PHARMACEUTICAL INFORMATION TECHNOLOGY TRENDS

WHITEPAPER

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EXECUTIVE SUMMARY

Today, the Indian pharmaceutical industry is the fourth largest around the world in terms of volume and thirteenth largest in terms of value and keeps on developing yearly at 14%. The industry is making significant IT investments to support this growth.

This paper overviews the IT usage in the pharma business. It portrays the opportunity in the market, the gaps that the industry is confronting presently in the services offered by IT Service providers and how the industry is coping with these gaps. The paper concludes by featuring the expected advantages that Industry will acquire by outsourcing their IT needs to Service Providers.
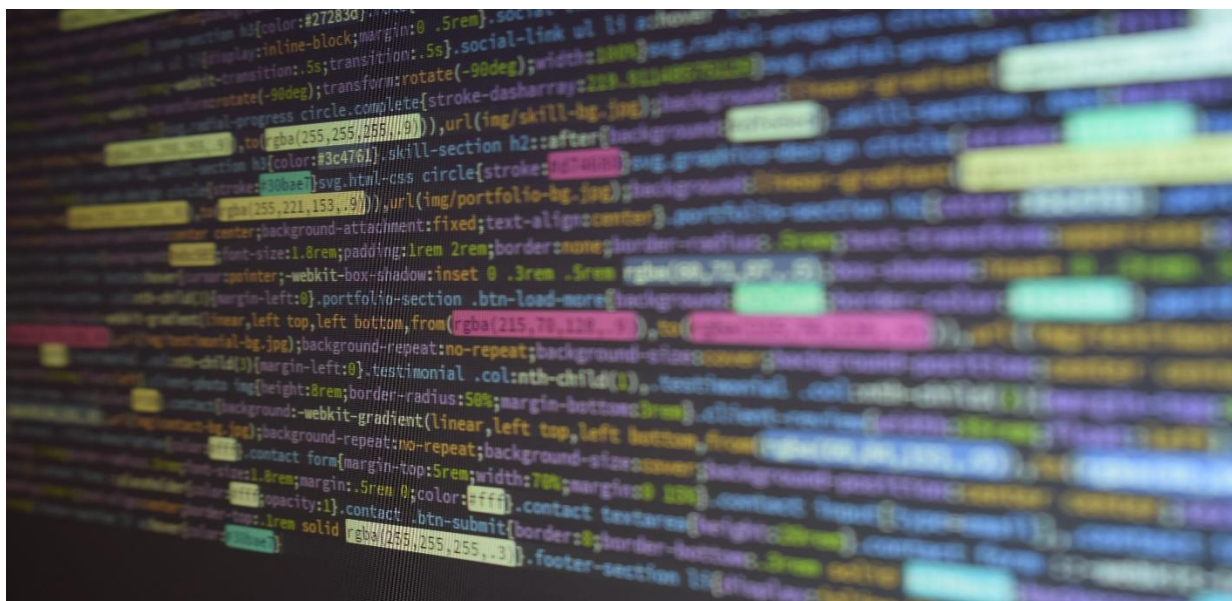
ADOPTION OF IT IN PHARMACEUTICAL COMPANIES

The pharmaceutical industry in India is estimated to be worth around INR 61,000 crore, growing at an annual rate of 14%.

Pharmaceutical companies need to keep up with their constantly changing industry dynamics to stay viable and competitive. Pharmaceutical companies face the challenges of simultaneously reducing costs, increasing revenues, improving operational efficiencies, shrinking drug pipelines, patent expiration, getting new products to the market faster, lowering supply chain costs, driving brand awareness and consumer loyalty, and meeting regulatory and security requirements.

With these growing challenges, pharma companies are compelled to adopt the advanced and latest IT technologies and automation levels to stay ahead of the competition. The role of IT is not limited to only being a supportive tool for operational activities, but also to be a strategic tool as well as a major enabler for organizational change, improved quality, and cycle-time reduction. IT solutions allow these companies to tap into their huge databases and deliver easy-to-comprehend insights to improve business performance and maintain regulatory compliance. Not only the large pharma companies, but small and medium scale enterprises (SMEs) are also realizing the importance of IT and using it in one way or the other.

HOW CAN PHARMACEUTICAL COMPANIES LEVERAGE IT?

Pharmaceutical industries are using IT across various functions like Production, R&D, Quality, Supply Chain, Finance, HR and Sales & Marketing. However, R&D, Supply Chain and Sales & Marketing are the three functions where usage of IT becomes critical as the huge amount of data generated by these verticals and complexity of their business processes.

Dashboarding and managing information

The management of any organization requires a real-time information system as they allow the continuous and quick display of the data. It is extremely important that any data generated within the organization should be analyzed and reviewed from a business point of view. The accumulated data can then be used to build an insightful dashboard, which can ultimately drive effective decision-making. The dashboards that can be related to quality, quantity or financial details are called the Performance dashboards. These indicators used for management are understood by readers easily and in no time. To make decisions purposeful and correct, it is vital that information is trustworthy, up-to-date, comprehensive, and relevant. Software solutions are capable of creating a specific dashboard for each manufacturing site that can support management when making decisions related to product planning, product quality and adverse events. Some of the relevant indicators which a dashboard contains, are given below:

- Confirmed Out of Specification (OOS) rate
- Overall equipment effectiveness (OEE)
- Deviation rate
- CAPA (corrective and preventive action) effectiveness rate
- Rejection rate
- Customer complaint rate

For the pharmaceutical industry, it is a distinctive regulatory requirement to conduct annual product quality reviews for individual product in order to recognize underlying trends. Usage of IT software has confirmed that trends of all critical process parameters can be reviewed online and alteration can be made in the process during the year as a part of continuous process verification.

Supply Chain

Implementation of IT is considered a prerequisite for the effective regulation of present day's Supply Chain. High levels of inventory and product obsolescence costs, high manufacturing and logistics costs, looming regulatory mandates and collaborations with channel partners, which could include suppliers, intermediaries, third-party service providers and customers, are the major areas of concern for Pharma companies. As a result of these challenges, Pharma companies are nowadays deploying IT solutions in manufacturing areas that have traditionally been carried out manually.

Sales and Marketing

Pharmaceutical companies are focusing their efforts on sales and marketing activities. In fact, industry estimates indicate that pharmaceutical companies are now spending more than twice as much on marketing and administration, than they are on research and development. The rise of generic drugs and of information available to consumers through the Internet – as well as the pressure from insurance companies and HMOs to fill prescriptions with generic drugs is making it vital for companies to target their marketing strategies to toughen customer loyalty to the brand-names of drugs that previously led the market. Besides, the pharmaceutical business has the largest sales force compared to any industry. By implementing IT tools, these companies are able to expand their marketing practices and empower their sales force to collaborate and communicate efficiently.

Planning and Scheduling

The five R's, i.e., produce the right product, with the right quality, in the right quantity, at the right price, and at the right time must be pursued consistently by any organization. Correct and timely information is extremely important for appropriate planning and scheduling. To fulfil the requirements as demonstrated by the 5 R's, IT solutions like DBMS (Database Management Systems), ERPS (Enterprise Resource Planning Systems), QMS (Quality Management Systems) and document management systems have become essential to most pharmaceutical companies which is well illustrated in Figure 1.
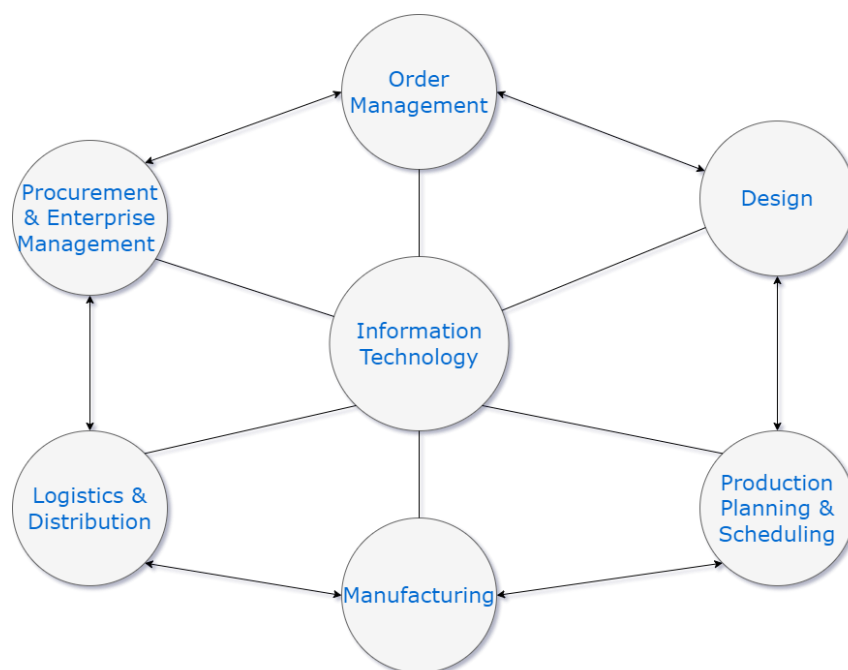

Figure 1 Role of information technology in the pharmaceutical industry

LEADING IT TRENDS

Nowadays, numerous IT solutions are utilized in pharmaceutical industries. ERP, SCM, CRM, SFA, LIMS, DMS and Analytics are some of the commonly used solutions. Organizations are moving towards leveraging these solutions that enables them to stay ahead of their competition and ease the regulatory process.

Analytical tools like BI (Business Intelligence) and Product Life cycle management system (PLMS) are also gaining momentum. BI provides the pharmaceutical companies with the ability to analyze vast amounts of information they already have, to make the best business decisions. The software allows these companies to tap into their huge databases and deliver easy-to-comprehend insight to improve business performance and maintain regulatory compliance.

Product Lifecycle Management system enables pharmaceutical companies to have a unified view of their entire product development lifecycle, with the ability to view and trace every product detail throughout the entire process. It provides the capability to both manage and centralize product information. This helps pharmaceutical companies to address some of the most essential needs, including hastening the time to market, lowering overall operation and production costs and realizing quality standards such as QbD (Quality by Design).

Advances in instrumentation through miniaturized biosensors and the evolution in smart phones and their apps are resulting in increasingly sophisticated health-measurement devices. Pharmaceutical companies can deploy smart devices to gather large quantities of real-world data not previously available to scientists. Remote monitoring of patients through sensors and devices represents an immense opportunity. This kind of data could be used to facilitate R&D, analyze drug efficacy, enhance future drug sales, and create new economic models that combine the provision of drugs and services.

Remote-monitoring devices can also add value by increasing patients' adherence to their prescriptions. Technology and mobile providers are offering services such as data feeds, tracking, and analysis to complement medical devices. The new generation of wireless sensors will be able to provide more sophisticated real-time insight.

Pharma companies need a collaborative IT infrastructure to grapple with the problem of data generated from highly heterogeneous sources. One of the biggest challenges of pharmaceutical businesses is to have data that is consistent, reliable, and well linked. The ability to manage and integrate data generated at all stages of the value chain, from discovery to real-world use after regulatory approval, is a fundamental requirement to allow companies to derive the maximum benefit from the technology trends.

CHALLENGES FACED IN IT PRACTICES

- Identifying right business process that needs automation
- Identification of right product/ solution that fulfills the need correctly and optimally
- Resistance to change/ adoption of new technology specially by medium & small companies
- High IT operating costs
- Segregation between regulated and non-regulated IT process
- Identification of a right technology partner/service provider

EXPECTANCY TOWARDS IT SERVICE PROVIDER

Pharma companies expect IT service providers to be technology partners and possess good industry knowledge to provide end to end services, which result in high ROI.

Companies need technology providers who possess good domain knowledge and understand their business operations well. This will assist companies to identify and suggest the business process/areas where IT implementation is critical with minimal investment leading to increased ROI.

Solution provider should possess a technically sound team with industry expertise. and They should also have the right automation level to suggest/develop/design the appropriate IT solution for the concerned division, which is required to meet the business objectives. The service provider needs to study the operating functionality of the segment of interest and based on the study, develop comprehensive solutions and services, which can sustain the complexities of the business and lower costs.

Regulations related to the Pharma industry and compliances with them are a major challenge for the companies. They would hence like to have a technology partner who has good knowledge of all the regulations followed in the industry and provide them solutions to ease the regulatory process.

CONCLUSION

To conclude, the advantages companies expect by outsourcing their IT to service providers. An organization will need the support of an IT partner offering a full range of services to master the 'digitized' business environment that is the new face of the Pharma industry to become a leader. The industry today seeks to leverage on business transformation capabilities of full-service integrators for:

- Help in bringing down the total cost of ownership (TCO) of IT Assets, and increase the return on investments (ROI) on the IT initiatives.
- Simplification, streamlining, consolidation of application portfolio and associated business processes to align with the business needs and objectives.
- Core IT team is free to focus on their core business, thus enabling sustainable growth.
- Ease down the regulatory process enabling them to timely reach the market and stay ahead of the competition.
- Access to global best practices and IT strategies.