

API Sourcing Risk Mitigation and Regulatory-Aware Network Design: AI-Enhanced Supply Chain Resilience for U.S. Pharmaceutical Manufacturing Competitiveness

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1. Introduction, The U.S. pharmaceutical supply chain responds to adherence with the Patient Protection and Affordable Care Act (PPACA), Food and Drug Administration's (FDA) 2013 Drug Quality and Security Act (DQSA), Drug Supply Chain Security Act (DSCSA), Good Manufacturing Practices (GMP), and Generally Recognized as Safe (GRAS) status. Adverse events such as Dynamic Disruptions (DDs), so-called onshoring, have critical domestic responses from state agencies. The research question, "what is the scope of pharmaceutical supply chain vulnerabilities (PSCVs) within an U.S. state, city, area of interest (region)?" is addressed. The paper summarizes findings from a novel multi-method qualitative and quantitative empirical research framework investigating regional PSCVs within one of New York's metropolitan areas to demonstrate diverse, transferable methods [1]. Major findings identified 12 broadly applicable PSCVs comprising a set of 41 scenario-specific vulnerabilities, building upon insights into regulatory, geographic, and social structures of the organization. Determining vulnerabilities greatly improves the industry's knowledge of supply chain network dynamics through proactive visibility, which encourages the preparedness of supplying pharmaceuticals within a region. The robust set of qualitative and quantitative methods uniquely elucidating risks of answering the RQ across publicly inaccessible, proprietary databases provides multiple transferable applications to future research. To ensure consumers adhere to PSA adherence, and avoid dynamic supply chain interruptions denoted as supply chain shocks, pharmaceutical supply chains (PSC) within the United States (U.S.) have domestic responses.

Artificial Intelligence (AI) techniques have gained popularity in the multidimensional areas of supply chains since the evolvment of Industry 4.0. The supply chain risk assessment (SCRA) field has also witnessed a profound evolution through the incorporation of artificial intelligence (AI) and machine learning (ML) techniques [2]. Industry 4.0 domains provide a competitive advantage, specially designed by game changing technologies. AI and ML enhance predictive capabilities of future risk events

and focus on risk mitigation strategies. Businesses' economic resilience, elasticity, and growth are maintained and improved through operational resilience. This approach permits food, pharmaceuticals, computers, and other critical product/service supply chains to weather disruptive global events such as the COVID-19 pandemic. Robust supply chain risk management strategies are crucial in ensuring the ongoing operational resilience and continuity of supply chains. Prior reviews have outlined established supply chain risk assessment methodologies, but emerging AI/ML techniques have been overlooked.

1.1. Background and Significance

The COVID-19 pandemic highlighted a national “wake-up call” to confront supply chain challenges. Several reports have pointed out US pharmaceutical supply chain vulnerabilities (e.g., API source reliance on offshore countries, negative public image of the pharma sector, and brittle supply chains). AI-enhanced supply chain resilience is an urgent need to meet challenges in building US pharmaceutical competitiveness. AI techniques can enrich categorical knowledge to identify new correlations in monitoring real-time and in-process data. To cope with sudden interruptions like firms in Taiwan, AI can keep going on system repair, recovery scheduling, and aberrant event forecasting, improving robustness. It can also design new processes and optimize production schedules with dynamic environmental factors, enabling supply chain adaptability. The applications of AI techniques covering several areas with a focus on pharmaceutical manufacturing are reviewed. The insights and findings aim to foster collaboration between the AI community and US pharmaceutical manufacturers, aiding in designing AI-enhanced resilient manufacturing supply chains.

Historically, biopharmaceuticals, including monoclonal antibodies, proteins, polysaccharides, and nucleic acids, were affordable, safe, and effective. The success in plant-based drugs led to US FDA regulations in 1900, ensuring the safety and effectiveness of new vaccines and antibiotics. In tandem, patent laws governed creativity and incentives for drug research, created the pharmaceutical industry, and drastically changed the world of medicine. The late 1930s-early 1970s was a golden age of antibiotics and vaccines. Concerns on drug cost efficiency, efficacy, safety, and the roles of generics rose during the 1960s-1990s biogeneric litigation and scandals [3]. A firm's manufacturing location is either domestic or international. Increasingly, firms are

moving their manufacturing operations to lower-cost countries in the Asia Pacific region, increasing storages and international transportation. Concerns include loss of control over product quality, difficulties in coordination and communication delays, and knowledge leakage due to imitation by competitors [1].

2. Current Challenges in U.S. Pharmaceutical Manufacturing

There have been significant challenges arising under the COVID-19 pandemic, including a supply chain shortage of personal protective equipment. Such challenges also extend to the U.S. pharmaceutical industry [4]. U.S. pharmaceutical supply chains are exposed to vulnerabilities due to prolonged lead times and offshoring manufacturing to low-cost countries. For instance, 72% of the U.S. active pharmaceutical ingredients (API) and 89% of the generic antibiotics were produced in other countries domestic pharmaceutical suppliers cannot control. The complexity and variety of supply chain structures and pharmaceutical products contribute to the difficulties in identifying supply chain disruption risks.

The regulations imposed by the Food and Drug Administration based on the drug approval submission model may further limit a flexibility supply chain reconfiguration. Additionally, pandemic-related challenges with heavy sequential facility closures, export restrictions, and panic buying phenomena heavily affect pharmaceutical supply chains by decreasing raw materials and active ingredients availability to manufacturers [1]. The sudden demand for COVID-19 mitigation and treatment drugs raises questions for the U.S. pharmaceutical manufacturing advance and self-sufficiency. Understanding such vulnerabilities and challenges is essential for firms to develop tactics to achieve resilience.

2.1. Supply Chain Vulnerabilities

The pharmaceutical industry has considerable vulnerabilities within its manufacturing supply chain, creating a potential for adverse global and national impacts on public health in the event of disruptions to operations and services. These vulnerabilities are compounded due to the multinational nature of pharmaceutical input supply, processes and product distribution. Supply chain disruptions can occur from a number of active or passive threats, presenting both low and high probability and low and high impact outcomes for operations and services. In this regard, a number of pharmaceutical supply chain vulnerabilities have been assessed based on an existing system representation [1].

A mathematical optimal control problem framework was then employed to evaluate impacts on operations and services (measured in terms of business cost) resulting from disruptions to pharmaceutical supply chain elements.

Given the essential role of the pharmaceutical industry in public health, the development of new methodologies, technologies, policies and regulations to bolster the security of pharmaceuticals is vital at the global, national and local level. The MVC4I framework developed in this research investigation can be applied to aid authorities, organizations and individuals in assessing vulnerabilities within health supply chains and determining consequences on operations and services, allowing for the identification of possible investments to bolster chain resilience [5]. Understanding these vulnerabilities is the first step to bolstering security in the pharmaceutical industry.

3. AI Technologies in Supply Chain Management

Artificial intelligence is a general purpose technology that encompasses various quantitative techniques. In recent years, many scientific and professional disciplines have begun to explore its applicability [6]. Supply Chain Management (SCM) is one of the fields in which AI might have a considerable impact. Modern supply chains can be characterized by the VUCA notion (Volatility, Uncertainty, Complexity, and Ambiguity). This term captures the rapid pace of change and the multitude of interactions that affect supply chains. To counterbalance these challenges, AI has the potential to leverage the wealth of available data in more advanced ways than traditional supply chain management tools. As a result, it is predicted that AI will have one of the greatest impacts on the supply chains of all industries. Nevertheless, until now, only limited scholarly attention has been dedicated to the applicability of artificial intelligence in the supply chain. The aim of this research is to focus on the assessment of artificial intelligence applicability in the end-to-end supply chain with a special emphasis on the six generic components of the end-to-end supply chain: planning, sourcing, manufacturing, warehousing, distribution, and customer interface.

Machine learning and predictive analytics are expected to reshape supply chain management (SCM). These technologies' capabilities in reasoning with uncertain data and extracting actionable insights from large datasets can greatly enhance the efficiency and effectiveness of traditional SCM components [3]. Machine learning involves computers' ability to undertake specified tasks without the need for detailed

programming by humans. In general, it refers to pattern recognition and the development of classifiers or predictions based on data input. Predictive analytics refers to the use of statistical analysis methods that analyze trends and patterns to gain insight into the probability of a future outcome or event. This can be colloquially regarded as anything from simple trend extrapolation to modern machine learning techniques with deep learning neural networks.

3.1. Machine Learning and Predictive Analytics

AI technologies, such as machine learning, predictive analytics, big data, and internet of things for manufacturers to develop smart factories, factories, logistics, and warehouses to create efficiency and cut costs [6]. Machine learning and predictive analytics are specifically explored within AI technologies. Predictive analytics is primarily focused on forecasting trends in business and operations. Automatic recommendations, upgrades, solutions, and assessments of operations would be provided to decision-makers through machine learning technology, artificial intelligence-based optimization, and analytics technology. The goal is to improve the reliability and efficiency of overall supply chain management through recommendations on production scheduling, risk analysis, inventory control and management, freight selection and transport modes optimization, supply chain network management and configuration, and pricing and promotion [2].

In the manufacturing industry, smart factories and factories are constructed through the adoption of AI technology. It builds a network of the factory through big data, the internet of things, and big data analytics to monitor the chain of production machinery and equipment in real-time operation. The predictions on machine failure, its location and the timing of failure would be provided to production planners, through AI predictive analytics on data collected by the operational activities such as temperature, noise, and pressure. To create new values in pharmaceutical supply chains, AI technology is utilized as an enabler to aggregate and utilize rumors on product shortages, potential risks on products, SNS usage, and other big data along with operational data in global supply chain networks and exponential growth in SNS-related data, e-commerce and internet information would be monitored.

4. Applications of AI in Pharmaceutical Manufacturing

In USA4's effort to create a more resilient and competitive US API and pharmaceutical manufacturing ecosystem, deeptech-enabled advances in this area, AI and machine

learning, are viewed as key enablers. AI on a broader level generally offers the potential to unlock insights from data by augmenting human decision-making and automating and optimizing more processes, particularly in domains that generate or consume large amounts of data. For example, AI has been applied to manufacturing and engineering environments in areas such as process monitoring and control, predictive maintenance, and risk mitigation and impact assessment.

Outside of pharma, AI and engineering data have been widely applied in manufacturing production and operations, creating AI-enhanced digital twins that embed physics-based models inside highly automated solutions to securely connect and synthesize process, equipment, quality, and control data across the manufacturing, lab, and supply chain environments. In proactive building block approaches, AI-based failure characterization, sequence and root cause analysis, and propagating data or AI models across plants have been proposed to predict the occurrence of failures or subpar performance across assets, process tool, or operating condition spaces in advance of their impact and allow appropriate interventions to prevent them.

4.1. Predictive Maintenance

Predictive maintenance is a proactive approach to equipment maintenance that uses advanced technologies and data analysis to predict when maintenance tasks need to be performed. It aims to anticipate issues before they cause equipment failures, reducing unplanned downtime, maintenance costs, and disruptions to production processes [7]. In the pharmaceutical manufacturing context, predictive maintenance can involve monitoring the health and performance of critical machinery, such as mixing equipment, granulators, tablet presses, and packaging machines, using various data sources (e.g., sensors, historical maintenance records, and production data).

Pharmaceutical companies can leverage advanced analytics, machine learning algorithms, and Internet of Things (IoT) technologies to continuously analyze data, detect early signs of equipment wear or malfunction, and trigger maintenance actions when needed. The main inputs for predictive maintenance predictive models may include time-series data related to equipment operating conditions (e.g., temperature, pressure, vibration) and associated historical data on previous failures and maintenance events. The effective use of predictive maintenance data can lead to increased

operational efficiency, enhanced production quality, reduced risk of stockouts and recalls, minimized compliance issues, and improved worker safety [3].

5. Case Studies and Best Practices

This section presents case studies and best practices that showcase successful implementations of AI in pharmaceutical manufacturing. It offers real-world examples to illustrate the impact and effectiveness of AI-enhanced supply chain resilience.

Robust pharmaceutical supply chain planning platform using AI algorithms: Case study at Bordeaux pharmaceutical company. Industry Overview: Global pharmaceutical industry supply chain undergoing drastic changes largely driven by COVID-19 pandemic, highly competitive market, and continuous regulatory changes. However, no robust, adequate supply chain planning platform is available in the industry. Solution and Impact: Technical overview of an alternative supply chain planning solution harnessing machine learning and advanced optimization technologies to better cope with uncertainty while reducing planning efforts. Solution success illustrated by a propulsion case study within Bordeaux, a large European pharmaceutical manufacturer. Outlined supply chain planning solutions enhance agility during uncertain times and react to changing supply chain constraints [5].

AI in Pharma for Drug Manufacturing Industry Promotions. Virtual or Augmented Reality. AI (Artificial Intelligence) enhances the Sleep and Nutrition science strategies of pharmaceutical manufacturing companies. With the Augmented Reality Class-Tree-based structure, common genre drugs can be brought as an AR/VR animated overall over the page. With the digital Twin Model expansion, AI during the pandemic can save drug manufacturing interests, sharing easy pivotal investments. AI representations of a photographical and pictorial world can be used for bio-interactive subliminal dramas and playful experiments [3].

5.1. Successful Implementation Examples

Manufacturers are exploring Intelligent Manufacturing (IM) to increase productivity while gaining flexibility and customization. These new paradigms result in complex interconnected supply chains, serving as the backbone of global trade and economic development. Global Chains, fragile by design, have been severely affected by various disruptions, including the recent COVID-19 pandemic. Supply Chain Resilience (SCR) is

introduced as a characteristic of supply chains. SCR measures a supply chain network's ability to anticipate, respond to, and recover from disruption events, ensuring the continuity of material and information flows. Artificial Intelligence (AI) is becoming a modeling and decision-enhancing tool. AI initiatives can be classified by the type of technologies used, covering predictive technologies that identify patterns from existing data to help anticipate future needs, technologies that monitor and recommend interventions in business processes, and generative technologies that design new products, processes, and solutions. Wong et al. present a predictive AI model for monitoring the time-to-delivery of shipment orders using Internet of Things (IoT) data. The model has been successfully applied within Ajinomoto Co., Inc., Japan, resulting in reduced shipment delays and improving overall customer satisfaction. AI has been increasingly incorporated into response and recovery planning, risk-adjusting supply-chain network design, optimizing lot-scheduling, and inventory management [3]. Han et al. explore global supply chains via AI technologies, focusing on forecast-driven reallocation and expansion decisions. AI is used to co-design forecasts with bidding strategies and to simulate and optimize multi-stage reallocation decisions.

A pharmaceutical manufacturer integrated AI models into existing processes after validating them in pilot productions. AI tools increased material handling accuracy and combined with GIS tools to develop a spatial visibility solution. Comparing the current building layout with AI-recommended layouts improved efficiency by 16%. Validation in real production environments proved returning on investment in less than five months [8]. The models also increased yield, reduced variability, and improved operational availability, outlining a roadmap that other manufacturers can follow.

6. Impact of AI on Supply Chain Resilience

The broader impact of AI on supply chain resilience is investigated with a strong emphasis on risk mitigation for niche environments, particularly in pharmaceutical supply chain materials and external environments. Outlining the value added by AI in terms of risk mitigation is accomplished through new techniques and applications of AI to enhance resilience. AI agents tasked with risk profile identification of a niche supply chain environment show reduction in cell line clearance, entry of new therapeutic entities, patent expiration, API suppliers, and clinical candidate supply. AI implementation will aid pharmaceutical manufacturers in proactively identifying

component risks within niche environments not currently leveraged by AI to protect long-term investments.

Pharmaceutical manufacturing has been identified as one of the most vulnerable from global supply chain disruption caused by the COVID-19 pandemic and growing geopolitical tensions. The past decade has seen a streamlining of the pharmaceutical manufacturing process, yet through the past two years a dramatic event has taken place, leaving behind a legacy effect that will be extremely difficult to recover from. Previous efforts to enhance resilience in the global pharmaceutical manufacturing network have focused primarily on alternative external vendor quotations and investment diversification to regions outside of India and China. During this search, internal sources have mostly been overlooked to strengthen a manufacturer's long-term competitive advantage and narrow the impact of disrupters caused by a downstream design, while industry 4.0 technologies have taken priority. Nevertheless, pharmaceutical manufacturers are encouraged to take a step back from the active pursuit of investment opportunities in resilience-aiding technologies to conduct a fundamental review of their long-term supply chains to maintain safe growth and competitiveness [6].

6.1. Enhanced Risk Mitigation

AI effectively prevents or otherwise minimizes disruptions in pharmaceutical manufacturing supply chains through smart investment decisions, planning, and scheduling modifications. AI technologies can manage procurement decisions proactively to enhance the resilience of supply chains by identifying cost-effectiveness and reliable vendors who comply with regulatory standards. In addition, they assist supply chain partners or vendors in hedging against risk escalation (e.g., price droughts or shortages) by exploring alternative suppliers or shipment routes. Flexible long-term contracts or options with alternative vendors or shipment routes can also be negotiated by intelligent AI agents to maintain a competitive advantage while avoiding escalation [1].

AI systems evaluate the potential impacts of disruptions in operations, orders, capacity, and lead times due to disruptions at suppliers, customers, or in manufacturing. After the identification of vulnerable supply chains, smart optimization or control mechanisms effectively mitigate these impacts through planning or scheduling alterations. Considerable AI techniques were developed for the evaluation of disruption impacts,

including neuro-fuzzy and fuzzy evidential modeling. The former is an adaptive neuro-fuzzy inference system leveraging fuzzy modeling performance, incorporating a neural network for optimal parameter adjustment. Predictive AI models were also employed to determine the operational impacts of potential demand and lead-time disruptions [2].

7. Regulatory and Ethical Considerations

AI-enhanced supply chain resilience offers innovative solutions to address various challenges in the pharmaceutical supply chain. However, the adoption of AI technologies in highly regulated industries such as pharmaceutical manufacturing raises complex regulatory and ethical issues that need to be carefully considered. Regulatory considerations include ensuring compliance with data protection regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) in Europe. These regulations govern the collection, storage, and use of sensitive health-related data, and pharmaceutical companies must assess the compliance of their AI-enhanced applications. Additionally, the confidentiality of manufacturing processes is safeguarded through trade secret protections. Use of third-party service providers to collect or process sensitive data may complicate data protection compliance, requiring well-laid privacy strategies [9].

In addition to regulatory compliance, ethical guidelines must address transparency and bias challenges concerning the fairness of AI algorithms. Transparency entails providing information on the reasoning behind algorithmic decisions, including the data sources, learning process, and accuracy. Pharmaceutical manufacturers must ensure that AI algorithms driving business-critical decision-making processes are transparent to relevant stakeholders. Bias may develop when the training sets used to build AI algorithms do not accurately represent the patient or population groups the model is intended to serve. Biases can significantly impact patient care, potentially resulting in unjust treatment decisions. Thus, manufacturers must ensure that AI models are appropriately validated across demographic groups and contain relevant covariates before deployment [10].

7.1. Data Privacy and Security

There is also the specific consideration of the potent supply chain, the drugs, and implementation of AI enhanced resilience to prioritize data privacy and security from regulatory and ethical angles. The assessment of any recommended or actively

implemented changes must ask: “from whom, and for what purposes is this data collected?” [9]. How will it be secured? How have similar changes worked in the past? In the area of sensitive health information empowered and ripe for commercial exploitation it is vital to set an ethical and legal analysis pre-implementation.

The deployment of AI in pharma augmented supply chains would lead to current patient and provider concerns being considered. Many AI and non-AI technologies provide a new interface to health information for pharma and tech corporations. In general, AI is being implemented and health data obtained, manipulated, and commercialized in relation to large populations, often outside of regulatory and transparency requirements [11]. Understanding potential supply chain vulnerabilities and counterfactual risk scenarios based on non-implementation need to be understood.

8. Future Trends and Directions

The future of AI-enhanced supply chain resilience is a critical area of focus for companies looking to enhance their competitiveness. In recent years, there has been a strong interest in the application of AI and machine learning techniques to enhance the resilience of supply chains [3]. Research has shown that AI techniques can be considered to model and predict the impact of ripple effects in complex SC networks and to smartly identify and evaluate suitable resilience measures and strategies [12].

In addition, the emerging trend of Internet of Things (IoT) and AI integration is considered. On one hand, the IoT could provide supply chains with comprehensive connectivity and visibility, thus enhancing their understanding of potential risks and disruptions. On the other hand, AI, as a high-level technology for big data analysis, simulation, and cognition, could support timely modeling and forecasting of risks, as well as automation of SC processes to meet users’ adaptive needs. The infectious disease outbreak shown the importance of enhancing the resilience of SC in the pharmaceutical manufacturing sector.

8.1. Integration of IoT and AI

The integration of IoT and AI is a promising future direction of AI-enhanced supply chain resilience. IoT and AI, as two key enablers of the next industrial revolution, create synergies to enhance supply chain resilience. As a crucial domain of Industry 4.0, IoT-enabled technologies significantly collect real-time data about supply chain operational

processes, driving the genesis of big data. Considering diverse types of data flow and sources, AI, encompassing deep learning, machine learning, natural language processing, and cognitive computing, is harnessed to drive supply chain intelligence [13]. Intelligent and resiliency-enhanced supply chains are not only the focus of current research hub but also the developmental trends in the manufacturing and service industries, revolutionizing business paradigms. Within the integrated context of IoT and AI, a systematic review of 244 papers published in 2022 and 2023 is conducted, focusing on the application of AIoT in the smart supply chain. AIoT is initially introduced with its paradigm shift and associated technology trends, and the overall supply chain's areas of impact are analyzed. To explore the application scenarios, a content analysis of publication sources and industrial domains is carried out. Moreover, a brief discourse of the AIoT-enabled use cases in the healthcare industry is provided as a representative application area. As an analysis framework for the academic and industrial research communities, research gaps and future directions are proposed from the study design aspects, formulation aspects, and technology synergy aspects. Industry 4.0 is regarded as the next industrial revolution that will fundamentally reshape industrial production processes. The new ecosystem of manufacturing is characterized by the comprehensive integration of cyber-physical systems (CPS) with the real world, the widespread use of Internet of Things (IoT)-enabled sensors, and the unprecedented proliferation of big data that brings industrial-wide allocation, collection, storage, and sharing of information [3]. As a crucial domain of Industry 4.0, IoT-enabled technologies significantly collect real-time data about the operation processes of supply chains, driving the genesis of big data on diverse types and sources regarding manufacturing production scheduling, logistics transportation, facility health monitoring, equipment capacities, and so on. In this context, artificial intelligence (AI), encompassing deep learning, machine learning, natural language processing, and cognitive computing, is harnessed to drive supply chain intelligence, the core upon which supply chain operability, controllability, visibility, and manageability are realized.

9. Conclusion

Due to growing complexity, challenges, and events in today's supply chain, the resilience of the pharmaceutical supply chain in the U.S. has been put in jeopardy. As a globally leading pharmaceutical producer, it is important for the U.S. to revamp its competitive edge in pharmaceutical production. Artificial intelligence (AI)-enhanced

supply chain resilience techniques were explored, to improve the robustness and sustainment of the pharmaceutical manufacturing sector in the U.S. Industrial case studies and real-world pilot applications were used to showcase AI-enhanced supply chain techniques focused on vulnerability mapping, risk prediction, and risk analytics. Self-learning models, monitoring tools, and exploration of misinformation to mitigate compliance risks were applied to demonstrate the benefits of AI techniques in boosting supply chain resilience. Compiled findings provide avenues for future research expansion, such as multi-party cooperation in improving supply chain resilience and the exploration of generative AI in boosting resilience across the pharmaceutical supply chain [1].

Resilience in the pharmaceutical supply chain is crucial to ensure the seamless production and distribution of drugs, especially during dynamic disruptions like the recent COVID-19 pandemic. Many U.S. pharmaceutical producers are now incentivized by the U.S. government to bring back their pharmaceutical manufacturing back to the U.S. To increase the competitive edge of pharmaceutical manufacturers, pharmaceutical supply chains are in need of AI-enhanced resilience techniques to understand their vulnerability landscape, predict future risks, and leverage vulnerabilities to mitigate risks [2]. A glimpse into real-world pilot applications was provided, which include exploring misinformation to prevent frauds, self-learning models to predict potential risks, leveraging supply chain vulnerabilities to mitigate risks, and professional tools to monitor constant regulatory updates. AI-enhanced resilience techniques can help U.S. pharmaceutical manufacturers remain on their feet during tumultuous global events that may threaten the supply of essential medicines.

9.1. Key Takeaways

AI-enhanced supply chain resilience is a vital safeguard for U.S. pharmaceutical manufacturing. As the pharmaceutical industry rapidly adopts AI technologies, the integration of AI tools with supply chain resilience strategies can augment resilience and enhance competitiveness. The National Institute for Innovation in Manufacturing Biopharmaceuticals includes the adoption of AI and other Industry 4.0 technologies in the road map for biopharmaceutical manufacturing. Supply chain resilience strategies could include diversifying raw material supply sources, increasing safety stock levels, integrating supply chain partners, redesigning products and processes, and relocating

manufacturing sites [5]. Adoption of AI tools includes optimizing businesses through robotics, machine learning, big data analytics, imaging process analytics, remote monitoring, and smart sensors. AI tools could include predictive analytics, augmented/virtual reality, natural language processing, and supervised/unsupervised machine learning [1].

Automated data collection through IoT sensors and supervisory control and data acquisition (SCADA) systems is a critical precondition for the productive use of AI tools in biopharmaceutical manufacturing. The FDA-recommended Process Analytical Technology (PAT) framework identifies analytical Voice of the Process (VoP) data collection as a core component for improving product quality, process understanding, and operational efficiency. Smart data collection approaches for drug product and drug substance use VoP technologies have been used to evaluate the effectiveness of machine learning approaches.

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