ROLE OF I.T. IN PHARMACEUTICAL INDUSTRY IN INDIA

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ABSTRACT
    The pharmaceutical industry develops, produces, and markets drugs or pharmaceuticals licensed for use as medications. Pharmaceutical companies are allowed to deal in generic and/or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs. Information Technology plays an important role in the economy in India and it gives good percentage growth to Indian GDP. Introduction of IT in India has made many changes in all the sectors, similarly in pharmaceutical industry. Introduction of IT brought many changes and has shown its impact towards the growth of the industry. This study throws light on the impact and role of IT on pharmaceutical industry in India.

INTRODUCTION

India is now among the top five emerging pharmaceutical markets globally and is a front runner in a wide range of specialties involving complex drugs' manufacture, development and technology. The Indian pharmaceutical industry is a highly knowledge -based industry which is growing steadily and plays a major role in the Indian economy. As a highly organised sector, the number of pharmaceutical companies is increasing their operations in India. The Indian Pharmaceutical industry is highly fragmented with about 24,000 players (around 330 in the organised sector). The top ten companies make up for more than a third of the market. The Indian pharma industry accounts for about 1.4% of the world's pharma industry in value terms and 10% in volume terms. The industry is expected to touch US $ 35.9 billion by 2016.The Department of Pharmaceuticals has prepared a 'Pharma Vision 2020' document for making India one of the leading destinations for end-to-end drug discovery and innovation.

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually. The "organized" sector of India's pharmaceutical industry consists of 250 to 300companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75 percent of India's demand for medicines is met by local manufacturing.

ROLE OF IT IN PHARMACEUTICAL INDUSTRY

Information technology is the application of computers and telecommunications equipment to store, retrieve, transmit and manipulate data, often in the context of a business or other enterprise. The automation of all the manual work of the pharmaceutical industry is based on the principles of IT systems. There are many different types of automated soft ware that aid the smooth functioning of pharmaceutical units and improve efficiency, accuracy and decision making.

Application of IT systems in pharmaceutical industry is called as Pharmacy Informatics. It deals with biomedical information, data and knowledge, their storage, retrieval and optimal use for problem solving and decision making. It is tightly focused on the optimal use of drug information for problem solving, decision making and promoting safe pharmaceutical care.

Today, a number of software solutions are commonly used in the pharmaceutical industry. Some of the popular ones are: Enterprise Resource Planning (ERP), Laboratory Information Management, System

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61

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(LIMS), Sales Force Automation (SFA), and Customer Relationship Management (CRM) etc. With all the above applications, huge amount of data is now available in the organizations, but the key challenge is to provide right information at right time to top/senior level management which can play a vital role not only in decision-making but also in identifying risks in time at all department levels.

IMPORTANCE OF THE STUDY

Pharmaceutical industry needs the informatics systems for preventing medication errors, to interconnect clinicians, to personalize care and improve health of people in general. Similarly there is a need to decrease the manual work, to smoothen the work- flow, to develop strict security, and to reduce paper work. This has lead to e-documentation and e-marketing and complete automation of manufacturing, accounting and distribution processes. Though there are many pharma companies which are using IT in India to compete with other pharma companies globally, there is no record or data available as to the extent of IT usage and the benefits derived out of it. There is a need therefore for collection of information about the positive role of IT in pharma industry in order to educate and enlighten the SMEs in pharma field about significance of IT in pharma industry and encourage them to compete effectively with other players.

No studies are conducted on the role of IT in pharma industry though some research was done on some aspects like investment in pharma industry, hospital management, CRM in pharma companies, HR practices in pharma companies etc.

OBJECTIVES OF THE STUDY

1. To study the various technologies that are used and adopted in Indian Pharmaceutical industry
2. To identify the benefits derived by users of IT in pharma business.

SCOPE OF THE STUDY

The study includes impact of Information Technologies, Various systems that are used and adopted in the Indian Pharmaceutical industry. It also includes a brief description about the technologies that are used in the Indian Pharmaceutical industry. The study gives information of Indian Pharmaceutical industry, its growth and number of firms in various locations across the nation in a bird's eye view.

RESEARCH METHODOLOGY

The data for this research paper has been taken form secondary sources. Articles, Research papers, annual reports, websites and studies conducted by organizations of pharmaceutical producers of India. This study is based on statistics available on aspects such as growth of the sector, technologies used by pharma companies in India, and impact of IT in the pharma companies.

VARIOUS IT SOFTWARES USED IN PHARMACEUTICAL INDUSTRY

- **Enterprise Resource Planning (ERP):** Pharmaceutical-specific ERP software system is the most effective way to identify and track every single raw material from receipt through processing, packaging and shipping, to the exact customer location. But however, the software package is very costly and can be afforded by large companies only. The high cost factor is preventing many small and medium enterprises in India from using this highly useful and effective tool. In the recent past, an resource ERP is made available at affordable price in the Indian market enabling SMEs to take benefit out of it. The advantages of eresource ERP software for pharmaceutical manufacturers are that it can effortlessly optimize and improve all the business processes like batch production, sales functions, inventory control, purchasing, quality assurance, accounting and financials, regulatory reporting etc.

- **Laboratory Information Management System(LIMS):** LIMS application supports analytical laboratory operations by providing complete sample tracking, user certification, instrument management, standard and reagent management, full auditing, report and sample scheduling. These analytical

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laboratories include research and development (R&D) labs, testing labs, quality assurance (QA) labs, contract labs, manufacturing unit's labs.

- **Sales Force Automation(SFA):**
It is a type of program that automates business tasks such as inventory control, sales processing, and tracking of customer interactions, as well as analyzing sales forecasts and performance. SFA packages typically include a Web-ready database, an e-mail package, and customizable templates. A three-tiered architecture is typically used to separate the database, server, and application to reduce programming demands on clients. A module-based design is generally used, to allow users to customize the package to suit their needs. For instance, Ranbaxy uses this software quite effectively and achieved networking of 7,000 field force with 300,000 doctors and pharmacists.

ELECTRONIC BATCH RECORDS (EBR)

The electronic batch record   (EBR) technology is useful in documenting every step in the production, packing, and holding of each batch of a drug product, batch dates, identity of major equipment/lines used, components/materials used and their weights, in-process and laboratory control results, complete labeling control records, sampling, and identification of personnel supervising or checking each step. It conforms to the Current Good Manufacturing Practice (CGMP), demonstrates accountability by providing proof of proper handling for every step in the production of each batch of a drug product.

Companies which effectively used EBR package could accomplish **reductions in:**

- Documentation/procedural errors
- Missing entries
- Time spent on investigations
- Product release cycle time
- Time spent on training
- Document creation/revision time

There are many consultants who help SMEs in addressing some of the major challenges that companies face in establishing and maintaining forms-based processes through EBR technology usage.

- **Customer Relationship Management System(CRM):**
Customer relationship management (CRM) is a model for managing a company's interactions with current and future customers. It involves using technology to organize, automate, and synchronize sales, marketing, customer service, and technical support. Pharmaceutical Customer Relationship Management analyzes the inner-workings of initiative development, management and improvement processes.

- **Corrective Action and Preventive Action(CAPA):**
Corrective action and preventive action (CAPA, also called corrective action / preventive action) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations. CAPA is a concept within good manufacturing practice (GMP), and numerous ISO business standards. It focuses on the systematic investigation of the root causes of identified problems or identified risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventive action).

Corrective actions are implemented in response to customer complaints, unacceptable levels of product non-conformance, issues identified during an internal audit, or adverse or unstable trends in product and process monitoring such as would be identified by SPC.

DISTRIBUTED CONTROL SYSTEM (DCS)

A distributed control system (DCS) refers to a control system usually of a manufacturing system process or any kind of dynamic system, in which the controller elements are not central in location (like the brain) but are distributed throughout the system with each component sub-system controlled by one or more controllers. DCS (Distributed Control System) is a computerized control system used to control the production line in the industry. The entire system of controllers is connected by networks for communication and monitoring.

- **Computerized Maintenance Management System(CMMS):**

A CMMS software package maintains a computer database of information about an organization's maintenance operations, i.e. CMMIS – computerized maintenance management information system. This information is intended to help maintenance workers do their jobs more effectively and to help management make informed decisions (for example, calculating the cost of machine breakdown repair versus preventive maintenance for each machine, possibly leading to better allocation of resources). CMMS data may also be used to verify regulatory compliance. The more sophisticated the package, the more analysis facilities are available. Many CMMS packages can be either web-based, meaning they are hosted by the company selling the product on an outside server, or LAN based, meaning that the company buying the software hosts the product on their own server.

FINDINGS

All the top companies are found to have been using IT for various processes and developed websites of their own and are available on line for any queries, placing orders, to give info about what medicine is used for what purpose etc.

ERP is the most efficient and effective IT system which is used by the major companies. It is one of the costliest systems when compared to rest of the systems. Efficient management of batch recipes is the most important and complex aspect of the pharma companies and this is done very efficiently by usage of ERP system. All the data is stored and maintained properly with the help of ERP. They have implemented eresource ERP software, a recent arrival in the market which helps SMEs to gain competitive advantage in their operational methods. Financial savings and increase in efficiencies is observed in these companies with use of ERP.

CRM is used in which a good relationship is maintained between the firm and the end user. R&D work and user certification has been made easy by using LIMS technology and tracking of the systems has also been easy. Usage of CPOE technology commonly used in hospitals is found to decrease delay in order completion, reduce errors related to transcription, provide error-checking etc.

LIMITATIONS OF THE STUDY

1. The present study is confined to Indian Pharma Sector only. The findings thereof cannot therefore be generalized.
2. It only deals with existing technologies used by Pharma industry in India and does not include position in any pharma companies abroad.

SUGGESTIONS

Government should take steps

1. To provide subsidies to the small and medium scale companies for procuring hardware and software.
2. To provide tax free benefits for the firms for these technologies.
3. The software companies should take a free demo session to the pharmaceutical companies to get aware of these technologies and their advantages which can change their internal growth and can be stabilized in the industry.

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4. Training regarding these technologies should be conducted so that they can make effective use of these systems.

CONCLUSION

Pharmaceutical companies have a key role in a nation's economy as it serves the human lives of a country. Use of IT in pharma industry enables them to serve the nation better. Although technologies are implemented in the major companies the SMEs are not able to get benefit due to in affordability of the softwares by them.

Use of IT in pharma sector resulted in ddevelopment of new drug delivery systems, Improvements in effluent treatment, pollution control, all-round safety standards, improvement in operational efficiency through reduction in batch hours, increase in batch sizes, better solvent recovery, simplification of processes, meeting norms of external regulatory agencies to facilitate more exports, development of products for import substitution, maximum utilisation of indigenous raw materials, product quality improvements, cost reduction, product development, import substitution etc. The continuous up gradation and adoption of new technology has benefited the companies in the form of better production process, better yields, better quality of the end product and cost reduction. The overall concept provided in this paper should enable pharmaceutical companies to improve their documentation processes by using advanced Information Technology.

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