

| OVERVIEW

Adapting to Change: Navigating New Regulatory Requirements in the UK

The UK regulatory landscape continues to evolve rapidly, with new legislation and frameworks shaping pharmacovigilance and clinical operations. This year's **UK National QPPV Workshop** will provide practical insights and updates on the latest developments impacting QPPVs and PV professionals across the UK.

Join regulators, industry experts, and your peers to discuss how to navigate recent and upcoming changes - including the implementation of the **UK Clinical Trials Regulation**, updates on **MHRA inspection** trends, and the latest **device post-marketing requirements**.

You'll also gain perspectives on **RMP effectiveness assessments**, **digitalisation of educational materials**, and **data protection** obligations within the UK framework.

Through interactive sessions and open discussions, participants will:

- Hear **quick regulatory updates** directly addressing audience questions and recent survey topics.
- Discuss practical implementation of **safety variations**, **ICSR submissions**, and **post-marketing surveillance**.
- Explore challenges and best practices around **risk minimisation measures** and **data protection**.
- Exchange experiences on **inspection trends** and **blue-sky thinking for innovation** in pharmacovigilance.

This annual workshop remains a trusted platform for QPPVs to share experiences, learn from MHRA representatives, and collaborate on solutions for real-world compliance and operational excellence in the UK market.

| Who will attend

- UK or EU QPPV
- UK NCPs
- Deputy QPPV
- Directors of Pharmacovigilance Oversight and Standards
- Drug Safety Managers/Leaders
- Regulators
- Auditors
- Pharmacovigilance Consultants

| PROGRAMME COMMITTEE

Elsbeth McIntosh, Director, Castle Pharmacovigilance Limited

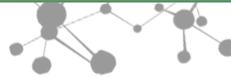
Sophie Radicke, Head of GPvP and Senior Pharmacovigilance Inspector, MHRA

Louise Woodward, UK QPPV, Roche

Helen Fiddes, Head of Patient Safety, UK and Ireland, Bristol-Myers Squibb

Lauren East,
Head Pharmacovigilance UK, AbbVie

Rory Littlebury,
Head of Pharmacovigilance System Oversight (PVSO) and QPPV Office, GSK



Wednesday, 30 APRIL 2026

08:30 Registration and Welcome Coffee

09:00 **Welcoming Words and Introduction to the Workshop**
Elsbeth McIntosh, Director, Castle Pharmacovigilance Limited
Claudia Ferreira, Scientific Programs Manager, DIA

09:15 **SESSION 1**
UK Regulatory Snapshot: What QPPVs Need to Know Now

Session Chairs:

Lauren East, Head Pharmacovigilance UK, AbbVie
Louise Woodward, UK QPPV, Roche

This session will provide a series of concise regulatory and operational updates on the most relevant UK developments impacting QPPVs. Speakers will cover recent changes to the MHRA Portal and ICSR submissions, the implementation of safety variations in the UK and their alignment with EU requirements, experience with the new device post-marketing requirements, and practical implications of the UK Clinical Trials Regulation. The session will also touch on the Medicines and Medical Devices Regulation consultation, offering participants clear, practice-focused takeaways to support compliant and efficient PV activities.

MHRA Portal and ICSR submissions

Anne Carter, Consultant in Regulatory Affairs & Pharmacovigilance, Carter & Associates Ltd

Safety Variation and Implementation in the UK

Nadine Anderson, MHRA

The new Device Post Marketing Requirements

MHRA Representative

UK CTR – Quick Update

Jason Wakelin-Smith, Expert GCP Inspector and Head of the Compliance Expert Circle, MHRA
Helen Fiddes, Head of Patient Safety, UK and Ireland, Bristol-Myers Squibb

Q&A

10:45 **COFFEE BREAK**

11:15 **SESSION 2**
Advancing RMP Effectiveness Through Evidence, Expectations, and Digital Innovation

Session Chair:

Helen Fiddes, Head of Patient Safety, UK and Ireland, Bristol-Myers Squibb

This session will explore the practical application and evaluation of Risk Minimisation Measures (RMMs) within the UK environment, focusing on both regulatory expectations and real-world implementation. Speakers will discuss how ARMM effectiveness is assessed, what “good” looks like from an MHRA perspective, and common challenges in ensuring meaningful patient and HCP impact. The session will also highlight the future of educational materials, showcasing how digital solutions - from QR codes to app-based resources - can support more accessible, efficient, and modern risk minimisation strategies.

ARMMs Effectiveness Checks

Robert Massouh, Head of Safety (PV) Risk Management and Benefit/Risk Evaluation, GSK

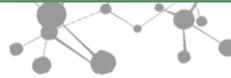
What does the MHRA expect? Implementation of RMMs

Kathryn Ord, Expert Assessor in Pharmacovigilance, MHRA

Digitalization of Educational Materials: General Aspects and Case Example

Louise O’Keeffe, Senior PV Process Director, Roche
Payal Gupta, Risk Management Plan Implementation, Roche

Q&A

**12:00 SESSION 3****Data Protection Landscape in the UK**

Session Chair:

Rory Littlebury, Head of Pharmacovigilance System Oversight (PVSO) and QPPV Office, GSK

This session will examine the current data protection landscape in the UK as it relates to pharmacovigilance activities. A legal expert will provide an update on UK GDPR requirements and their practical implications for PV teams, followed by an update on the PIPA Guidance. The session will explore key compliance considerations, areas of ongoing uncertainty, and opportunities for modernising data protection approaches within PV systems.

UK legislation Concerning the Protection of Personal Data Related to PV**Francesca Blythe**, Sidley Austin, LLP**PIPA Guidance****Jo Elsdon**, Windsteer Consultancy**Q&A****12:45 LUNCH****14:00 SESSION 4****Trends in Inspections**

Session Chairs:

Sophie Radicke, Head of GPvP and Senior Pharmacovigilance Inspector, MHRA

This session will provide an in-depth look at current and emerging trends in UK pharmacovigilance inspections. MHRA representatives will outline recent operational updates, key findings, and evolving expectations - including insights from NIS-related inspections, the Implementing Regulation, and much more. Attendees will gain a clearer understanding of inspection priorities, common challenges, and how to prepare effectively for the changing inspection landscape.

Inspection Trends, Metrics and Hot Topics**Helen Emery**, Pharmacovigilance Inspector, MHRA**Regulatory Updates****Sophie Radicke**, Head of GPvP and Senior Pharmacovigilance Inspector, MHRA**Anastasia Daskajiannis St John**, Pharmacovigilance inspector, MHRA**Joint Inspections with Health Canada****Silvia Danesi**, Pharmacovigilance Inspector, Healthcare, Quality and Access group, MHRA**Pramod Wable**, Inspection Management Team Lead, Pfizer**Valentina Chavez**, Pharmacovigilance Country Head UK and IE / UK QPPV, Bayer**Q&A****15:30 SESSION 5****Round Up of the Workshop – Rapid Fire Questions**

Session Chairs:

Elspeth McIntosh, Director, Castle Pharmacovigilance Limited

Time to address remaining questions from the audience!

16:00 Chair Conclusions and End of the Workshop**Elspeth McIntosh**, Director, Castle Pharmacovigilance Limited**Claudia Ferreira**, Scientific Programs Manager, DIA