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Monitoring Pharmacovigilance quality system is important indicator for pharmaceuticals' compliance

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Pharmacovigilance science has made a significant improvement during the last period where its pivotal role becomes more evident in pharmaceutical industry during the products' life cycle. The quality management of the safety information by pharmaceutical industry is crucial for proper safety information handling including detection and monitoring adverse drug events. There are well-known challenges that the reporting System faces such as quality status and underreporting The most known example of underreporting is spontaneous reports of adverse events that might impact assessment of safety profile of pharmaceutical products. The quality strategy for the handled pharmacovigilance data has to be regularly evaluated by pharmaceuticals, fulfilling risk-based approach. This presentation provides an overview of the main requirements for a compliant pharmacovigilance system, the required quality parameters and measurable key performance indicators. Pharmaceuticals' effective monitoring of the pharmacovigilance system and its quality parameters will enable them to face relevant challenges for compliance.

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