

Making **Pharmaceutical** **Supply Chains** More Resilient

Building a resilient supply chain framework for pharma companies requires

- 1** Understanding where the company is now, vs where they want to be.
- 2** Creating new business relationships with raw materials suppliers, transportation providers, & more
- 3** Weighing the benefits of a robust and versatile pharmaceutical value chain & the impact on working capital.

Pandemics, natural disasters, cyber-attacks, political turmoil, and other unplanned events are often well beyond a company's control.

Any one or combination of these can thoroughly disrupt a smoothly running supply chain.

Critical supply chain areas can be affected by these disruptions resulting in **reduced or non-existent access** to things like



API's & Raw
Materials



Vital Staff &
Management



Fully Functioning
Production Facilities



Transportation & Logistics
for Raw & Finished Goods

Precursor Chemicals & Supplies

“ U.S. biotech firms making medicines here get their active pharmaceutical ingredients (APIs) from U.S. suppliers..

\$86.5 billion

These precursor chemicals accounted for \$86.5 billion in the U.S. alone during 2019.

Avalere | 2020

One issue U.S. companies are facing is the location of active pharmaceutical ingredient (API) manufacturers.

According to the U.S. Food and Drug Administration (FDA), the top four regions for production include:

28%

U.S.

510 facilities for FDA regulated drugs

26%

European Union

18%

India

13%

China

230 facilities for FDA regulated drugs

Canada and the rest of the world produce the remaining 20 percent of APIs used in medicines.

Adding to the importance of having resilience in the pharmaceutical supply chain are potential supply chain disruptions caused by using overseas suppliers. **These include recalls, such as two from China cited by the FDA within the last six years.**

The FDA suggests one way to counter a dependency on foreign API supplies is by using **advanced technology to produce chemicals and medicines at lower costs.** Using the continuous manufacturing (CM) process to make finished products instead of producing batches with gaps between steps can be more effective.

Another method of reducing reliance on foreign API suppliers is using advanced technology. **Newer methods producing APIs and finished dosage forms (FDF)** helps in supply chain management in the pharmaceutical industry.

The ability to rapidly respond to changes in demand, using smaller physical footprints that require smaller facilities, helps reduce pharmaceutical manufacturing costs, potentially offsetting overseas production advantages. High tech production methods, such as those in smart factories, also tend to have lower environmental impacts.

Pharmaceutical companies looking to boost their pharmaceutical value chain using this method can get help from the FDA.

The FDA has an Emerging Technology Program (ETP) described in **“Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry.”**

The FDA is also working on a [framework to develop miniature mobile manufacturing “Pharmacy on Demand” platforms to produce essential drugs at or near the point of care](#). This method, while requiring capital costs, provides the means of eliminating delivery costs.

Risk Sources

Before making changes to the current supply chain, CFOs should look at **four primary sources of risk:**

Risk Sources

1

Sourcing of APIs and other raw materials.

Counter risk by locating and establishing working relationships with secondary suppliers.

2

Staffing and transportation

Consider access to remote workers with multiple ways to deliver finished goods to customers.

Risk Sources

3

Inventory risks.

Contrast cash flow with inventory to withstand short-term disruptions, accounting for perishability.

4

Distribution risks.

Use multiple methods to deliver finished products to customers. Consider outsourcing part of the distribution to minimize problems.

Strategic Questions

Before investing in building a resilient supply chain, CFOs need to be sure to ask the following:

How can we obtain the most accurate data on what we currently have? Is investment in today's IIoT sensors and other technology warranted?

1/5

Strategic Questions

2/5

Before investing in building a resilient supply chain, CFOs need to be sure to ask the following:

How do *our* risks integrate with risks from our third-party partners? How will a disaster impact *their* ability to supply critical products or services we **need**?

Strategic Questions

Before investing in building a resilient supply chain, CFOs need to be sure to ask the following:

What are our priorities based on what we have learned from the current pandemic? Is digitizing our data stream the top priority, or is securing a second or third API source more critical?

3/5

Strategic Questions

4/5

Before investing in building a resilient supply chain, CFOs need to be sure to ask the following:

How do we balance internal conflicts? What will we do if a secondary API source that can deliver in the event of a natural disaster is more expensive than our primary source that cannot provide when we need the raw materials?

Strategic Questions

5/5

Before investing in building a resilient supply chain, CFOs need to be sure to ask the following:

What do we consider a resilient supply chain? How much impact on near-term profitability is acceptable if we ensure that we can continue operations in the event of a significant supply chain disruption?

By the Numbers

\$16 trillion

Estimated total cost of the COVID-19 pandemic in the US alone.

\$85 million

Lost by the Nasdaq Biotech Index in the week ending March 6, 2021, It's third weekly loss in a row.

\$242 billion

Lost by the Health Care Select Sector SPDR Fund (XI,V) in the week ending March 6, 2021, bringing the total loss to date to approximately \$1.68 billion

Source: U.S. National Library of Medicine and National Institute of Health

Strategies for Greater Supply Chain Resilience

According to a recent Deloitte article, CFOs can reduce their chain disruptions and improve their supply chain resilience by using these strategies:

Identifying and mitigating their most significant supply chain weaknesses.

Questions to consider include:

- 1** Where are your API manufacturers located?
Are there alternative sources able to deliver the required quantities when needed?
- 2** Are the raw material sources within an acceptable range of the production plants?

Identifying alternative suppliers helps ensure a more continuous input of raw materials.

Strategies for Greater Supply Chain Resilience

According to a recent Deloitte article, CFOs can reduce their chain disruptions and improve their supply chain resilience by using these strategies:

Creating a playbook to handle the cause of any supply chain disruptions that occur.

Strategies for Greater Supply Chain Resilience

According to a recent Deloitte article, CFOs can reduce their chain disruptions and improve their supply chain resilience by using these strategies:

Balancing the supply chain investments with competing company requirements, such as costs and services. Deloitte cites, “managing working capital while restarting operations and rebuilding inventory as one major challenge of a supply chain disruption.”

Strategies for Greater Supply Chain Resilience

According to a recent Deloitte article, CFOs can reduce their chain disruptions and improve their supply chain resilience by using these strategies:

Prioritizing investments in the supply chain infrastructure to ensure significant delays do not occur when disaster strikes.

Technological improvements supporting product storage and movement (e.g., [Microsoft Dynamics Supply Chain Management](#)) can make processes more transparent and improve efficiency in financial transactions and information exchanges.

Strategies for Greater Supply Chain Resilience

According to a recent Deloitte article, CFOs can reduce their chain disruptions and improve their supply chain resilience by using these strategies:

Implementing updates from the standpoint of cost, speed, and efficient operation. The Deloitte report states that supply chain leaders should work with CFOs to determine the effects of supply chain changes on their working capital.

Before Making Any Decisions

Before making changes to their current supply chain, CFOs, chief technology officers, and other executives should consider the following:

1

Evaluating where the current pharmaceutical supply chain stands.

2

Analyzing the cost versus benefits of making the current pharmaceutical value chain more robust and resilient.

3

Creating a plan or series of methods for sourcing alternate raw materials, workers, and production facilities should any natural or human-made disasters strike.

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Our team is comprised of forward-thinking, experienced Subject Matter Experts (SMEs) and Technology Consultants with decades of business, industry, and regulatory experience.

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