Virtual

Oct 15, 2024 1:00 PM - Oct 15, 2024 4:30 PM

(Central Europe Standard Time)

UK National QPPV Forum - Windsor Framework Webinar

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Print Agenda

Day 1 Oct 15, 2024

12:30 PM — 4:30 PM

Webinar Live-Stream

1:00 PM — 1:15 PM

Participants Log-In

1:15 PM — 1:30 PM

Housekeeping and Welcoming Words

Speaker(s)

Claudia Ferreira

Scientific Programs Manager
DIA, Switzerland

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.

1:30 PM — 2:15 PM

Windsor Framework Recap and Practical Implications by the MHRA

Speaker(s)

Windsor Framework Recap and Practical Implications by the MHRA

Stephanie Millican, PhD, MSc

Head of Immunology, Biocompatibility and Non-clinical, Safety and Surveillance
MHRA, United Kingdom

Stephanie is Head of the Immunology, Biocompatibility and Non-clinical team in the Safety and Surveillance group at the MHRA. Prior to her current role she held a variety of management and assessor positions in the Agency. She has a masters degree in Clinical Pharmacology and a PhD in Cell Biology. She joined the Agency following a career in academia and has now over 20 years experience in drug regulation with particular experience in post-authorisation procedures and pharmacovigilance.

Windsor Framework Recap and Practical Implications by the MHRA

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.

Windsor Framework Recap and Practical Implications by the MHRA

Sophie Radicke, MSc

Head of GPvP and Senior Pharmacovigilance Inspector
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Sophie is the Head of the MHRA GPvP Compliance Team and a senior pharmacovigilance inspector. She became an inspector 2018 and has since led a number of complex and technically diverse inspections. In her current role, she is responsible for ensuring the operational delivery of pharmacovigilance inspections and refining the MHRA's GPvP inspection programme. Inspector training, the development and update of pharmacovigilance legislation and guidance as well as stakeholder engagement and education continue to be a key part of her work. In previous roles, Sophie was responsible for the assessment of safety variations at the MHRA, and worked in medical information and on a regulatory affairs project in industry.

2:15 PM — 2:45 PM

Q&A: Pre-Submitted Questions to the MHRA

This session is dedicated to addressing participant questions about the pharmacovigilance aspects of the Windsor Framework. We have collected pre-submitted questions to ensure that we cover the most pressing topics. While our primary focus here is on pre-submitted questions, there will be an opportunity for live questions during the “Open Q&A from the Participants”.

Session Chair(s)

Louise Woodward, PhD

UK QPPV and Local Safety Responsible
Roche Products Ltd, United Kingdom

Louise began her career in pharmacovigilance over 20 years ago and has held a variety of roles, including Safety Advisor and Team Leader within a UK Safety function and Clinical Safety Scientist within a Global Safety department, gaining experience in all aspects of PV. She moved to work with EU QPPV Office roles for over 7 years, as PSMF Manager/Process Owner and also as a PV Governance and Policy Leader. Louise has been the UK Local Safety Responsible for Roche Products Ltd for over a year now and took on the role of UK QPPV in October 2021.

Speaker(s)

Q&A: Pre-Submitted Questions to the MHRA

Claire Longman, MSc

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

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2:45 PM — 3:00 PM

Coffee Break

3:00 PM — 3:30 PM

Aspects for Practical Implementation of the Windsor Framework – Small Pharma and Big Pharma Perspectives

We will discuss the practical issues that companies need to consider when implementing the Windsor Framework and share preparations being considered and planned by a range of company types.

Session Chair(s)

Lauren East

Head, Pharmacovigilance UK
Abbvie, United Kingdom

Lauren is currently Head of Pharmacovigilance and Named Safety Contact for Abbvie UK. Lauren has worked in the pharmaceutical industry for over 20 years in a variety of commercial, medical and PV roles which most recently has seen her take on the challenge of leading a team of PV professionals successfully through the changing BREXIT landscape.

Speaker(s)

Small Pharma Perspective

Nicola Lawson

Associate Director, EU/Int PV & QPPV Office, PV Intelligence and UK QPPV
Jazz Pharmaceuticals, United Kingdom

Nicola is the UK QPPV for Jazz Pharmaceuticals based in the UK. She has over 18 years' experience in Pharmacovigilance, in both pre and post-marketing settings within Global Drug Safety. She has extensive PV system knowledge, having held roles in Global Case Management, PSMF Administration and PV Intelligence, as well as acting as UK National Contact Person for Pharmacovigilance. Nicola joined Jazz in 2014 and has worked in Jazz's EU/International PV and QPPV Office since 2021 and took on the role of UK QPPV for Jazz Pharmaceuticals in April 2023.

Small Pharma Perspective

Deborah Robinson

Senior Manager, Deputy UK QPPV
Jazz Pharmaceuticals, United Kingdom

Deborah Robinson is a Senior Manager and Deputy UK QPPV at Jazz Pharmaceuticals. She has over 20 years' experience in PV and Drug Safety and has a BSc(Hons) in Pharmacology and a Post Graduate Diploma in Pharmacovigilance. Deborah has extensive experience in developing and maintaining safety and pharmacovigilance systems in both the pharmaceutical and service provide sectors. She has held positions of EEA QPPV and UK NCP post Brexit and she has also spent a brief period of time working in the UK National Health Service in Primary Care Development.

Big Pharma Perspective

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.

3:30 PM — 4:15 PM

Open Q&A from the Participants

Questions will be chosen through Slido. If the committee or MHRA needs further clarification, we will allow attendees to unmute and ask the question themselves. What to expect: Comprehensive Answers: Our aim is to provide thorough and clear answers to your questions. Engagement: We encourage active participation and will strive to address as many questions as possible. Follow-Up: For questions that require more detailed responses or further information, we will provide follow-up materials after the Webinar.

Session Chair(s)

Elspeth McIntosh, MBA, RN

Director
Castle Pharmacovigilance Ltd, United Kingdom

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UK National Contact Person for several small pharma companies and provides general PV support to a wide range of pharma companies.

4:15 PM — 4:30 PM

Wrap-Up and Closing Remarks