

# **Cold Chain Integrity and Shortage Prediction Intelligence: AI-Driven Supply Chain Resilience Frameworks for U.S. Pharmaceutical Manufacturing**

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*1. Introduction, The past few decades of globalization were filled with hopes and dreams of clever market-oriented solutions to social problems, aided by advances in information technology. But the crystal-ball vision increasingly gives way to despair about stable local employment, clean air, and benign urban conditions. What happened? Where did the hopes run off track? And can today's great panacea, the internet revolution, change the outcome? In addressing these questions, this essay investigates the economic geography of market-driven planning in its local, regional, national, and international variants [1]. The main argument is that the active pursuit of free markets has displaced earlier Keynesian planning by local councils, regional authorities, and national governments. This has opened the door to a ruthless market coordination of many social and economic processes. Inevitably, various losers fall by the wayside and the growth of a dual economy often ensues. While it is easy to blame the market, the irony remains that today's crises stem from a series of public decisions to promote market-oriented social orders in the first place. The only scaling of protectionism, localism, and plan-based allocation can effectively prevent future escalation.*

Today the U.S. pharmaceutical manufacturing base is declining. Between 1990 and 2005, the number of domestic pharmaceutical establishments fell by two-thirds (from 550 to 179), with further closure plans of U.S. plants announced as recently as Q2 2016. This loss of manufacturing base led to a rising import dependence, loss of innovation, and increasing concern for the ability to ensure national drug supply in the face of global catastrophic threats. Yet, in today's pharmaceutical market, one still finds comfort in a few hundred firms worldwide that conduct up to 90% of the industry's business but operate more than 1000 firms. Facing intensified competition undermining drug prices, domestic pharmaceutical firms downsize their manufacturing base, off-shore operations, and buy-up rival firms, thus transferring the control of drugs and drug technologies to foreign competitors [2].

### **1.1. Background and Importance of Supply Chain Resilience in Pharmaceutical Manufacturing**

The pharmaceutical sector is one of the most critical industries for human life on the planet. It ensures the availability and quality of a wide range of medicinal products for population health, such as vaccines, chemotherapy, antibiotics, anesthetics, serious disease treatments, and other pharmaceuticals necessary for long-term use. In recent decades, this industry has extensively adopted supply chain globalization, and today the majority of ingredients and pharmaceuticals are produced in Asia. Large pharmaceutical companies operating in the United States import more than 80% of active pharmaceutical ingredients (APIs) and up to 95% of some dosage forms from foreign countries, such as India and China. Numerous disruptive events in recent years, including the COVID-19 pandemic and high-profile drug shortages, flu vaccine challenges, extremely difficult hurricane seasons, earthquakes, floods, and fires, have amplified the risks and vulnerabilities to health care. These vulnerabilities are often hidden, and due to the high level of supply chain complexity and length, their effect is not immediately apparent [1]. However, they have a damaging effect, resulting in the loss of millions of dollars, scarcity of vital medications, loss of patients' lives, and bioterrorism, which severely affects the country's economy and health [3].

Resilient supply chains are an important aspect of the U.S. pharmaceutical manufacturing revitalization strategy, and resilient supply chain networks need to be further developed to ensure proactive and rapid responses and adjustments to potential disruptive events. Such network redesigns often involve strategic and complex modifications, such as altering logistical flows and transportation modes, changing warehouse and facility locations, or adding new sources to exploit synergies. However, these can result in other undesired outcomes (e.g., increased costs), thus requiring careful modeling, analysis, and comprehensive decisions. Disruption events have become quite common due to various causes, such as extreme weather conditions, natural disasters, accidents, supply shortages, geopolitical tensions, terrorism, industrial espionage, sabotage, explosions, workplace violence, pandemics, and economic crises. They disrupt normal processes in all parts of the global economy and are often unexpected.

## **1.2. Role of AI in Enhancing Supply Chain Resilience**

[4]. [2].

## **2. Current Challenges in U.S. Pharmaceutical Manufacturing**

U.S. pharmaceutical manufacturing has been traditionally strong, however this has eroded over the recent decades. The most obvious recent example is the COVID-19 pandemic, which highlighted the fragility and risks in the globalized pharmaceutical supply chain. The pandemic has raised awareness about the reliance on foreign sourcing of drugs and drug components, especially those manufactured and imported from China and India.

There is an urgent need to increase the resilience of the pharmaceutical supply chain, which encompasses all aspects from raw materials to manufacturers through to distribution of drugs to hospitals and pharmacies. Recent and ongoing events such as the pandemic, hurricanes, the invasion of Ukraine, and political tensions have in different ways introduced dynamic disruptions to the supply chain that has amplified existing issues. Currently there are reported shortages of over 100 drugs (including many generics) in the U.S. Overall, the U.S. pharmaceutical supply chain is vulnerable to market manipulation, safety/risk concerns, as well as geopolitical concerns. In particular, the legislative and regulatory landscape of U.S. manufacturing has grown more complex over the years [3].

### **2.1. Dependency on Global Supply Chains**

With responsible and pay-as-you-go policies, the U.S. drug supply chain is robust for everyday expected incidents but needs to develop resilience measures for rare but catastrophic events [3]. Using input-output tables with the topologic Pharmaceutical Supply Network as an example – despite 100% cyanide in the same time zone CMO supply or remove all bioassay trial supply – large containment target area and relief risk is possible. Results rank raw materials supply chain and proposed CMO/specialty labels, and injectable ignore problematic off shore components [1]. The supply chain vulnerability analysis provides support for public decisions that are now badly needed and as critical after pandemic risk mitigation and implementation agents. Both the pandemic landscape and concurrent recent climate change disasters provide further motivation for resilience investment.

Over the past several decades emerged with the increasing cost of medicines and the escalating number of drug shortages, warning of a looming crisis in the pharmacy. Crisis prospects seem alarming as Pharma turns parasitic all pharma supplies that were once consider domestic U.S. are now import: in 1990, 70% of production was in the US, today: 95% of antibiotics pharmaceutical ingredients, 75% of all injectables. Unfortunately, poorly design production services leadership, C-SPAN last year/year public event say only thing to be done move these selfish companies back this country, and “no compelling economic argument mitigate against the most devastating risks” the company choose mass extinction over 200 companies gone.

## **2.2. Regulatory Hurdles and Compliance Issues**

Regulatory hurdles and compliance issues significantly affect supply chain management of U.S. pharmaceutical manufacturing. The pharmaceutical sector is one of the tightly regulated businesses in the world. Pharmaceutical supply chain companies must comply with a complex web of regulations that govern every aspect of their supply chain. Recent plant closures and drug shortages have raised concerns about the ability of the U.S. pharmaceutical supply chain to cope with disruptions. Increasingly, regulatory concerns have made supply chain management more complex and costly [1].

Narrowing the focus on a single type of drug or drug product will not be effective as it limits flexibility and ability to maintain a robust manufacturing pipeline/balance cash flow. The best approach for manufacturing strategy pipeline diversification is to make discrete classes of products (e.g., generics, high-volume OTC medicines, biologics, etc.) and hold multiple products from that class/manufactured in multiple plants. This also requires a strong culture of regulatory compliance and high plant inspection success rates. Understanding drug regulatory compliance issues like controlled substance handling, drug embargo restrictions, and pre-market review timelines is critical for analyzing U.S. pharmaceutical manufacturing pipeline [3].

## **3. AI Applications in Pharmaceutical Manufacturing**

Advancements in Artificial Intelligence Applications. Artificial Intelligence (AI) is a vital part of Technology Development and Development Programs offering a broad range of “intelligent” technologies, capabilities, and solutions. In general, AI applications can be grouped into a few categories such as 1) Deep Learning Algorithms; 2) Robotics Process Automation (RPA); 3) Virtual Agent Technologies; and 4) AI-based Search Technologies

and Text Analytics [5]. In general, AI technologies and mechanisms could maintain productive performance for up to 90% [6]. It is envisioned that by 2030, the global contribution of AI is expected to reach US\$15 trillion, with North America accounting for US\$6.5 trillion.

Commercial AI applications continued to grow rapidly across all industries. It is estimated that over 350 global AI vendors have been providing AI technology and solution products, targeting almost every area of industry, including manufacturing. AI-driven technology resources accumulated by technology vendors are vast and computing power can be sent anywhere (e.g. be “the cloud”) at a very small expense. Such rapid growth of AI technology and adoption has opened up many opportunities and promising prospects for industrial companies. In particular, AI applications have become a critical element and essential capability to enhance the smart manufacturing goal. As a result, various AI technology applications have been actively pursued and studied by different manufacturers and industrial companies to facilitate advanced manufacturing goals, operations, and applications. AI-driven tools and algorithms can also be designed and targeted for specific industries and support enhancement of performance in different manufacturing sectors, including Aerospace, Automotive, Electronics, Food and Beverage, Paper, Pharmaceutical & Biopharmaceutical, Steel, etc.

### **3.1. Predictive Analytics for Demand Forecasting**

Accurate demand forecasting is a vital prerequisite for pharmaceutical companies to ensure a resilient supply chain, thereby safeguarding patients’ lives and health through the provision of continuous drug availability. In a broader sense, predicting demand patterns is viewed as a predictive analytics task and preferably performed by AI-based approaches that can model non-linear and complex relationships between large amounts of historical data [7]. In the pharmaceutical industry, the demand for prescription drugs depends on many factors that reflect both customer behavior and external impacts. Drug life-cycle phases, tier drug categorization (e.g., blockbuster, specialty, or generics), or a drug’s extent of use in off-label therapy are examples of significant scenarios born from the demand side. Alternatively, even if no specification has occurred at the demand side, unexpected external impacts may lead to unpredictable patterns of demand. Price changes due to the deregulation of pharmacy benefits are past examples of such effects. The COVID-19 pandemic is arguably the most recent once-in-a-century disruption in the

industry's history, with an associated massive increase in demand for certain drugs (e.g., antibiotics, antivirals, and anesthetics) and significant drops in demand for others (e.g., drugs for elective surgeries), thereby showcasing the drastic alteration of otherwise stable patterns [8].

Fulfilling patients' prescriptions unanticipated due to such extraordinary demand scenario would call for great effort in driving production and distribution so as to contain lead-times. In contrast, prediction based upon historical data is potentially less accurate for new drugs right after their launch, drugs accompanying formulation changes, or drugs with build-to-order production policy. Additionally, omitting the impact of historical prescription data on the demand history is bound to a limit in predictive power. Robustness against operational impacts (production halts, capacity expansions, etc.) that may cause sharp drops in actual production and hence, forecasting data deprivation is also questioned. To address these challenges, the manuscript implements an AI-driven supply chain resilience framework for revitalizing the U.S. pharmaceutical manufacturing by connection with Industry 4.0.

### **3.2. Optimization of Inventory Management**

The task of automatically tracking the required inventory levels at the point of care is emerging in hospital pharmacy sector. AI application comprise forecasting drug consumption and computing order quantities and lot sizes, providing the prediction of each drug availability and automatic resupply in a fixed period [8]. Inventory management is also a strategy to mitigate supply chain risks, which can be modeled in AI. AI driven inventory management is the latest and effective way to manage supply of raw and manufactured pharmaceutical products. The usage of AI in inventory management can affect supply chain resilience. AI can be divided into types based on application: operation techniques/inventory decisions and forecasting techniques/bias computation. Operation techniques decided order quantity/lot sizes/EOQ of orders and controlled stockout thresholds. Forecasting techniques computed expected bias/availability and tracked design. Both application types of AI characterized drugs/worst cases.

Inventory management is a critical component of supply chain management that deals with the efficiency and effectiveness in scribe strategic decisions regarding stock control policies concerning order placement, replenishment quantities, safety stocks, and

stockouts [2]. The purpose of the stock control policies is to reduce pharmaceutical firms' risk of running out of some drugs to deliver and avoid the negative economic and social impact of having drug shortages. The COVID-19 pandemic illustrated how devastating a drug shortage can be for the pharmaceutical supply chain. Both the demand and supply have been significantly disturbed with sudden high demand patterns combined with stockouts incumbent of long lead times for manufacturing and shortage of active pharmaceutical ingredients (APIs). It is thus important to better understand stock control policy parameters' implication on the performance of the pharmaceuticals supply chain.

#### **4. Case Studies and Success Stories**

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##### **4.1. Implementation of AI-Driven Supply Chain Solutions in Pharmaceutical Companies**

A survey across varied pharmaceutical companies shows that many companies globally have incorporated AI-driven supply chain solutions with substantial benefits in terms of Improved Visibility and Transparency, Reduction in Surprise Factors, Improved Returns on Assets, Enhanced Inventory Efficiency, Improved Overall Supply Chain Performance, and others. Notable implementations details are presented in this section together with benefits realized [4]. An on-demand production and dispatching system was developed and implemented with capital investment of US\$ 650 K and annual operational costs of US\$ 400 K on 3-shift basis for a large vaccine manufacturing facility. The new system technology was used for a mixed-load delivery vehicle for a decentralized vaccine distribution network. This vehicle is smaller than a conventional one and temperature-controlled in compliance with US WHO recommended Good Distribution Practice for vaccines. The vehicle also has a smart monitoring system at every stage of transport and enables online tracking of both vehicle and vaccine temperature through an internet-connectible laptop or hand-held device. This vehicle could allow reducing vaccine distribution costs of 54%. Human resource training at different levels is equally important for smooth implementation of any new IT system. Some other indirect expected benefits include using the company's capacity for carrying out different clinical trials for new vaccines using the same vehicle, compliance to FDA-HQ requirements on vaccine transport guidelines, and success in international tenders

as the company would have a more technically sounded distribution network complying with international standards [5].

#### **4.2. Benefits and Key Outcomes**

The work will showcase the benefits and key outcomes derived from the AI-driven supply chain resilience solutions proposed in Transportation Research and Applications for pharmaceutical companies that have deployed them in their supply chains. A quantitative and qualitative assessment of these benefits will be undertaken, showcasing the value that the AI-driven solutions in terms of overall resilience and efficiency brought to the supply chain value chain of the respondent companies, all leading to a successful revitalization of US pharmaceutical manufacturing capabilities.

The proposed AI-driven solutions enhance the continuous monitoring, identification, and forecasting of supply chain vulnerabilities and risks, enabling the assessment of their impact on resilience level and operational performance. Their visualization on digital dashboards supports decision-makers in devising or optimizing preventive and impact-mitigating actions, including contingency plans for reacting to potential or actual disruptions. During the COVID-19 pandemic, firms improved resilience and supply chain efficiency by re-balancing pharmaceutical market demand and operational level through AI-driven supply chain mode selection. Additionally, the holistic resilience impact assessment of risk mitigation strategies leveraged AI technologies to streamline the impact of disruptions throughout the supply chain network [9].

Overall, pharmaceutical companies scored, on average, above 90% robustness and opportunity utilization regarding the operational performance benefits derived from the AI-driven supply chain resilience solutions. Benchmarking this percentage to companies encompassing European countries, where the majority of the respondents from Yaroson et al. (2018) study come from, places US pharmaceutical companies as leading firms across the globe in their supply chain efficiency evaluation space. This advantage is expected to continue promoting the revitalization of U.S. pharmaceutical manufacturing.

#### **5. Ethical and Regulatory Considerations**

The utilization of artificial intelligence (AI) methodologies in pharmaceutical manufacturing raises ethical and regulatory considerations that should be deliberated.

First, AI applications in manufacturing tend to depend on data acquired from the manufacturing process, which in turn leads to questions about data ownership and usage [10]. In particular, questions arise regarding who should own and have access to data collected throughout the manufacturing process of pharmaceuticals. Such data could contain sensitive information, especially if the pharmaceuticals are prepared on the basis of individual patients' test results. There are also concerns regarding whether data might be used inappropriately for purposes other than the initial use (e.g. used by manufacturers to "steal" formulations developed by competitors) and regarding the possibility that competitors will be able to access proprietary data if connected to external cloud servers.

Related to the above point, there are questions about data security. Unsecure communications and databases might be accessed by hackers who can manipulate data acquisition and storage/processing, with dangerous results on the quality of medications administered to patients. Regulatory institutions need to set up guidelines and firm actions that should be enforced if procedures are not followed [5]. In addition, local legal frameworks do not exist in many countries to address the above concerns, and efforts have to be made in this direction. Specific to AI, there are also concerns regarding possible bias in AI algorithms. Such biases could originate from unrepresentative training sets or from inappropriate reinforcement and corrective measures to AI faults, which might propagate these faults (e.g. a company enabling erroneous predictions on batch quality because of incorrect data registration/faulty manufacturing). There are also questions regarding the interpretability of AI recommendations (e.g. suggesting the use of certain additives and/or manufacturing procedures), which will be harder to acquired compared with traditional statistical approaches (e.g. models based on multiple linear regression, ANOVA questions). Nevertheless, regulatory authorities and the industry will have to set up means to guarantee that AI methodologies will be implemented responsibly and without putting patients at risk (e.g. establishing levels of performance and safety in AI algorithms, ensemble approaches for critical AI-based decision-making where different AI strategies should achieve converging results so that they are considered valid, and so forth).

### **5.1. Data Privacy and Security**

The rapid developments in artificial intelligence (AI) technologies offer the potential to address critical supply chain resilience issues faced by U.S. pharmaceutical manufacturers. However, such AI applications involve the handling of sensitive proprietary and customer data between corporations and their suppliers/partners. Data privacy and security concerns introduced during the installation and operating of AI systems, which typically involve elaborate external consultant support, need to be examined. A data privacy and security framework based on ISO standards is proposed to uphold the required standards in light of AI implementations.

On account of the increased digital transformation brought about by the COVID-19 pandemic and concomitant disruptions to both domestic and global supply chains, a focus on the resilience of those chains to future threats has, appropriately, taken on increasing priority [10]. Though those chains are unique to individual manufacturers, the storage and movement of materials, partly manufactured items, or finished goods not only have to comply with internal operational practices but with external regulations imposed by concerned authorities, which may vary from state to state within the U.S. and country to country globally [11]. Additionally, innovation and the introduction of advanced new technology require, at least in the short term, a consideration of appropriate change management practices and more immediate cultural change to ensure acceptance and effective application.

### **5.2. Compliance with FDA and Other Regulatory Bodies**

Compliance with FDA and Other Regulatory Bodies. When incorporating AI within any aspect of pharmaceutical manufacturing and supply chain management, one of the most critical steps is to ensure compliance with the FDA and other regulatory bodies. There are numerous regulatory standards pertaining to AI in pharmaceutical manufacturing and chain management systems that ought to be honored by all stakeholders. In the United States, the FDA regulates the use of AI in medical devices and other applications. A representative list of regulatory standards to embrace is 21 CFR Part 11, 21 CFR Part 820, 21 CFR Part 820.70, 21 CFR Part 1280, and GxP [5]. Regulatory compliance in such a dynamic and complex AI-driven system is a difficult task. It involves a tremendous effort to develop, support, and maintain a system in compliance with regulatory standards because compliance requires all relevant aspects to be known and

continuously checked to ensure conformity. Currently, regulatory compliance is commonly manually checked by an auditor based on extensive documentation. This means that the documentation acts as a clear decision basis for the auditor (in terms of compliance or non-compliance), whereas the actual system usually does not match the documentation exactly. Compliance Innovators works to develop an automated machine learning-based compliance application to automate compliance checks in GxP-compliant preclinical research industry laboratories [10].

## **6. Future Trends and Innovations**

### Blockchain Technology Integration

While the Covid-19 pandemic has exacerbated growing concerns about supply chain fragility and inefficiencies, it has also highlighted the increasing importance of maintaining wholeness through connectedness and supply chain agility [12]. Blockchain technology has emerged as a promising solution for increasing coordination and connectedness throughout the multi-tier supply chain. Specifically, it can not only provide real-time visibility of goods, process flows, and transactions along the supply chain but also offer traceability of the production, handling, and transfer of goods through a system of permissioned informational nodes. Thus, with the increasing awareness of blockchain technology benefits, prospective efforts should be made to extend the adoption of blockchain technology beyond the crucial layer of the tier-1 suppliers and brand owners.

### AI-Driven Automation

With a growing capacity of pharmaceutical manufacturing companies to collect and analyze data, the increasing role of robotics and other digital technologies all can influence supply chain future trends [4]. Due to improved predictability of human behavior, better understanding of threats, and growing importance of comfortable working conditions for personnel, independent tasks can be outsourced outside of companies. Investments into intelligent machines, devices, and other elements of digital management can strengthen the link between the real and virtual worlds. AI-driven automation can become important in terms of labor cost improvements and enhancing knowledge gained through data analysis.

### **6.1. Integration of Blockchain Technology**

The absence of transparency and trust among pharmaceutical supply chain actors may lead to compromised drug quality and counterfeiting, greatly affecting public safety [12]. One prominent technology that is considered for the integration into drugs and pharmaceuticals supply chains is blockchain, a new decentralized, distributed, and immutable ledger technology [13]. By maintaining consensus rules among multiple parties, blockchain provides high security and privacy while eliminating the need for a trusted third party. The integration of drugs and pharmaceuticals supply chain with blockchain can provide a wide range of benefits for all the actors. First, the supply chain becomes more transparent and tamper-proof. Each actor can review the entire process of medicines from suppliers to patients, especially data related to the reproduction of drugs and scandals with former medicines. All types of modifications in this chain will be visible, enabling participants to check the source of distortion. Advantages from the view of a more trustworthy supply chain are the prevention of counterfeiting, the option to connect directly to producers without intermediaries, and the lower dependency on a single actor. With software provided by the pharmaceutical industry, prescribers' and dispensary's control over their drugs from production to the patient is greatly enhanced. Establishing warning mechanisms, e.g. when purchases are made outside of physicians' or dispensers' control, contributes to upgraded drug (re)production and trade security. Overall, blockchain-based architectures enable the simultaneous use of digital contents by multiple participants without compromising ownership of the digital objects.

### **6.2. AI-Driven Automation in Manufacturing Processes**

AI-driven automation extending from storage to the entire pharmaceutical supply chain to eliminate drug shortages is at the forefront of technology adoption. AI technologies for automation have matured recently, notably Artificial Intelligence, data and data analytics, Intelligent Robots, Drones, the Internet of Things, Virtual & Augmented Reality and 5G technologies. AI in conjunction with these technologies could automate many processes in pharmaceutical supply chains including automatic picking of drugs in the store, automatic driving within warehouses, automatic routing of transportation of drugs, remote monitoring of treatments to patients, use of robotic surgeries and planning of drug development processes. All these applications could revolutionize pharmaceutical supply chain operations [5] ; [4].

## **7. Conclusion and Recommendations**

Resilience is defined as the system's ability to withstand or recover from a shock. There is no single fixed approach that companies or industries can rely on to become resilient. Resilience is a function of events and time. As shown above, certain techniques can help industries better withstand shocks, but the effectiveness of these plays can diminish over time. All of the above can be enhanced by AI technology that can help develop and widen the playbook and quickly adapt to the nuances of different shocks, such as changing economic or regulatory environments. In the clean freight sector, AI has been used to model resilience and calculate metrics that highlight opportunities for companies to deploy resilience strategies. This general approach should be deployed across other sectors to build out AI models of resilience.

Resilience should be viewed as a practice and not an end state [1]. An industry cannot be perfectly resilient. Such a state would likely require stringent limit plays that could impair competitiveness. An industry's landscape and threats are constantly evolving, making it impossible to be perfectly resilient. For example, a regulatory change could alter the strategic landscape for an industry. Or the economy could change to promote or increase certain kinds of demand shocks (potentially leading to price spikes). Moreover, a resilience playbook may lose effectiveness over time as other players adapt. For example, temporarily freezing pricing may provide advantages at first, but over time, competitors would likely match that strategy, rendering it less effective. Resilience must embrace continuous improvement and frequently revisit the playbook and its effectiveness. AI technology can extend the toolbox, provide better insights, and better understand the evolution of those plays in different circumstances [2].

### **7.1. Summary of Key Findings**

[3]. Key findings were that the PSC is somewhat unreliable, as the network reliability index is 0.919. Network capacity is a dominant factor in network performance. The sensitivity of PSC reliability to capacity is stronger for drugs with lower utilization levels. Here, the existing drug shortage risk metric excludes consideration of supply chain network structure and plan, which are variable between drugs, salient to shortage probabilities, and implementable for prioritization of medicines at risk for high shortage probabilities. The PSC structure is characterized and insights into the mechanisms behind demonstrated PSC reliability and drug shortage probabilities are offered [1]. AI-

Driven Supply Chain Resilience for Revitalizing U.S. Pharmaceutical Manufacturing: Techniques and Applications. *Concurrent Engineering: Research and Applications*, 30(2), 129-139. The U.S. pharmaceutical supply chain is significantly concentrated on foreign manufacturing operations, leading to increased reliance on foreign suppliers, instabilities in the global supply chain, shortages in critical medicines, and national strategic security concerns. To tackle the challenges, pharmaceutical supply chain competitiveness must be recovered by revitalizing manufacturing back to the U.S., enabled by emerging AI technologies of machine learning, optimization, and artificial intelligence. A systematic approach to AI-driven supply chain resilience is proposed, consisting of the evaluation of supply chain vulnerabilities, identifications of resilient reconfigurations, assessments of resilience-enhancing strategies, and optimization of supply network designs. Techniques and applications of progressing supply chain resilience methods in various industries are introduced, along with the needs to advance and generalize those technologies for enhancing competitiveness and resiliency of the U.S. pharmaceutical supply chain operations.

## **7.2. Recommendations for Implementing AI in Pharmaceutical Supply Chains**

Specific recommendations drawn from the analysis and discussions presented above are suggested for implementation of the AI/offshoring-enabled resilience building techniques in pharmaceutical supply chains. The adoption roadmap specifically designed for pharmaceutical companies is provided as a comprehensive guideline to leverage AI for fortifying the resilience and efficiency of their pharmaceutical manufacturing supply chains.

Pharmaceutical companies should firstly engage third-party data monetization platforms to curate suppliers' non-public mobility and trade flow data as shared digital resources, which can be utilized for AI modeling and analysis of trade-off performance under offshoring. Tapping into these platforms can resolve the common data accessibility challenge encountered by manufacturing companies looking to model mobility and trade flows of entities other than themselves [5]. The utilization of shared digital resources may further lower high upfront investments in data acquisition, modeling, and computing typically associated with direct engagement of companies in building their own AI/hybrid models to analyze offshoring actions.

Pharmaceutical companies should augment their curative mobility and trade flow data with public trade data and national census data to procure a robust set of comprehensive digital resources for the robust modeling of mobility and trade flows of entities other than themselves. Additionally, pharmaceutical companies should develop in-house digital twins of their digital resources and apply hybrid modeling architectures that combine knowledge-driven modeling and data-driven modeling to build robust AI models [14].

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