Print Agenda

Day 1 Oct 12, 2022

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: Pharmacovigilance Guidelines And Regulations Updates (EU, Non-EU, Global)

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD B.V., 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.

10:30 AM — 11:00 AM

Coffee Break

11:00 AM — 12:30 PM

Session 2: Globalisation Of PSMF : Practical Implementation

Session Chair(s)

FRANCOISE SILLAN, MD

VP GPS TA ENDO-ONCO & EU 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.

Willemijn van der Spuij, MSc

Executive Director, WorldWide Patient Safety International, Europe
Bristol-Myers Squibb, 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)

Sean Burke, MS

Regional Director, Pharmacovigilance
MSD, United Kingdom

Melanie Weber, MSc

Pharmacovigilance Expert
Pietrek Associates Gmbh, Germany

Over 10 years of experience in the CRO industry, expert in drug safety processes and regulatory requirements. Special interests include process analysis and enhancement, pharmacovigilance system audits and mock inspections as well as in-depth knowledge of international PV regulations and guidelines.

12:30 PM — 2:00 PM

Lunch

2:00 PM — 3:30 PM

Session 3: Lessons Learnt From The Experiences With COVID-19 Vaccines

Session Chair(s)

FRANCOISE SILLAN, MD

VP GPS TA ENDO-ONCO & EU 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.

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.

3:30 PM — 4:00 PM

Coffee Break

4:00 PM — 5:30 PM

Session 4: Workshop: Future Changes And Challenges In PV

Day 2 Oct 13, 2022

9:00 AM — 10:30 AM

Session 5: Data Science And Standards: Impact on Pharmacovigilance

Data Science And Standards: Impact on Pharmacovigilance

Session Chair(s)

Bianca Mulder, PharmD, MPharm, MSc

Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

Bianca Mulder is a pharmacist with a PhD in pharmacoepidemiology. Her research focused on the use of medication during pregnancy and the development of atopic diseases in children. She worked briefly in a pharmacovigilance position at a pharmaceutical company before she started working as a pharmacovigilance assessor at the Dutch national agency (MEB) in 2016.

James Whitehead, MSc

Patient Safety Medical Device Lead
Astrazeneca, United Kingdom

James Whitehead is the Patient Safety Medical Device Lead at AstraZeneca working within Patient Safety Center of Excellence, having started his career with AZ as a Pharmacovigilance Scientist in Oncology and then Principal Process Owner. 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.

Speaker(s)

Isobel Anderson

Astrazeneca, United Kingdom

10:30 AM — 11:00 AM

Coffee Break

11:00 AM — 12:30 PM

Session 6: Social Media And Patient Support Programmes

Session Chair(s)

Wendy Huisman, PharmD

Director
Vigifit, Netherlands

Over the past 23 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.

Bianca Mulder, PharmD, MPharm, MSc

Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

Bianca Mulder is a pharmacist with a PhD in pharmacoepidemiology. Her research focused on the use of medication during pregnancy and the development of atopic diseases in children. She worked briefly in a pharmacovigilance position at a pharmaceutical company before she started working as a pharmacovigilance assessor at the Dutch national agency (MEB) in 2016.

12:30 PM — 2:00 PM

Lunch

2:00 PM — 3:30 PM

Session 7: Medical Devices, Wearables, Combination Products

Session Chair(s)

Maarten Lagendijk, MSc

Deputy EU QPPV
MSD B.V., 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, MSc

Patient Safety Medical Device Lead
Astrazeneca, United Kingdom

James Whitehead is the Patient Safety Medical Device Lead at AstraZeneca working within Patient Safety Center of Excellence, having started his career with AZ as a Pharmacovigilance Scientist in Oncology and then Principal Process Owner. 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.

Speaker(s)

Emma Woods

Astrazeneca, United Kingdom

3:30 PM — 4:00 PM

Coffee Break

4:00 PM — 4:30 PM

Conclusions and Wrap-Up of the Workshop and Closing Words