

Fast forward

Future proofing the life sciences supply chain

KPMG International

kpmg.com/lifesciences

Authors



Chris Stirling Chairman Global Life Sciences KPMG in the UK christopher.stirling@kpmg.co.uk

Chris is the Chairman of the Global Life Sciences practice at KPMG and has over 20 years of experience advising clients in the life sciences sector. He has a background in audit and was one of the founding Partners of KPMG's Transaction Services practice in Europe.

Chris works closely with life sciences clients around the globe to provide insight on the issues and trends impacting the sector. He has significant experience in large complex cross-border transactions including acquisitions, divestments, mergers and IPOs. His experience also includes a number of major transactions in the life sciences sector as well as a significant number of transactions in emerging markets.



Roger van den Heuvel Partner KPMG in the Netherlands vandenheuvel.roger@kpmg.nl

Roger is a Partner within KPMG's Global Strategy Group focusing on Supply Chain and Operations within the life sciences industry. Roger combines 5 years of industry with 18 years of consulting experience. His areas of expertise are strategy development and transformational performance improvement. Roger has worked across the globe with numerous leading companies in life sciences and other industries.

Preface

Life sciences companies are at a crossroads. In the face of enormous pressures across the industry, traditional business and operating models are being reviewed, and often replaced by new strategies designed to accommodate the rapidly evolving and globalized marketplace.

This applies to all life sciences segments but is especially true for pharmaceutical supply chains. Designed years ago to support the centralized, high-volume production of blockbuster products, these supply chains were undeniably successful in an industry where blockbusters accounted for well over half of the industry revenues. Price points were high enough and margins wide enough to encourage a conservative approach to supply chain management. Optimization usually led to squeezing out operational costs or bargaining with suppliers. The basic supply chain design was rarely questioned. However, major changes in healthcare services, technology, regulations and payment systems - not to mention patent expirations for most blockbuster drugs - mean that pharmaceutical companies need to look at how suitable and applicable their supply chains still are now and in the future.

In effect, what happened to automobiles and consumer packaged goods in the 1990s and 2000s is now happening to pharmaceutical companies. The supply chains that worked so well for decades need to become more flexible, resilient, efficient, cost-effective and customercentric, in essence — **future proofed**.

In the following report, we make the case that future proofing the life sciences supply chain will require redefining the supply chain to become more agile, increasing capabilities to support demand-driven performance, and aligning value to unleash untapped assets and expertise. We also share some promising strategies to address today's disruptive threats and give a sense of the degree of agility required.

Any change in the supply chain involves an element of risk. Life sciences companies have typically been risk aware but risk averse — the health and well-being of consumers around the world depends on the accessibility and guality of their products. This cautious approach also makes business sense for an industry that requires complex infrastructures, capital-intensive R&D, and long-term market strategies. At the same time, risk can lead to opportunities for strong growth, product diversity, and entry into new markets. We believe that taking the right steps today for future proofing the life sciences supply chain can balance risk with reward and turn an operational cost into a true competitive advantage for companies.

Examining the supply chain and optimizing for the future is not a matter of if, but when.

- Chris Stirling and Roger van den Heuvel World-class supply chain performance will rapidly become a powerful differentiator in the life sciences industry.

> — Roger van den Heuvel Partner KPMG in the Netherlands

Contents

What next?	04
Future proofing the life sciences supply chain	05
Redefining for agility	80
Redefining for capabilities	13
Emerging markets: Challenges and opportunities	14
Redefining for value	17
The impact of tax	20
Looking ahead	21
How KPMG can help	22





What next?

The old supply chain model isn't working any more. It has too much capacity in the wrong location at too high a price.

> — Kevin O'Laughlin Principal KPMG in the US

After years of stripping out supply chain costs by reducing inventory and improving efficiencies, life sciences companies now have to support strong growth, new market entries and multi-channel distribution. As a result, supply chains need to be optimized for enhanced agility, capability and value.

Critical attributes for optimization involve high levels of right first-time performance, improved complexity management including SKU reduction and product standardization, enhanced supply chain planning capabilities, and lot-size reduction to match demand profiles.

Creating the life sciences supply chain of the future should be understood as a challenging initiative requiring significant changes to a company's business and operating model.

Despite the challenges, we have seen when organizations adopt future proofing as a business-critical strategy, they can significantly improve their performance, enhance their competitive advantage, and support their development as an industry leader, both now and in the years ahead.

Throughout this report, as we explore where and how the life sciences supply chain should develop for the future, there are disruptors that comment on the 'noise' in the industry and how the supply chain can be adapted for the future (Future 2030). We think you will agree, there are many aspects to this challenge and the process for change must start somewhere.

Future proofing the life sciences supply chain

The supply chains of major pharmaceutical companies are typically constructed on a model designed for the production of blockbuster drugs. However, innovations like specialty medicines are revolutionizing the healthcare industry. Supply chains that support centralized, high-volume manufacturing of a few products sold to mass markets will be supplemented or even replaced in the next 5 to 10 years by the distributed manufacturing of a larger number of different products in smaller volumes for niche markets.1

Other forces impacting supply chains include increased supply chain complexity, stronger pressure on gaining access to emerging markets, the need for improved connectivity in a changing manufacturing network, and an increased focus on anticipating and embedding regulatory change.

When companies anticipate future innovations, adapt to change, and seize valuable opportunities, they can help future proof not only their supply chain but the organization as a whole. For the life sciences industry, future proofing involves an ongoing process of redefinition in terms of three areas — agility, capabilities and value, with each area supported by specific key strategies for development. We elaborate on each of these areas in more detail throughout the following pages. We have seen when organizations adopt future proofing as a business-critical strategy, they can significantly improve their performance, enhance their competitive advantage, and support their development as an industry leader

Future proofing the supply chain by redefining:



¹ The Growth of Specialty Pharmacy, UnitedHealth Center for Health Reform & Modernization, April 2014

Toward a breakthrough supply chain

Early 2015, KPMG International polled executives of 55 Medical Devices and Diagnostics (MD&D) manufacturers to discover their strategies for staying competitive and driving growth in the future. As a sub-sector within life sciences, MD&D manufacturers share many of the same supply chain issues as pharmaceutical or biotechnology companies. All have to drive for breakthrough innovation and to boost speed-to-market by deepening collaboration and tightening integration with their suppliers.

of MD&D companies say a **globally integrated supply chain** is achievable in the next 3–5 years.

Are the companies underestimating the investments required to achieve a truly breakthrough supply chain?

According to our survey results:

FUTURE

Only 1 in 5 consider their processes, systems and reporting to be very effective: highly automated and integrated and able to produce insights to drive competitive differentiation

Only slightly more than 1 in 10 have complete visibility of supply and capacity information over their Tier 1 and Tier 2 suppliers and beyond

80% of MD&D respondents believe partnerships, rather than in-house efforts, characterize the future of innovation 82% are adopting more collaborative business models with suppliers and customers

The majority of MD&D companies are shifting their innovation strategies from incremental innovation towards achieving breakthrough innovations.



A more in-depth examination of these survey results will be published in late 2015.

© 2016 KPMG International Cooperative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated

Obstacles to closer integration and collaboration:

47 %	Flexibility and responsiveness to changes in demand or product mix
44 %	Effectively supporting new product launches
33 %	Aligning operations to real-time fluctuations in customer demand
29 %	Lack of competitive cost structure
27 %	Ensuring sufficient supplier capacity to meet demand
27 %	Supplier performance in terms of risk, reliability and quality
24 %	Lack of skilled talent to manage supply chain execution/planning
22 %	Excess inventory
13%	Inadequate IT systems for supply chain visibility, planning and execution
13%	Lack of information and material visibility across the extended supply chain
5%	Inefficient supply chain tax structure

Innovation and working with promising external parties not only feeds the product pipeline but also taps into new ways of thinking.

- Gerald Dunstan

7

Director Life Sciences Strategy KPMG in the UK

Redefining for agility

Life sciences should be thinking more like consumer goods or even tech companies to redefine their agility.

Erich Gampenrieder
Head of the KPMG
Supply Chain Center
of Excellence,
KPMG in Germany

Supply chain agility involves adapting to variations in demand, supporting shorter supply cycles, and rapidly recalibrating plans in the face of market, price and supply volatility. Companies must be able to constantly adjust to benefit from new manufacturing platforms and processes and to rebalance 'pull' versus 'push' models.

Key strategy: Standardized, manufacturing platform collaboration

The use of standardized materials, design and processes has long been a successful strategy across a variety of industries. For human vaccines, manufacturing processes are often customized and carried out in dedicated facilities. However, biopharmaceutical companies can standardize processes and technologies in a way that makes maximum use of existing facilities, equipment and a regulatory track record, helping to improve cost efficiencies and time-to-market across the supply chain.²

Considering the following examples, Pfizer Inc. has experienced tremendous growth through both market development and acquisitions.³ This adds to the overall complexity of their manufacturing process and creates challenges for supply chain management. In particular, newly built or acquired facilities results in more products, processes and technologies that need to be integrated at the operational level to support the global brand. To address these challenges, Pfizer Global Manufacturing (PGM) launched a plan to simplify its manufacturing network and standardize processes and technologies. PGM also assigned vice presidents to each Pfizer unit to better understand customer demand and avoid any adverse impacts to service levels. By considering viable alternatives outside internal operations, the company was able to reduce manufacturing costs globally by 25 percent.

Sun Pharmaceutical, India's thirdlargest generic drug maker by sales, has standardized operations globally to streamline production, improve manufacturing efficiency, and enhance product quality.⁴ Sun Pharmaceutical has also added a global technical

³ The smarter supply chain of the future, IBM, 2009, accessed December 17, 2014

© 2016 KPMG International Cooperative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated

² Vaccine manufacturing platforms, Pall Corporation, www.pall.com

⁴ Sun Pharmaceutical standardizing manufacturing globally, FiercePharmaceuticalManufacturing, July 25, 2012

head, a critical benefit for a company that manages operations across four continents.

At Janssen Pharmaceuticals, the company's Design to Value initiative develops the right mix of priorities around R&D, revenues and operations, all supported by standardizing production technologies across sites and products.⁵The savings from this standardization are applied toward further innovation and product quality.



As specialized medicines replace blockbuster drugs, supply chains will be restructured to support a larger and more diverse portfolio of products.

Specialized medicines provide effective treatment for complex or chronic diseases, but their cost, already relatively high, is expected to soar in the next few years.

However, low-cost sequencing is driving a shift to more affordable specialized medicines tailored for specific patient populations or even individuals. The cost of decoding an individual's genome is expected to fall in the next 3 years, from up to US\$25,000 to only US\$1,000.⁶ Despite the high cost of specialized drugs, many US citizens have said that they would be willing to pay out-of-pocket for whole-genome sequencing.⁷

Supply chains will also be affected by the advent of specialty pharmacies that have the enhanced capabilities, patient services and infrastructure required by specialty drugs. As a result, pharmaceutical companies may provide some drugs exclusively to specialty pharmacies or acquire these pharmacies as a fully owned distribution channel.





Source: Fast Forward, KPMG International, 2015

- ⁶ The personalized medicine revolution is almost here, Venture Bear, January 2013
- 7 Ibid.

⁵ Value based healthcare, Economist Intelligence Unit, August 21, 2014



3D printing for drug production and research



3D printing technology may also require pharmaceutical companies to completely rethink the supply chain where raw ingredients are 'ink' cartridges, product development lead times are slashed, distribution to customers is radically simplified, and drug production is far more cost-effective.

In 2030, doctors may no longer write prescriptions but provide patients with algorithms that allow the medication to be printed at home with a 3D printer.8

Organova is a 3D printing company specializing in organ re-creation for medical research purposes. Recently, their researchers successfully tested the effects of Tylenol on an array of 3D printed liver cells.⁹ The company received positive results from a lab owned by Roche Pharmaceuticals. If carried forward, this testing technique will significantly reduce product development costs for pharmaceutical companies.

Advanced 3D printing is also being used for print-on-demand hip and knee replacements created at the hospital. Traditional supply chain costs for centralized manufacturing, warehousing and distribution are significantly decreased or eliminated. In addition, hospitals do not have to store as much equipment, and patients heal faster because each piece is custom designed and sized for their body.

lbid.

³D printing set to revolutionize pharmaceutical, Eyeforpharmaceutical, July 15, 2014

Key strategy: Continuous modular processing

Centralized batch manufacturing for pharmaceuticals suffers from a series of 'stop-and-start' steps in its production chain. This includes the isolation and transportation of chemical intermediates — including active pharmaceutical ingredients (APIs) — across the different unit operations and facilities, where issues with quality can occur.

Batch manufacturing also encourages a slow-paced, inventory-heavy operating model that is increasingly regarded as inflexible and unsustainable. Indeed, new markets and the rapidly evolving technology landscape will drive more product variety, shorter product lifecycles, and smaller drug volumes.

By contrast, continuous modular processing supports a supply chain flow-through operating model, with substantial opportunities in inventory reduction, lead-time to patient, and radically different product assurance/ stability regimes.

Decentralized production models can produce a greater variety of products in the right locations with enhanced volume flexibility and enable clinical trial and drug product development at a low cost, thereby supporting accelerated market entry.

Bayer Technology Services (BTS) has worked with industrial and academic partners to develop modular, continuous processing for pharmaceutical intermediates.¹⁰ The Bayer project assessed the potential to replicate the cost, quality and efficiency benefits of large-scale continuous production in modular, flexible, small-scale container-based production units. Implementing this new process on a large scale has reduced starting material costs by an average of 15 percent, simplified work-up processes, and decreased design and installation costs.

Novartis has developed an end-toend continuous manufacturing facility with the Massachusetts Institute of Technology to improve quality and flexibility, resulting in operational cost saving opportunities of 25 to 60 percent.¹¹

The project has led to the development of the first prototype process that produces finished drug tablets from raw chemical ingredients through a fully integrated, non-stop, end-toend continuous process. Small-scale technologies are integrated into a seamless manufacturing process so raw materials can be transformed into finished tablets without interruption.

In addition, quality has improved through a plant-wide Quality by Design (QbD) strategy where automated corrective actions occur real-time during manufacturing to mitigate disturbances and allow for real-time release of pharmaceuticals. This will help ensure that medicines are within pharmaceutical specifications during the entire production cycle. New markets and the rapidly evolving technology landscape will drive more product variety, shorter product lifecycles, and smaller drug volumes.

¹⁰ Modular, flexible continuous production of active pharmaceutical intermediates, www.f3factory.eu

¹¹ Continuous Manufacturing of Small Molecule Pharmaceuticals: The Ultra Lean Way of Manufacturing,

presentation, MIT and Novartis. See also Advancing Pharmaceutical Manufacturing, http://continuuspharmaceutical.com/technology/



We have yet to fully realize the impact of ecosystem approaches on manufacturing in life sciences.

An initiative used many years ago at European chemical companies such as BASF was an approach called Verbund ("combined") manufacturing, that allows for production plants and their suppliers to operate side-by-side in the same industrial park. Placing companies just a few feet from each other in a single location was the beginning of ecosystem thinking. This strategy enables companies to create efficient, value-adding supply chains starting with basic chemicals and extending to higher value products like advanced intermediates and active ingredients for pharmaceuticals. In addition, by-products from one plant can be used as raw materials elsewhere, further increasing supply chain efficiencies.

Perhaps by 2030, pharmaceutical companies will share the same industrial park where chemicals are manufactured for key components to drugs. Or, startup companies will be contained by an arm of the pharmaceuticals venture capital division.

Key strategy: Shared resources during demand surges

Resource sharing and supply flexibility are pivotal to handling changing demand. Competitors Nestlé and Mars share logistical resources for periods of peak demand, such as the Christmas season. This strategy has eliminated over 7,500 miles of truck journeys and reduced delivery costs. In much the same way, Kimberly Clark and Unilever operate a joint warehouse to level out demand fluctuations and reduce operating costs.

In Pfizer's virtual site operating model, dedicated cross-functional teams manage and improve collaboration with strategic, external manufacturers. This has created step-change improvements toward robust, end-to-end processes and the ability to rapidly respond to changing portfolio needs.

Endo Pharmaceuticals is sometimes referred to as a "virtual company" because it relies on third parties for all of its manufacturing and distribution. This business model provides the company with operational cost savings, lower capital expenditure levels, greater flexibility in production and enhanced productivity. However, the company also has to mitigate the potential risks of outsourcing — loss of control, loss of intellectual property (IP), and loss of visibility into operations.

Endo and its supply chain provider – UPS Supply Chain Solutions — are interconnected not only in terms of facilities and processes but also through information systems. UPS employees work directly with Endo's ERP system, which, in turn, is fed by the vendor's warehouse management system. The close interconnectivity between the companies provides Endo with a handson view of its entire supply chain and helps mitigate risks without limiting the benefits of outsourcing.

Redefining for capabilities

Life sciences companies need to expand and strengthen their partnerships by complementing internal capabilities with external resources and suppliers to effectively adapt to the changing landscape. They also need to create online capability teams to enable crossfunctional knowledge management, develop close partnerships in local markets, and leverage data as an asset through predictive analytics.

Key strategy: Demand-driven contracting

Retail companies are working with end-to-end supply chain technology and networks of third-party suppliers to scale production up or down based on customer demand.12 Transitioning from traditional push supply chains to pull-driven operations, these companies have adopted technology to monitor and analyze demand signals based on the point of sale. Properly designed and integrated with their ERP platforms, suppliers and social networks of customers, these pull supply chains allow retailers to react quickly to changing customer demands. Equally important, retailers and their supply manufacturers can eliminate unnecessary supply chain complexities, identify non-profitable products or assets, and significantly reduce costs by limiting excess manufacturing capacity and inventory.

In the pharmaceutical industry, managing demand peaks and troughs can be supported through active collaboration with other players. Bayer has organized its human resource pool as an external company, supplying labor both to Bayer and other companies while easing Bayer's own fluctuations in labor demand.¹³

AstraZeneca is outsourcing all its API production, and Pfizer is outsourcing as much as 40 percent of its API needs.¹⁴ For both companies, this outsourcing strategy has provided greater flexibility in addressing market volatility and requirements for new products.

In the life sciences industry, managing demand peaks and troughs can be supported through active collaboration with other players.

¹³ Annual Report, Bayer, 2013

¹² Getting started with demand-driven manufacturing, Manufacturing ERP, podcast, accessed at http:// searchmanufacturingerp.techtarget.com/podcast/Getting-started-with-demand-driven-manufacturing

¹⁴ Taking over Big Pharma Plants, C&EN, February 8, 2010



Emerging markets: Challenges and opportunities

The greatest share of regional growth in the global life sciences industry is found in emerging markets. China, India and a host of other economies across Southeast Asia, Africa and South America are changing the shape of the pharmaceutical sector at multiple levels.

The rise of generics manufacturing in Asia is driving cost pressures and encouraging pharmaceutical companies in developed economies to re-think their portfolio of products and long-term R&D planning. Multinational supply chains are being restructured and relocated as suppliers and manufacturers move closer to local consumers. In 2013, non-branded drugs, mostly generics, constituted over 80 percent of pharmaceutical sales for emerging markets.¹⁵

Along with high growth, emerging markets also present several challenges. For instance, China, India, Korea, Japan and the ASEAN countries support a large number of Free Trade Agreements (FTAs), each with a separate set of rules and regulations. These FTAs need to be brought into closer alignment to reduce administrative burdens in getting goods cleared through customs. Different structures for royalties, taxes and license fees in different countries are also causing complications in customs valuation and the transfer pricing of goods crossing borders, raising supply chain costs and hampering the flow of goods and materials to overseas markets.

Government policies are being reconsidered to address some of these challenges. New laws in Brazil, for example, allow companies to manufacture products in one province and sell them in another for tax advantages.

Brazil: National growth with regional differences

In both the north and the south, Brazilian supply chains have to keep pace with national growth, but this growth also needs to stay in close alignment with local markets that can differ significantly from one area to the next.

Brazil has long been recognized as a showcase for emerging markets. For the life sciences industry, the country can also be seen as an example of how supply chains need to address different regional requirements in a rapidly growing economy.

The national economy has performed below expectations in recent years, but steady growth is expected to return. For life sciences, over the next 5 years, the market is expected to increase by 5.9 percent,¹⁶ spurred by a growing population and a greater number of older consumers. By 2050, healthcare expenditures are estimated to reach 10 to15 percent of total GDP.

Currently, the Brazilian healthcare markets are concentrated in the southeast, including the states of São Paulo, Rio de Janeiro and Minas Gerais. These are relatively mature, urban markets, and quick wins in operational optimization — usually involving cost-cutting — need to be captured now for pharmaceutical companies to maintain their competitive posture. At the same time, companies also need to expand distribution supply chains in the faster-developing north and northeast regions.

These differences can include per capita income, demographics, pricing strategies for specific patient population groups, disease severity, and access to healthcare providers.

¹⁵ Global Outlook for Medicines Through 2018, IMS Institute for Healthcare Informatics, November 2014

¹⁶ Thomson Brazilian Pharmaceutical Markets Analysis Report 2014



Customers have high service-level expectations, so customer engagement and distribution models will need to change.

The China pharmaceutical market is rapidly maturing, and technologies will enable more sophisticated customer engagement models to be adopted along the supply chain. All Chinese hospitals and over-the-counter channels buy pharmaceuticals from multinational companies (MNCs) and local companies.

The companies are using business-to-customer (B2C) technology to shift their existing sales force model, based on a high number of representatives, to a highly mobilized sales team that is smaller in number but more effective in building customer relationships and meeting demand.

"

In emerging markets, supply chains are being rapidly redesigned to keep pace with regional changes in infrastructures, tax laws and customs regulations.

> — **Peter Liddell** Partner KPMG China



81

4 10



Mobile phones might play a vital role in helping pharmaceutical companies develop stronger end user relationships and address the 'last-mile problem' that challenges many supply chains and distribution systems.

In Africa, telecommunications is based almost exclusively on mobile phones instead of landlines, which are far more expensive to build and maintain. The continent has become the world's second most connected region by mobile subscriptions, and one billion mobile subscriptions are expected by the end of 2015, surpassing American and European figures.¹⁷

GlaxoSmithKline (GSK) was able to leverage this mobile phone network in a recent initiative to boost vaccination rates in Mozambique by 10 percent. Mobile phones also helped them overcome the biggest barrier to vaccination in the region — the lack of vaccine availability at local clinics.

GSK teamed with Vodafone in Mozambique and rolled out the project in 100 clinics across the country. Each facility receives regular prompts telling them to report vaccine stock levels by SMS text message. The companies also distributed smartphones to healthcare workers so they could manage the planning of vaccinations.

¹⁷ How Africa's mobile revolution is disrupting the continent, cnn.com, January 24, 2014

Redefining for value

Increased visibility is a key value as the industry moves from volume-based to value-based models centered on patient care and wellness, a development that could benefit the industry as a whole.

As noted in KPMG International's report, *More than Medicine*,¹⁸ companies clearly demonstrating the value that their products bring to patient outcomes can access broader patient populations. At the same time, organizations that work more closely with patients can better fulfill care requirements and strengthen brand loyalty. This will involve the use of data analytics to enable faster, more efficient drug development and targeted pricing. Emerging customer trends will also need to be identified on a continuous basis, and service offerings should be expanded through strategic partnerships.

A more informed understanding of patient needs and usage patterns can also help improve demand forecasting along the supply chain, supporting the paradigm shift from push to pull supply chains. Demand forecasting based on data analytics will enhance working capital management and support tax strategies based on a regional perspective in relation to local and national tax regimes. Pharmaceutical companies should work more closely with patient communities to better understand and predict demand.

> —**Vir Lakshman** Partner KPMG in Germany

Trend intelligence and data analytics

With this type of information at hand, pharmaceutical companies will be able to monitor the 'noise' in the industry and analyze the trends in order to match their business strategy.

KPMG Capital recently invested in Bottlenose, a pioneer in real-time trend intelligence.¹⁹ The company helps clients detect patterns in high-volume real-time streaming data, capitalize on emerging opportunities, and mitigate potential threats.

In the same way, Explorys, a healthcare data solutions provider, has anonymized and integrated more than 315 billion clinical data points related to over 50 million patients.²⁰ This includes clinical, operational, and financial data elements.

When combined into analytical models, these elements provide the insights that healthcare professional leaders need in order to make data-driven decisions about their care-delivery models.

Data analytics might have mitigated the situation experienced by a large medical device client when one of the metals required in its manufacturing supply chain became less available, resulting in a mark-up that impacted revenues for 2 years afterwards.

¹⁸ KPMG International, 2013, kpmg.com/lifesciences

¹⁹ KPMG Capital Takes Equity Stake in Bottlenose, a Pioneer in Real-time Trend Intelligence, KPMG press release, December 5, 2014

²⁰ Enterprise Trend Visualization and the Potential of OSINT, CSC blogs, February 17, 2015

Key strategy: Marketing internal assets and expertise

Opening up internal networks to improve utilization can help monetize company assets, streamline product development, strengthen customer relationships and improve innovation through a better understanding of customer needs.

For example, companies can monetize their data centers, networks and licensed software by sharing these assets with outside parties. They can also share proprietary software and other internally developed intellectual property with select partners in codevelopment agreements involving products designed for specific customer requirements.²¹

The growth of strategic partnerships with contract development and manufacturing organizations (CDMOs) in pharmaceuticals will help increase business agility and sustainable growth. Pfizer CentreSource (PCS) is a pharmaceutical contract manufacturer that provides flexible access to its global manufacturing network for numerous small and large clients and partners. PCS also improves utilization of internal assets by providing clients with access to flexible, high-quality assets and capabilities throughout the product lifecycle.

²¹ Enabling Software Co-Development With Partners, CollabNet, 2004

^{FUTURE} 2030 Pharmaceuticals from a vending machine?

In the future, will patients be able to access their prescription medicines through a vending machine?

The concept might not be far-fetched. In 2009, Coca-Cola introduced Freestyle, a touch screen soda fountain that can dispense almost 150 flavors. Freestyle uses micro-dispensing technology developed by pharmaceutical companies, and industry researchers are studying how a similar machine can be used by patients to select the drugs they need, record the transaction with their doctor and healthcare program, receive their prescription, and request refills if required — all without the help of traditional supply chain structures and activities.

A smart pill box

Liif connects to smartphones via Bluetooth and through the iOS and Android app. It also provides ongoing reports to track medication adherence.

Seventy percent of patients have issues with taking their medications on schedule. Tricella has developed Liif, a hi-tech pillbox that reminds patients to take their medications on time and records what pills they have taken and when. The device also provides caregivers with notifications if a dose is missed.

ative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated

© 2016 KPMG International Cod

b

The impact of tax

Tax implications have always been a significant consideration for life sciences companies. In today's environment, the proper alignment of tax planning with the underlying supply chain is more important than ever.

By their nature, national tax policies have a major impact on the competitiveness and market valuation of life sciences businesses. The principle of national tax sovereignty allows individual countries to set their tax policy without considering the rates and tax policies set by other countries.

This has led to a large variation in corporate income tax rates. Accordingly, many companies have structured themselves to take advantage of the lower tax rates offered by a number of jurisdictions.

Recently in the public arena, these structures have been criticized as a way for multinational businesses to achieve non-taxation on profits or artificially shift profits across borders to exploit lower corporate income tax rates. In response, the G20 has tasked the Organisation for Economic Co-operation and Development (OECD) to develop an Action Plan on Base Erosion and Profit Shifting (BEPS).

The Action Plan is designed to address the arbitrage between different tax rates and different interpretations of tax principles that arise as a result of tax sovereignty. The aim is to produce a revised set of guidelines to help eliminate non-taxation, increase transparency to tax authorities, and ensure that profits are correctly allocated to the functions or activities that give rise to these profits.

The OECD is currently exploring issues related to the BEPS Action Plan and aims to produce final recommendations by December 2015.

The BEPS initiative is especially relevant to life sciences companies with global supply chains supported by inter-company transactions involving manufacturing and supply, intellectual property (IP), R&D and other areas that impact profit allocation. In the case of IP, for example, the life sciences company must ensure that profits are returned to those parties that actually control the development, enhancement, protection and exploitation of the IP and not simply given to the party that has legal ownership and is funding the IP. This may affect both the reward and how it is split among various companies along the supply chain.

In addition to the exploitation of intangibles like IP, the Action Plan will impact other key elements such as centralized management activities (Is the reward in line with the substance?) or manufacturing and the route to market (Should there be a taxable presence for representative offices and agents?). The Action Plan will also affect the overall allocation of profit throughout the value chain. Nevertheless, companies should not lose sight of the importance of optimizing the location of activities in the supply chain through the use of lower tax locations, tax-favorable IP regimes, and countries that have introduced additional reliefs for R&D activities.

In responding to the Action Plan, the key for life sciences companies is to fully assess and develop a tax-efficient alignment between the supply chain and inter-company arrangements. This may involve a review of current transactions and allocation of profit, the use of low tax regimes and a detailed understanding of the overall company value chain.

As a general rule, companies should always take tax considerations into account as their supply chains grow and evolve, helping to ensure that post tax returns are protected or optimized where possible.

The Action Plan will most likely lead to an increase in tax audit scrutiny for life sciences companies. In a worst-case scenario, companies may face significant tax costs if their supply chains and tax structures are misaligned.

In any case, a proper consideration of tax implications will be essential to future proofing the life sciences supply chain. Otherwise, significant risk exists that cash tax costs will increase, reducing the cash available for reinvestment in the business.

Looking ahead

The need for transformative change across the life sciences supply chain is greater now than at any other point in the history of the industry.

Companies should determine a future vision now, map the current state, and start the process in carefully selected areas to support enhanced agility, capabilities and value. The benefits of future proofing are being proven every day in global markets, increasing revenue growth, optimizing new product pipelines, and improving material flows and reduced operational risk.

Future proofing requires a high degree of commitment, discipline and buy-in from stakeholders both within and outside the organization. However, future proofing the supply chain should be a part of any company's strategy. Waiting is no longer an option. The organizations that survive the complexities of tomorrow are the ones that act today.

© 2016 KPMG International Cooperative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated

How KPMG can help

KPMG member firms can help you every step of the way on your journey toward future proofing the supply chain.

The KPMG Global Life Sciences practice is dedicated to assisting businesses of all sizes to identify opportunities and take advantage of industry developments.

Life sciences professionals work with all top 20 global pharmaceutical companies, the top 10 medical technology companies, and almost half of the top 50 biotech firms. They also stay in touch with current trends and issues, providing relevant insights and advice to help organizations address their specific business challenges.

KPMG member firms help clients around the world to increase the efficiency of their business and operating models through enhanced professional project management, cost-efficient organizational structures and streamlined reporting and approval processes. Life sciences professionals also work intensively with start-ups to help fuel innovative approaches for businesses on their future proofing journey.

With a combination of life sciences and financial expertise, member firm professionals can introduce a tested scientific and business rationale to supply chain management, helping to improve the return on investment and support sustainable growth.

Capabilities across the life sciences sector

© 2016 KPMG International Cooperative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated.

Global Life Sciences thought leadership

KPMG generates industry white papers and research across a wide range of topics that have direct relevance to clients' businesses. These global publications discuss current issues and implications for our client's business and represent the kinds of insight available in our library of resources.

Global business services in life sciences: A window to the future

Global business services can help businesses unlock value and potentially gain efficiency with a truly transformative model. With the explanation of five key benefits and the dimensions and levels of GBS maturity, this report can help companies gain perspective in the years ahead.

Collaboration — The future of innovation for the medical device industry

Medical device companies need to embrace more inclusive innovation models, collaborate more frequently and with a broader range of partners, and pursue greater integration with suppliers, development partners and healthcare providers. This report examines the data from the KPMG Global Manufacturing Outlook survey.

More than medicine

This provocative report examines a number of emerging opportunities for the life sciences industry to use its talents, scale and data to partner with healthcare systems to support transformative change and create new growth for the sector.

The post Base Erosion and Profit Shifting world

This report focuses on providing a viewpoint for multinational life science companies to address the Base Erosion and Profit Shifting (BEPS) Action Plan being completed by the OECD.

Growing the pipeline, growing the bottom line

This report looks at the research challenge through the eyes of senior R&D executives from some of the world's leading pharmaceutical companies. Their responses towards productivity, attitudes towards risk, organizational structure and governance offer some valuable insight for increasing innovation.

The agricultural and food value chain: Entering a new era of cooperation

This report explores the complex challenges facing the agricultural and food industry, such as climate change, technological innovation and demand for greater transparency.

Acknowledgments

© 2016 KPMG International Cooperative ("KPMG International"). KPMG International provides no client services and is a Swiss entity with which the independent member firms of the KPMG network are affiliated.

Gerald Dunstan Director Life Sciences Strategy KPMG in the UK

Erich Gampenrieder

Partner Head of the KPMG Supply Chain Center of Excellence KPMG in Germany

Kevin O'Laughlin Principal KPMG in the US

Mark Ginestro

Principal Life Sciences Strategy KPMG in the US **Marcio Ikemori** Partner KPMG in Brazil

Vir Lakshman Partner KPMG in Germany

Peter Liddell Partner KPMG China

Michael van der Boom Director KPMG in the UK

Global Life Sciences contacts

Chris Stirling

Global Head of Life Sciences KPMG in the UK **T:** +44 20 73118512 **E:** christopher.stirling@kpmg.co.uk

Roger van den Heuvel

Partner KPMG in the Netherlands T: +31 206 567 044 E: vandenheuvel.roger@kpmg.nl

Kelly Dane

Global Sector Executive KPMG in the US T: +1 917 273 8677 E: kdane@kpmg.com

Download on the

App Store

kpmg.com/lifesciences

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

© 2016 KPMG International Cooperative ("KPMG International"), a Swiss entity. Member firms of the KPMG network of independent firms are affiliated with KPMG International. KPMG International provides no client services. No member firm has any authority to obligate or bind KPMG International or any other member firm vis-à-vis third parties, nor does KPMG International have any such authority to obligate or bind any member firm. All rights reserved.

The KPMG name and logo are registered trademarks or trademarks of KPMG International.

Designed by Evalueserve. Publication name: Fast forward — Future proofing the life sciences supply chain Publication number: 133165-G Publication date: May 2016