Achieving 360-Degree Pharmaceutical Supply Chain Visibility.

Identifying Global Risk Factors for a Safer and Higher-Functioning Supply Chain in 2017 and Beyond

LogiPharma bsi. WBR DIGITAL

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Executive Summary.

In the first quarter of 2017, BSI and LogiPharma partnered to research how global pharmaceutical executives are identifying and mitigating global threats to their supply chains. What global markets are currently being looked at for the sourcing of active pharmaceutical ingredients, as well as excipients? What tools and strategies are being adopted for the development of heightened visibility over each point of articulation within the supply chain? What are the current significant risk factors that jeopardize the security and continuity of pharmaceutical products quality, life cycle management and logistics? This report seeks to illuminate the answers to these questions through analyzing the anonymous responses of 73 executive members of the LogiPharma event community.

The global reach of the pharmaceutical supply chain is such that visibility remains the number one metric that quality executives including logistics managers are currently focusing on improving. Products and raw ingredients often pass through multiple international ports and customs processes before arriving at their final destinations. The ability to track shipments and ensure product quality and supplier qualification and compliance makes the difference between a high-performing organization and one that is overexposed to significant material and reputational risks. The rise of counterfeit medicinal products globally is an example of material and reputational risk entwined in one challenge. Within various international markets, serialization and traceability requirements have been implemented to combat illegal retail and counterfeits, presenting its own compliance challenges. Combatting many challenges present in this global supply chain environment will come down to product quality and qualification and compliance of suppliers that an organization allies itself with.

Over the next three years, the most pressing challenge that pharmaceutical executives will be facing is the addition of cumulative cost pressures on their operations due to changing compliance requirements globally, unexpected challenges to business continuity, market development leading to increasing supplier costs, and the potential for geopolitical upheaval. The imperative to develop a lean supply chain is significant, based on these challenges alone. Supplier compliance management was also cited as an area of focus looking forward to 2020. To preserve resources when managing supplier compliance and audits, respondents are developing their own internal capabilities, while at the same time relying on process automation and external resources. By aligning with the strongest solutions and service providers, pharmaceutical executives are gaining a higher-level view of their supply chain today, and building security and continuity for tomorrow.

Key Findings.

With the expectation of growing cost pressures, pharmaceutical quality executives must prioritize a lean supply chain that is still flexible enough to avoid continuity and security gaps.

Cost pressures are one of the defining challenges that quality executives including logistics managers face on the road to 2020. That said, an overly lean approach that doesn't account for the risks of conducting global business can quickly become a liability.

Visibility over suppliers continues to lead executives wish lists, though more may need to be done to assess geographic risks in the supply chain and other risk factors not related to compliance and quality.

Gaining visibility into supplier quality and compliance is one of the most important tasks that quality and logistics managers are engaged in, although nearly a quarter of respondents don't conduct country risk assessments when sourcing for suppliers. This may be related to the high levels of representation of European and North American markets as sources for active ingredients and excipients, however with global market development and cost pressures leading many organizations to branch out globally, it could represent significant oversight if not applied.

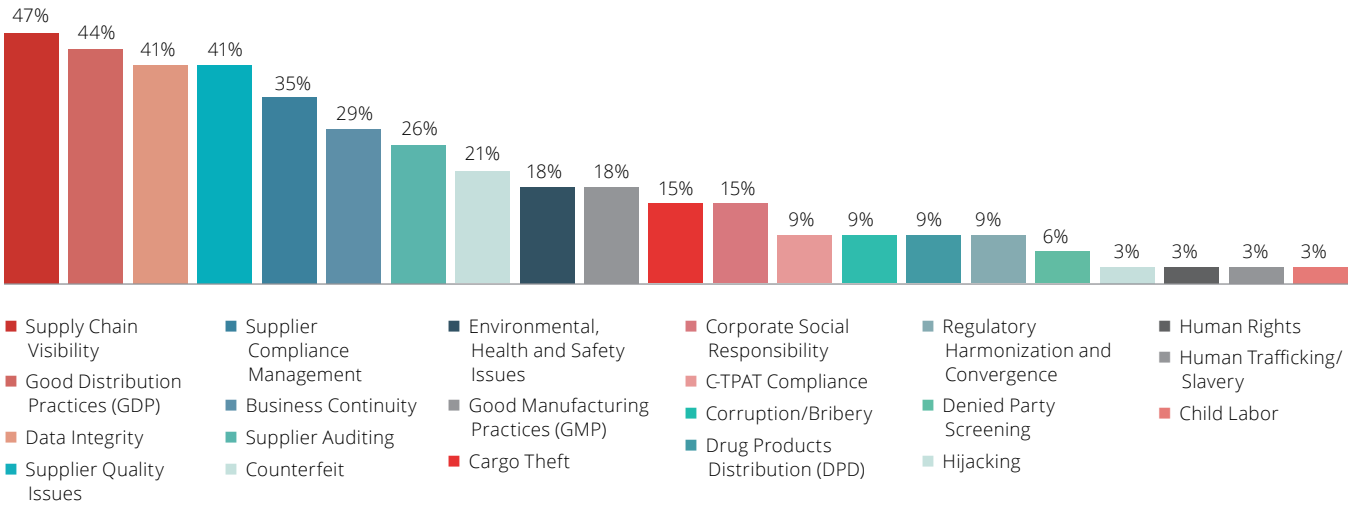
Respondents are largely planning on investing in risk management strategies leading up to 2020, and believe the solutions are in the market that can help them achieve their goals.

Despite cost pressures, respondents are willing to invest in risk management solutions that can help them meet their compliance, quality, and continuity goals in 2020. They believe overwhelmingly that the solutions they need to meet their goals are out there, so the question becomes how pharmaceutical executives choose to allocate their resources including budget to gain all the capabilities they consider that they need, while respecting a lean supply chain imperative and identifying country risk factors when seeking cost savings.

Research Analysis.

Supply Chain Risk on a Global Scale

What challenges are you currently facing related to supply chain risk and compliance management?



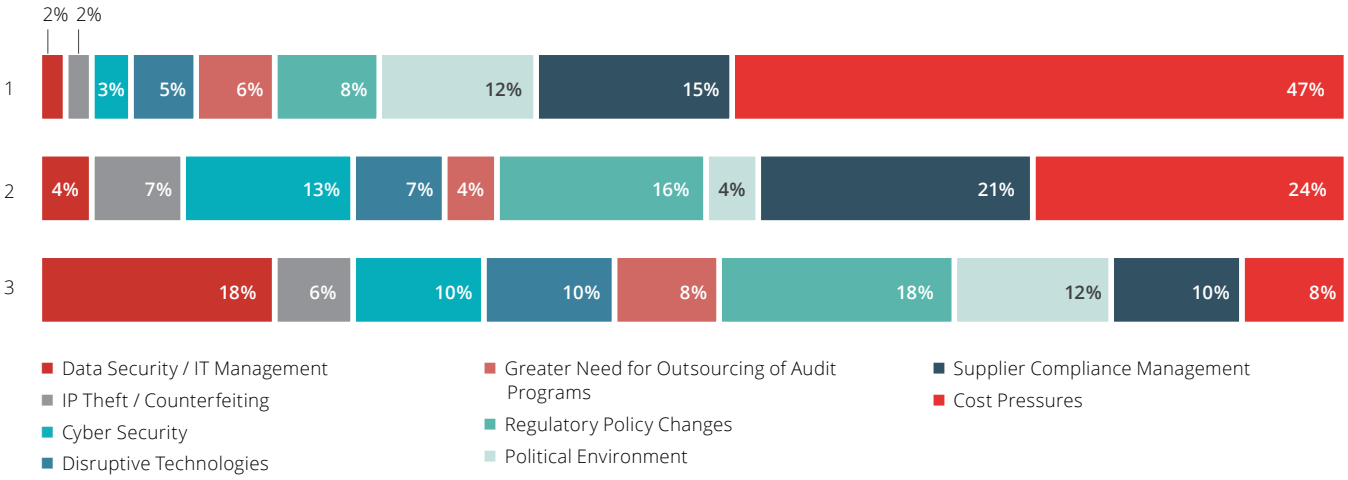
Supply chain visibility continues to be the leading challenge facing the Pharmaceutical supply chain, followed closely by meeting Good Distribution Practices (GDP) standards, as well as data integrity and supplier quality issues.

Out of a field of 21 major challenges, supply chain visibility stands out as the overarching issue that defines the roles, and displays the focus point and challenge for pharmaceutical executives. Within the top four challenges, meeting GDP requirements, data integrity, and supplier quality create a picture of an industry where regulatory requirements and standards and the complexities of global commerce make full visibility over supply chain and suppliers into the most critical metrics for success.

Ranking at number five, supplier compliance management is a complementary issue to overall quality, and is followed by business continuity, supplier auditing, and counterfeiting to round out the top eight challenges. If a supplier must be dropped due to compliance issues, the ability to pivot is critical to avoid significant disruption in operations. Supplier auditing can help identify where problem areas might be initiated, though going through an audit process presents challenges of its own. Counterfeiting of drug products presents its own problems, partly thanks to the rise of global e-commerce, with Interpol's Operation Pangea seizing 20.7 million counterfeit medicinal products in 2015 alone[1]. Complex international criminal enterprises are often able to slip their counterfeit products into the supply chain as legitimate drug products move around the world, creating another area where supply chain visibility and supplier reputation must be rigorously managed to avoid significant fallout and reputational damage.

Running the gamut from responsible manufacturing requirements and environmental, health, and safety concerns to hijacking and forced labor concerns, the truly global nature of the pharmaceutical supply chain means that risk is present at every point of articulation as medicinal products including their ingredients, raw materials and packaging materials travel around the globe.

What do you see as the next set of big challenges over the next 3 years?



Over the next three years, cumulative cost pressures are the most widely cited challenge, with supplier compliance management coming in second and regulatory policy changes in third.

While supply chain visibility is the cornerstone issue that pharmaceutical executives must come to grips with in the immediate term, cost pressure is the leading issue within their three-year challenge projections.

This is partly due to costs associated with global regulatory compliance, which in a global commerce environment can be considerable. In the face of regulation that threatens to erode profit margins, the creation of a "lean supply chain" that is cost optimized is one of the most common strategies that pharmaceutical and medical device manufacturers are assessing to cope.

The foundation of a lean supply chain is the ability to rely on highly qualified suppliers. For this reason, supplier compliance management comes to the fore as the second most pressing three-year challenge. Considering the breadth of security issues that can arise from a poorly vetted supplier relationship, strong solutions are needed to monitor for compliance within the supplier base.

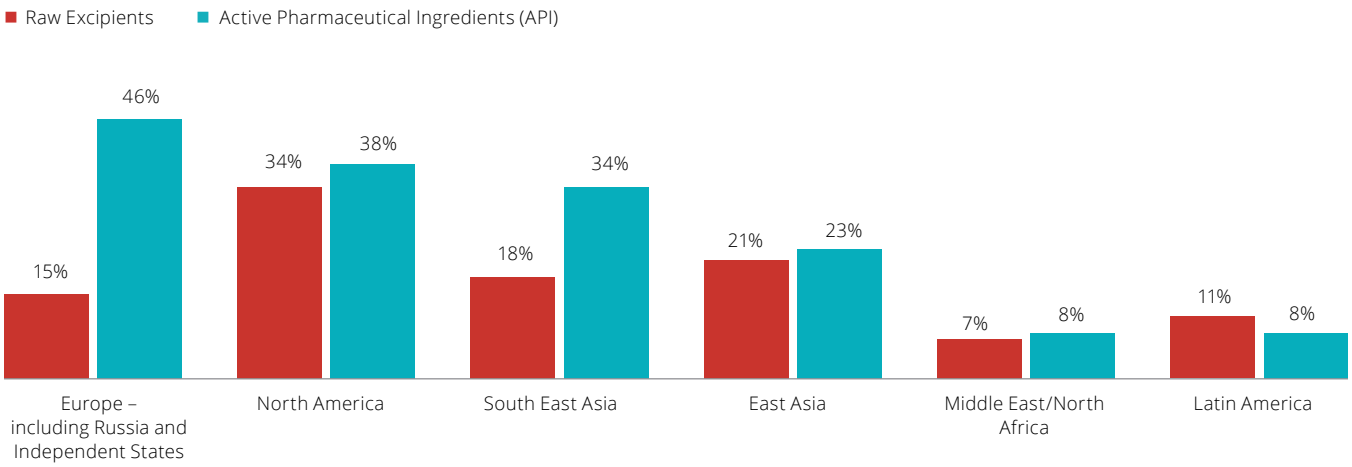
Sharing the highest ranking as a third priority, regulatory policy changes as well as data security and IT management are front-of-mind topics that regulatory affair professionals, quality managers, data analysts and IT managers need to address within the years leading to 2020. Regulatory change is a significant challenge, and with a time horizon that extends over the years, it's a virtual certainty that key markets will create regulatory changes that must be addressed. A good example can be found in serialization and traceability requirements for tracking and tracing drug products and their packaging materials, which are already rolled out or in the process of being introduced across many major international markets.

> When it comes to their most significant data integrity challenges, 28% of respondents are experiencing data security challenges, 17% are concerned with a lack of documentation, while 10% are struggling with breaking down silos.

Data security and IT management are significant, as global supply chains rely on data to track their operations and suppliers. A data breach opens tremendous material and reputational risks, and should data become corrupted, the implications for overall visibility and operational tracking can be huge.

Managing Country Risk: A Global Interplay

What part of the world do you source from for the following?



Europe and North America are the leaders in Raw Excipients and Active Pharmaceutical Ingredient (API) sourcing, though Southeast and East Asia are both fast-growing markets.

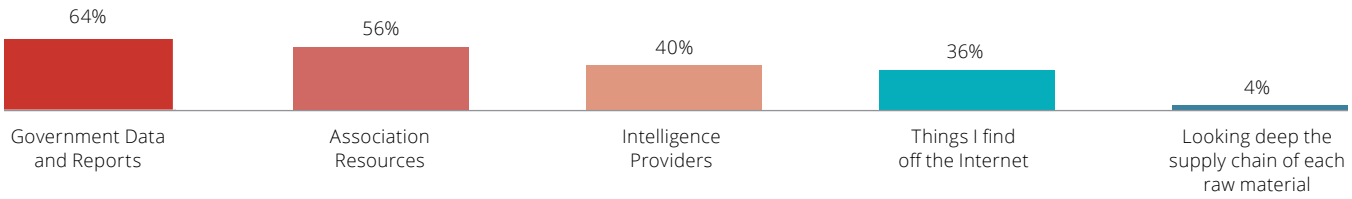
Notably, Southeast Asia is the third most common source of APIs and the fourth most common source of raw excipients, while East Asia is third for excipients and fourth for APIs. The growth of global commerce across Asia means that there are many opportunities to create a supply chain that takes advantage of favorable pricing, however there are associated risks with doing business in markets that are still developing, making supplier reliability into a major factor in procurement decisions. That said, Asia's rapid development over the past decade means that long-term investments in Asia can be focused not only on cost reduction, but also on the development of strategic growth to support servicing a robust and productive Asian market[2].

Latin America as well as the Middle East and North Africa are also developing into procurement points along the pharmaceutical supply chain, and though they are advancing and hold logistical benefits for North American – and European – based production, they are still trailing behind the significant developments in Asian markets led by powerhouse economies such as China, Japan, South Korea, and India.

Europe leads the market as the most commonly cited source of APIs, though it ranks fourth as an exporter of raw excipients. North America is the leading source of excipients and the second most common source of APIs as well. Both markets are well developed, which can account for their strong showings as sources of procurement for pharmaceutical ingredients. There may be a further benefit for these markets through mutual recognition of GMP inspections, entering into force Nov. 1, 2017[3].

> 32% of respondents feel that US FDA and EU EMA mutual recognition will have a positive impact.

What kind of country risk analysis are you utilizing to identify and evaluate high threat countries/suppliers?



"I think if you look at those first four categories that respondents are looking at for information, they are relatively passive. Government data and reports have information, but it's not personalized or targeted. It's the specialized data and analysis that people can use from intelligence providers that shows a deeper, active role on behalf of the folks monitoring supply-chain or the folks looking for information. I think people are going to the FDA and ENA websites, and looking for whatever they can find related to warning letters, compliance information, instances of supply chain disruptions or government involvement. Those tools are out there in Google and similar sites, but that's cherry-picking and not a deep enough level of analysis"

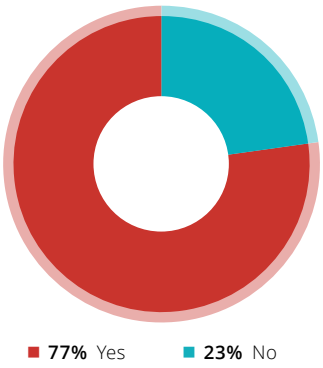
- Ben Mills, Pharmaceutical Technical Lead, BSI

Over half of respondents will use government and association resources to assess high-risk countries and suppliers.

When avoiding high-threat countries and suppliers, trustworthy information can make the difference between a sound business decision and a potentially serious misstep. For this reason, it pays to prioritize high-credibility sources. For 64% of respondents, government data is a part of their assessment process because of its ready availability as well as its accuracy and amount of broadly available information. Similarly, association resources are being used by 56% of respondents to gain a more complete picture of the markets and suppliers with which they are engaging.

This issue with these popular sources is that their approach is normally very broad and not focused specifically on how disruptions and potential risks impact the supply chain. Obtaining a more fine-tuned report on the countries or suppliers one is engaging with can be achieved by getting more in-depth research from dedicated intelligence providers. For 40% of respondents, that's among their primary methods of assessment. Rounding out these more formal strategies, 36% of respondents will conduct their own research through the internet. This method doesn't provide the level of detail and analysis needed to accurately identify high-risk suppliers. Manual search normally focuses primarily on travel security or areas outside the supply chain. Significantly, only 4% of respondents will look deep into the supply chain of each raw material that they work with, relying on research in the aggregate rather than taking the more exhaustive, yet revelatory steps of a more hands-on analysis.

Do you evaluate geographic risk when sourcing and assessing suppliers?

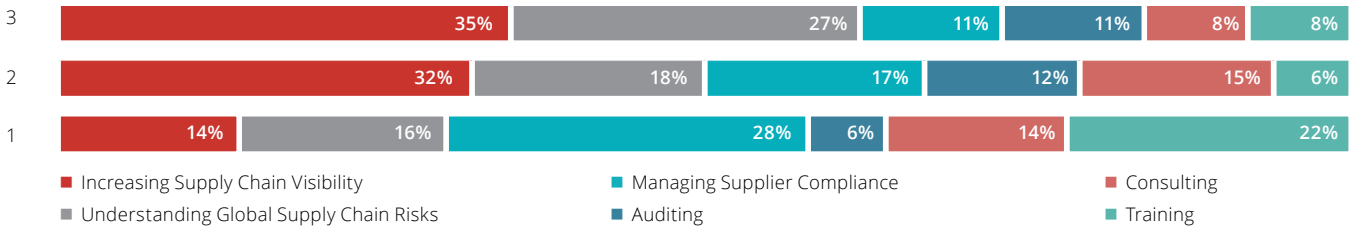


Nearly a quarter of respondents don't evaluate geographic risk when selecting their suppliers.

Another significant finding, while 77% of respondents will assess geographic risk during supplier sourcing, nearly a quarter of their peers do not. Although most respondents replied yes, that doesn't mean the level of intelligence they find or use is accurate or of the best quality. Geographic risk is a broad category that often relates to travel risk and other factors not related to the movement of goods. When leveraging intelligence to make important sourcing decisions, it's vital that you utilize a source that is credible, and focused on the supply chain. In a time with many geopolitical flashpoints across the globe, neglecting to analyze the long-term implications of every aspect of supplier partnerships can be a costly oversight.

Articulating investments in supply chain risk management today and in the near future.

Where do you see yourself investing the most money in 2017 as it pertains to managing supply chain risk?

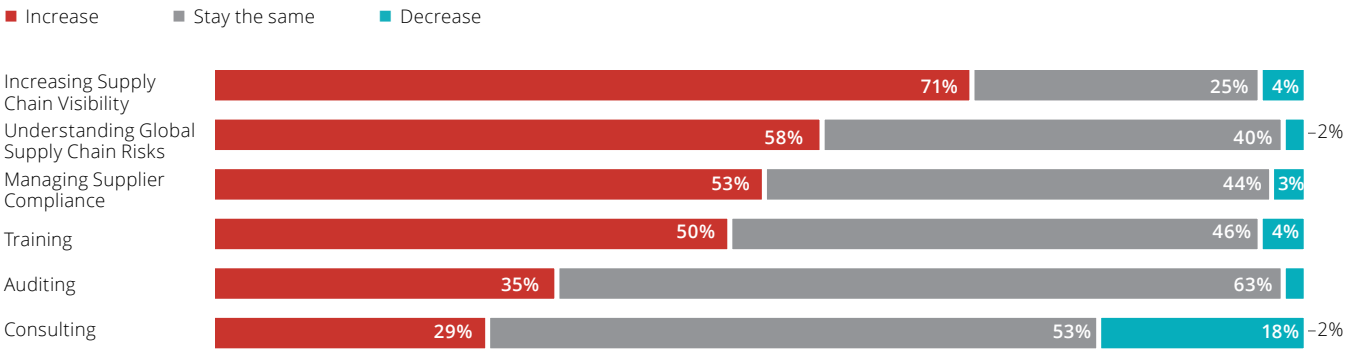


Increasing supply chain visibility is the highest ranked area of risk management investment in 2017, aligning with its status as the leading challenge facing supply chain managers.

Where supply chain managers are planning on investing in 2017 closely reflects the primary challenges that they are facing. Apart from investing in greater visibility, a broader understanding of global supply chain risk is on the wish list for respondents, with the second strongest showing. Coming in third, supplier compliance solutions are a definite priority. After doing the work of creating a supply chain that has been optimized for external risk avoidance, with clear visibility solutions in place, a non-compliant supplier can endanger the sustainability of these hard-won milestones.

> “I think that it’s critically important to understand who your suppliers’ supplier are (N-1). One of the things we find quite often is that manufacturers don’t have any insight into who their suppliers’ suppliers are, and that can be a huge risk. If there’s any material issue from those N-1 suppliers, and if there isn’t a good communication system put in place between the suppliers and their suppliers, then those issues can cause deeper impact.
>
> When we audit suppliers on behalf of pharmaceutical manufacturers, and we ask them what kind of control they have over their suppliers (N-1 suppliers), quite often we find that the control they have is substandard. They might have a supplier management program, but we find many times that they’ve never audited their suppliers.”
>
> **- Ben Mills, Pharmaceutical Technical Lead, BSI**

How do you think your spending will change by 2020 as it pertains to managing supply chain risk?



In four out of six risk management metrics, at least half of respondents are planning on increasing their investments by 2020.

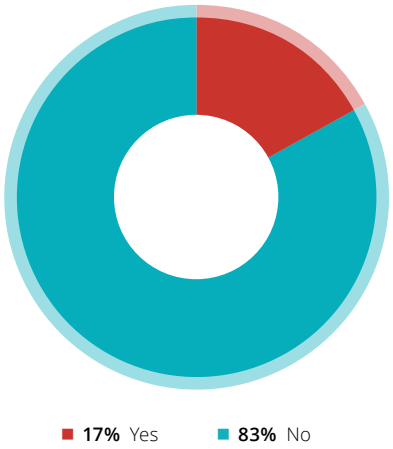
Building off where pharmaceutical supply chain managers are currently investing, their three-year plans indicate a desire to broadly develop their capabilities with regards to gaining visibility, understanding risks, then managing and training suppliers to avoid them. Over a quarter of respondents are investing in auditing and consulting, respectively. Taken all together, what can be seen is a clear desire to consolidate views of the global supply chain and a willingness to invest in developing strategic visibility and closer supplier relationships.

"A lot of manufacturers' perception is that supply chain visibility is strictly the responsibility of logistics or supply chain management. It is encouraging to see that 71% of respondents want to increase supply chain visibility. Quality and safety considerations should be of utmost importance in understanding supply chain elements."

- Ben Mills, Pharmaceutical Technical Lead, BSI

Supplier risk wish list: strengthening the independent links in the supply chain.

Do you feel there are needs that have not yet been met by third-party solution and service providers to help you identify and mitigate supply chain risks?



When it comes to supplier risk mitigation factors, most quality including logistics managers feel that the solutions they need are out there, though not necessarily in place within their organizations.

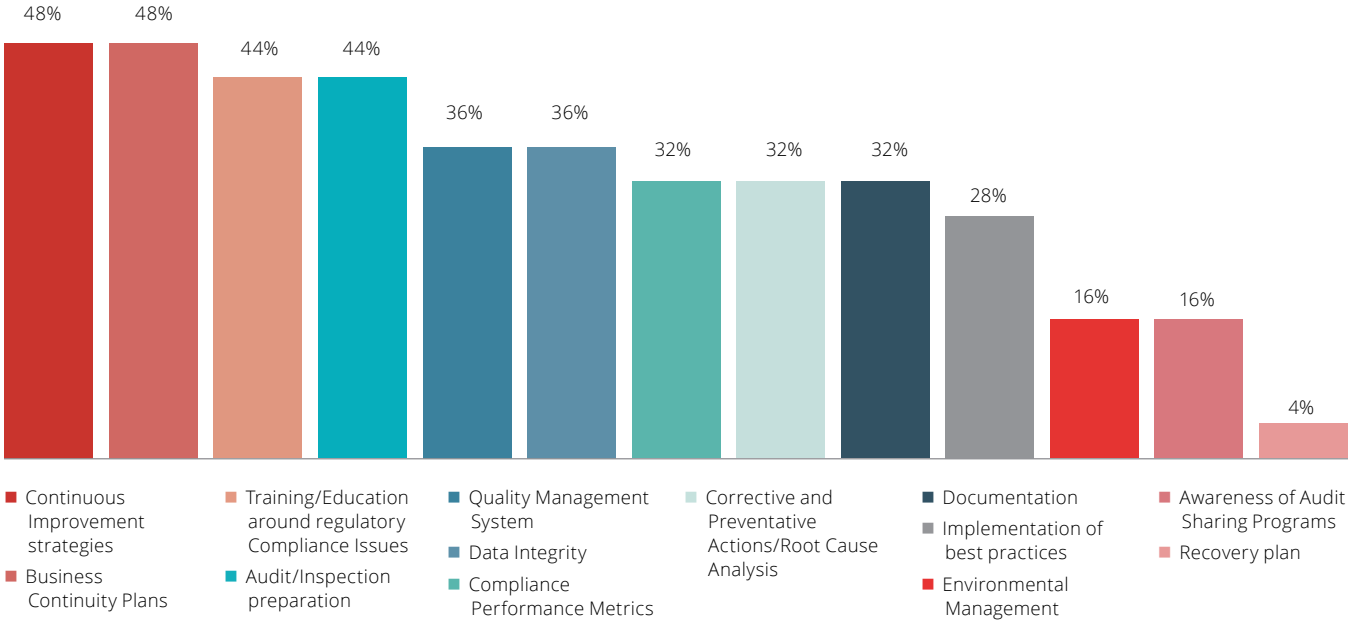
Creating visibility over the supply chain is one of the most important goals that supply chain managers are charged with. It's a goal that is part and parcel with risk mitigation in the supply chain. When it comes to the tools that can help to control risk, 83% of respondents feel that solutions providers can meet their needs and there is not a gap in the tools available to them within the market. This doesn't necessarily mean that these solutions are already in place within respondents' organizations; however, the consensus is that if implementation was unimpeded by factors such as budget or time, risk mitigation would be fully supported.

"We constantly work with procurement people to say cheapest isn't best. It ends up costing a lot more down the road if you select the cheapest option in terms of suppliers rather than getting quality partners. If you go with the cheapest quality, issues are going to arise, there's going to be remediation, and there is going to be a lot of money tied up in fixing those issues. That could be issues before the product is released, when the pharmaceutical is being released, or worst-case scenario, after the pharmaceutical is released.

Logistics are looking for the fastest way to do something and procurement is looking for the cheapest way to do something. Not that they don't have quality in mind, but it's not often a part of their search criteria. So quality management has to be included as a partner because they have the responsibility for the overall quality of the supplier materials."

- Ben Mills, Pharmaceutical Technical Lead, BSI

What do you feel your suppliers are lacking?



Business continuity plans and continuous improvement are key areas where pharmaceutical executives feel their suppliers need to make progress.

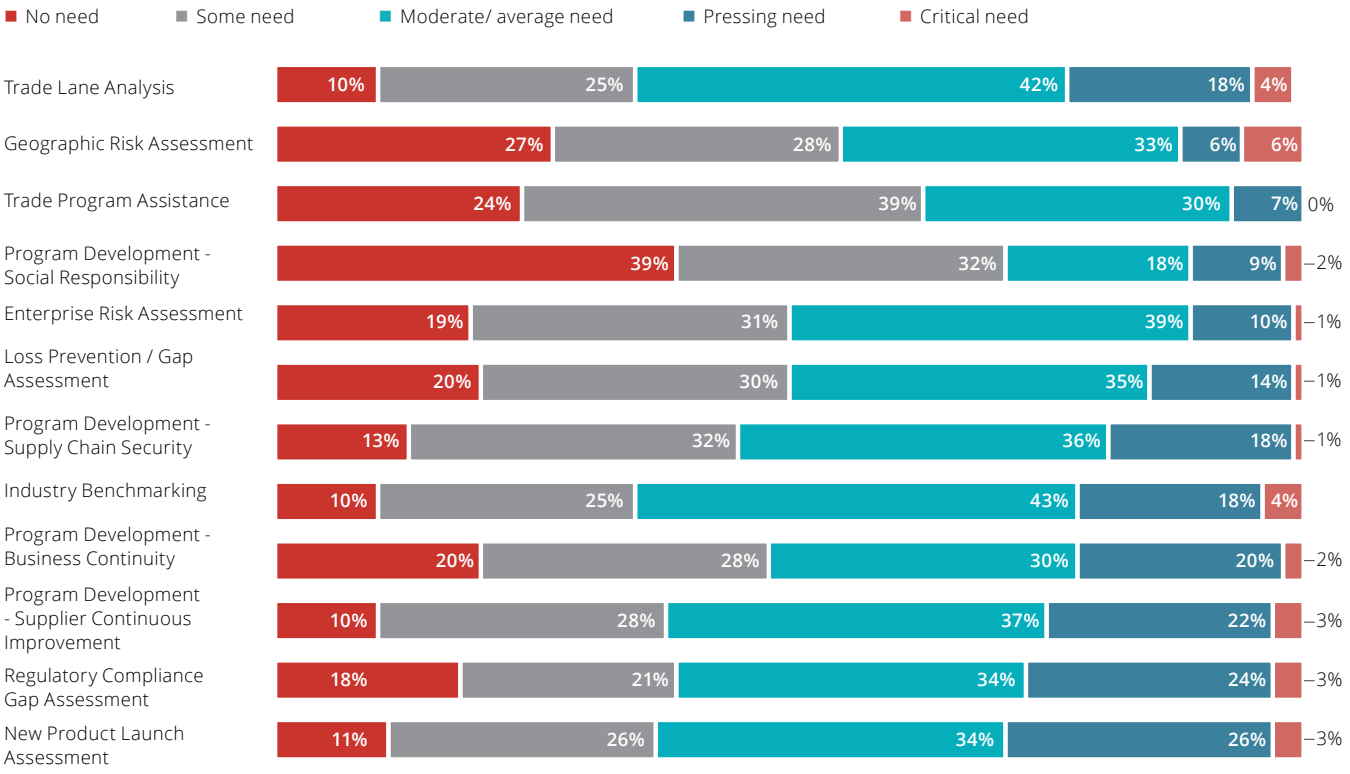
While respondents have largely confirmed that they believe the capabilities that can allow them to manage supply chain risk exist in the market, there is a long list of areas where many believe that their suppliers are currently lacking or could stand to improve. Notably, almost half of respondents felt that continuous improvement strategies and business continuity plans are metrics that their suppliers need to improve, suggesting that they want to ensure that the relationships they create with suppliers are insulated from possible business disruptions in the future. Education and training around compliance, as well as audit or inspection preparation are recognized as prevalent issues by 44% of respondents, respectively; another sign that the relationship between the organization and its suppliers is something that is being purposely emphasized for cultivation.

Quality management systems and data integrity are evenly matched as third-tier concerns, and reflect the need for solutions that can report on critical supplier activities across the global supply chain, as well as keep all data in product life cycle management complete, consistent and accurate.

Leveraging third-party solutions and expertise and protecting data integrity.

Third-party auditors and consultants have a significant role to play in risk reduction through the pharmaceutical supply chain identifying gaps in due diligence, and performing the critical work of educating and auditing suppliers for quality and compliance standards. Additionally, solutions for supplier compliance automation can add to the tool belt of supply chain managers. This allows them to extend their visibility and enforcement standards far past their manual capabilities.

For consulting, where do you see the biggest need?



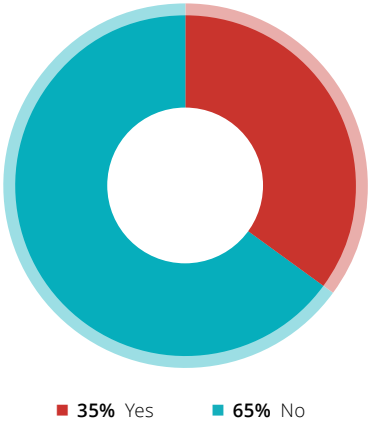
Where pharmaceutical executives see a pressing need for consulting is primarily on new product launch assessments, regulatory compliance gap assessments, and developing programs for supplier continuous improvement.

Within the pharmaceutical supply chain and product life cycle management space, third-party consultants are helping meet a broad range of needs. Where respondents are reporting the most need on average is in assessing their new product launches, understanding the strengths and weaknesses of their target markets, the threats posed by suppliers and geographic risks as well as the readiness of their products for launch.

Regulatory gap assessment, continuous improvement for suppliers, and business continuity plan development are all high-ranking priorities as well. This indicates that supply chain managers see utility in using consultants to help bring their suppliers up to their quality standards. As a risk management tool, the ability to marshal support that strengthens external links in the supply chain is vital.

Industry benchmarking is another area where 65% of respondents felt that they had at least a moderate need for assistance from consultants. Creating a clearer picture of the supply chain and the industry is one of the strengths that a consultant relationship can provide, setting up the next step of supplier coaching to conform to regulatory and business needs.

Do you outsource your audits to third-party service providers?



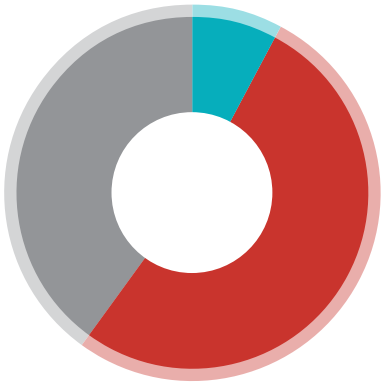
Over a third of respondents outsource their audits to third-party service providers.

Supplier audits are a necessary part of quality control for suppliers of both APIs and excipients, and as such, it's common for organizations to leverage third-party expertise to thoroughly vet the links throughout their supply chain. One of the most important capabilities of third-party audit service providers is their ability to perform on-site verification of supplier practices. Going deeper into the supply chain is a critical element of risk reduction, something that only 4% of respondents report they do already. With the trend of sourcing suppliers from developing markets, this kind of due diligence is essential and should not be overlooked.

"We're slowly and steadily seeing a shift towards manufacturers using joint audits. This is going to be necessary simply because of things such as increased governmental regulations and expectations, or suppliers not having enough staff to accommodate all the audit requests they get each year. Some of the major suppliers have people on board who specifically host audits and that's all they do, 365 days a year. Whether or not manufacturers feel like they want to use third-party audit providers, they're probably going to have to simply because leverage is moving against them in terms of those expectations and the resource drain that is impacting the supplier."

- Ben Mills, Pharmaceutical Technical Lead, BSI

How are you managing supplier compliance today?



Over half of respondents take a manual approach to their supplier compliance management.

Despite the potential to save time and resources through automation, the slight majority of respondents don't have any automation at play within their compliance management strategies. Only 8% of respondents have full automation in play, though 40% have implemented some automated processes alongside their manual processes.

The most successful supply chain managers will utilize all the visibility tools at their disposal. With the volatility of the current geopolitical landscape, as well as the virtual certainty of regulatory changes across the many markets touched by the global supply chain, cultivating transparent supplier relationships, encouraging their compliance, and helping to foster their continuous improvement are of paramount importance, which is very difficult using a completely manual system.

Key Recommendations.

Achieving closer alignment with your suppliers is at the heart of improving the supply chain.

Adopt solutions that will give you greater visibility over suppliers and help to automate compliance. Additionally, set goals for mutual development that can bring your operations more in sync. With a high degree of confidence that the solutions needed by the market are out there, it's a question of identifying the right tools and gaining internal buy-in.

With challenges around the global supply chain including theft and counterfeiting that present material and reputational risks, performing country risk assessments and engaging dedicated resources beyond what's commonly available on the internet is a vital part of supplier due diligence.

It makes sense to pursue cost savings, where appropriate, by leveraging suppliers in markets with favorable pricing. It is vital that you understand the potential threats associated with the supplier and the environment they operate in. With international trade laws set to enter a period where there is a strong possibility of Western markets exerting outsized gravity, be prepared to be flexible when seeking the most viable options for long-term success.

Preparing for the future, pharmaceutical executives are anticipating cost increases, as well as uncertainty related to an unpredictable geopolitical environment.

In the pursuit of visibility, gaining a new wealth of data is one of the most important ways forward, however this underscores new requirements for digital security. Currently, 28% of respondents are experiencing data security challenges, and that number may increase as new solutions are implemented and more points of supply chain articulation are linked. Protecting supply chain data should be approached with as much attention as is paid to ensuring that suppliers are compliant and upholding GMP standards.

Appendices.

Appendix A: Methodology

The results analyzed in this report were gathered from responses to a digital benchmarking survey delivered to the LogiPharma event database. 73 executives responded to the survey.

Appendix B: Related Research

1. Ossola, Alexandra. "The Fake Drug Industry Is Exploding, and We Can't Do Anything About It." Newsweek, 15 September 2015. Web. <http://bit.ly/1F4B6XV>.
2. "The Changing Dynamics of Pharma Outsourcing in Asia: Are You Readjusting Your Sights?" Vested Outsourcing, Second Edition, PricewaterhouseCoopers, 2008. Web. < http://pwc.to/2qBjX20>.
3. "European and US Regulators Agree on Mutual Recognition of Inspections of Medicines Manufacturers." European Medicines Agency, 02 March 2017. Web <http://bit.ly/2lBCcRL>.

About the Author.

LogiPharma is now in its 15th year and draws 300 senior executives from the Life Sciences industry responsible for the supply chain of pharmaceuticals. LogiPharma clarifies what a successful supply chain should look like in the pharmaceutical industry. The event accomplishes this through peer-to-peer teaching and networking. There is no other North American event that provides access to the senior supply-chain executives from all the top pharma companies worldwide.

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BSI (British Standards Institution) equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. From assessment, certification and training to software solutions, advisory services and supply chain intelligence, BSI provides the full solution to facilitate business improvement and helps clients drive performance, manage risk and grow sustainability.

BSI's Supply Chain Services and Solutions Group empowers organizations to strengthen their supply chain, transparency, agility and build resiliency through intelligence based solutions and services. Our services and solutions help organizations identify and assess areas of vulnerability, and develop scalable due diligence programs to protect their supply chain, brand and reputation. With our real-time geographic risk intelligence tool, SCREEN, and supplier compliance and performance improvement platform, SCM, coupled with our industry risk management advisors and global auditors, BSI provides a one stop shop for pharmaceutical executives to monitor and protect their global supply chain.

To learn more, visit www.bsi-supplychain.com

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