Future-proofing the pharma supply chain

The experts impart their top tips for making sure a supply chain is ready to face anything thrown at it

Like most global industries, the pharma industry has challenges to face. Population growth, especially in emerging markets, means that the demand for pharma products and the desire for companies to diversify and grow into different global markets is increasing.

But this diversification brings with it risk. As a necessarily risk-averse industry, pharma operates in an environment where the risks associated with this global growth could restrict the opportunities that firms can capitalise on.

Surveys show that these are key concerns of supply chain managers within pharma.

A 2013 worldwide healthcare industry study by UPS found that 60% of people questioned said regulatory supply chain compliance was their key concern – including fears about "a legislative outlook that is murky, unstable or changing" – followed by product security (46%) and managing supply chain costs (44 per cent).

More recently the results of a LogiPharma Europe 2014 survey painted a similar picture. Around 200 supply chain executives from large European pharma companies found cost, service and compliance trade-offs were cited by 32% of managers as the biggest challenges facing their supply chain, closely followed by risk management and continuity of supply and increasing regulatory compliance by 30% and 29% respectively.

So companies must create agile, flexible and efficient supply chains that are equipped to cope with today's demands and have a strategy in place to overcome future challenges, such as coping with regulatory demands, keeping costs down and making the most of new technology.

Two pharma supply chain experts give us their insights into how companies can best do this.

The 'temple' of supply chain resilience

Professor Richard Wilding, professor of supply chain strategy at Cranfield University school of management and a fellow of the Chartered Institute of Logistics and Transport, says supply chain resilience is key to avoiding financial losses.

After a decade-long dash to globalise their supply chains, many of the world's large manufacturers have paused to reflect on the strategy that they have been following, and are in some cases moving to once again shorten supply chains as a way of reducing risk. But is this the right strategy, or does it risk manufacturers throwing out the baby with the bath water, actively adding cost to supply chains in an attempt to make them more resilient? In other words, might it not be better to address the root causes of that lack of resilience?

When examining the root causes, one thing is clear: organisations seem to have little understanding as to how decisions made at a strategic, tactical or operational level subsequently impact the risk profile of supply chains.

The good news is that by following some simple guidelines, organisations can mitigate against these risks, without necessarily retrenching en masse from the benefits of the longer supply chains that bring them about. How? By using a conceptual framework that I call the temple of supply chain resilience.

Supply chain resilience is built upon the foundation of an effective supply chain strategy – in other words, the operational execution of the business mission through the supply chain. To achieve this, managers need a clear understanding of the business mission in the context of the competitive strategy of the business, as well as the markets within which it operates.

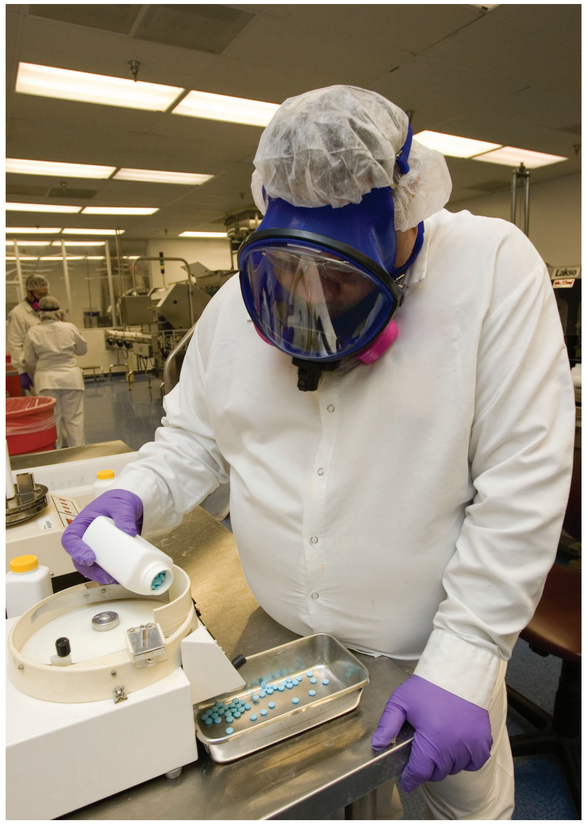
For a supply chain strategy to be effective, four distinct aspects of supply chain management must be aligned with the business mission: supply chain processes; the supply chain infrastructure, including where facilities are located and what equipment is used; the supply chain information systems; and the supply chain organisation itself.

The foundation is the floor of product design for the supply chain, and here, the message is simple: be careful not to design additional risk into your products.

During the product design process, ensure that the implied supply chain is considered – for example, what materials are used? Would alternative materials reduce risk?

Could the product function just as well if manufactured with different grades of steel, and could steel be substituted with aluminium or even plastic? Can electronic equipment function using components from different manufacturers? Where does the final customisation and configuration of the product to local customer and market requirements take place?

By applying such principles and asking questions during the design stage, it often turns out that simple modifications in the product design can greatly increase the resilience of the supply chain for that product.



First pillar: supply chain collaboration

Look at businesses that have survived major disruptions to their supply chain and you will typically see effective supply chain collaboration in action. To create a truly resilient supply chain, successful and mutually rewarding collaborative relationships are key, but organisations often overlook the investment in internal resources required to manage such relationships.

That is shortsighted and, in the event of supply chain disruption, it could potentially be damaging.

Second pillar: supply chain design and engineering

To maximise supply chain resilience, it is important that supply chain risk management is integrated into the design of the supply chain.

The logic is that a supply chain that has simply evolved over time will not be as resilient as one in which network design principles have consciously been applied to balance efficiency against redundancy.

In practice, supply chain design and engineering involve making conscious decisions about such things as where inventory is held, how much inventory is held, the desirability of alternate sources of supply, and supplier development in order to reduce risk and postponement.

Also important is having an understanding of the network that connects the business to it suppliers and, in turn, to their suppliers, and the downstream links that ultimately connect to the end customer.

Third pillar: risk management culture

A business' internal culture has an impact on its supply chain resilience, in terms of mitigating against risk and in dealing with disruption once it has occurred.

In short, contemplating a given action, the business should ask itself: how this action will impact on the risk profile of the supply chain. Will it make us more vulnerable to disruption to events? Will it make us better able to cope with disruptions?

Such a supply chain risk management culture does not occur by accident, and typically requires a leadership that encourages the organisation to respond to disruptions in an appropriate way and a top-down review of how company policies and practices can impact on the risk profile of the supply chain.

Assigning formal responsibility for supply chain resilience and the creation of supply chain continuity teams can also help.

Fourth pillar: agility

To reduce the overall risk of a supply chain and to increase its resilience, an element of supply chain agility is clearly vital.

The trick lies in achieving the required level. Agile supply chains not only need to be network based, but they also need to be market sensitive, with highly integrated virtual and critical processes. What is more, if they are to respond in ever-shorter timeframes to volume and variety changes, agile supply chains need to synchronise supply and demand.

The agile supply chain also needs to be able to adjust output quickly to match market demand or post-disruption supply constraints, and to switch rapidly from one variant to another.

Remember that competition is no longer between individual companies but between supply chains. Supply chains that are resilient and risk-minimised will compete more effectively than those that are not, which is precisely why it is in every organisation's interest to build its own temple of supply chain resilience, in order to ensure sustained competitive advantage into the future.

Taking a proactive approach to quality

Michael Lyle, a US-based process control expert, says that taking a proactive approach to quality can improve pharma supply chain quality and confidence.

Ever since Henry Ford installed the first moving assembly line for mass production, each operation became critically important to the quality and reliability of the finished product. If we apply this concept to the pharmaceutical industry, scrutiny is required for each line, cell, room, and operation.

Today, companies employ thousands in an effort to reduce potential risks and variations inherent within their processes.

It is stories like that of Johnson & Johnson – who had to recall a number of their mainstream products including children's Tylenol liquid in 2010, suffering losses of $665 million (£412 million) – which keep many executives up at night.

The motivations for maintaining an effective quality control process in the pharmaceutical industry are clear, as operational inefficiency causes delays and shortages, while a recall can have disastrous consequences for any business.

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> Richard Wilding, professor of supply chain strategy at Cranfield University

The implications of quality or operational concerns can degrade confidence in the brand and incur regulatory action, ultimately leading to less market share and a negative impact on shares. Worse still, the biggest risk is one that impacts human wellbeing due to contaminations or wrong dosage.

Closely observing processes and production flows within your four walls is essential to help pharmaceutical companies avoid disastrous recalls and stay on top of industry regulations, but a system of monitoring only goes so far.

In order to meet the ever stricter standards and requirements imposed by governing bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA)'s Good Manufacturing Practices (GMP) guidelines, pharma manufacturers must not only look beyond their own operations, but employ scientific and statistically real-time quality control solutions throughout their entire supply chain.

Evidence suggests that this not only improves quality and efficiency but reduces overhead at the same time. This will ensure the quality and safety of not only the final products, but also of the raw materials and components produced along the way. As a result, internal experts are empowered to have a true understanding of their entire supply chain and the quality of the products and raw materials they receive from their suppliers.

Testing, testing, 1, 2, 3…

As 'big data' gains momentum, the pharmaceutical industry has had its share in the mountains of papers that are collected and stored.

That being said, there is quite a difference between having data and having intelligence.

One of the most effective ways to ensure a proactive approach to quality is to implement quality tests as a matter of routine within the manufacturing process, rather than relying on the final inspection of a product.

Data may come from any number of sources; product specific (characteristics) or process specific (parameters).

Intelligence is when we are able to define the relationship between these parameters to their output and take action.

Testing products for metrics such as tablet weight, compression strength and fill weight during the production process can help manufacturers ensure consistency and safety.

How great would it be if we understood how compression force and feed rate affected the tablet? Or, how different fills were related to pressure and container?

Pharmaceutical manufacturers can also test various machines across production cells to ensure the correct measures of ingredients and components – such as the different chemical ingredients – have been compounded correctly and consistently.

This proactive approach to quality testing allows companies to identify, address and remedy any inconsistencies or quality issues before the product is released.

Unearthing relevant data

Currently, a large number of pharmaceutical manufacturers are still relying on paper-based systems to record and file their quality data.

This makes traceability a long and arduous process as the manufacturers are required by the MHRA to keep up to seven years' worth of data.

To give you an idea of the scale of records manufacturers have, one well-known pharmaceutical company in the US actually keeps its data records in a secure storage facility known as the 'Atchison Caves'.

This may seem like a strange solution, but with the amount of paper records compiled over a seven-year period, this was the biggest and cheapest space available. You can imagine a spelunking expedition to access records and data might be adventurous and even exciting, but it is by no means efficient. It can take days and sometimes even weeks to locate the paperwork.

These timescales are not conducive to unscheduled inspections or traceability requests. Older data records are literally buried – making it very difficult for manufacturers not only to access it, but also to apply past learning to new products.

In the pharma industry, the public safety risks are too high to cut corners in quality control.

The technology available today allows for a more collaborative supply chain that improves efficiency, using real-time process data.

A more streamlined, more visible supply chain gives a competitive edge that helps companies to gain traceability in the event of a recall, mitigate the risk of defective products going to market and, most importantly, guarantee the safety of customers.

Whether globally or more locally, the key changes and challenges affecting healthcare delivery – regulatory compliance, product security, managing supply chain costs, and product damage and spoilage – are here to stay.

There are challenges, however, that the industry has been slow to tackle – often because of the risk associated with making changes to supply chains – but they are not insurmountable with robust, future-proofed strategic plans.