

Pharma Supply Chain

Challenges and Trends

Supply chain management in the pharmaceutical industry is complex and companies must address not only the common challenges of any supply chain but also a series of demanding, tightly controlled, and constantly changing regulations to obtain their raw materials, maintain a safe and continuous manufacturing process, and ensure patients get their needed medications efficiently.

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PHARMA SUPPLY CHAIN

By Rafael Vela / May 2021

Abstract

Pharmaceutical supply chain challenges have always been a major cause of concern for the industry. COVID-19 not only made the need to solve those challenges a matter of survival but also created new challenges that need immediate attention even as the world moves ahead in the era of the new normal.

The pandemic led to disruption in almost all facets of the industry. Modern companies equipped with the right tools and technologies have been quick to adjust to the changes. Organizations that still functioned on legacy systems were struggling to adapt to the changes brought about by the pandemic.

Companies that were slow to adapt had to put in more effort to understand the new demands brought by the changes imposed by the pandemic and in many cases, after understanding what was needed, the lack of the right technology and processes made the task of achieving those changes hard to attain.

Major Challenges in Today's Pharmaceutical Industry

The supply chain challenges faced by the pharmaceutical industry changed dramatically due to COVID-19. Prior to the pandemic almost everything the industry saw as serious issues impacting their operations and efficiency was suddenly substituted by a totally new set of challenges and issues.

Let us look at what the industry considers today as their most pressing challenges:

1

Preparedness for Future Disruptions – On a global scale, due to the pandemic, the transportation industry took a big hit. Ports and airports stopped operating. Trade was reduced to levels never thought possible. Production facilities everywhere shut down operations and employees were sent home indefinitely. Raw materials were scarce and when available there was no way to transport them. Supply chains in all industries were disrupted everywhere and nobody saw it coming. Nobody knew how long the situation would last and the few companies that foresaw the potential disruption were not prepared to maintain a minimum of normalcy in their operations.

2

Keeping up with Pharmaceutical Safety Guidelines and Regulations – These differ across borders and the pharmaceutical industry must be extra vigilant and alert when adhering to ALL existing safety guidelines and regulations. This supply chain challenge is hugely magnified since both, raw materials and finished products usually cross many international borders and regulations from country to country are rarely the same and keep changing constantly.

3

Managing the cold chain: Pharmaceutical products need to be transported and stored at specific temperatures, usually exceptionally low temperatures. The logistics necessary to ensure that temperatures are maintained through the entire distribution process is extraordinarily complex, full of challenges, and very resource intensive. Keeping track of all product movement and their environment (temperature, humidity, etc.) and maintain a structure capable of taking immediate action to resolve

any problem that may arise during the manufacturer-to-end user transport and storage is of extreme importance and when not done properly it costs pharmaceutical company millions of dollars.

4

Lack of integration across processes: When your inventory, manufacturing, labeling operations don't talk to each other and are manually managed, the error rate will go up and business productivity will go down.

5

Rapid drug delivery: The historical task of bringing medicines to market is a race against time. Pharmaceutical operations and supply chain management handling need to be as efficient as they come to ensure lesser bottlenecks and plausible errors in these testing times.

6

Shortage of raw material: The inability to plan effectively during the pandemic can cause many hurdles if procuring raw materials. Knowing lead times and accurate inventory quantities without a planning tool can slow you down significantly as you try to extrapolate data and understand your supply schedule.

7

Technological bottlenecks: The pharmaceutical industry has been highly apprehensive and traditional in adopting newer technologies. While the last decade has seen major leaps, there are still many bottlenecks in leveraging technologies to their full potential.

8

Real-time transparency: Pharmaceuticals need to ensure precise conditions, on-time delivery, full compliance, and stability. Visibility is crucial to be sure product shipments will turn up on time and in the right condition.

Smart Container Monitoring Systems (SCMS) are part of the answer as it allows logistics teams to view, analyze, monitor 24/7, and manage temperature, humidity, and other elements of vital shipments while they are in transit. Containers are consistently evolving to meet pharmaceutical needs however, they are only one piece of the puzzle. The drive for full end-to-end transparency of all the moving parts of the supply chain is a massive, and ongoing, challenge for pharma logistics,

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Reliability in logistics operators: As one of the most regulated, expensive, and fragile cargo markets in the world, pharma companies need to be confident that machinery is operating correctly, and the logistics can handle issues in case something goes wrong. Tech as well as skills and expertise are fundamental on every stage of the logistics process.

Reliability is also about predictability and agility. Data should allow logistics teams to map suggested delivery routes quickly and easily. Integrated systems need to connect shipping, air, overland, storage and final mile delivery to give a single view in real-time. In extreme cases, the ability to redirect cargo should be reactive to problems on the ground or even revenue opportunities, again in real-time. The industry is well on the way to delivering this, but there are still opportunities for improvement.

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Digitization: The digital wish list for pharma logistics is a long one. The digitization of documentation and standardization across industry platforms, digital signatures for regulatory documents, smart contracts, blockchain, and automation - digital can improve many areas.

The challenge for pharma companies is how to deliver changes securely, enhancing data security to protect post-COVID work environments. And how to fast-track transformation and reinvention of supply chain tools and techniques for continuous improvement in the digital world.

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Sustainability: Political pressure, shareholder intent and changing consumer behaviors have thrust sustainability front and center.

For many pharmaceutical organizations, that has meant moving from air to ocean transport as ocean transport produces less CO2 emissions compared to air. The industry faces stricter environmental controls as part of the international drive to reduce carbon emissions. But sustainability does not stop there, and any future supply chain innovation, change, or program will have to align what is good for profit and what is good for the planet.

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Risk management: Managing risks in the drug manufacturing process and quality systems is of great importance. For pharmaceutical industry players, it becomes especially important to maintain product quality therefore being able to identify risks is of utmost importance. Some of the areas to maintain always under close monitoring include:

- Suppliers' capabilities
- Availability of raw materials
- Manufacturing processes
- Quality of materials (both, raw materials and finished products)
- Resource's availability
- Market trends. Not only in pharma but in areas that could impact their operations (logistics trends, shipping companies, customs operations, etc.)
- Potential new regulations
- Development, and distribution of the product.

13

Demand forecasting: Considered one of the biggest challenges in the pharmaceutical industry players is to devise market forecasts and improve their customer service levels. Demand forecasting is an essential component for the pharmaceutical companies to stay ahead in the competition and match the supply to demand. Ensuring that all the goods are produced at the desired time and delivered seamlessly poses a big challenge to the pharma companies.

14

Price fluctuation assessment: Recent analysis of the pharmaceutical industry shows that many big players in the industry are poised to witness tough times if they fail to adapt with healthcare analytics and other data analytics trends. The pharmaceutical industry needs proper techniques to analyze pricing structures to boost profit margins. Analyzing the shifting customer behavior and fluctuating prices is one of the biggest challenges in pharmaceutical industry.

15

Product lifecycles are becoming shorter: This is due mainly to the rise of biological and genomic medicines. As a result, the market is evolving away from traditional small molecule and solid dose products towards larger bio-engineered, complex, and technical products. This is placing increasing pressure on supply chains to deliver sensitive medicines within tighter timeframes.

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Cybersecurity threats: Cybersecurity threats remain one of the most common challenges for the industry. In 2017 alone, a single pharmaceutical company suffered a **claimed \$1.3 billion loss** as the result of a single cyberattack. Despite an increasing frequency of attacks, the quality of data protection remains subpar. According to statistics, **89% of healthcare organizations** experienced data breaches with nearly half of them suffering multiple attacks each year.

The ongoing epidemic and rising costs do not help the situation. Pharma companies simply cannot focus on improving their security now.

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Remove falsified medicines from circulation. This point does not need further explanation. There is a lot of pressure worldwide on pharma for this issue as it represents a serious global health problem.

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Protect children from accidental ingestion of medicines: This is a double challenge as they must do this while making advances in senior-friendly packaging in response to ageing populations.

Major Trends in the Pharmaceutical Industry

After having a look at the most significant challenges the pharma industry is currently facing, it is clear to see that, on a global scale, the industry is struggling with numerous stress elements that have been intensified by the pandemic.

It is therefore convenient to look at some of the key trends taking place now to diminish or eliminate some of the mentioned challenges. These trends will impact and shape the industry in the short and medium term.

Trend 1

Use of Artificial Intelligence: The use of AI in the pharmaceutical industry will expand significantly covering different areas of the industry such as accelerating drug discovery and development. Other areas that will benefit from AI include clinical trials, fraud detection, supply chain) logistics tracking, procurement, etc.), quality assurance, and the overall improvement of medications, among others.

Trend 2

Integration of Blockchain Technology: As the use of blockchain technology has expanded in the financial arena, others have started to identify ways to use this innovation, including companies in the pharmaceutical industry. The primary purpose of blockchain technology is to simplify the way transactions occur while also optimizing security and transparency without requiring a third party. When used by pharmaceutical companies, blockchain technology can help with boosting efficiency by streamlining processes. This applies to transactions that involve suppliers of raw materials, quality inspection of raw materials at origin, cargo tracking and the ability to track in real time cargo location

and condition in real time, inventory management, product life cycle control of, storage, distribution, healthcare clinics, hospitals, regulators, and other stakeholders. It can also maximize the outcomes of research and development.

Trend 3

Use of Cloud Technology: This has been embraced in the pharmaceutical industry, and this is a trend that will continue. Cloud technology enables pharmaceutical companies to partner with multiple stakeholders with a greater level of effectiveness. Implementing a strong infrastructure using cloud technology also offers an opportunity to improve the integrity of data. There has been increased compliance with good practice quality guidelines and regulations because of applications used in the cloud. Just as this technology is expanding across all other industries, it will support the pharmaceutical industry's growth.

Trend 4

Greater Focus on R&D Value: There is an increased focus on the value of medications. As a result, pharmaceutical companies are more concerned than ever to ensure research and development hits the intended target. There is an effort to achieve greater effectiveness and efficiency to meet the needs of patients while also protecting the bottom line. For instance, there is research designed to identify medications that can improve the experience and quality of life for patients in a way that is more meaningful. This has required pharmaceutical companies to examine their research and development practices to ensure they are refined and focused.

These top trends are changing the pharmaceutical industry in ways that are transformative and likely to have both a short- and long-term impact. The level of innovation taking place in the industry will create tremendous value.

Trend 5

Digital Training: As is the case in other industries, employees within pharmaceutical companies and pharmacies must have a firm and updated knowledge of regulations and be able to navigate the different systems that are implemented in a way that complies with those regulations. Employees must undergo intensive and constant training to ensure the proper and efficient use of technologies in place and be prepared for the new technologies that will be adopted. Knowledge building at all levels will be fundamental to attain and maintain high productivity and overall efficiency. The use of digital platforms for training is also cost-effective because you can train personnel on-demand at anytime and anywhere.

Trend 6

Precision Medicine: This is medication produced based on a specific patient diagnosis. The purpose is to ensure the drug is tailored for optimal outcomes. The problem for manufacturers is that a smaller quantity of medication is produced, which means there is more than one treatment variation. Notably, the production of precision medicine requires facilities that are specialized and smaller than most factories. Although it has posed problems for manufacturers, this is a trend that is expected to continue as processes are refined. In fact, the number of investors that have embraced precision medicine has been higher than anticipated.

Trend 7

Smaller Production: This one comes hand in hand with precision medicine. Requires smaller manufacturing facilities, which is the opposite of facilities today for the mass production of

pharmaceuticals. There will be an increasing number of small production facilities that will produce a smaller number of higher quality medications. The main challenge is ensuring maximum profits through fast production to accommodate demands.

Trend 8

The Rise of Telehealth: Physical interaction between the patient and prescriber was the traditional form of treatment however, the pandemic has altered familiar models. 2020 gave rise to new trends in pharma marketing, such as [Telehealth](#), with software tools that allow doctors to deliver healthcare services to patients *remotely*.

According to the Future of Work 2020 IPA and BCG report, over 70% of prescribers are willing to engage with healthcare companies exclusively using digital mediums. Therefore, you should take part in the adoption of new technology in the pharmaceutical industry.

Trend 9

Migration from Europe: There is rapid growth in the market and research environment in emerging economies such as Brazil, China, and India, leading to a gradual migration of economic and research activities from Europe to these fast-growing markets. During the period 2014-2019 the Brazilian, Chinese, and Indian markets grew by 11.2%, 6.9% and 11.1% respectively compared to an average market growth of 5.4% for the top 5 European Union markets and 6.1% for the US market (source: IQVIA MIDAS, May 2020).

Important Data Regarding the Pharmaceutical Industry

In addition to the trends discussed, there is interesting data surrounding the pharmaceutical industry as shown by the statistics below:

1. The pharmaceutical industry is responsible for the research, development, production, and distribution of medications. The market has experienced significant growth during the past two decades, and pharma revenues worldwide totaled US\$1.25 trillion in 2019
2. The pharmaceutical industry is expected to increase to US\$1.5 trillion by 2023.
3. In 2019 the pharmaceutical industry invested an estimated € 37,500 million in R&D in Europe.
4. It directly employs some 795,000 people in Europe alone and generates about three times more employment indirectly – upstream and downstream – than it does directly (PwC, Economic and societal footprint of the pharmaceutical industry in Europe, June 2019)
5. On average, researchers identify one promising compound among 5,000–10,000 screened. Researchers then extensively test the compound to ensure its efficacy and safety, a process that can take 10 to 15 years for both a medicine and a vaccine.
6. Approximately 38% of industry experts expect big data to have the greatest impact in the pharmaceutical industry.
7. More than 450 medications were withdrawn over the past 25 years because of adverse reactions. This is one of the reasons why precision medicine is expected to be such an integral part of the change in the industry.
8. There are 66 biologic patents in the United States that will expire from 2021 to 2025. As a result, the FDA anticipates an increasing number of biosimilar applications.
9. Pharmaceutical companies can speed up to \$100 million per year on recalls that are linked to labeling mistakes.

Conclusion

The past few months have made pharma companies aware of the need to rethink everything, from research, sourcing, and manufacturing to distribution, passing through engagement channels, technology in place, etc. but it has also left some of them paralyzed by uncertainty. Should they invest now in transforming their process models or wait to see how things evolve?

Most of the challenges and trends are directly associated with a lack of digital maturity. Though most pharmaceuticals have yet to become digitally mature, almost half of leading companies believe they are moving in the right direction and are close to taking full advantage of the new technologies. COVID-19 accelerated many current trends in the pharmaceutical industry, chief among them being the digital transformation.

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