

Companies clearly cannot afford the financial and reputational risks associated with an insufficient pharmacovigilance function. A critical re-evaluation of your pharmacovigilance programme and the supporting information systems can help your company minimise the risks of costly development setbacks and possible product withdrawals from the market.

Pharmaceutical, biotechnology and medical device companies must go beyond simply meeting regulatory reporting deadlines. They must continually analyse data for trends that might 'signal' a potential safety risk, and actively investigate to determine the need for further action.

How can pharmaceutical and life sciences companies effectively implement proactive pharmacovigilance and drug safety programmes?

The challenge of maximising drug safety and maintaining public confidence has become increasingly complex. Pharmaceutical and biotechnology companies must not only monitor, but also proactively assess and manage drug risk throughout a product's lifecycle, from development to post-market.

Should the FDA, EMEA or other government regulatory agencies have reason to question the safety of a drug, any one of these agencies could halt a clinical study, delay drug approval or recall an approved drug from the market. The consequences of ineffective adverse drug event reporting and pharmacovigilance processes, procedures and plans could include brand damage, class action suits and exorbitant fines, among others.

Strengthening your drug safety & pharmacovigilance programme

Regulations and guidelines from the FDA and ICH specify that pharmaceutical companies must implement a pharmacovigilance risk management plan. The FDA may also require companies to provide a risk minimisation action plan (RiskMAP) for high-risk products.

To fulfill these requirements, companies must:

Collect, assess and report adverse events within the specified reporting time on a global basis

Comply with local and global pharmacovigilance requirements

Manage the process of risk mitigation throughout the product lifecycle by reviewing safety data, acting on 'signals' and updating product labels when necessary

Evaluate data and prepare periodic safety update reports (PSURs)

How can PwC help your organisation?

PwC works closely with manufacturers to assess the effectiveness of existing pharmacovigilance and drug safety programmes and to identify practical solutions for enhancing the internal and contracted processes that impact the entire life cycle of a company's adverse event reporting and pharmacovigilance system. We identify and assist with implementation of systems and tools that increase the value and accuracy of data collection and reporting. Finally, PwC provides detailed recommendations for strengthening adverse event monitoring and control mechanisms.

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Our services target key operational and systems areas that involve compliance and control as well as the resolution of issues. We can help to:

Develop procedures for the identification, reporting and follow-up of adverse drug events

Provide advice on the development and implementation of a pharmacovigilance specification document and pharmacovigilance Plan

Assess the current technology used in the drug safety process and assist with implementation of new systems

Design processes to identify, capture, monitor and report safety data

Evaluate data quality and the data integrity controls in place throughout the drug safety process

Evaluate, recommend and implement information security solutions

Prepare risk minimisation action plans (RiskMAP)

Develop efficiency and effectiveness process improvements for risk identification and assessment throughout the adverse event reporting life cycle

Assess current drug safety and pharmacovigilance training programmes

Review drug safety and pharmacovigilance standard operating procedures for compliance with GCPs as well as local and global regulatory authority requirements

Reconcile internal processes for recording safety data received from multiple sources

Review and provide advice on summary safety reports provided to regulatory authorities

Assess the requirements for establishing an independent data safety group

Provide recommendations for the creation and development of a safety database

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Global Pharmaceutical and Life Sciences Industry Group

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