Global Pharmaceuticals and Life Sciences Industry Group

Supply Chain & Distribution/Manufacturing Services

Are you unlocking the value of your supply chain?

The days of the high-margin ‘blockbuster’ are over; the competition from generics manufacturers is intense; and the products that the life sciences industry makes are becoming increasingly complex. So unlocking the full value of the supply chain is now more important than ever.

Yet providing an efficient, reliable and cost-effective and tax efficient supply chain presents small and mid-sized life sciences companies with many challenges. So what should they consider in approaching the task? PwC has identified six key areas for attention.

**Benefits**

- Aligns decision making with governance model
- Reduces manufacturing costs
- Provides simplified and transparent cost models
- Maximises tax position
- Improves understanding of opportunities presented by QbD, PAT, QMS and Lean Manufacturing
- Reduces compliance risks and enhances operational efficiencies
- Ensures aligned IT investments

**What does my operating model look like?**

Providing an efficient, reliable, cost effective supply chain presents many challenges to a growing pharmaceutical and life sciences organisation. The challenges will vary from access to funding to growth strategy, internal capability and capacity. For an organisation to truly unlock the value of its supply chain, many factors need to be considered and specific questions answered:

- How can I design the best operating model for my needs?
- What levers impact the profitability of my product or technology asset?
- How do I make the most of my internal operations?
- How can I use contractors to add value?
- What is the best tax structure for my operation?
- How can I create a regulatory affairs function that is a source of competitive advantage?

**Should I make, buy or sell?**

Numerous factors determine whether a company should make its own products or use a contract manufacturer but the starting point should be a clear grasp of its core strengths and weaknesses. This will enable it to distinguish the areas where it is well placed to handle production itself (or even to sell its services to others) and those where it would be better off using a contract manufacturer.
This will enable it to distinguish the areas where it is well placed to handle production itself (or even to sell its services to others) and those where it would be better off using a contract manufacturer. If it decides to use a third party, it will also need to consider whom it should trust with its business and which levers will affect the profitability of the product it plans to outsource in order to shape the contract:

Perform a detailed analysis of your internal capabilities and product flows.

Assess each product in terms of the profits you expect it to generate throughout its lifecycle. Bear in mind that the best way of sourcing a product may vary at different stages in its lifecycle, so you should review your sourcing decisions on a regular basis.

Compare your own costs with the ‘landed’ cost of potential suppliers.

Complete thorough product revenue modelling to determine if outlicensing presents the approach to maximise lower risk returns.

**How can I make the most of my internal operations?**

Lean systems and processes are critical in maximising the value of a growing organisation’s operations. But the processes pharmaceutical and life sciences companies use may be more complex than those used in a simple, high volume manufacturing plant and may challenge the principles of lean. It is also important to consider the restrictions involved in ensuring compliance with Good Manufacturing Practice.

Design operational procedures that comply with the regulatory requirements while simultaneously supporting continuous improvement.

Define each process to clarify who is responsible for what, and promote an environment in which problems are rapidly identified, shared and resolved.

Define work flows for each product and service. This will expose areas where improvements can reduce cycle times, costs and compliance.

Measure your processes and outputs to ensure that you realise the benefits you anticipate and can intervene at the first sign of trouble.

**How can I use contractors to add value?**

Growing companies often face more challenges than their larger counterparts when it comes to managing contracts, for example competitive pricing and flexible service offering. Choosing partners with similar cultures or growth aspirations can provide opportunities for mutual benefit.

Move away from blanket tendering. Focus on a small set of contractors.

Work closely with potential suppliers during the tender process to ensure that they have a clear grasp of your business, your needs and the complexities of your product or process.

Maintain a close relationship with suppliers, once the contract is in place. Lifecycle management of contracts is crucial in realising value and minimising contract ‘leakage’ through off-contract buying or poorly aligned service levels.

**How can I create a regulatory affairs function that is a source of competitive advantage?**

Many pharmaceutical and life sciences companies have responded to increasing regulation by building large regulatory affairs functions and hiring external experts to supplement their internal resource. This can result in considerable complexity and duplication, as well as driving up costs. However, small and mid-sized firms have an advantage over bigger companies as they are not hampered by large portfolios and complex legacy organisations.

Ensure that you understand the real drivers of complexity.

Provide resolute governance in the form of active risk management, standardised procedures and information flows.

Balance central control with local relationships with the authorities.

Invest in people with suitable skills and measure the efficiency and effectiveness of your regulatory affairs function.
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The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry, PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC’s professionals. More than 195,000 people in 157 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.

Proven experience

Niche Japanese pharmaceutical company

Client issue

The client had recently submitted a Marketing Authorisation Application for a new pharmaceutical product to be supplied for the first time outside its local market and needed help to design and develop its supply chain management capability.

PwC solution

The PwC team worked with the client team to understand the key success criteria for the launch and define the value levers impacting profitability.

In three weeks a target operating model was agreed with the parent company and identification of potential service providers started.

Global pharmaceutical leader

Client issue

The client needed to reduce the cost base of its finishing and packaging operations and set itself an aggressive target to remove up to $180m from the gross margin.

PwC solution

PwC research and analysis from across the pharmaceutical industry and other cost sensitive industries provided the client with a platform to develop various strategic models through an Accelerated Solution Design event. The output of this activity also included a peer review of pharmaceutical finishing and packaging strategies and a review of supply chain techniques from other industries to address margin erosion.

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