



RISK MANAGEMENT IN THE PHARMACEUTICAL SUPPLY CHAIN

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As production and distribution through the pharmaceutical supply chain grows increasingly globalized and complex, stringent risk management has become an essential measure.

As a key player in the supply chain process, pharmaceutical companies face a range of risks. In fact, failing to adequately prepare for disruptions can reduce a company's profitability, lead to devastating damage to a company, and even cause harm to patients.

With so much at stake, pharmaceutical manufacturers must identify and mitigate those risks with policies and processes tailored specifically to their company and products.

BEST IN CLASS

According to Martin Lush, Global Vice President, Pharmaceutical Services and Medical Devices, NSF International, effective risk management starts at the top: "Best-in-class practices start with leadership. In companies where we see really good quality risk management, we always find leadership who understand its importance. They understand that quality risk management is not just a regulatory requirement but is actually common sense. It's a core competency without which their business would not survive.

"Leadership plays a really important role not just in the words they use, but in the actions they apply – for example, implementing key performance indicators (KPIs) that drive the right behavior and measures that ensure culture is transparent and open, where risk is acknowledged, and improvements are made following mistakes."

Leadership should also ensure that knowledge is shared across departments and external partners in order to drive continuous improvement, which helps to manage and reduce risks accordingly. Importantly, the leadership of companies who exhibit successful risk management have a great understanding of risk aversion.



Lush continues: "The pharmaceutical industry is, of course, risk averse. After all, we're making medicines and devices and any error or mistake can have catastrophic consequences.

"However, when we try to ignore the reality of risk, we expose ourselves to considerable danger. Risk aversion involves maintaining the status quo and not improving. It can often result in increased bureaucracy and increasing complexity with the misunderstanding that more documents and signatures actually reduce risk. It also drives people to focus on the system rather than the patients and ultimately creates a level of inefficiency that is unaffordable."

TAKING A PREVENTATIVE APPROACH

While leadership must fully comprehend risk management and put into place actions that meet its demands, the importance of this process should be understood at all levels of a company. From VP to the shop floor, where decisions are routinely made, all personnel should understand what quality risk management is and how to apply it.



Staff should be educated on key quality attributes, with a significant amount of time invested in ensuring all roles understand their products and processes and the risks that surround them. That knowledge should be easily accessible so that it is available when risk-based decisions are being made in order to work in a preventative, rather than reactive way.

According to Lush: "Best-in-class companies apply most of their focus to preventing errors and risk rather than in reaction to it. They use quality risk management in designing their self-inspection program, deciding which areas to spend longer on, making decisions around audits, supplier management, and working out where the greatest risks lie."

GAINING AN EDGE

While the benefits to quality risk management are far-reaching, the key purpose is to improve a company's competitive edge, which can only be achieved by effectively balancing profit-efficiency, ensuring the license to operate remains intact, and supplying customers with the right medicines at the right price.

NSF International works with pharmaceutical companies around the world to improve their understanding of quality risk management and make effective changes to their processes. NSF's combination of former regulatory agency staff and industry professionals can help companies to achieve and maintain compliant, future-proof quality management systems.

The experienced team will work with staff at all levels in order to maximize their contribution to the company and help manufacturers improve their competitive edge in an increasingly complex and challenging marketplace.

Learn how to become risk smart – view Martin Lush's white paper:

[White Paper: Is Fear of Risk Your Biggest Risk?](#)

MARTIN LUSH



Martin has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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