient Registry, Netherlands

Domenique is manager Research and Quality of Care at the Dutch Cystic Fibrosis Foundation (NCFS). The NCFS plays a central role between all stakeholders involved in CF. One of the main tasks of Domenique is coordinating the Dutch CF Registry, existing since 2007. She is also a member of the Executive Committee of the European CF Patient Registry. Domenique is a pharmaceutical scientist by training and obtained her PhD in 2018.

Patient Registries – Patients as participants and partners in generation of knowledge

Mariette Driessens, PhD

Stichting HemoNED and VSOP
VSOP – Patient Alliance For Rare and Genetic Diseases, Netherlands

Mariette Driessens is policy officer at VSOP - Patient Alliance for Rare and Genetic Diseases and the haemophilia patient society NVHP, in the Netherlands. As former patient representative of the Committee for Advanced Therapies, she is stimulating patient engagement in application of innovative genetic therapies in the clinic. Mariette is currently a member of the Round table on Orphan Drugs at the Dutch HTA agency (Zorginstituut). As board member of HemoNED, the Dutch registry of hemophila and other bleeding disorders she has expertise in representing the patient perspective in the governance of a registry.

12:00 PM — 1:30 PM

Lunch

1:30 PM — 3:30 PM

Session 7: Risk Minimisation Measures And Digitalisation

The pace at which technology is advancing is requiring Healthcare to transform. For pharmacovigilance, one of the key areas transforming is risk management and how risks are minimised. This is to address the expectations of healthcare professionals, the needs of patients and utilize technology to improve our ability to maintain safety.

With risks minimised in multiple ways, from communication through to remote patient monitoring, this session will present several case studies on what that transformation looks like. From Industry and Academics, you will hear what has gone well and what part of the transformation has not been as smooth. The session will finish with a panel where our academic and industry presenters will be joined by a regulator to discuss the digital risk minimsation transformation.

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.

James Whitehead, MBA, MSc

Senior Director, Device & Digital Safety
AstraZeneca, United Kingdom

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Speaker(s)

Transitioning from Paper to Electronic Distribution of DHPCs and EMs

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.

Studies to Evaluate the Effectiveness of Risk Minimization Measures – The Need for Speed

Sharon Essink

PhD Candidate, Division of Pharmacoepidemiology and Clinical Pharmacology,
Utrecht Institute for Pharmaceutical Sciences, Netherlands

General Update on Module XVI with Focus on Risk Minimisation Evaluation Methods (Addendum II)

Thomas Goedecke, PharmD, PhD

Senior Pharmacovigilance Specialist
European Medicines Agency, Netherlands

Since joining EMA in 2006, Thomas Goedecke has worked in all major areas of pharmacovigilance. His roles encompassed data collection and management in EudraVigilance, risk management for authorized medicines, with a focus on medication errors. Since 2015, he spearheads the implementation of the PRAC Impact Strategy,coordinating impact assessments and regulatory research for the European medicines regulatory network. He has contributed to the ENCePP Methods Guide and GVP guidelines on RMM effectiveness evaluation. Additionally, he oversees medication error reporting guidelines.

Risk Minimisation Measure and Digital: Impact and the Strategy behind Digital

Ryan Marshall

Associate Director, Risk Management
AstraZeneca, United Kingdom

With Additional Participation Of:

Priya Bahri, PhD, RPh

Senior Lead (Pharmacovigilance and Risk Management Guidance and Policy)

European Medicines Agency, Netherlands

Priya Bahri, RPh, PostGradDipEpi, PhD, at EMA since 1996, is now EMA's Lead Pharmacovigilance and Risk Management Guidance and Policy. In this role, she also instigates research and regulatory frameworks for risk communication, stakeholder engagement for pharmacovigilance and implementation of risk minimisation in healthcare. Pro bono, she is active in the learned societies ISoP and ISPE and as associated researcher at Utrecht University. She is the editor of the Springer textbook "Communicating about Risks and Safe Use of Medicines - Real Life and Applied Research", published in 2020.

3:30 PM — 4:00 PM

Conclusions and Wrap-Up of the Workshop and Closing Words