

LIFE SCIENCES

Quality and
Compliance

Performance
monitoring
Supplier capability
Assurance

how to achieve
global supply
chain oversight

why

wci

**“we understand
compliance
requirements
and supply chain
complexity”**

Over the last decade the pharmaceutical industry has changed dramatically. The need to continue to reduce costs has resulted in the outsourcing of manufacturing, and increasingly complex supply chains. Globalisation has become a feature of the industry. The FDA reported that in the USA the number of foreign drug products and manufacturing sites doubled over the course of only six years; involving many imports from countries with less developed regulatory systems. Between 2001 and 2007 the number of manufacturers in India increased by a factor of twenty five, and in China by a factor of seven.

The main challenge associated with this change is that functional organisations of pharmaceutical companies are simply not designed to deal with this degree of complexity. Supply Chains now run through too many different parts of the organisation, without having clear ownership established, or shared objectives for the overall process. Certain issues are not picked up because they fall between departments, increasing both the overall problem and the risk.

One direct result has been the increase in product recalls; up by a staggering 400% between 2008 and 2009. Furthermore, ingredient adulteration has become a serious problem. Everyone in the industry is familiar with the recent cases of OSCS contamination in Heparin and the recurring contamination of Diethylene Glycol in Glycerin.

Due to the complexity, most companies struggle to gain full oversight of the supply chain. Given this lack of oversight, what level of confidence can a company truly have when releasing the end product to market? Are quality agreements in place with all suppliers? Are all suppliers regularly audited? Even if agreements are in place, it is unlikely that all the required information is available at the point of release.

A benchmarking study¹ of a number of major pharmaceutical companies has

shown that the areas furthest away from the supply centres present the highest quality oversight risks as shown in Figure 1 below.

On the market facing side of the supply chain these risks are primarily caused by the lack of oversight of the local operating companies, re-dressers and distribution network. On the raw materials side of the supply chain the oversight risk is most significant with the manufacturers and

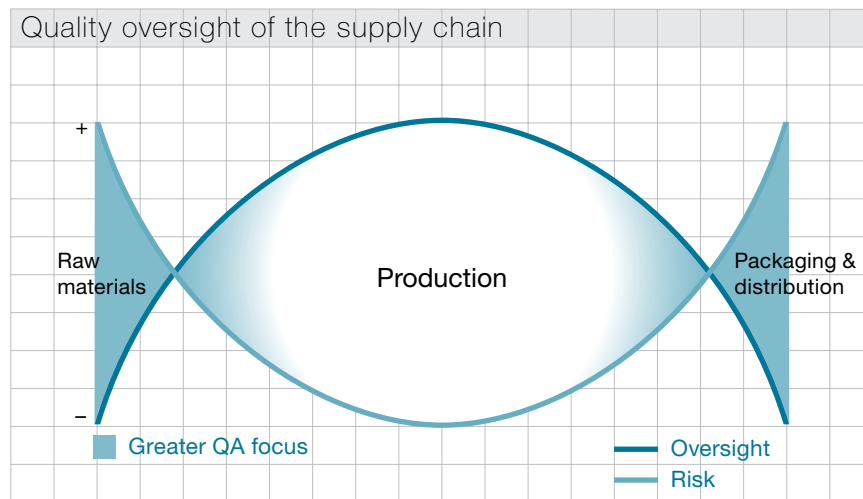


Figure 1: Results from Benchmarking Study Identifying Quality Oversight of the Supply Chain

“we focus on bringing customers and vendors closer together”

suppliers of starting materials and drug substance.

The authorities are responding to the increasing number of quality issues. The EMA are consulting on the requirement for the Qualified Person to confirm that the active ingredient supply chain is documented for all critical materials and that a supply chain risk assessment has been performed². In addition, the priorities for the human drug cGMP programme of the FDA in 2010 focused on knowing the whole supply chain, up to and including, original manufacturers. Increasing supply chain security enforcement aims to better protect customers against falsified products: companies shall establish QA processes and systems to prevent and detect adulteration, counterfeiting, illegal diversion, and theft.

To answer the question of how to achieve quality oversight across the supply chain it will be necessary for technology to provide at least part of the answer, especially through integrated tracking systems, tamper-proofing and Radio Frequency Identification (RFID), all of which will enhance supply chain integrity. Other measures will come from tighter control of distributors by limiting the number of distributors/wholesalers and preventing practices such as grey imports. However, these measures alone are not enough; the industry will have to adopt three additional elements in its approach to quality management to address the challenges.

Firstly, a proactive, risk-based surveillance and monitoring of the product supply chains will need to be implemented from raw materials to market distribution. The surveillance and monitoring must begin in product development to ensure that commercialisation risks are addressed prior to commercial supplier selection. Signal detection will need to be in place, so if an issue emerges with, for example, a material in the food industry, a risk assessment will be performed to determine if this may affect the company's pharma products. A fully functional quality management system is essential. All supply chains will require dashboards reporting key performance indicators and companies should compare internal and external manufacturing performance. Oversight of performance will need to be encompassed in the overall Management Review process. Clear responsibilities for oversight are required, including the establishment of supply chain controllers with overall accountability for particular supply chains, driving both maintenance and improvement activities.

Secondly, to facilitate quality oversight an improved management of suppliers, contractors and distributors is required. The focus needs to be on bringing clients and vendors closer together; with the client helping the vendor to develop and improve quality and compliance. Strategic partnerships with a smaller number of preferred suppliers will be essential based on clear requirements set down in Quality

“we develop a culture of total disclosure”

Agreements. Supply chain simplification and shorter supply chains will have to become part of the industry's overall quality management approach. To achieve this, Supplier Management needs to be a single, cross-functional process across Quality Assurance, Auditing, Purchasing and Supply Chain.

Finally, a culture of total disclosure is required and risk-based auditing needs to be implemented using the results of the surveillance and monitoring of the individual supply chains. The practice of total disclosure is essential to ensure trust in the Supply Chain Oversight dashboard and to foster collaboration between sites. Risk-based auditing will ensure that the company focuses its monitoring and improvement activities on the areas with the highest risk.

It is clear that obtaining full quality oversight is no simple task and will require considerable effort across a number of functions to succeed. However, the benefits of effective oversight make this effort very worthwhile, especially when compared with the risk of continuing with the status quo. Having full quality oversight is no longer an option. The question is, therefore, no longer *IF*, but *HOW* to implement oversight most effectively?

² http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/01/WC500100727.pdf



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