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A Study on Integrated Supply Chain Strategies in Pharma Manufacturing

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Abstract: ***Today, efficiency of R and D processes, products' declining life cycle and patent life exclusivity, increasing generic competition, production compliance, and costs, are some of the major complications that pharmaceutical companies encounter with them. A study by Oliver Eitelwein shows that many pharmaceutical companies have to enhance the main supply chain sections including customer satisfaction, forecasting accuracy, inventory level, and total supply chain costs. The pharmaceutical industry is responsible for the product development, manufacturing and marketing the product. The population is going to be globally increasing by over 1% percent per year by 2030 and ageing at the same time. Increasing urbanization and changes in lifestyle are creating more demands for medication and it is also affordable for more people. For a long period, the pharmaceutical industry was being dominated by American and European markets. However, as these developed markets are becoming saturated, growth of pharmaceutical industry is now accelerated by emerging markets. The worth of North American pharmaceutical market is $ 341.1 billion, which is about 36.7% of global market and it is the largest in the world. This is due to the presence of many major pharmaceutical companies, improving access to affordable medicines and increasing patent expirations in this region. The second largest pharmaceutical market in the world is Asia; it is currently about 21.5% of the global pharmaceutical market.***

Keywords: Integration, Partners, Operations, Efficiency

1. Introduction

The Indian pharmaceutical industry currently tops the chart amongst India's science-based industries with wide ranging capabilities in the complex field of drug manufacture technology. An highly organized sector, the Indian pharmaceuticals market is expected to expand at a CAGR of 23.9 per cent to reach US$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally.

The Indian pharmaceutical industry has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production. Even while undergoing restructuring, it has established its presence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups. Strong scientific and technical manpower and pioneering work done in process development have contributed to this. The nation also has a huge pool of engineers and scientists having the capability to steer the business forward to a much greater degree.

Pharmaceuticals are produced through *primary* (drug substance) and *secondary* (drug product) manufacturing (Marques et al., 2020). *Primary* manufacturing converts raw materials into the active pharmaceutical ingredient (API) through reaction and separation steps usually performed in batch mode. Increasingly, many processes begin with a fermentation that produces the product or its precursor, which is separated from the fermentation broth in a recovery step. Next, the purification step removes contaminants and impurities through several separation tasks to achieve the required product quality. The entire process can be decoupled in multiple stages with intermediate storage in between, and a manufacturing line may produce several products in a campaign production mode with long times for changeovers between products due to strict cleaning requirements. All processes must be approved by the regulatory authorities and a quality control of produced materials is performed before they can be released for further manufacturing or sold (Collins, 2018). S*econdary* manufacturing produces the drug in its required form and dose. The API is therefore mixed with other materials (excipients) in formulation and is then filled into a container (for injectable products) or tabletted (for oral products) before it is packaged for shipment. The decoupling into primary and secondary manufacturing means that the API demand is a function of both the external patient demand and secondary production plans, and the multi-stage API manufacturing process requires the coordination of campaigns on multiple production stages and the lines on each stage. An additional feature of pharmaceutical manufacturing is the distinction between legacy products and products undergoing clinical trials.

Supply Chain Integration:

Graham C. Stevens, who was a senior managing consultant at Peat Marwick McLintock in London published the article called "*Integrating the Supply Chain*" in International Journal of Physical Distribution & Logistics Management. According to him, Supply Chain Integration is a close alignment and coordination within a supply chain. A supply chain refers to everything required to produce a product from raw materials, to manufacturing, shipping and support services.

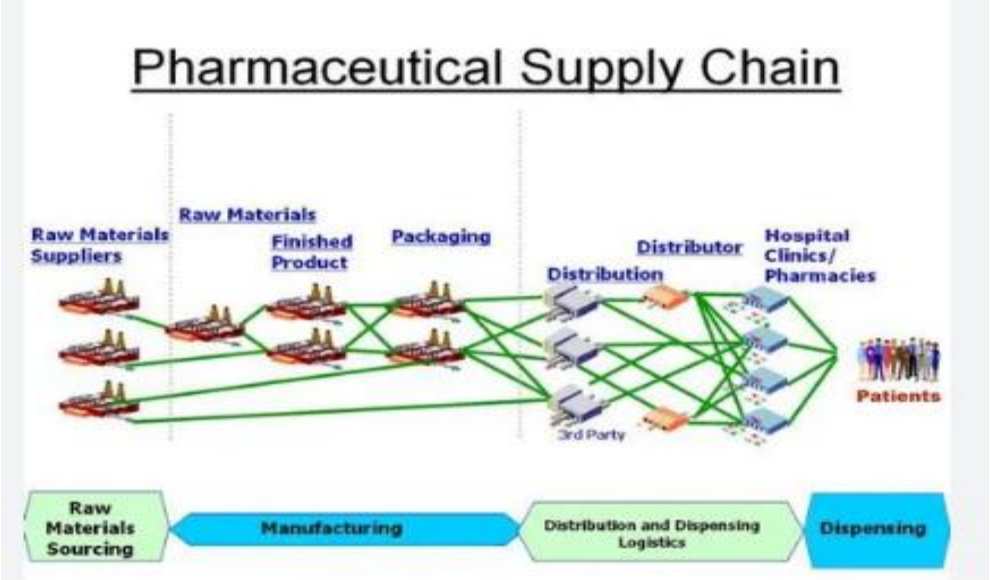

Figure 1: Integrated Supply Chain (Source: *www.pwc.com/pharma2020*

There are a variety of aspects of evaluating in the supply chain; eliminating bottlenecks, balancing between tiniest material cost and transportation, optimizing manufacturing flow, maintaining the right mix and location of factories and warehouses, vehicle routing analysis, dynamic programming and efficient use of capacities, inventories, and labors are of main aspects of supply chain optimization. All stockholders need to institute the right configuration and adaptability to create best practice and to overcome the obstacles in continues changing environment. Pharmaceutical supply chain should provide medicines in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to be consistent with health system's objectives and also it should make benefits for its stockholders. Supply chain is a set of players, processes, information, and resources which transfers raw materials, and components to finished products or services and delivers them to the customers.

Integrated supply chain management refers to an enterprise resource planning approach to SCM. A business facilitates relationships with all of its suppliers and manages all distribution and logistics activities through a centralized system rather than having multiple systems within the organization. To understand integrated supply chains, it's first important to grasp just what a supply chain is. A supply chain is a collection of suppliers required to create one specific product for a company. Each supplier is a "link" in the chain that adds time and monetary costs. Supply chain management is the collection of methodologies, theories, and practices that go towards keeping a supply chain running and improving its efficiency for the benefit of most, if not all of the links.

2. Literature

Simon. B et.al (2023) presents a 7-step framework for setting up, solving, and presenting results for production planning problems with an extension for integrated capacity and production planning that is triggered whenever KPIs from the nominal production planning solution are outside specifications. The information needed to solve a problem is explained in terms of processing details that are categorized such that they can be translated into mathematical constraints. Mixed-integer linear programming models are used to solve the problems and different constraints are presented which can be assembled to construct models for specific problems.

Marques et al., (2020) explained the capacity can be increased by strategic investments in new facilities, or by applying changes to existing manufacturing lines, which are limited since the new process must be approved by regulatory agencies worldwide. Therefore, a CPP problem must be formulated appropriately and analysed, in which the production capacity decisions influence the production plans that in turn influence the amount and timing of capacity construction. The aim of this paper is to develop a method for CPP applied to primary pharmaceutical manufacturing, including the development of the corresponding mathematical models for proper analysis and solution of the problem.

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Outsourcing is inevitable in pharmaceutical industry in which pharmaceutical supply chain professionals consider the factors like R&D capabilities, Economic advantages, Management capabilities, relational fit and organizational fit while selecting partner for outsourcing (Chie Hoon Song, 2019)

The supply chain in pharmaceutical companies started using scientific method for partner selection. The supply chain

professionals started considering the factors like Quality, Delivery, Technology, Reputation, Environmental affairs, Flexibility, Information systems, Costs and Environmental risks for selecting partners (Gholamhossein Mehralian et. al 2011)

Internal integration deals with internal operations within the organization boundaries like raw material, production, packing and parcel of finished goods to outside organization. (Chen, Daugherty, and Roath 2008). The main theme of internal integration is to develop process- oriented approach to manage internal hurdles effectively. Integration illustrates "how harmoniously different departments of an organization work together and how tightly coordinated their activities.

3. Methodology

Objectives:

1) To analyze the Cross Functional team Coordination impact on Supply Chain Integration Strategies
2) To analyze communication and Outsourcing strategies impact on Supply chain Integration success.
3) To identify Supply chain Integration impact on Make or Buy decision making strategy.

Hypothesis:

H_{01}: There is no significant association between type of pharma Company and their opinions on impact of make or buy decision on integration.
H_{02}: There is no significant association between type of Pharma Company and their opinions on impact of cross functional coordination on Integration.
H_{03}: There is no significant association between type of functional area and their opinions on impact of speed for process development on integration.

Sample & Sample Size:
The sample for the study consists of Managers / Assistant Managers/ senior management team of various Pharma Supply Chain related wings like Process development team, Manufacturing team, Supply chain Management team, business management team and other supportive departments who are facing daily Supply Chain challenges in the organization. The valuable opinions of above sample are captured with the help of structured questionnaire. The present study carried out with **565 respondents** with above mentioned designation.

Study Variables: The study analysis carried out based on type of company (Small, Medium and large) depend on annual turnover as per GoI, MSME guidelines and various supply chain functional areas like Manufacturing team, Supply Chain team and marketing wing etc.

4. Data Analysis:

Table 1: Qualification wise Frequency values of respondents.

Qualification				
		Frequency	Percent	Cumulative Percent
	UG	79	14.0	14.0
	PG	372	65.8	79.8
	Ph.D	114	20.2	100.0
	Total	565	100.0	

The Education qualification of the respondents reflects that, 65.8 % are PG qualified people and 20.2% are Ph.D Doctorates and finally 14.0 % are UG qualified people.

Hypothesis:

H_{01}: There is no significant association between type of Pharma Company and their opinions on impact of make or buy decision on integration.

Table 2: Chi Square Values of company type and make /buy decision

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	14.486[a]	4	.006
Likelihood Ratio	13.045	4	.011
Linear-by-Linear Association	4.959	1	.026
No. of Valid Cases	565		

Interpretation: From the above table chi square is significant (Chi-square sig. Value is 0.006 < 0.05), **Reject null hypothesis**. It means that there is a significant association between type of Pharma Company and their opinions on impact of make or buy decision on integration. It means that impact of MAKE or BUY decision on Integration is dependent on type of Pharma Company.

H_{02}: There is no significant association between the type of Pharma Company and their opinions on impact of cross functional coordination on Integration

Table 3: Chi Square Values of company type and Cross functional link

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	11.764[a]	6	.067
Likelihood Ratio	13.220	6	.040
Linear-by-Linear Association	1.026	1	.311
No. of Valid Cases	565		

Interpretation: From the above table chi square is not significant (Chi-square sig. Value is 0.067 > 0.05), no evidence to **Reject null hypothesis**. It means that there is no significant association between type of Pharma Company and their opinions on impact of cross functional coordination on Integration. It means that impact of cross functional coordination on Integration is independent on type of Pharma Company.

H_{03}: There is no significant association between type of functional area and their opinions on impact of speed for process development on integration.

Table 4: Cross Tab Values of Functional area and Process Development

Functional area / department			4.7 The overall impact of Speed for process development on Integration is significant			Total
			Neutral	Agree	Strongly Agree	
	Process development team	Count	15	64	101	180
		% within Functional area/ department	8.3%	35.6%	56.1%	100.0%
	Manufacturing team	Count	5	47	63	115
		% within Functional area/ department	4.3%	40.9%	54.8%	100.0%
	SCM team (supply chain Management)	Count	10	103	55	168
		% within Functional area/ department	6.0%	61.3%	32.7%	100.0%
	Top management, Sales, Marketing & Business Development	Count	10	51	41	102
		% within Functional area/ department	9.8%	50.0%	40.2%	100.0%
Total		Count	40	265	260	565
		% within Functional area/ department	7.1%	46.9%	46.0%	100.0%

Interpretation: From the below Chi Square table, it is significant (Chi-square sig. Value is 0.000 < 0.05), **Reject null hypothesis.** It means that there is a significant association between type of functional area and their opinions on impact of speed for process development on integration. It means that impact of speed for process development on integration is dependent on type of functional area.

Table 4.1: Chi Square Values of Functional area Process Development

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	29.554[a]	6	0
Likelihood Ratio	29.846	6	0
Linear-by-Linear Association	11.01	1	0.001
No. of Valid Cases	565		
a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 7.22.			

5. Discussion of Results

The paper revealed that the first and highest level of integration is related to the Cross Functional coordination which is actually the most important variable among supply chain integration. Capacity building (out sourcing for additional capacity to access additional capacity/resources) for R&D by supply chain team will have a significant impact on quick development of the new product. Speed for process development, which is a dependent variable has positive relationship with independent variables (MAKE or BUY decision on Integration, cross functional coordination on Integration, Partner selection and evaluation on Integration, communication on Integration, Outsourcing on Integration and Usage of IT System on Integration).

The development of strategic business partner is of prime importance of supply chain team and their responsibility is also to continuously evaluate and ensure the strategic fitment of companies. The strategic fitment is not only based on technical, commercial or quality fitment but also based on cultural, ethical practices and policy fitment. The core activity of supply chain team is not only to make strategic business partners but also to continually engage them and make them to add value to the product development and manufacturing.

To obtaining value for consumers and supply chain network which is the final purpose of supply chain management, supply chain entities must integrate inter and intra organizational processes. A firm's competitiveness is extremely related to integrated management. Process integration refers to coordination, and resources and information sharing to manage the process cooperatively Chopra and Mendhl enumerated the benefits of SC integration including safety stock and costs reduction, flexibility, responsiveness and quality enhancement, optimum resource utilization. However, process integration may have very difficulties in terms of organizational culture, infrastructure and facilities, willing to learn and prepare for changes. Therefore, this model could be a basis for configuration of supply chain system.

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