EMA Risk Management Information Day

21 November 2024
13:30 – 17:30 CEST | Virtual Event

PROGRAMME COMMITTEE

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Director of Pharmacy
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| OVERVIEW

The **revised Guideline on good pharmacovigilance practice (GVP) module XVI on risk minimisation measures (RMM)** will come into effect in Summer 2024.

The focus of this interactive Information Day will be on implications and first experiences with implementing GVP module XVI (Rev.3) from Regulators, Industry, Patients as well as Health-care professionals' perspective.

Different aspects of the revised guideline will be discussed such as the nature and principles of risk minimisation, its life-cycle management with stakeholder engagement, the specifics and development of RMM tools and points to consider for requesting additional RMM tools. Furthermore, success factors for RMM effectiveness, regulatory impact of results of RMM effectiveness evaluation, the role of the Marketing Authorisation Holder (MAH) as well as the coordination of RMM for generic products and the national approval of RMM materials will be reviewed.

Preparatory reading of the guideline and addendum is highly recommended:
- GVP module XVI - Risk minimisation measures: (Revision 3)
- GVP module XVI Addendum II: Methods for effectiveness evaluation

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions by 04 November 2024 latest to emaevents@diaglobal.org

| KEY TOPICS

- Tools of Risk Minimisation Measures
- Risk Minimisation Measures Effectiveness Studies
- Engagement of Patient and HCPs and Implementation of RMM in clinical practise
- Regulatory Impact Research

| TARGET AUDIENCE

- Individuals experienced in risk management, risk minimisation development and evaluation at small to medium enterprises (SMEs)
- MAAs/MAHs for generic products
- MAAs/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)

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AGENDA | 21 NOVEMBER 2024 | 13:30 – 17:30 CET

13:30 WELCOME NOTE

13:40 SESSION 1 – GVP MODULE XVI - THE 3RD REVISION
Session chair: TBC

THE REVISED GVP MODULE XVI – WHAT TO FOCUS ON FOR IMPLEMENTING THE GUIDANCE
Priya Bahri, Lead PhV and Risk Management Guidance and Policy, PhV Office, EMA, EU

14:00 CONCEPTIONAL APPROACH TO RMM EFFECTIVENES EVALUATION
Thomas Goedecke, PRAC Impact Strategy Lead, PhV Office, EMA, EU

14:20 ENGAGEMENT OF PATIENTS AND HEALTHCARE PROFESSIONALS IN RMM
Roberto Frontini, Director of Pharmacy, Centre for Patient Safety Leipzig, DE

14:40 Q&A

15:00 BREAK

15:30 SESSION 2 – FIRST EXPERIENCES AND PRACTICAL ASPECTS
Session chair: TBC

REVISED GVP MODULE XVI – IMPLEMENTATION – THE INDUSTRY'S VIEW
Speaker invited

REVISED GVP MODULE XVI – IMPACT RESEARCH FROM A REGULATORY PERSPECTIVE
Liana Martirosyan, PRAC member, MEB, NL

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REVISED GVP MODULE XVI - DIGITAL TOOLS
Speaker invited

16:40 Q&A AND PANEL DISCUSSION

17:20 WRAP UP

17:30 END OF THE INFORMATION DAY