

The Pharmaceutical Industry

The pharmaceutical industry is perhaps the most highly regulated in the world as evidenced by the vast array of regulatory guidelines which require companies to improve compliance, data collection and the accuracy of information. Medical product safety and pharmacovigilance risk management has become increasingly important as the development, marketing, and use of medical products have grown in complexity and magnitude globally.

The inherent limitations of clinical testing and a renewed focus on risks associated with medical products use have resulted in new thinking and methods for monitoring the evolving risk profiles of marketed products throughout their life cycle. To ensure product safety and pharmaceutical regulatory compliance throughout product life cycle, companies need software that integrates compliance with business and manufacturing processes together with a dynamic risk management program that stays current with regulatory activities and the major regulatory initiatives

Risk management adds a new dimension as a continuum in which product safety and a medical product's benefit/risk balance is monitored and re-evaluated on an ongoing basis. In particular, risk assessment of Adverse Drug Events (ADEs) in both pre- and post marketing environments has become a key component of this risk management continuum. Ongoing investigation and assessment of ADEs are crucial to the development of a company's Standard Operating Procedures (SOPs). Well written SOPs describe a product's risk profile in terms of the seriousness, likelihood, and public health impact of an ADE. The end result is the development of testable controls and a roadmap for risk mitigation and minimization along with detailed instructions for how to achieve compliance with regulatory and company requirements.

These new approaches in risk management, risk communication, labeling and packaging have demonstrated success in optimizing medical product benefit while minimizing preventable harm. However, these approaches are themselves at risk if they cannot be sustained as value added processes. A risk management program can become cost prohibitive if it is not designed and executed correctly.

Software developers have recognized the complexities and regulatory challenges in pharmacovigilance and medical product safety. But few have responded to industry expectations for an integrated risk management solution which enables companies to identify, assess, and manage safety risks while optimizing benefits to patients through the development and testing of controls.

The goal is to find a risk management and compliance product aligned with the objectives of the pharmaceutical industry for product safety, quality assurance, and pharmacovigilance throughout the medical product life cycle. By clearly linking risks and controls to organizational objectives, users are constantly aware of the importance of ongoing review and management to ensure objectives are met.

Ideally, a risk management and compliance tool should offer a logical and hierarchical framework, providing a solution that manages and minimizes risk while creating a sustainable environment that maximizes the business value of a competitive and timely market position.