Risk Management Information Day
Best practices in applying EU-GVP Module XVI Rev.3
10 December 2025 | 13:00 - 17:30 CET | Virtual Event

| PROGRAMME COMMITTEE

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Mark Perrott
Managing Partner, Axian Consulting Ltd., UK

Meredith Yearsley Smith
On behalf of Consortium of Implementation Science, US

Ryan Marshall
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AstraZeneca, UK

Vicki Edwards
VP, PV Excellence and International QPPV
Abbvie, UK

| OVERVIEW

Revision 3 of Good pharmacovigilance practices (GVP) Module XVI has been in effect in the EU for over a year. The guideline describes a lifecycle approach in development, execution and evaluation of risk minimisation measures (RMMs) to ensure their effective implementation.

The programme committee has structured this interactive Risk Management Information Day to transition from conceptual discussions to practical applications, focusing on the key themes of GVP Module XVI rev 3 and providing practical solutions to support their application.

Ample time is foreseen for Q&A. The faculty invites participants to submit questions by 26 November 2025 latest to emea.meetings@diaglobal.org.

| KEY TOPICS

- Determining the key themes of revision 3 of GVP Module XVI
- Practical solutions to support application of GVP Module XVI
- Understanding the impact of implementation science on RMM effectiveness

| TARGET AUDIENCE

- Individuals experienced in risk management and RMM development and evaluation at small to medium enterprises (SMEs)
- Marketing authorisation applicants (MAAs)/marketing authorisation holders (MAHs) for generic products
- Marketing authorisation applicants (MAAs)/ marketing authorisation holders (MAHs) for innovator products
- Contract Research Organisations (CROs)
- Assessors at National Competent Authorities (NCAs)
- Risk communication experts
- Patients and Healthcare Professional (HCP) group representatives
- Qualified persons responsible for Pharmacovigilance (QPPVs)

DIA

AGENDA | 10 DECEMBER 2025 | 13:00 – 17:30 CET

13:00 **WELCOME NOTE**
Priya Bahri, EMA, EU and Rob Massouh, GSK, UK

SESSION 1 - METHODS AND CASE EXAMPLES OF PRACTICAL APPLICATION
Session chair : Rob Massouh, GSK, UK

13:10 **DETERMINING GLOBAL RMM APPROACH**
Speaker: Jamie Wilkins, Pfizer, US

13:40 **STAKEHOLDER ENGAGEMENT IN ARMMS – MAXIMISING VALUE AND MINIMISING TOKENISM**
Speaker: Vicki Edwards, Abbvie, UK

14:00 **FAILURE MODES EFFECT ANALYSIS TO PROACTIVELY REDUCE DISABLING FACTORS OF RMM EFFECTIVENESS**
Speaker: Mark Perrott, Axian Consulting Ltd, UK

14:25 **MIXED METHODS TO SUPPORT FORMATIVE AND EVALUATIVE RMM ASSESSMENT**
Speaker: Meredith Yearsley Smith on behalf of the Consortium of Implementation Science, US

14:55 **BREAK**

15:25 **SESSION 2 – CASE EXAMPLES OF PRACTICAL APPLICATION IN IN LOCAL CONTEXT**
Session chair: Priya Bahri, EMA, EU

15:30 **A MEMBER STATE'S APPROACH TO IMPLEMENTING GVP MODULE XVI REV 3**
Speaker: Krystyna Cegielska-Perun, Office for Registration of Medicinal Products, Poland

15:50 **LOCALISING ADDITIONAL RMM FOR IMPLEMENTATION AND DECISION MAKING ACROSS THE PRODUCT LIFECYCLE**
Speaker: Ryan Marshall, AstraZeneca, UK

16:15 **Q&A AND PANEL DISCUSSION**

17:20 Wrap up
Priya Bahri, EMA, EU and Rob Massouh, GSK, UK

17:30 END OF THE INFORMATION DAY