Practical approach: End to end management of safety updates - signal to label

Vishakha Oza
Grünenthal GmbH, Germany

Problem Statement: Many companies (MAH) struggle with timely management of safety signals and its implementation into the product labeling. All audits and inspections safety changes are very critical aspect, triggered from signaling activity at PV function.

Practical Approach: A medicinal product is approved in the market based on the evaluation of its benefit risk profile at the time of the initial marketing authorization. The evaluation of the benefit/risk ratio will need to continue during the whole life-cycle management of a product taking into account any additional knowledge gained from post marketing. In order to ensure the safe and effective use of a medicinal product, routine signaling is an important aspect of the product surveillance. Any new safety significant information lead to update of Reference Safety Information of the product. Once the need to make a safety updates is identified, MAH should have an adequate process in place to ensure timely submission and implementation. Management of RSI update based on signals and its implementation in product label is critical to the patient´s safety.

Solution: Presenter will elaborate the concepts and practical solutions of identifying signals, types of signals, end to end management of signals till implementation in product label. This presentation is designed for intermediate and experienced professionals.

Biography

Vishakha Oza is a Registered Pharmacist and completed masters in Pharmaceutical Sciences and Post Graduate Diploma in Business Management. Vishakha is working in pharmaceutical and biotech industries since 13 years. Currently, Vishakha is a Lead Safety Scientist at the Grünenthal GmbH, Germany. Previously, she had been collaborated with esteemed MNC like Novartis, GSK. Vishakha has a robust experience in drug safety and labelling aspects of the product. Vishakha has delivered a guest lecturer for Masters in Vaccinology, Siena University, Italy.

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