INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X
Impact factor: 4.295
(Volume 5, Issue 5)
Available online at: www.ijariit.com

Application of Operations Research in the pharmaceutical industry

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ABSTRACT

The flux of pharmaceutical industries has altered a lot over the last 30 years. Innovation is extremely necessary for such industries and this innovation comes from research and development. Operations Research is needed as drugmakers around the world want to manage cost, quality and speed. Maximising the efficiency of production, labour and equipment is an important way for top-quartile drug makers to break out of the pack. The purpose of this research paper is to highlight OR approaches used in the pharmaceutical industry, that are backed by statistics, and observe the changes related to this industry, over the years. We went through qualitative research papers and gathered various mathematical models that link Operations Research with the current happenings of the Pharmaceutical Industry. The paper illustrates the main issues related to optimization in the industry and how science and technology help to overcome them by making the right forecasts and decisions.

Keywords— *Pharmaceutical industry, Operations Research, Optimisation, Decision-Making, Research work*

1. INTRODUCTION

"Pelosi's Drug Plan Would Let U.S. Negotiate Prices of 250 Medications" (Goodnough, 2019). With the soaring prices of medicinal drugs around the world, US comes up with its long-awaited statement, to help reduce pharma product rates. With fines over excess of rates, this is the time where pharmaceuticals start developing efficient cost-effective processes. Pharmaceutical processes are complex, which involves many steps, agencies, ministries and manufacturers. The sum total of these activities is a huge task to manage, and pharma companies deploy a number of resources and manpower to manage these activities. According to Rastogi (2019), India is among the leading global producers of cost-effective generic medicines and vaccines, supplying 20 percent of the total global demand by volume. The country has an established domestic pharmaceutical industry, with a strong network of 3000 drug companies and about 10,500 manufacturing units. India's current foreign direct investment (FDI) policy allows 100 per cent FDI under automatic route in green field pharmaceutical projects and up to 100 per cent FDI under government approval in brownfield projects.

India's CRAM sector is globally recognized for its high-end research services and is one of the fastest growing segments of the country's pharmaceutical industry. The country has a low cost of production, low RandD costs, innovative scientific man power, and a large number of national laboratories that have the potential to steer the industry ahead to a higher level. With such a big reach and growth potential, pharmaceuticals in India try to innovate and advance. With the role of medicinal drug innovation, they are the supporting hand to the healthcare industry, to help them fight diseases. However, the arbitrary and unpredictable nature of India's regulatory interventions, including restrictions on pricing and licensing are among the several challenges that global drug companies face in securing easy market access to India. Business managers, face an endless list of complex issues, every day. They must make decisions about financing, location, product mix, etc. These issues are usually challenging and complex to comprehend hence operations research is utilised to make work easier. Operations research is a quantitative approach that solves problems, using a number of mathematical techniques. In order to meet world regulations and cost-effective policies, pharmaceuticals, too, need to make important decisions regarding their process which is supported by operations research. This research paper aims to analyse the various operations methodologies that pharmaceutical companies utilise in order to be cost-efficient and safely innovative.

2. OVERVIEW

Pharmaceutical industry is undoubtedly one of the riskiest businesses in which to invest money, yet it is perceived by the general public to be excessively profitable. The late 18th century, saw the emergence of pharmacology (study of the actions of drugs and

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how they exert their effects). Oswald Schmiedeberg, is rightly known as the founder of pharmacology. The modern pharmaceutical industry emerged in the middle of the 19th century with companies such as Merck, Eli Lilly and Roche that previously supplied natural products such as morphine, quinine and strychnine, moving into large-scale production of drugs, whilst newly established dyestuff and chemical companies, such as Bayer, ICI, Pfizer and Sandoz, establishing research labs and discovering medical applications for their products. However, the industry was not rightly developed as at the start of the 1930s, most medicines were sold without a prescription and directly by the physicians. Nevertheless, a number of major advances were made in the early part of the 20th century. In 1897, scientists at Bayer demonstrated that a chemically modified version of salicylic acid had much improved efficacy and the product, aspirin, is still in widespread use today. In the 1920s and 1930s both penicillin and insulin were identified and manufactured, albeit at a modest scale.

The post-war period from the 1950s to the 1990s saw major advances in drug development with the introduction of new antibiotics, new analgesics, such as acetaminophen and ibuprofen, and complete new classes of pharmaceuticals such as oral contraceptives, ß-blockers, ACE inhibitors, benzodiazepines and a wide range of novel anti-cancer medicines. The thalidomide scandal of 1961 triggered a complete reassessment of state controls on the industry, leading to extensive environment control policies, hence, high-cost production. In 1977, Tagamet, an ulcer medication, became the first ever blockbuster pharmaceutical, earning its manufacturers, GSK, more than US$ 1 billion a year and its creators the Nobel Prize. Prozac, the first selective serotonin re-uptake inhibitor (SSRI) was launched by Eli Lilly in 1987 and omeprazole, the first proton pump inhibitor (PPI), was introduced by Astra in 1989. Atorvastatin, marketed as Lipitor in 1996, became the world's best-selling drug of all time, with more than US$ 125 billion in sales over approximately 15 years. This was indeed a Golden Age for the pharmaceutical industry. In 1970, Indira Gandhi enacted legislation which barred medical products from being patented in the country. In 2002, over 20,000 registered drug manufacturers in India sold $9 billion worth of formulations and bulk drugs. 85% of these formulations were sold in India while over 60% of the bulk drugs were exported, mostly to the United States and Russia. Over the years, great innovations have taken place in the pharmaceutical industry including:

2.1 Precision Medicine

Precision medicine is an approach that integrates clinical and molecular information to understand the biological basis of disease. This information can be obtained by converting DNA into data through a process called genome sequencing. For this innovation, President Obama donated $215 million for this innovation. Other companies like GSK, Roche, are also working together to make this innovation a success.

2.2 mHealth Sensors

Apple currently has several mHealth apps for clinical research on the iPhone, including apps targeting Parkinson's disease, diabetes, cardiovascular disease, asthma and breast cancer, which have been developed by leading research institutes. This helps find customer continuous data trend and reduces additional research costs.

2.3 3-D printing

Epilepsy drug Spritam is the first 3D printed drug to be approved by the FDA. It is manufactured by Aprecia Pharmaceuticals through a three-dimensional printing process, which allows the pill to deliver higher doses as well as dissolve quickly. India supplies over 80% of antiretroviral drugs to combat AIDS. The pharmaceutical sector was valued at US$ 33 billion in 2017.
As of 2019:

- Between Jul-Sep 2018, Indian pharma sector witnessed 39 PE investment deals worth US$ 217 million.
- Investment (as % of sales) in research and development by Indian pharma companies increased from 5.3 per cent in FY12 to 8.5 per cent in FY18.
- In 2017, Indian pharmaceutical sector witnessed 46 merger and acquisition (MandA) deals worth US$ 1.47 billion
- The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments.
- The government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

Therefore, pharmaceutical industry can never setback. With an increase in innovations and research investments, there lies a lot of development ahead.

3. RESEARCH OBJECTIVES

a) To understand the dimensions of the Pharmaceutical Industry.
b) To find the various types of Operations Research in Pharmaceutical Industry.
c) To elaborate the uses of Operations Research in the Pharmaceutical Industry.
d) To outline the key processes in need of Operations research
e) To describe how Operations Research helps in efficient working of the key processes.

4. RESEARCH METHODOLOGY

The type of research that will be used in this study will be qualitative research based on past research papers. Qualitative researchers aim to gather an in-depth understanding of human behaviour and the reasons that govern such behaviour. The discipline investigates the "why" and "how" of decision making. In order to go about with the process, we searched for the topic as whole before segregating it as per the different uses. Each uses were dealt with a specified research paper that gave us the observations that were required. The research papers were analysed to find the different ways in which operations research was connected to the pharmaceutical industry, before summarising the found information. For the uses, we took the mathematical data in order to illustrate how OR is uses in the working of pharmaceuticals. Moreover, we took data from newspapers in order to connect the industry to the current developments.

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5. LITERATURE REVIEW

Traditional pharmaceutical manufacturing is being challenged by emerging requirements, such as greater drug product personalisation, more participative healthcare enabled by the adoption of digital information and communication technology, and by the advancement of innovative technology interventions like continuous producing, that promise to attain smaller footprints and larger responsiveness. Hence, pharmaceuticals use a variety of techniques and scientific management in order to increase their productivity while reducing costs, risks and unexpected failures. Research is currently paying larger attention to the interdependencies between Pharmaceutical Offer Chains and therefore the broader health care bundle.

Settani, Ettore and Harrington, Tomàs and Srai, Jagjit (2017) in their paper suggest that coordination between actors, and inventory management are still perceived to be the primary challenges in strengthening global health pharmaceutical delivery, however, the deployment of sophisticated inventory models is deemed insufficient per se to improve the current situation. A significantly high proportion of Supply Chain and Operations Management research promotes a view of the researcher as tasked with discovering cause-and-effect relationships within an objective reality from which they postulate to detach themselves. A common narrative in SCandOM is that an operations model is a miniature representation of a supply chain, and the extent to which a model differs from the 'real thing', is a matter of comprehensiveness. The problem is obviously very challenging because the aim is to bridge the gap currently existing between decision makers in traditionally isolated areas, such as product development, manufacturing, accounting, and commercialisation. Here, it is expected that large benefits stem from coordinated planning across sites, in terms of costs and market effectiveness. Most business processes dictate that a degree of autonomy is required at each manufacturing and distribution site, but pressures to coordinate responses to global demand while minimising cost imply that coinciding designing of production and distribution across plants and ware- homes ought to be undertaken. The need for such unified planning has long been recognised in the management science and operations research literature.

According to **Papageorgiu, Rotstein andShah (2001)**, there are three main issues that are to be considered during optimisation of the product portfolio of a typical pharmaceutical industry.

- Product Management
- Capacity Management.
- Trading Structure

They consider a company which can produce 7 products (P1-P7) over a planning horizon of 10 years. A discretisation interval of 1 year is used for our mathematical model, resulting in 10 time periods. The data used in the example are modified versions of actual data based on a family of respiratory, dermatology, and arthritis products of a major pharma company.The optimisation algorithm has selected five products out of the seven potential ones, rejecting products P2 and P4 as non-promising. Also, production locations B and D have been selected for further capacity investments without allocating any capacity at location C. In total, six additional suites are going to be invested in, thus resulting in a cumulative production capacity of eight suites between locations B and D. Two of these suites will be added to location B and the rest to location D.The main objective was to apply mathematical programming techniques so as to facilitate the strategic supply chain decision-making process for pharmaceutical industries. An optimization-based approach has been presented to select both the optimal product development and introduction strategy together with long-term capacity planning and investment strategy at multiple sites.

Furthermore, pressure from the market and difficult socio-political regulations are among the current factors that are changing the way in which the pharmaceutical business is operated. The pharmaceutical industry is faced with the dilemma of the best use of the limited resources available to obtain the highest possible profit from a potential product portfolio. Thus, they are being forced to consider ever more systematic approaches to optimize their potential product portfolio.

Gatica, Papageorgiou and Shah (2003), in their paper aimed to support an optimisation-based approach to capture the above issues so as to select simultaneously the optimal capacity planning and investment strategy subject to uncertainty of clinical trials for each potential drug. Four possible clinical trial outcomes (High success, Target success, Low success, Failure) for each product are considered as is typical in the industry. As the results show various probabilities of occurrence and the information from the trials will be available at different times resulting in a multistage, multi-period stochastic optimisation problem, which is then reformulated as a large-scale, multi-scenario, mixed integer linear programming (MILP) model. As the resulting detailed model is quite large to tackle, an alternative efficient solution strategy is required without compromising the quality of the final solution. In our example, there is one initial existing product C1 and other three potential drugs (C2, C3, and C4). In the first stage, only product C1 exists for the first 10 time periods, initially there is one manufacturing suite per production line. In the second stage, which involves product C1, as well as potential product C2, 4 scenarios are generated. The second stage lasts until time period 20. Then for the third stage, the third potential product is added to the product portfolio at time period 21, giving a total of 16 scenarios until period 31, when the last potential product C4 is added. The fourth stage then has 64 scenarios. So, for each scenario, additional capacity investment may be made. For every case, the solutions included a complete profile of the sales, production amounts, manufacturing times, inventories, wastes and, if needed, investment capacity for each product. Objective function values of the aggregated procedure for most tests were close enough to the detailed model solution. After analysing the particular solution for each test it was found that the capacity planning decisions taken were slightly different from one case to the other. This indicates that the model is quite robust and that a wrong decision taken in the last part does not significantly affect the final expected profits.

Moreover, pharmaceutical is one of the most sensitive industry that deals with human and animal life. In this industry inventory is the largest asset and its value rises due to growth in variety and cost of the product. In this industry efficient inventory management is important as it can increase profits by reducing cost of products procured. In the paper R. Uthaykumar, S.Priyan(2013) have shown a step by step OR model development for a pharmaceutical company. The paper has mentioned why a company should

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include raw materials and associated costs such as ordering, purchasing and holding costs for managing the total inventory cost. We can see in the papers that equations have been formed for calculating total costs of both finished products and raw materials. In the paper a two echelon inventory system model with multiple constraints was developed for the calculation of optimal inventory policies for multiple pharmaceutical products. Also a lagrangian multiplier algorithmic approach was used to determine the optimal lot size, lead time and total number of deliveries from a pharmaceutical company to a hospital in a production cycle.

According to **G.Santhi and K. Karthikeyan (2016)** Inventory could also be controlled by using **ABC and VED analysis**. A combination of ABC and VED could also be employed to evolve a meaningful control over material supplies.

ABC (Always Better Control) analysis based on Pareto's principle of distinguishing the vital few from trivial many is being used in identifying items that need greater attention in control. Conceived by **Nag, Kaushik and Anany, Mohammed (2016)**, ABC analysis suggests that all items can be classified into three categories. Category an items are suggested to be kept under strict control, category B items are to be kept under moderate control, and category C items require low or no control. A major limitation of the sole implementation of ABC analysis in a pharmaceutical set up is that it is restricted in classifying items on its usage value. Further, with the recent advances in medical sciences and pharmaceutical technologies along with drug regulatory laws, it is probable that a significant number of vital drugs are now available at a lower cost, and hence would be categorized under the second or third category in the ABC analysis. Categorization based on the criticality of the items and stock out costs can be done by VED analysis whereby items are classified into vital (V), essential (E) and desirable (D). Vital items are those that are critical for the survival of the patients, Essential items are the drugs with lower critical need, the remaining drugs with lowest criticality are considered desirable, the absence of which will not have detrimental effect on patients‟ health and hospital's functioning will not be adversely affected. ABC-VED matrix covers the criteria of usage value and criticality for item categorization and is formulated by cross tabulating the ABC and the VED analysis. The matrix is an important tool for inventory management in pharmaceutical set ups and has been used in a number of studies. The matrix classifies the items under three different categories: Category I consists of vital and high valued items (AV, BV, CV, AE and AD), Category II comprises essential and less valued items (BE, BD and CE) and the remaining desirable and cheaper items are included in Category III. The ABC–VED analysis is found to be an efficient inventory tool for distinguishing the drugs requiring stringent control for optimal use of financial resources and elimination of out-of- stock situations.

Furthermore, according to **David Humerphy (2013)**, in the face of globalization and changing market dynamics the pharmaceutical industry confronts a variety of new and complex challenges. Pharmaceutical industry is known for the high amount it spends on research and development of new drugs every year. The manufacturers are now finding a solution for the challenges of manufacturing through measures that reduce their costs and increase their production efficiency. According to the article the Food and Drug Administration (FDA) is using one such initiative Quality by Design (QbD) with the goal of improving cost and increasing efficiency. Process analytical technology (PAT) is an enabling technology for QbD. Measurement of critical quality attributes and process parameters in real time while being in the production line is enabled by PAT tools and can be adjusted quickly. By using PAT, the quality of the product can be verified and improved in multiple steps and this also helps shorten the batch release time. PAT also helps the manufacturer increase batch yields, reduces wastage, results in shorter time to market and helps understand the process and control it better.

Manufacturing productivity can also be established using portfolio management. Portfolio management describes the process of maximizing the value of RandD spending through proper resource allocations. Strategic and operational portfolio management is a methodology that enables the alignment of project decisions with corporate strategy and defined business objectives. Over the years, growing drug development costs along with rising competition, has led pharmaceuticals to indulge in portfolio management to assess their opportunities and reduce risks and costs. Thus, using operations research is very important and vital for the companies.

According to **Bode-Greuel and Nickish (2008)**, pharmaceuticals are vastly invested in the portfolio management of development. It has a set of four common tools that provide information to evaluate and prioritise projects.

- Target product profile (TPP) acts as a blueprint of the desired product. It plays a beneficial role in aligning project activities between the development functions and marketing and sales, by taking into account both regulatory and market requirements.
- Stage-gate process is used to decide whether the achieved results support the continuation of development, and how to reprioritise the project line-up with the existing ones.
- Timeline and budget management is used to gain an insight into the production years and hence plan the product and its development accordingly.
- Sales forecasting and financial project evaluation use a variety of probability based techniques, like Decision-tree analysis and augmented NPV, to find the risks associated with the development, its success ratio and the expected returns of the project.
- Portfolio decisions are usually based on the expected returns however; it also needs to be based on the needed capacity to reach the goal. A proper strategic framework outlining growth and productivity goals and the therapeutic area focus serves as guidance for portfolio decisions.While portfolio management is widely known for development, it's recently been found an important part of the research process too. It helps decline low-profit projects at the early stage and mainly focusing on successful investments. Portfolio management is an important tool to increase productivity. However, for an effective management, the overall profile and process needs to be cross-functional, involving the entire organisation.

Next, quality control is an essential part of the pharmaceutical industry's primary process. Companies need to ensure that their drugs are safe, and comply with all quality standards and regulations set by local and/or international bodies, such compliance would result in a competitive advantage resulting in reduced Quality-related costs, improved brand perception and revenues. In today's time proper use of operational research can help companies meet their quality levels.

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According to, **Reham M. Haleem, Maissa Y. Salem (2015**) efficient quality risk management, process capability analysis, process analytical technologies and lean manufacturing can help companies gain sustainable customer satisfaction and performance. The models help achieve is development of quality and compliance strategies, cost benchmarking, optimizing the quality management system (QMS), delivering compliance and remediation services.

According to **Lubis, Muharman (2012), Data management** is one of the critical solutions that needs high concern from organization to support business process in terms of analysis and development. POBOS™ Pharma manufacturing benchmarks cost allows productivity, quality, and service performance of finished plants. All metric comparisons are based on the normalized POBOS™ production unit (PU). The database covers over 50% of the top pharma companies globally, with over 400 sites and over 10,000 production lines across different technologies (solids, semisolids, sterile, liquids).

Hence, pharmaceutical companies are high capitalized firms, with greater expenses and risks. Operations research is a helping hand to increase the productivity of its risk- taking projects and creating a profitable firm.

6. FINDINGS

a) Three main issues are to be considered during optimisation of product portfolio
- Product management.
- Capacity management.
- Trading structure.

b) The optimal capacity planning are subject to uncertainty of clinical trials, the results of which are used to form a Mixed Integer Linear Programming (MILP) Model.

c) A two echelon inventory system model was developed for calculation of optimal inventory policies for multiple pharmaceutical products.

d) Lagrangian Multiplier Algorithmic approach is also used to determine optimal lot size, lead time and total number of deliveries from a pharmaceutical company to hospital in a production cycle.

e) ABC-VED Matrix covers the criteria of usage value and criticality of item categorization. ABC and VED analysis could be used to derive a meaningful control over material supplies.

f) For overcoming manufacturing problems process analytical technology is used which helps us reduce costs and increase profits etc.

g) In portfolio management there are four common tools which are used to evaluate and prioritize projects:
- Target product profile.
- Stage gate process.
- Timeline and budget management.
- Sales forecasting and financial project evaluation.

7. CONCLUSIONS

To sustain and reign in today's highly competitive and demand driven market, stress is on management to make economic decisions. One of the important managerial ability is the skill to allocate and use resources appropriately in the efforts of achieving the optimal performance effectively. Using Operations Research approaches comprising of Linear Programming, Discrete Event Simulation and Queueing Theory, organization managers can make good quality decisions. Operations managers are not expected to be experts in any decision science tools; however, he or she must have basic knowledge of such tools to get the correct resources and to make the most economically viable decisions for the company as a whole. Operations research analysis combines together the objectives of various departments. The techniques of operations research aid managers allocate resources more efficiently and helps them to better optimize the performance of their company.

8. LIMITATIONS

As with any management system, there are flaws with operations research. In fact, some of the biggest limitations stem out of the advantages. For example, comparing fairly accounts for a completely impartial statistical analysis, but with people there are factors that cannot be quantified. Limitations of operations research include:

- Higher cost: Operations research has a high upfront cost for everything, including thorough analysis, professional assessment, and consultation fees. Because the field of study is so detailed, most companies need to pay a consultant for an operations research analysis.
- Relying on technology: The math required to analyze situations needs to be done by a computer. If technology fails or you lose records somehow, the operations of the company would be affected.
- Not considering for the human element: While math is essential and impartial in assessment, there is always a human element to business.
- Non-Quantifiable Factors: OR approaches provide a solution only when every element related to a problem can be quantified. All applicable variables do not lend themselves to quantification. Factors that cannot be quantified find no space in O.R. models.

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