

Medication errors: Detection, impact, and risk reduction through pharmacovigilance

Punam Kumari

Clinixel, United Kingdom

Medication errors are a leading cause of preventable harm in healthcare systems worldwide, with significant implications for patient safety and therapeutic outcomes. Within the European Union (EU), addressing medication errors has become a key priority to enhance public health and ensure safe use of medicines. To support this goal, the European Medicines Agency (EMA), in collaboration with national competent authorities, developed the EU Good Practice Guide on Medication Errors. This guide offers a comprehensive framework for identifying, reporting, evaluating, and preventing medication errors within the EU pharmacovigilance system.

This presentation will delve into the essential elements of the Good Practice Guide, including its definitions, classification of errors, the role of risk minimization measures, and integration with adverse event reporting systems. Emphasis will be placed on the distinction between medication errors and adverse drug reactions, and on how marketing authorization holders and healthcare professionals should manage such events in compliance with EU regulatory requirements. Case studies and real-world scenarios will be presented to illustrate how proactive error identification and reporting can prevent recurrence and reduce patient harm. Furthermore, the broader impact of medication errors—ranging from patient trust and treatment outcomes to regulatory action and healthcare costs—will be examined.

By fostering awareness and promoting consistent practices, the Guide aims to support a culture of safety and continuous improvement in medication use. This presentation will equip attendees with the practical insights needed to align with regulatory expectations and contribute effectively to medication error prevention efforts.

What will audience learn from your presentation?

- Participants will gain a clear understanding of the EU Good Practice Guide on Medication Errors, including its purpose, structure, and regulatory importance.
- They will learn how to identify, classify, and report medication errors within the EU pharmacovigilance framework.
- Through practical examples, attendees will explore the roles of stakeholders—such as healthcare professionals and marketing authorization holders—in preventing and managing these errors.
- The session will highlight the real-world impact of medication errors on patient safety and healthcare systems, and provide actionable strategies to mitigate risks, promote safe medication use, and strengthen compliance with EU regulatory standards

Biography

Punam Kumari is a Pharmacovigilance Consultant at Clinexel. She is a Postgraduate in Pharmacology and Drug Discovery from Coventry University, UK. Based in the UK, she has 10+ years of experience in the pharmacovigilance field, having worked with leading companies such as TCS and GSK. Her expertise includes case processing, quality control, aggregate report writing, signal detection, and risk management, and she has also served as a Subject Matter Expert. Additionally, Punam is an ISO-certified auditor and has delivered guest lectures at various universities and institutions.

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