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A DETAILED OVERVIEW OF THIRD-PARTY LOGISTICS (3PL) SERVICES, CHALLENGES AND TRENDS IN THE PHARMACEUTICALS INDUSTRY

Rohit Singhal
Supply chain consultant
Rudra Technologies Inc.
Houston, USA
rohitsinghal@outlook.com

Abstract

A Third-party logistics provider or a 3PL works on behalf of the pharmaceutical manufacturer to take over warehousing, order processing, and logistics related business processes and the respective nodes of the supply chain. 3PL companies, through their modernized IT and physical infrastructure, domain knowledge, ability to execute regulated business processes, provide a myriad of services to their manufacturing clients thereby enabling the clients to focus on their core competencies of drug development. In addition to going into details of these services, this paper also explores the current and future trends in this outsourcing relationship between the two parties as well as the challenges faced by 3PL providers in the current economic climate.

Index Terms – 3PL, pharmaceutical manufacturing, outsourcing

I. INTRODUCTION

In the dynamic world of logistics, the business relationship between pharmaceutical manufacturers and logistics providers have undergone significant evolution over the past decades. The logistics sector has come a long way from simplistic 1PL or 2PL models and has now standardized the 3PL outsourcing models with clients in various industries. To satisfy the ever-evolving needs of their pharmaceutical manufacturing clients, 3PL providers must innovate new service models, keep abreast of regulatory requirements laid down by various health agencies around the world, and develop new solutions brought forth by newer categories of pharmaceutical products. On the other hand, manufacturers must make careful assessment of their own business requirements, and the integration capabilities offered by the 3PL providers to choose the right partner for them.

II. KEY SERVICES OFFERED BY PHARMACEUTICAL 3PL COMPANIES

3PL logistics providers cater a variety of services to the specific needs of the pharmaceuticals industry. The main warehousing service provided by most 3PL companies plays a vital role in maintaining the integrity and quality of pharmaceutical products delivered to customers. These warehouses comply with stringent regulations set by health authorities in each country (such as the Food and Drug Administration in the U.S.) while adhering to the standards of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), and Good Warehousing Practice (GWP). Key requirements of these practices include procedures for receiving goods, accurate inventory management, storage temperature and humidity control, quality control

procedures, executing proper transportation management with appropriate vehicles and equipment, shipping conditions (with appropriate documentation to ensure traceability), handling procedures, and returns processing (if applicable) [4]. To deliver on these aspects, a 3PL warehouse must follow appropriate warehouse design principles, employ qualified staff, implement appropriate software systems and processes to be able to support any future audits. Thus, by partnering with a 3PL provider, pharmaceutical manufacturers can ensure regulatory compliance in the warehousing and distribution segments of the supply chain.

Foremost amongst specialized services is logistics/transportation consulting services for pharmaceutical manufacturers. Herein, 3PL partners leverage their industry wide expertise and technology to enable decision making for their clients in the areas of supply chain network design, facility/ warehouse location, transportation modes and routes and strategic sourcing. According to recent surveys by Inbound Logistics, the proportion of 3PLs offering this service has been growing with 89% of survey respondents offering this service [10].

One of the areas with the most growth potential and the most cited criticality is cold chain pharmaceuticals. According to shipping giant Mersk, medicines requiring a cold chain storage enabled supply chain are taking up increasing market share in the pharmaceuticals space, with approximately 50 percent of all planned launches in the next 5 years requiring some form of cold storage and distribution capabilities [1]. This can be attributed in majority to the heavy investments made in their respective cold chain pharmaceutical supply chains by all stakeholders namely manufacturers, wholesalers, pharmacies, healthcare institutions, transportation/ logistics providers, freight forwarders. Reports by health and clinical research company Iqvia cite that specialty immunology, oncology and antidiabetic related brands account for about three quarters of the global cold chain value. Interestingly, the rankings change when global cold chain volume is accounted for with antidiabetics, dermatology and hormones leading the way. This volume-value gap can be attributed to high value biologics products [2]. Other trends in this domain include the deployment of IoT sensors through the supply chain to monitor the real-time environmental attributes such as temperature and humidity and subsequently employ AI/ML based predictive modeling to forecast potential issues and optimize routes. Sustainability is also an emerging theme in an energy intensive pharmaceutical cold chain with the industry transitioning to more eco-friendly or solar powered based solutions.

3PL providers leverage their widespread network of transportation routes to ensure order processing, picking, packing and delivery of pharmaceutical products to customers. Traditionally, air freight has been the preferred mode of transport primarily due to the need for speed in delivering across the globe. However, ocean transport is gaining traction amongst pharmaceutical companies due to the increased amount of control this mode offers on temperature control along with the ability to act upon any changes in temperature during transport. Leading logistics providers such as Maersk offer technologically advanced remote container management solutions that enable their clients to closely monitor shipments from pickup through final delivery and to make rectifications in case of temperature fluctuations [3].

The Healthcare Distribution Management Association's (HDMA) research report "The Role of Reverse Distribution" published in 2018 makes the difficult estimate of pharmaceuticals returns amounting to 3.5 to 4 percent of all sales, which equates to more than 120 million units and a product value exceeding $13 billion. A large percentage of this returned inventory is either non-productive or may be quarantined for destruction [5]. 3PLs provide an opportunity for pharmaceutical manufacturers in this process to control costs associated with these returns though

optimization of non-productive/excess/scrap inventory processes, employing best practices and technology integrations, and ensuring proper documentation and tracking of returned product. Such recall management services enable a manufacturer to work with a customer to effectively extract defective, non-compliant products from the market, and take appropriate actions on the recalled product.

Another service that is advantageous particularly for smaller pharmaceutical manufacturers is the ability of 3PL companies to Serialize and Aggregate products to comply with The Drug Supply Chain Security Act (DSCSA) requirements. Under the 2024 DSCSA's serialization mandate, each saleable unit of a drug must be assigned a unique identifier that may represent the product's batch number, expiration date and a unique serial number. This unique identifier must be both in human readable form and machine-readable barcodes to facilitate verification by both media at various nodes in the supply chain [6]. Pharmaceutical manufacturers who work with external partners such as contract manufacturers and/ or contract packaging organizations may not have the desired level of control over serialization processes. Furthermore, they may also face high up-front investment costs to transition to the respective equipment and software required to implement serialization processes for any in-house manufacturing/ packaging operations. In a shared services supply chain model, 3PL companies can provide serialization services with the ability to disassemble non-serialized products and re-package/ re-label received products at their warehouses to meet DSCSA guidelines. Although not explicitly required by the DSCSA, some 3PLs provide product 'aggregation' capabilities as well by creating a serialized relationship between unique identifiers assigned to the individual packaging containers.

In instances where a manufacturer wants to bring emerging therapies or a new product to market faster, it is advantageous for the manufacturer to relinquish the title of the pharmaceutical goods to a 3PL company which possesses the required state and country licenses to be able to distribute the product. This may prevent time delays, lost revenue, and loss of market share to competing products since, the 3PL, who effectively owns the product and can manage the order-to-cash processes independently until the time the manufacturer acquires the licenses to take over. This model may also be employed as a long-term distribution strategy for manufacturers who intent to focus on their core competency of research and development of pharmaceutical products while still maintaining control over branding, drug product positioning and customer service [7].

III. HOW TO CHOOSE THE RIGHT 3PL PARTNER

A 3PL distribution model can benefit pharmaceutical manufacturers of all sizes. However, each organization's level of reliance on 3PL services is unique depending on the stage and size of the company. Large manufacturers with global supply chains and established logistics process may outsource certain parts of their distribution/ storage processes to 3PLs only to fill specific gaps in the existing network. They may use 3PL warehouses as overflow storage for business continuity needs in case of disruptive events, thus further bolstering the robustness of their existing supply chain. Another scenario may be where a large manufacturer acquires/develops a new product that requires specialized storage and transportation services which only a niche 3PL can provide. Mid-sized and emerging manufacturers may look to utilize 3PL services when their logistics needs exceed the capacity of their internal or existing 3PL network. An existing logistics solution may have helped mid-sized firms reach the current scale of operations but as the business adds more customers, routes, products and storage types, outsourcing to 3PLs will help the business grow

more effectively and apply economies of scale to future operations. Emerging pharmaceutical companies may be more resource conscious in the face of research and drug development priorities and may outsource large parts of their supply chains to 3PL partners. Processes such as new commercial product launches, warehousing, accounts, full scale order management, chargebacks/rebates, title model state licenses may be outsourced to leverage economies of scale, and the expertise brought forth by the 3PL [8].

However, regardless of the level of engagement, there are many factors that a manufacturer must consider when evaluating proposals from 3Pl companies.

- Accessibility and dedicated bandwidth of 3PL leadership and project teams will help a manufacturer implement projects which might have immediate priority.
- In times of high variability of supply and demand, 3PL capacity must demonstrate flexibility and scalability in terms of capacity, technology and support teams to ensure business continuity. From a long-term perspective, as the manufacturing business grows, a 3PL provider should scale their services and solutions accordingly to meet growing demands.
- Real time data accessibility, processing and reporting will help the manufacturer take stock of the current inventories and respond to real time events faster. Sales and customer care reports may help the manufacturer make strategic decisions on their distribution strategy.
- The 3PL must have a demonstrated history of successful regulatory compliance and respective governance mechanisms in place to update processes based on new laws, regulations and requirements. Excellent audit history, a National Association of Boards of Pharmacy (NABP) accreditation, Current Good Manufacturing Practice (cGMP) compliance, ISO 9001 certification, and Food and Drug Administration (FDA) registration are some of the qualifications that pharmaceutical manufacturers look for in a 3PL when evaluating for quality and compliance.
- Partnering with a 3PL company in specific healthcare niche can go a long way in developing the synergy required for a successful relationship. A niche 3PL may already possess the industry expertise, distribution strategy, storage capabilities and compliance specific to the products at hand.
- The technology landscape of the 3PL must align with the manufacturer's requirements. Advanced enterprise resource planning (ERP), customer relationship management (CRM), warehouse management systems (WMS), inventory management systems (IM), transportation management systems (TMS), electronic data interchange (EDI), order management systems (OMS) are just some of the modern platforms that enable automated, real-time operations.

Before reaching out to the larger 3PL market to invite proposals, it is recommended that a manufacturer dives deeper into the specifics of the desired distribution model specific to their business scenarios and derive all the necessary attributes such as services, regulatory compliance, technology, reporting, capacity, scalability and other requirements.

IV. CURRENT AND FUTURE TRENDS

The pharmaceutical industry continues to evolve in the face of disruptive events such as Covid-19, climate change, geopolitical conflicts and trade wars, there are several trends that 3PL companies must keep abreast of as they look to adjust business priorities for the future.

- With inflation headwinds looming strong in 2024, high distribution service fee is forcing manufacturers to look for alternative distribution models and innovative pricing mechanisms. Contracts based on subscription, health outcomes, sharing of financial risk, volume and therapeutic area are some alternates that the two parties can explore [9].
- Manufacturers continue to seek opportunities to consolidate their vendor base including 3PL partners. This implies further consolidation of services and associated prices from existing 3PLs.
- In line with the larger trend in the manufacturing space in general, pharmaceutical companies are also increasingly turning to nearshoring. 3PLs also have to adjust their physical footprint accordingly and meet customer expectations of nearshore warehousing and distribution.
- 3PLs with the ability to handle evolving distribution models such as direct from manufacturer to patient or direct from manufacturer to point of sale will thrive as retail drug chain traffic slows down.
- 3Pls are better suited to accelerate the digitization and innovation of supply chain processes supported by artificial intelligence (AI) and machine learning (ML) based applications compared to pharmaceutical manufacturers who are more focused on drug research and development. Manufacturers who partner with world-class 3PL partners will be able to foster intelligence, scalability, resilience and flexibility in their supply chains as they look to gain an edge over competition.

V. COMMON CHALLENGES FACED BY 3PL COMPANIES

Rising operational costs associated with strong inflationary headwinds, labor costs, technology implementation costs and customer retention comprise some of the top challenges for 3PL providers in the pharmaceutical industry. The complexity of the pharmaceutical supply chain combined with the strict regulatory compliance requirements lead to a need for a very specific technological framework solution deployment and, subsequently, staff that is trained and equipped to utilize the implemented technology. To stay competitive, 3PL providers must continually implement solutions in the domains of warehouse automation and robotics, mobile cloud solutions, real time automated monitoring and AI/ML enabled predictive analytics.

Another common effect of the rapid growth of the pharmaceutical industry is the growing lack of warehouse capacity. Rising real estate costs in major distribution centers around the world, the growing capacity needs of manufacturing clients and the general industry shift towards nearshoring renders challenges for 3PLs to expand. Optimization of existing warehouse business processes, implementation of automated picking and sorting equipment, vertical space utilization are some of the immediate solutions that 3PL providers are looking at.

In the domain of cold chain management, pharmaceutical 3PL companies must employ specialized infrastructure, processes and personnel to ensure regulatory compliance throughout the end-to-end process. This includes active (energy/battery powered) equipment and facilities along with passive materials such as insulants, refrigerants or phase change materials. Research shows that

while temperature excursions work well during the initial/ longer leg of transportation i.e. sea or air freight, issues occur more commonly during the last mile delivery. The high rate of failures experienced during global distribution of high-volume products such as vaccines or high value advanced therapy medicinal products is testament to this [2]. To counter these challenges 3PL companies must incorporate processes to increase robustness and accuracy of the temperature monitoring systems – regular equipment calibration, validation and maintenance, corrective and preventive action (CAPA) initiatives, and staff training. The firm must also implement detailed standard operating procedures (SOPs) for aspects such as contingency plans, temperature monitoring, and product transfers.

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