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5. A System-Based Model for Global Pharmacovigilance

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Background: Patient safety is a primary goal for medicinal product manufacturers. A system-based model for Pharmacovigilance is imperative for optimizing safety and minimizing risk. Such a system must be agile to comply with evolving regulations and guidances (e.g., EU legislative framework and risk management strategy, FDA Risk Management guidances, FDA TOME) and scaleable to effectively and efficiently respond to process improvement initiatives.

Objective: To describe a recently implemented system-based model for global Pharmacovigilance at a biotechnology company.

Methods: There are 3 main components for the model:

1) Process stages - data collection, data management, signal detection, safety issue assessment, decision making, communication/ action and outcome.

2) Pathways for the process system - The Compliance and Risk Management pathways drive the process stages. The Compliance pathway satisfies international safety reporting regulations and produces Individual Case Safety Reports (ICSRs) which represent the primary unit of production in the Pharmacovigilance system. The Risk Management pathway assures efficient risk detection, risk assessment and risk mitigation.

3) Decision making bodies - The Signaling Committee and Product Safety Review Board are empowered to serve as corporate toll gates for decisions on benefit-risk. These entities, on a regular and as-needed basis, review both ICSRs and aggregate safety data from diverse sources including, but not limited to, product complaints, medical inquiries, clinical trials and post-marketing studies to detect potential safety issues. Product labeling changes and other forms of risk communication and/or mitigation are employed to address any identified safety concerns.

The Coding committee influences all Pharmacovigilance stages and facilitates creation of optimal safety datasets for risk identification and assessment.

The backbone of the Pharmacovigilance system is the Pharmacovigilance plan which is maintained throughout the lifecycle of a product and provides the basis for targeted risk-based activities.

Results: We anticipate implementation of this system will result in favorable GMP, GCP, and Pharmacovigilance regulatory inspections. We also expect enhanced efficiency in risk detection and risk assessment activities and improved effectiveness in mitigating identified risk issues.

Conclusions: We describe a system-based model for global Pharmacoviligance for reaching the goal of optimal patient safety. Our experience thus far suggests that this model will enable us to achieve this goal.