



Performance Under Pressure

Product Safety and Drug Development



When golf champions win, it's often in the spotlight, watched carefully by competitors, fans, and television audiences potentially totaling millions of people. The stress is extraordinary. Likewise, pharmaceutical, biotech, and medical device companies are closely scrutinized by regulators, investors, the medical community, patients, and the public. These businesses have the potential to change lives, but do so under extraordinary pressure.

Since years often pass between the time a product is conceived, approved, and made available to the market, a major drug safety concern can create a revenue swing of many millions, if not billions, of dollars and put a company at further risk of government investigations and civil and criminal litigation. In such an environment, regulatory compliance, product efficacy, and patient safety are imperative.



As the development of drugs and medical devices grows more complex, the importance of regulatory compliance, product efficacy, and patient safety increases significantly.

Scrutinized closely across the life cycle of a drug or device, life sciences companies strive for performance under extraordinary pressure.

How we can help

Deloitte works with life sciences companies to develop practical, executable strategies for addressing critical issues such as pharmacovigilance (PV) execution and drug safety compliance, document management, adverse events processing, and product safety monitoring. Our practitioners have significant experience across a broad cross-section of life sciences organizations addressing PV. Deloitte is recognized as world class and a thought leader in the life sciences industry.

Our services include:

- **Product safety and drug development.** We specialize in promoting operating model growth for drug safety by defining a strategic plan and corresponding road map that leverage global regulatory intelligence.
- **Process design.** We help transform the drug safety process through insightful analysis, organization and process design, and key performance metrics. We also help with deployment of standard operating procedures (SOP), work instruction (WI) development, training, organizational change management, and risk management.
- **Business intelligence.** We help incorporate analytics, visualization, and reporting to address compliance, measure performance using process metrics, and institute continuous improvement. We leverage hands-on experience with signal detection, data warehouses, and datamarts for consolidation of safety data and training.
- **Implementation services.** Our services include software development life cycle (SDLC) support for system implementations and upgrades; configuration implementation; E2B implementation and agency consultation; and data migration, vendor management, and integration design.

Potential bottom-line benefits

- Regulatory compliance and effective product defense
- Improvements in operational efficiency and risk management
- Resource utilization improvements and scalable processes
- Improved use of performance measurements
- Informed decision making through improved access to business intelligence data and analytics

Ways to get more value now

- **Know about product issues before regulators do.** Use data analytics to monitor product safety in different areas of the population. Identify and address potential risks, and proactively address regulatory scrutiny.
- **Focus on emerging regulations and drivers.** Leverage insight into trends that will require changes to business processes and systems. Be aware of the European Medicines Agency (EMA) good pharmacovigilance practices (GVP) modules as they are rolled out and understand their inherent challenges.
- **Use “accelerators” to approach a safety system implementation.** These can facilitate rapid and precise transition to new processes and applications via the usage of specialized documents and tools with content and capabilities specifically designed for the purpose.
- **Leverage specialists with hands-on experience addressing drug safety and PV.** Our practice leaders have been working in the safety areas across a cross-section of clients for more than 25 years.

The big idea

Life sciences companies rely on very complex processes and systems that can benefit from Deloitte’s broad-based product safety and PV services and capabilities.

Learn more

To learn more about Deloitte’s Product Safety and Drug Development services and other related capabilities, visit www.deloitte.com/us/SCproductsafety.

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