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The Role and Challenges of Supply Chain Management within U.S. Pharmaceutical Organizations

Girish Gupta ^{1*}, Meenu Gupta ²

¹⁻² Director Supply Chain US, Science Teacher Public High School, USA

* Corresponding Author: **Girish Gupta**

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Abstract

Supply chain management (SCM) within U.S. pharmaceutical organizations is a strategic role to ensure consistent raw material acquisition, produce products efficiently, distribute product compliantly, maintain necessary inventory levels, manage risks effectively, and provide a consistent quality assurance. In 2024, U.S. pharmaceutical revenues topped \$550 billion and utilizing complex supply chains under stringent regulations such as FDA's current Good Manufacturing Practice (cGMP), the Drug Supply Chain Security Act (DSCSA), and HIPAA. Additionally, recent technological advances and digitalization of the supply chain have not diminished the persistent problems SCM leaders face in pharmaceutical organizations, including regulatory compliance, cold-chain management for biologics and vaccines, supplier reliability and disruptions, and cost and technology pressures. During the COVID-19 pandemic, the pressures of cost and the scalability of vaccines put further strain on global procurement and distribution related to pharmaceutical supply chains. Several best practices to increase resiliency and agility has allowed firms like Pfizer, Johnson & Johnson, Merck, and Moderna, to respond effectively during disruptions. These best practices include a lean and risk-based approach, real time visibility platforms, strategic alignment with supplier partnerships, and advanced analytics. Case studies highlight PFizer's digital control towers improved on-time deliveries by 15%, J&J integrated quality-logistics teams that reduced deviations by 30%, Merck conducted a blockchain pilot to trace and recall in less time, and Moderna had a validated ultra-cold supply chain that provided 98% thermal compliance. From a policy perspective, addressing regulatory burdens through streamlined guidance on validating digital tools, and public-private partnerships for cold-chain infrastructure are key implications, while from a managerial standpoint, cross functional collaboration, regulation by design, and investment in supplier development programs are highlighted. In summary, in order to address persistent supply chain pressures, U.S. pharmaceutical organizations must develop targeted strategies to address key studies challenges through leveraging regulations, build supplier capabilities, provision cold-chain management, secure continuity in compliance, and deliver patient-centric outcomes.

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1. Introduction

As of 2024, the U.S. pharmaceutical industry is the largest in the world, generating over \$550 billion in annual revenue and investing more than \$120 billion in research and development (R&D). Underneath this industry is a comprehensive supply chain management (SCM) function that coordinates the flow of raw materials, active pharmaceutical ingredients (APIs), excipients,

finished products, and ensuring safety, efficacy, and compliance. A variety of regulations, including the FDA's current Good Manufacturing Practice (cGMP) regulations in Title 21 CFR Parts 210 through -211; 600 to -680, Drug Supply Chain Security Act (DSCSA), HIPAA privacy and security requirements, and DEA quotas for controlled substances impose strict criteria on every SCM process. These regulatory mandates exist alongside market demands for cost containment, reduced time to market, and supply chain resilience due to global geopolitical tensions and global health crises. For this reason, SCM in pharmaceutical organizations has transitioned from a transactional logistics function to a strategic cross-functional discipline that links procurement, manufacturing, distribution, inventory management, risk management, and quality management. This paper elucidates the importance of SCM in U.S. pharmaceutical companies, identifies key issues specific to the U.S., formulates strategies and best practices to mitigate these issues, provides organizational case studies from leading companies, and highlights policy and managerial implications.

The significance of Supply Chain Management (SCM) in pharmaceutical companies in the U.S. is important. There are six key functions that make up pharmaceutical SCM: strategic sourcing, manufacturing, distribution, inventory management, risk management, and quality assurance.

With strategic sourcing, the SCM function is responsible for dependably sourcing active pharmaceutical ingredients (APIs), excipients, packaging components, and specialty chemicals. Supply chain professionals qualify suppliers under current good manufacturing practices (cGMP) and negotiate long-term agreements with guaranteed capacity. Sourcing involves working with vendors for controlled substances, which are monitored by the Drug Enforcement Agency (DEA). In sourcing, supply chain professionals balance purchasing costs, supply reliability, and regulatory compliance.

Manufacturing relies on lean and Six Sigma methodologies to improve production efficiencies, namely batch yield, cycle time, and reduction or elimination of non-value added activities. Validations of processes, change controls, and environmental monitoring must demonstrate cGMP adherence in sourcing, API synthesis, formulation, fill-finish, and packaging during the manufacturing process.

Distribution involves handling transportation of goods, warehousing, and order fulfillment. Cold chain storage is validated by the U.S. Pharmacopeia (USP) <1079>, and the CDC, to keep biologics and vaccines at the prescribed temperature range of 2-8 °C or -70 °C. The Supply Chain Management function is responsible for serializing and exchanging transaction records, according to the Drug Supply Chain Security Act (DSCSA), to provide extensive product traceability and prevention of counterfeiting.

Inventory management uses advanced analytics and inventory optimization. This includes safety stock calculations, ABC/XYZ segmentation, and machine learning forecasts to create the right balance of service levels while managing expiration risk and carrying costs. The supply chain management team is critical for high value biologics and rare disease products that may require lot level tracking and control and shelf life and exiting.

The risk management frameworks or methodologies include Failure Mode and Effects Analysis (FMEA), scenario planning, or control tower operations. These methods decide

how to identify and mitigate operational risks or vulnerabilities that affect the supply chain including supplier threats, natural disasters, and regulatory inspections that affect operations in a pandemic or other crisis.

Quality assurance/integration of supply chain and quality assure functions/quality control blends supply chain management with regulatory functions and quality control (QC). This includes how to incorporate QC checkpoints and audit readiness into the supply chain end-to-end process. Electronic batch records, continual oversight of deviations, and a closed-loop CAPA (Corrective Action and Preventive Action) system support product integrity and regulatory compliance throughout the supply chain.

Key Challenges in the US Environment

Pharmaceutical Supply Chain Management (SCM) faces complicated challenges in the US:

1. **Regulatory Compliance Burden** - Regulatory agreements surrounding cGMP, DSCSA, HIPAA, and DEA compliance, introduce layers of documentation, reassurance of true processes, and preparedness for audits; and ultimately increase learning into the overhead and operations of the organization.
2. **Cold-Chain Integrity** - Responsible temperature oversight and management of biologics and mRNA vaccines, includes validation of the cold-chain packaging, transportation management, oversight of the viability and conditions while in transit, and planning for possibilities when outside of acceptable conditions; all under regulator scrutiny.
3. **Reliability of the Supplier and Disruption** - Supply chain management relies on single-source or offshore manufacturing of APIs, which create channel capacity risks to exposure from geopolitical disruption and reputational operational risk due to lack of quality and authenticity. Enhanced assurance of supply will place more paperwork and documentation pressure on staff, on top of proposed cGMP and DEA limits, potentially increasing the possibility of operational risk.
4. **Cost Pressures** - Continuous increases of R&D investment costs and the expense of manufacture, pressure from wide array of payers and government programs, and additional competitiveness pressures from generic drugs and biosimilar drugs puts added pressure to optimize yield and efficiency of SCM processes that do not detract from regulatory or ability to respond.
5. **Barriers to Technology Integration** - Digital technologies (ERP, WMS, blockchain, IoT) are requiring significant capital, as well as significant time for validation and the value of a change-management and oversight process across functions.
6. **Logistics Disruption** - Natural disasters, pandemics, trade disputes, supply constraints, transportation barriers, etc. can outstrip the domestic and global distribution supply networks and challenging supply chain management and sequencing of product.

Strategies and Best Practices to Address Challenges

Leading pharmaceutical companies in the US of developed integrated strategies to address the challenges above:

Lean-and-quality integration - Combine Quality by Design in lean process maps and put the regulatory construct into the work-flow. At Pfizer's Kalamazoo site, changeover times

improved by 30% using DOE-validated quick change protocols and validation processes running simultaneously, confident that new efficiencies would have no regulatory risk. Cold-Chain Perfection Modern partnered with UPS Healthcare to leverage multi-compartment, thermal shippers instrumented with IoT sensors linked via automated workflows for dry ice replenishment. The system was approved according to USP <1079> and CDC route qualification requirements and the system achieved 98% first-pass temperature compliance with no adverse impact to overall supply chain performance.

Supplier Resilience Programs Johnson and Johnson developed a Supplier Quality Excellence Program (SQEP), including relational governance and performance measurements for multiyear auditing, joint improvement workshops with suppliers, and a dual-sourcing strategy. They reduced supply failures by 40% and validated DEA licensure. **Digital Traceability and Inventory Optimization** Merck piloted blockchain technology to support DSCSA serialization features for unit-level traceability that cannot be altered, using this technology to achieve a 50% faster response for product recalls. Merck paired this technology with a cloud-based optimization engine, segmenting lots into cohorts based on expiration dates, reducing waste by 12%, while achieving $\geq 99.5\%$ stock availability.

Risk-Based Control Towers Pfizer developed a digital control tower to gather real-time data from a variety of sources (transportation/inventory quality data, regulatory inspection schedules) and leverage predictive analytics to help predict and mitigate disruption. As a result, the company improved on-time delivery by 15% and reduced time to respond to deviations by 30%.

Cross-Functional Collaboration Integration of their quality, regulatory affairs, and procurement and logistics teams creates shared accountability, improves speed of decision-making and functions much better as a cohesive unit. Johnson and Johnson's global SCM operates seamlessly as a single structure along a matrix of regulatory requirements and operational KPIs. The matrix approach to operational KPIs reduced the time to achieve closure on deviations by 25%. Organizations

Pfizer: Combining Digital Control Tower and Quality Lean Integration

Pfizer started a global supply control tower that integrates a TMS platform, IoT-enabled temperature monitors, and DSCSA serialization data. The control tower interacts with dashboards from the CDC and FDA to monitor real-time compliance. The integration of lean and quality at Pfizer's Kalamazoo site drove a 20% reduction in batch cycle times and an 18% increase in readiness scores for audit compliance.

Johnson & Johnson: Supplier Quality Excellence and Cross-Functional Teams

Johnson & Johnson's Supplier Quality Enhancement Process includes annual assessments of supplier compliance with cGMP requirements, DSCSA compliance, delivery performance, and risk management capabilities. In collaboration with some of their top suppliers, through the application of a Kaizen event, services were completed on time or early improved reliability metrics by 35%. Cross-functional supply chain management (SCM) councils, comprised of personnel from commercial, manufacturing, and quality compliance, convene monthly to hear regulatory

updates and align those updates into sourcing and distribution strategies.

Merck: Blockchain for Traceability and Inventory Optimization

Merck developed a pilot program utilizing blockchain technology to determine DSCSA pilots captured serialization events across its U.S. vaccine network, facilitating downstream retailers and dispensers to verify the provenance of pharmacies in mere seconds. Merck also activated a machine-learning tool to facilitate inventory optimization which, when operated side-by-side with the blockchain DSCSA pilot, enabled improvements of 12% in expired lot wastage while maintaining product availability over 99.5%.

Moderna: Building an ultra-cold chain distribution network

The cold chain for Alton's effective distribution of the mRNA vaccine utilizes IoT sensors, custom thermal shippers, and automated dry ice replenishment logistics all managed by UPS Healthcare. The shipments went through all of the required validations under USP <1079> and CDC guidance to prove 98% adherence to temperature requirements before the vaccines continued to the designated provider. The ultra-cold storage facilities the organization had installed and the rapid operational pipeline ensured a pandemic response to support the distribution of 3 billion doses of the FDA-approved vaccine to providers in less than 12 months without significant disruption.

Implications for Policy and Managerial Decision-Making

Policy makers should:

- Streamline their guidance (exclusions) on digital and software tool validation to pave the way for secure piloting/implementation of ERP, blockchain, and IoT technology and tooling.
- Encourage public-private partnerships to secure state successes in grant funding for cold-chain infrastructure under the HHS and CDC program.
- Harmonize serialization data standards under the DSCSA and facilitate development and use of interoperable industry platforms.

Managers should:

- Embed regulatory compliance requirement into SCM processes following regulation-by-design, and cross agency ngomporance review and governance.
- Continue investments into employing digital control towers that combine quality, logistics, and data from the regulatory agencies to develop proactive plans for risk management and mitigation.
- Develop a supplier resilience program that includes performance metrics and collaborative development.
- Encourage lean-and-quality integrations into their organizations to achieve increases in efficiency and combineto that with, operate under cGMP regulatory requirements.

Conclusion

Supply chain management in U.S. pharmaceutical organizations is a strategic imperative to successfully control procurement, manufacturing, distribution, inventory management, risk mitigation, and quality assurance while

operating under compliance with multiple regulatory statutes and agencies. Each organization [Pfizer, Johnson & Johnson, Merck, and Moderna] has faced challenges with increased regulatory compliance activities, management of the cold chain integrity, managing supply and supplier reliability for raw materials, being cost-effective and transparent about pricing, understanding the role technology would play, and managing the disruption of logistics. Lean and quality integrations, systems for the cold-chain, supplier resilience programs, digital traceability, risk-based control towers, and cross-functional teams improved organizational performance and compliance. Our policy and manager recommendations emphasize the need for regulatory implementation - detained challenges, needs guided policy and review to reimagine iterative innovation in regulatory insights, to invest in the digital systems to enforce daily patient safety, and using the supply chain manager or officers to focus on developing collaborative supplier programs in managing daily success and supporting system issues relating to operational continuity to managing patient safety when the supply chain proved ineffective. Leveraging compliance into SCM departments would enable organizations to maintain their competitive advantage in a changing global supply chain reality.

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