The European Medicines Agency has revised the Good Pharmacovigilance Practices (GVP) Module V on Risk Management Systems. The revised module (Revision 2) is effective from March 31, 2017. These revisions to the GVP Module V are intended to provide a more concise and clear description of risk management and how safety risks evolve through a product’s lifecycle based on the evidence from a variety of sources.

The guidance is updated in parallel to an amended RMP template for initial marketing authorization application. RMPs submitted for initial marketing authorization applications and Day 121 responses applying GVP Module V Revision 1 will be accepted until September 30, 2017, and all other RMP submissions (including Day 91 responses for an initial application under accelerated assessment) will be accepted until March 31, 2018.

In view of the updated regulatory requirement, the marketing authorization holders (MAHs) should be prepared with a plan to transfer all existing RMPs to the new template to comply with the revised regulations for different types of RMPs (innovator, generic, hybrid, biosimilar, well-established products, etc.).
How can Indegene help you?

The revision has resulted in major changes to the RMP template – thorough revisions to many sections, updated and additional requirements, and other format-related changes. Manual transfer of content from existing to new template would be a challenge in terms of effort time, data accuracy, and regulatory compliance.

Indegene has mapped new requirements with the existing template and we can simplify the process of adaptation of existing RMPs to the revised template with desired quality and in compliance with the regulatory requirements with our in-house automated tool.

The tool retrieves content from each heading/subheading of the existing RMP and maps it to the relevant heading/subheading of the revised RMP template. This tool reduces manual effort, eliminates errors due to manual content mapping, and also identifies and highlights new sections and/or subsections to be authored.

Additionally, Indegene provides a cost-effective and quality-driven workforce to efficiently understand the RMPs and their regulatory requirements. Our capabilities include authoring and updating all types of RMPs based on client/regulatory requirement. We provide end-to-end support including literature search, risk profile creation, authoring, quality control, and delivery of submission-ready RMPs. We provide authoring support for both EU-RMPs and Local RMPs.