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Review Article

Pharmaceutical supply chain: The importance of outsourcing

Özlem Akbal Dağıstan[1]

[1]İstanbul University, Faculty of Pharmacy, Department of Pharmaceutical Technology, İstanbul, Türkiye.

✉ Özlem Akbal Dağıştan
ozlemakbal@istanbul.edu.tr

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ABSTRACT

A vast web of organizations, companies, and teams involved in creating, researching, and producing drugs and associated products makes up the pharmaceutical sector. In this context, the term "supply chain" refers to the network of individuals, processes, information, and resources that transform raw materials and parts into finished goods and services before being supplied to customers. The pharmaceutical supply chain system, then, offers customers medications in the right amount, at the right time, with acceptable quality, and for the lowest feasible cost. Pharmaceutical companies are increasingly contracting out their supply chain activities due to the severe push to keep R&D expenses under control. Instead of being a cost-cutting measure, global supply chain outsourcing can be seen as a strategic competitive weapon that can improve positional advantage, offer production flexibility, and meet the ever-increasing expectations of final consumers. Global supply chain outsourcing is crucial for pharmaceutical firms to enhance performance and profit margins by leveraging core skills and resources beyond other strategies which can lower risk, increase flexibility, improve returns on capital, and improve a company's ability to respond to the needs of its shareholders and consumers. Even while there is widespread recognition of the alluring advantages of global outsourcing, many of the related concerns are frequently disregarded. In addition to briefly discussing risk assessment methods, the goal of this work is to offer manufacturer-focused insight into supply chain-related outsourcing concerns within the pharmaceutical industry.

Keywords: Outsourcing, Pharmaceutical supply chain, Risk assessment, Risk management, Risk mitigation

1. INTRODUCTION

The pharmaceutical industry is a complex system that includes the processes, businesses, and groups engaged in developing, discovering, and manufacturing medications and related goods [1]. However, the pharmaceutical sector is unique in that it differs from other industries because of having unique requirements for distributing and storing various kinds of products, as well as distinct laws and regulations regarding quality standards, safety and security, and perishability of products [2]. And once more, it varies from other industries and associated supply chains of goods because of its urgency, critical state, and importance, the requirement for high levels of regulation in storage and transportation safety, general regulatory requirements that precisely define the limits and boundaries, etc. [3].

The supply chain is a network of participants, procedures, data, and assets that moves raw materials and components into completed goods and services before delivering them to consumers [3]. Customers, vendors, middlemen, and outside service providers are all included [4]. It also encompasses all production, logistics, marketing, sales, product

design, financing, and information technology-related tasks [5].To provide value for consumers and stakeholders, supply chain management, or SCM, is described as the integration of critical business operations throughout the supply chain [6]. Supply and demand are, in fact, integrated within and between businesses through supply chain management, creating an effective business model [7].

The supply chain units of a typical pharmaceutical firm can be classified as primary and/or secondary manufacturing, pharmaceutical warehouses/ distribution channels, and hospitals. Global regulations create a broad framework; however, each of the aforementioned main units also has strictly limited regulations that vary from a regulatory body perspective as well as from nation to nation locally in certain aspects [3].

Worldwide, one of the top priorities is the provision of pharmaceuticals, including drugs, treatments, and related commodities. As such, managing the pharmaceutical supply chain is becoming increasingly important compared to other supply chain networks.

To benefit all parties involved, an effective pharmaceutical supply chain (PSC) provides clients with medicines in the appropriate quantity, at the correct time, with acceptable quality, and at the best possible price [8].

The PSC should maintain regulatory compliance to ensure better and best product quality, as pharmaceutical goods, i.e., drugs, vitamins, vaccines, etc., can only have one quality, which is the best quality that can be produced at that time [9]. The PSC system has particular challenges regarding data complexity and supply chain sufficiency, which require special consideration. The PSC as a whole is made up of the need for human resources, the management of warehouses, the absence of demand information, and inventory management, all. Additionally, because their supply chains contain several goods, markets, procedures, and intermediaries, pharmaceutical companies must manage a complicated network of supply networks. Consequently, the pharma industry requires a sophisticated, high-quality approach, information exchange capabilities, and effective supply chain networks to meet customer demands [10].

Considering all challenges and needs, a primary factor contributing to PSC network insufficiency is a lack of coordination between stakeholders and supply chain participants, which can reduce overall efficiency. To simplify the global health crisis and save lives, necessary steps should be taken to improve the delivery of pharmaceutical-based products in places that require them [11].

Due to many internal and external influences, organizations must have a systematic and disciplined approach to risk management and mitigation. The risks that businesses confront are increased by the markets' ongoing growth and change, rivals, rising technology, increasingly dynamic client requirements, a reduction in response times, and the strategic use of global outsourcing [12, 13]. Pharmaceutical companies involved in outsourcing agreements should pay more attention to risk management even though it is a crucial issue in global outsourcing because of supply chain strategies' expectations. Risk management is essential for the pharmaceutical sector, given the hazards connected to supply chain logistics outsourcing [14]. "Increased shareholder value, cost reduction, business transformation, improved operations, overcoming a lack of internal capabilities, competitive advantage, improved capabilities, increased sales, improved service, decreased inventory, increased inventory velocity and turns, mitigated capital investment, improved cash flow, and other tangible and intangible benefits have made global supply chain outsourcing an increasingly attractive strategic option for businesses" [9].

The hazards attached to outsourcing in the pharmaceutical industry are expanding along with it. These risks include mistakes that could result in FDA rejection, lengthy lead times, following Sarbanes-Oxley Act requirements, complying with regulations, and protecting private information. Global outsourcing's associated risks are being managed more extensively as supply-chain tactics for the pharmaceutical business change [14,15]. Reputable multinational pharmaceutical companies

are forming risk-sharing outsourcing partnerships to share management and financial obligations to reduce operational risks associated with the costlier and risky process of discovering and developing new medications. Outsourcing can assist businesses in growing their R&D pipelines and increase the likelihood that a treatment will eventually reach the launch phase by managing risk appropriately [16].

The risk associated with the pharmaceutical supply chain endangers patients' lives in addition to wasting resources. It is imperative for health systems to evaluate and put into practice methods aimed at managing the many stakeholders in the pharmaceutical supply chain. Nonetheless, a few review studies on enterprise risk management, supply chain logistics, quality assurance, cyber security, and counterfeiting have been done in the pharmaceutical business. This work aims to provide insight into supply chain-related risks of the pharmaceutical industry from a manufacturer's perspective while briefly` mentioning the risk assessment techniques. Additionally, it focuses on the value of outsourcing for the pharmaceutical industry in terms of challenges and benefits as a risk management option.

2. OUTSOURCING IN THE PHARMACEUTICAL INDUSTRY

Nowadays, companies are concentrating more on their core competencies and outsourcing functions in which they lack the experience to survive and prosper in the competitive global economy of today, maintain efficient cost structures and increase their top and bottom lines. The decreased number of new blockbuster medications in the pipeline and competition from generic companies have caused especially original drug-producer pharmaceutical companies to examine their operations more closely to increase profit margins and shareholder value [17]. Pharmaceutical outsourcing, in particular, is now more than ever a feasible strategic business choice to obtain a competitive edge. The most prominent explanations for the rise in pharmaceutical outsourcing include lower labour and infrastructure costs, less pressure on the company to focus on drug research and development, the switch to a variable cost model, and the opportunity to obtain novel technology and expertise by working with specialized outside providers [1,12]. It is no longer necessary or crucial to have pharmaceutical R&D developers these days. The expenses of developing pharmaceuticals may severely strain a company's resources.

2.1. Outsourcing Strategies in the Pharmaceutical Industry

Despite years of growth and profitability records, the pharmaceutical industry faces difficult times as a declining rate of novel chemically based small molecules produced conventionally and decreasing R&D productivity [18,19]. Therefore, with the need to penetrate unexplored markets and improve R&D productivity and efficiency, multinational pharmaceutical companies are outsourcing more and more of their activities to contract research organizations (CROs) in Asia, especially to two forthcoming players, China and India. Pharmaceutical companies not only outsource their R&D activities but also information technology, logistics, and manufacturing services to enhance their product pipeline and obtain a tactical edge over competitors [20]. So, pharmaceutical global outsourcing has developed into a successful business strategy that allows companies to outsource non-core operations to contract manufacturing organizations and/or contract research organizations to reorganize their distribution networks, spread risks, and focus on matters that are critical to their survival, competitive advantage, and long-term growth [16,20,21].

Pharmaceutical global outsourcing is growing due to several factors, the most important of which are the competitive global marketplace, increased productivity flexibility, achieving global manufacturing presence, expanding capacity, improved asset utilization, reduced capital asset investments, and improved product quality attained through cost reduction and better focus on core competencies which triggers time to market, cost advantage, risk management, and strategic focus [22].

The pharmaceutical and biotech industries are becoming more globalized, which supports outsourcing to take advantage of the market to get

a competitive edge. Pharmaceutical companies also have realized it is impractical to have every skill set needed for a particular business. Focusing on core capabilities is an efficient and effective strategy for organizations to achieve maximum value, as flexibility has become increasingly important in the market. In fact, the number of services and operations that can be outsourced to contract manufacturing and R&D companies has increased significantly as a result of the recent growth in pharmaceutical contract services [12,14,15].

Pharmaceutical companies have been actively reviewing their financial status and, at worst, pursuing mergers and acquisitions in recent years due to growing cost pressures and a survival instinct. The pharmaceutical industry's pursuit of global outsourcing can be attributed to several key factors, including the need to streamline the drug development cycle, expand a company's capacity, consolidate the industry, gain access to specialized therapeutic expertise, globalize the market across the United States, Europe, and Asia, and capitalize on new personalized therapy options [11,12].

2.2. Supply Chain Risks in The Pharmaceutical Industry and Position of Outsourcing

Access to healthcare systems, medicines/drugs, and related goods is accepted as a basic human right and one of the major concerns of the public, healthcare systems, and governments. In connection with the pharmaceutical industry, the supply chain is a primary part of the healthcare systems in distributing drugs to patients. Risks that directly affect supply chain systems can cause waste of allocated resources and deteriorate PSC performance. Also, waste of resources has a direct effect on patients' lives. Therefore, proper identification and risk analysis are crucial, as they could affect life/death conditions, in designing strategies to minimize the risks in the PSC.

According to the European Medicines Agency (EMA), which sets standards for Quality risk management and defines the related frame, "Risk is defined as the combination of the probability of occurrence of harm and the severity of that harm. However, achieving a shared understanding of risk management among diverse stakeholders is difficult because each stakeholder might perceive different potential harms, place a different probability on each harm occurring, and attribute different severities to each harm. About pharmaceuticals, although there are a variety of stakeholders, including patients and medical practitioners as well as government and industry, protecting the patient by managing the risk to quality should be considered of prime importance." [23]

One way to characterize supply chain risk is "any risk to the information, material and product flow from original suppliers to the delivery of the final product" [24]. A worldwide supply network is susceptible to several hazards [9]. These risks include disruptions in supply, delays in supply, variations in demand, price changes, and volatility in currency rates. Three categories of business risks are identified as arising from labour concerns in suppliers: "cost risk, operational risk, and reputational risk." In this way, "the ability to react rapidly to assure continuity" is the aim of supply chain risk management, or SCRM which is also a significant and essential component of a working pharmaceutical supply chain [25, 26]. Supply chain risk can also be described as "the process of identifying and managing supply chain risk utilizing a coordinated strategy among supply chain participants."[27]. To lower and manage the likelihood and effects of unfavourable events, it is crucial to recognize, evaluate, and rank every risk [28]. Concerning the supply chain literature from the standpoint of pharmaceutical enterprises, Two primary categories of supply chain can be distinguished regarding uncertainty and risk in the pharmaceutical industry as internal and external risks (Figure 1) [16].

Internal uncertainty and risks can be briefly defined as "the risk related to operations uncertainty and risk, financial uncertainty and risk, and quality-related uncertainty and risk", whereas internal operations uncertainty and risk may refer to "unexpected events, outcomes, and/or accidents during the internal processes, they mainly occur within pharmaceutical firms, such as errors in decision-making, quality issues, machine failure, mistakes, unexpected costs, etc." [16]. Since pharmaceutical products are highly regulated goods that fall under the jurisdiction of public regulatory bodies, quality-related uncertainty,

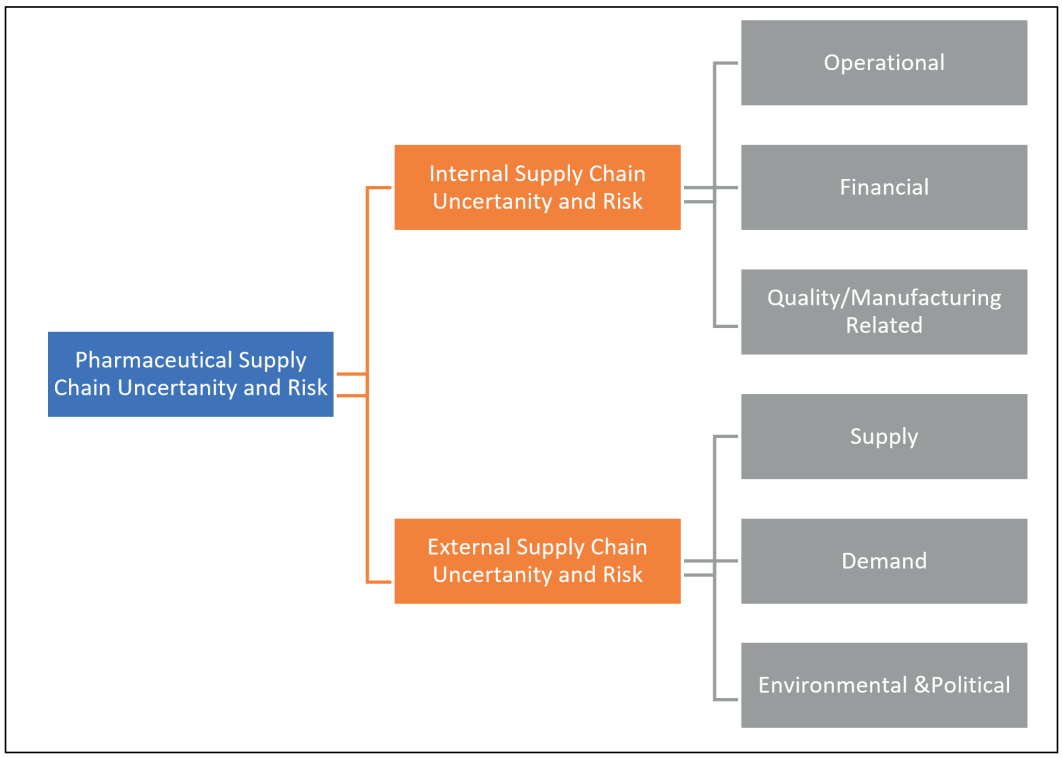

Figure 1. Types of supply chain uncertainty and risk from the pharmaceutical company perspective [16].

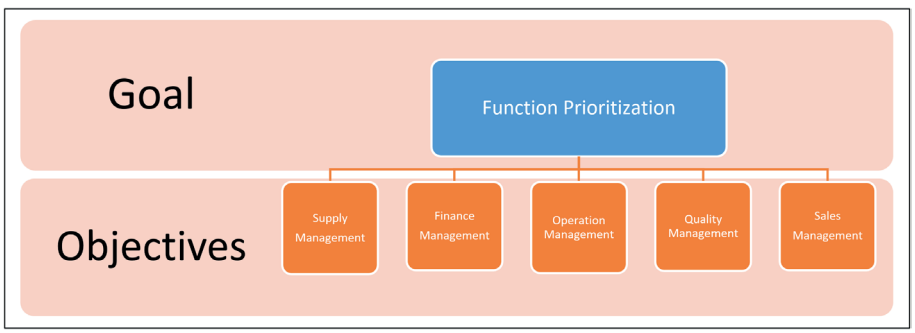

Figure 2. The hierarchy structure of PSC [31].

and risk have received increased attention due to the significance of the finished product and its direct impact on human life. Three primary components make up external uncertainty and risk as well: supply, demand, and environmental uncertainties and risks [29]. Furthermore, because poor nations often experience social, political, and economic unrest, the supply of medications is fraught with additional risks and vulnerabilities such as counterfeit drugs, unavailability of certain drugs, and so on. Over time, pharmaceutical companies may encounter a range of obstacles and hazards, including those related to operations, politics, economics, culture, environment, and ethnicity. [30]. The hazards associated with the pharmaceutical supply chain are examined by using the supply chain functions as a "hierarchy, which includes supply, finance, operation, quality, and sales management" (Figure 2).

Pharmaceutical companies are beginning to understand the possible financial benefits of contracting out non-core supply chain tasks to other parties. In addition to the benefits of outsourcing from a strategic, financial, organizational, and operational

standpoint, there are certain hazards associated with outsourcing that might have a negative impact on the partnerships [15]. The risks associated with outsourcing encompass a range of issues, such as possible inefficiencies in management, latent information asymmetry, loss of innovative capacity in logistics, hidden costs, reliance on third-party logistic providers, that can cause loss of control over them and also challenges assessing and tracking over their performance, and cultural alignment issues between participating firms [14]. Other issues and risks associated with pharmaceutical outsourcing can include but are limited to transaction costs, higher monitoring expenses, losing direct control over the launch of a product, losing internal competency and capacity, potentially losing crucial intellectual property, possible after-market competition, and higher costs associated with legal compliance and reputation [31].

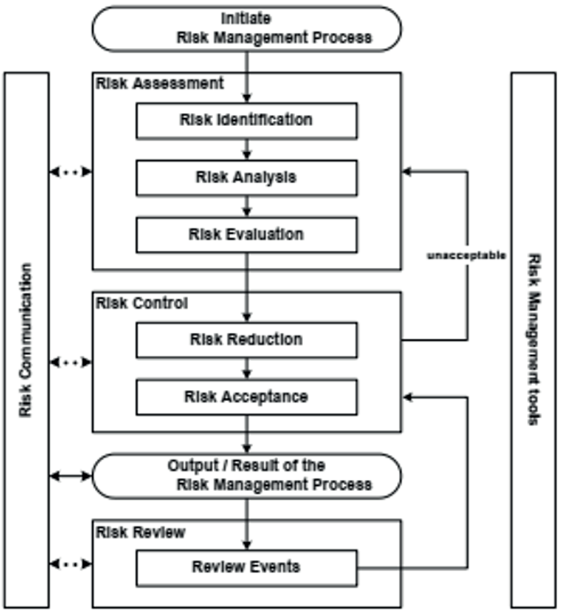

Figure 3. Overview of a typical risk management process of ICH Q9 [23].

2.3. Risk Management and Risk Mitigation Approaches in Pharmaceutical Supply Chain Outsourcing

The systematic process of assessing, controlling, communicating, and reviewing hazards is known as risk management. By using the right plans and tactics, risk management in supply chains can raise performance levels and lessen uncertainty and susceptibility [1, 32]. According to several suggestions, firms should manage risk according to a systematic framework that aids in supply chain risk identification, quantification, and mitigation. Despite the widespread recognition of supply chain risk management as a crucial topic within supply chain systems, the sector faces risks due to inadequate knowledge of supply chain risk management [11]. These risks are mostly caused by the gap between theory and practice. An outline for risk management is briefly schematized in Figure 3.

Risk management is initiated with a holistic approach to the system in which the below-mentioned steps can be followed;

i. Describe the issue and/or risk query, mentioning relevant presumptions that highlight the possibility of risk;

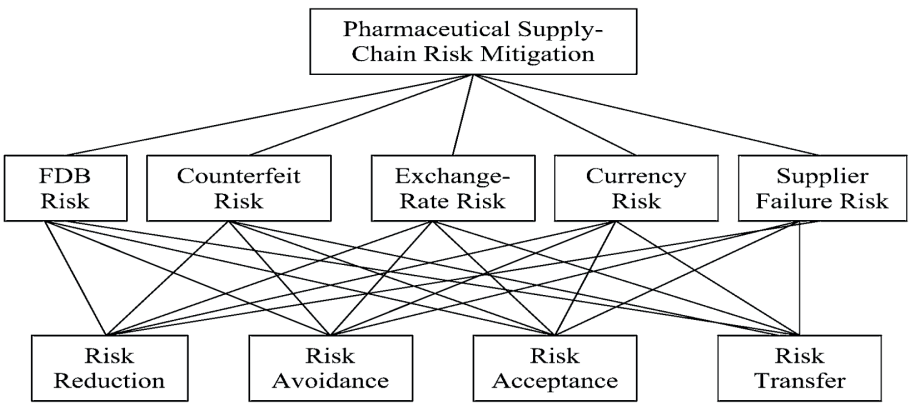

Figure 4. Decision hierarchy to mitigate PSC risk [47].

ii. Gather background data and/or information pertinent to the risk assessment regarding potential harm, hazard, or influence on human health; Identify a leader and necessary resources;
iii. Establish a schedule, deliverables, and suitable degree of decision-making for the risk management procedure.

This is followed by a stage called risk assessment, which entails identifying hazards, analysing and calculating the risks of being exposed to those dangers, and asking fundamental questions to determine the risk;

i. What might not work well (or wrong)?
ii. How likely is it that something will not work well (or wrong)?
iii. What are the repercussions (level of severity)?

The whole process is carried out step by step, which is schematized in Figure 3.

Supply-chain risk management is becoming a must for many forward-thinking pharmaceutical firms due to the surge in supply-chain risks in the industry and the pressure from regulatory bodies, evolving laws, customers, and fierce competition [1, 33].

Table 1. Recent publications related to risk management tools

Method	Contributions	Reference
AHP	Outlined a methodology for evaluating outsourcing risks in global PSCs.	[12]
AHP	Created a PSC risk assessment methodology focused on Iran.	[11]
A probability impact matrix based methodology	Evaluated the supply chain risks in the pharmaceutical industry's logistics.	[39]
Conceptual model	Created a framework to improve supply chain robustness within the Malaysian pharmaceutical sector.	[40]
Combined descriptive and application-based approach	Presented a risk-management strategy for PSCs that combines an application- and descriptive-based approach.	[41]
ELECTRE TRI	Suggested a method for assessing risks related to outsourcing PSC logistics.	[1]
Fuzzy AHP PROMETHEE	Assessed the PSCs' outsourcing risks.	[42]
A mathematical model	Emphasized the development of PSC resilience by taking capacity, inventory, and dual sourcing into account.	[43]
A two-stage stochastic programming model	Investigated supply chain design concerns to balance and reduce risks in PSCs.	[44]
Delphi model and AHP	Evaluated the relevant risks regarding PSC in the context of Bangladesh.	[45]
Data envelopment analysis (DEA) and fuzzy data envelopment analysis (FDEA) approaches	Assessed the impact of resilience indicators on PSC through DEA/FDEA and statistical methods in the veterinary organization.	[46]
Mixed-Integer Non-Linear Program Model Fuzzy	Evaluated risks and the uncertainty level of PSC process tools.	[47]
Fuzzy Cognitive Map	Evaluated risks related to PSC and distinguish the importance levels	[48]
Decision Making Evaluation and Laboratory-based Analytical Network Process	Risks involved in the generic medicine supply chain in Indonesia is assessed.	[33]
Ontologies and Fuzzy Quality Function Deployment	PSC risks associated with the transport and storage of finished products for export in Columbia were evaluated	[49]
2-Tuple ARAS-BWM approach	PSC risks faced during the COVID-19 period in Tunisia were evaluated and mitigation strategies discussed	[50]
Taguchi Orthogonal methodology	Uncertain variables associated with PSC risks were investigated and the effect of logistics evaluated	[32]
Pythagorean fuzzy AHP and Pythagorean fuzzy WASPAS method	Procurement risks and PSC risks are investigated	[51]

The latest risk management methodology, which is focused on the pharmaceutical supply chain system, is summarized in Table 1.

Depending on their vulnerabilities and circumstances, pharmaceutical companies in the public and private sectors confront varying supply chain risks and uncertainties, and it is challenging to offer a consistent strategy to reduce them. It is feasible, therefore, to put businesses' skills and assets to use in managing specific supply chain risk and uncertainty. A decision hierarchy to mitigate PSC risk is defined in Figure 4. In the frame of the decision hierarchy, regulatory-related issues, business-related issues, technical-related issues, and intellectual property are accepted as primary risk factors, therefore, reduction of risk avoidance from risks, acceptance of risks and transfer of risk proposed as direct risk mitigation approaches [34].

Global outsourcing's associated risks are being managed more extensively as supply-chain tactics for the pharmaceutical business change. "Developing new drugs carries more risks and is costlier than ever. Many leading pharmaceutical companies are entering into risk-sharing outsourcing partnerships to lower their operation risks by sharing management and financial responsibilities. Through proper risk management, outsourcing enables companies to expand their R&D pipelines and provide a greater chance for a product to launch, ultimately lowering overall business risks"[12]. The risks associated with global outsourcing include those related to intellectual property and proprietary confidentiality, technical expertise, capacity, resource availability, production risks, firm volatility, and management difficulties. Pharmaceutical companies must implement risk-reduction strategies to have successful outsourcing contracts.

Pharmaceutical companies benefit from outsourcing pharmaceutical products, but it's important to remember that hazards are involved, such as FDA rejection, longer lead times, noncompliance with regulations, and more. To prevent unanticipated resource waste that could significantly negatively influence patient health, a proper risk assessment and management strategy should be developed in compliance with regulatory guidelines when a decision to outsource is needed in the pharmaceutical supply chain [35].

3. CONCLUSION & FUTURE DIRECTIONS

Global pharmaceutical companies are facing more and more pressure to boost profit margins in an environment of diminishing R&D productivity, rising pricing pressure, and shifting regulatory constraints. Pharmaceutical companies are exploring consolidations through mergers and acquisitions and international outsourcing to address these issues. Pharmaceutical companies may afford to concentrate on their core skills, gain access to specialist knowledge, and increase cost-saving advantages that can increase shareholder value by forming strategic outsourcing partnerships. Global outsourcing of production and research and development activities has grown in importance in the pharmaceutical business in recent years due to the competitive nature of the modern market. Pharmaceutical companies have advanced up the outsourcing value chain from non-core to secondary core services [36].

Increased clinical trial complexity, regulatory requirements, data requirements, cost savings, market time, and therapeutic expertise access drive pharmaceutical outsourcing R&D. Global supply chain outsourcing efficiently utilizes labour, capital, technology, and resources [37]. Pharmaceutical companies see outsourcing their worldwide supply chain operations as a smart move that may provide flexibility, satisfy their expanding customer base, cut expenses, boost productivity, and increase profit margins. Supply chain operations can be globally outsourced, which enables businesses to utilize their core competencies and assets to far greater extents than possible with alternative approaches [38]. Companies can increase returns on capital, lower risk, increase flexibility, and become more responsive to the value requirements of shareholders and customers by implementing outsourcing strategies that are well-executed and based on core strengths.

Ethical approval

Not applicable because this article does not contain any studies with human or animal subjects.

Author contribution

Concept: ÖAD; Design: ÖAD; Supervision: ÖAD; Materials: ÖAD; Data Collection and/or Processing: ÖAD; Analysis and/or Interpretation: ÖAD; Literature Search: ÖAD; Writing: ÖAD; Critical Reviews: ÖAD.

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