

Why Pharmaceutical Supplier Quality Management Presents Special Challenges for Risk Management By Mark Frankcom

Introduction

The increasing number of incidents involving raw materials supplied to the pharmaceutical industry has put the regulatory spotlight firmly on the issue of managing suppliers. Regulatory bodies such as the F.D.A. have themselves come under congressional pressure due to deaths/illness caused by raw materials. The Heparin and Chinese tainted milk powder issues of 2008 are examples which have increased public concern. The industry and regulatory bodies are now looking for systemic improvements in managing supply chains and suppliers.

While the pharmaceutical industry can learn many lessons from the automotive and electronics sectors about managing risk, there are characteristics unique to the industry that make implementing supplier quality management challenging with regard to risk management. Throughout this article I will use the term pharmaceuticals to embrace both the traditional pharmaceuticals as well as the biotechnology sector.

All industries face the issue of multiple stakeholders. The pharmaceutical industry has four primary groups of stakeholders - R&D, Operations, Procurement, Corporate Compliance and Risk Management. Their interactions and the inherent risks are amplified by the long development cycle of a new drug (typically 10 years or longer), and the long period of commercialization thereafter (up to 20 years or more). During this extended lifecycle, the influences of various stakeholders and suppliers changes. This takes place in a highly regulated environment; whereas, product recalls and regulatory actions can severely impact the shareholder value.

Overcoming Challenges

Having outlined some of the unique challenges faced by the pharmaceutical industry in supplier quality management, I believe there are specific ways to overcome these issues.

The first requirement is the most difficult of all – unifying the missions across functional groups with regard to suppliers and contractors. Nowhere is cross-functional collaboration, over long periods of time, more necessary to reduce the risk to the corporation. A failure of quality or a significant disruption of supply has a major impact on companies. In addition, the hidden costs of manufacturing failures, which are discovered internally (and attributable to both suppliers and contractors), can be significant. It is in the best interest for all parties involved, that a mechanism for cross-functional cooperation be found.

The best vehicle for this is a comprehensive risk management system, which extends over the complete product lifecycle. In the early phases of product development, there should be a rough risk assessment based on the data available. This should include evaluations of supplied raw materials and services and the appropriate functions – Quality, EH&S and Procurement. This early stage assessment can be enhanced as the life cycle develops. Building in risk assessments at critical stages, with the appropriate follow-through on actions identified, will ensure that this cross-functional alignment occurs.

As part of the risk assessment process, there will be execution of pre-qualification processes for new suppliers, and accompanying follow-up audits. Given the scarce resource available for audits, a risk-based approach is essential and must be grounded in the process described earlier. There must be agreement across functions on how to best deploy the audit resource, including shared audits and the use of a third party. The pharmaceutical industry needs to improve the standards of auditing by qualifying external auditors in a more rigorous way – similar to the standards expected by the accounting profession. Over time, the availability of high quality third party auditing will improve. Before deployment, an audit resource is a severe resource constraint requiring a rigorous risk assessment.

Having described the need for a well-structured risk management process over a lengthy pre-approval and post-approval lifecycle, it is also clear that it cuts across multiple functions. This being said, information and data management are other essential components. While agreeing that a comprehensive cross-functional process may be a major challenge for most companies, providing a supporting information management system is equally complex.

Transaction-based systems, such as SAP or Oracle, are not designed to provide good general information sharing beyond transaction details (prices and quantities). The attachment of files is usually far from optimal. Additionally, there may be strong reasons to restrict access to the transaction systems. Beyond this is the issue of sharing critical information with and between suppliers and contractors.

Given the number of stakeholders, it is not atypical for major functions to have their own information management systems, which usually reflect that function's unique focus. As examples, an electronic catalogue for researchers will be focused on scientific aspects of raw materials; whereas, an occupational health system for EH&S will reflect different aspects. This problem multiplies itself as more and more functions are involved.

Suppliers, contractors and auditors also have their own unique systems. In the case of the latter, given the fragmentation of the Pharmaceutical auditor community, this is extremely varied. Pharmaceutical companies typically deploy their own unique audit management systems, which often differ between functions.

In recent years, with industries ranging from oil and gas to apparel and textiles, there has been development of web-based information management platforms for the purposes of this sharing. End users of raw materials and services bring their suppliers and service providers into an open web-based platform where information can be shared. This can be publicly available information fed from other databases. Examples are company information which is publicly available and confidential information and audit reports, which can only be accessed with appropriate authorization.

This type of web-based communication allows different functions, suppliers and auditors to download and upload appropriate files, thus maintaining live shared data and information. Without access to such a system, it is almost impossible achieve a unified approach to managing the risks across multiple stakeholders.

For example, in the automotive industry, large companies, such as Toyota, have been able to deploy a company-based system, similar, to share information with the entire supply chain. While this is not a scalable solution for all companies, the development of third party systems maintained by Information Technology companies focused on this task seems a more likely outcome.

Summary

This article has sought to describe the unique challenges of supplier/quality risk-management in the Pharmaceutical industry. The challenges are a function of long life cycles, severe constraints on changing suppliers, and the involvement of multiple stakeholders. Supply chains are complex, global in nature and involve sometimes very small quantities with quality requirements unique to pharmaceutical usage.

To ensure that quality is maintained, there must be a risk management process that covers the entire lifecycle and unifies the cross functional interests. This will require strong supporting audit processes and an improved quality of third party audit resources. Lastly, there needs to be an information management system that allows in-company functions and external supply chain partners and auditors to share information.

None of the above is easy to achieve. The Pharmaceutical industry will need to divert resources to this area, which is disproportionate to the actual financial expenditures involved. Although raw materials and services may be inexpensive compared to the prices of the pharmaceuticals products, the risks to supply chain security can have devastating quality and financial consequences well beyond any measure of value.

About the author: Mark Frankcom owns his own consultancy business focused on Risk Management in the Pharmaceutical and Biotechnology industries. He was previously with Astra Zeneca and Amgen where he held positions of increasing seniority in Supply Chain, Manufacturing, Quality and Environmental Health & Safety. He is an Adjunct Professor of Risk Management with the Center of Applied Health Sciences at Virginia Tech University.

October 21st, 2009