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Webinar on

Pragmatic Approach To Pharmacovigilance/Drug Safety System Update Against The Latest New Requirements

Learning Objectives

- *To understand what should be prioritized in terms of changes to Pharmacovigilance Systems as result of the recent new PV requirements, how to map such changes and the check of the appropriateness/ correctness of associated outputs.*

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This webinar you will learn terms of changes to Pharmacovigilance Systems as result of the recent new PV requirements, how to map such changes and the check of the appropriateness/ correctness of associated outputs.

PRESENTED BY:

Marco Sardella, Chief Pharmacovigilance Officer EU-QPPV-ADIENNE Pharma & Biotech Dr. Marco Sardella is a PV Person with significant experience in setting up pharmacovigilance and risk management systems worldwide (experience with EMA, USA, Canada, Switzerland, Russian Federation, Asia, Middle East). Former European QPPV of Gentium S.p.A/Jazz Pharma.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

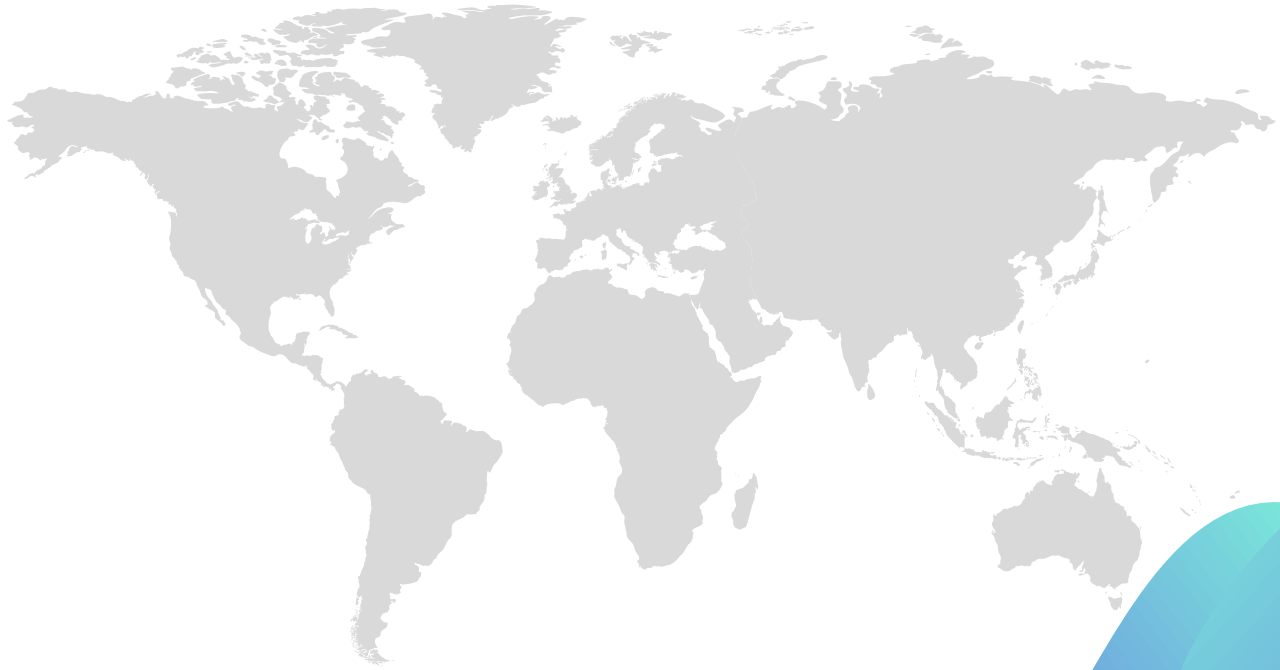
In the last year/recent months, there have been a lot of changes in the pharmacovigilance requirements especially impacting the reporting to EudraVigilance, the Signal Detection Management (e.g. inclusion of EudraVigilance Data Analysis System as part of the Signal Detection Management, etc.) and the Risk Management activities. The course is aimed at providing some practical examples of the application of the new requirements to PV Systems.

The recent new published modules of the Good Pharmacovigilance Practice (GVP) and in particular the new GVP module VI "Collection, management and submission of reports of suspected adverse reactions to medicinal products", the new GVP module V "Risk Management Systems" and GVP module IX "Signal Management" require for update to Safety Databases/electronic interchange systems, processes/working instructions, contracts with Third Parties affected from such legislative changes, etc. The review and update of Pharmacovigilance Systems as a result of the new requirements must take into account the type of medicinal products covered by the systems. Any update required to meet new local requirements from a specific territory will have to be performed in a way that does not generate conflicts with the functionalities of the system in place to meet the requirements of other territories.

The course will also provide some practical aspects to detect and communicate the presence of duplicates to the EMA.

Who Should Attend ?

EVWEB Users of EudraVigilance; all professionals involved in the Signal detection, Risk Management activities; Pharmacovigilance Officers involved in the Maintenance of the Pharmacovigilance System Master File (PSMF); pharmacovigilance inspectors and auditors.



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