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Managing Pharmaceutical Regulatory Compliance through Smart Knowledge Management Systems

Joseph Kiran Kumar M

Eisai Pharmatechnology & Manufacturing Pvt. Ltd, Ramky Pharma City (SEZ), Parawada, Visakhapatnam- 531019, A.P. India

Abstract- Research and Development (R&D) function in the Pharmaceutical organization works towards the discovery of new drugs, development of drugs and repositioning of the drugs. It is very important that all the activities that are carried out in R&D comply with the standards of various regulatory and statutory authorities so that the organizations produce drugs with care and ensure that they are safe for human consumption.

This study is aimed at studying how knowledge management systems ensure compliance to regulatory and safety standards

Index Terms- Regulatory compliance; Pharmaceutical organization; Knowledge management ; KM systems; Collaborative systems

I. Introduction

Pharmaceutical industry like most of the industries is facing stiff challenges both outside and within to deliver shareholder/stakeholder value. Challenges are due to low growth business environment, questions raised on the R&D productivity in relation to the investments, rising risks and also due to the changes in the marketplace. With many socio economic changes facing the pharmaceutical industry the industry is pressed to deliver value to the patients and also bring the benefits to the pharmaceutical companies.

Pharmaceutical industry is striving hard in view of the management mandate to produce drugs at lesser cost while it is consistently expected to improve the quality of the drugs as desired by the consumers and the regulatory authorities.

The pharmaceutical industry is experiencing regulatory scrutiny across the globe and across the spectrum of the industry especially in clinical operations, quality control activities, drug safety reporting, and manufacturing operations. The outcome of such scrutinies has resulted in the companies being prosecuted and in extreme cases barred from marketing the drugs.

Inspections have become tougher and the pharmaceutical organizations big and small are not having respite and therefore are gearing to be compliant in all the areas possible. Organizations have thus started paying more importance to reduce the risks through the implementation of strong management controls.

Regulatory authorities have also started taking more proactive approach by conducting series of education and training programs which provide guidance for compliance. As the organizations start following the guidance they would become compliant to the guidance which could potentially become a regulation in the future.

Critical Compliance challenges faced by pharmaceutical companies include

II. Validation

Validation is a process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in production or testing maintains the desired level of compliance at all stages. In Pharma Industry it is very important apart from final testing and compliance of product with standard that the process adapted to produce itself must assure that process will consistently produce the expected results Here the desired results are established in terms of specifications for the outcome of the process. Qualification of systems and equipment is therefore a part of process of validation. It is a requirement of food and drug, pharmaceutical regulating agencies like FDA's good manufacturing practices guidelines. Validation is critical for the organizations as it would not be feasible to use the equipment without knowing whether it will produce the product we wanted or not, use expensive and latest facilities and equipment, efficient usage of the resources is necessary, organizations strive towards the reduction of failures and improvement of productivity. At the end of the day organizations would like to ensure Assurance of quality, Cost reduction and meet Government regulation. Managing the equipment and the systems in the validated state as per the regulatory guidelines is a very challenging task as each location has to manage many equipment and systems at different intervals and at different level of complexity.

III. Data Integrity

Data integrity refers to the overall completeness, accuracy and consistency of data. It is to do with the generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data over its entire life cycle in compliance with applicable regulations as per ICH 10 guidelines on Pharmaceutical Quality Systems. Regulatory authorities often check the accuracy and completeness of the data in quality control and manufacturing, Data on finished product stability, dissolution, content uniformity, and impurity , Comparison of raw data (hardcopy or electronic) such as chromatograms, spectrograms, laboratory analyst notebooks, etc. Incomplete data is also classified under lack of data integrity.

Data integrity could be compromised by various factors including human errors, errors due to the data transmission, and unauthorized changes to data after the acquisition of the data etc. The integrity of data generated by a regulated laboratory can make or break a regulatory inspection or audit. It only requires a

single adverse non-compliance to cast a shadow over all work undertaken by a regulated laboratory.

There has been lot of incidences in the recent past about various organizations caught on the wrong side of the regulations due to compromise on data integrity. While the motive of the organizations on such compromise is questioned by regulatory authorities it is a fact that many organizations have been facing the wrath of the regulatory authorities due to their ignorance of data integrity lapses. Many organizations have since received warning letters from FDA and other regulatory authorities. Many organizations especially the ones in the developing nations have been facing scrutiny regarding integrity of the data.

IV. Electronic Records and Electronic signature management

Pharmaceutical organizations slowly but steadily are moving towards the electronic records and electronic signatures as they seem to be more cost effective for the industry and the FDA. Unlike the traditional physical record keeping the approval process is expected to be shorter and access to documentation will be faster and more productive.

Though it is not mandatory to use of electronic records and signatures the companies are keen on moving over to them as computers have now become part of operations at every level and also the possibility of FDA may in the future only prefer to seek electronic records.

Implementing Part 11 has a significant impact on the instrumentation, the work processes and on the people in operations such as quality control laboratories and manufacturing operations. Managing electronic records and signatures has been a challenge for the organizations as any let off on these would result in non-compliance to the records which could implicate the organizations of indulging in malpractices.

V. Good manufacturing practices (GMP) compliance

GMP are the practices required in order to confirm to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines define the minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumers.

Good manufacturing practice guidelines provides guidance for manufacturing, testing, and quality assurance in order to ensure that drug product is safe for human consumption. GMP practices are recommended with the goals of safeguarding the health of patient as well as producing good quality medicine, medical devices or active pharmaceutical products. Complying with GMP is a mandatory aspect in pharmaceutical manufacturing as they need to be observed at the time of manufacturing.The Pharmaceutical industry faces the task of meeting all FDA regulatory compliance requirements including ISO 13485 and 21 CFR Part 11, and other ISO compliance standards. From discovery to clinical trials to patient delivery, quality assurance etc. is a very stringent and a very exhaustive process. This is one such process that the pharmaceutical organizations can think of ignoring at their own risk. Building compliant systems to meet the regulatory requirements is associated with investment of millions of dollars in addition to the millions that one spends in Research and development and in their promotion.

It is very critical for the organizations to meet the regulatory requirements while producing safe and effective products. Organizations would find it difficult to comply with GMP practices with so many elements coming under the roof of GMP.

VI. Knowledge management

The importance of management of Knowledge has never been more important than today. Knowledge management (KM) comprises of a range of strategies and practices used in an organization to identify, create, represent, distribute, and enable adoption of knowledge which exists in human capital or organizational capital. It is very important as well to understand the generation of knowledge and the resources that are responsible for generation of knowledge so that better processes can be engineered to ensure that knowledge flows are consistent in the organization.

VII. Knowledge management systems

Knowledge management systems (KMS) refer to tools that are employed to achieve various goals of knowledge management and are manifested in various ways (Davenport et al. 1998), which include discussion lists, document repositories, context-specific retrieval systems and expertise databases integrated with collaborative filtering technologies.

Knowledge management systems are very important components of research and development organizations as they play a vital role in identifying the sources of knowledge and disseminating the same.

A well-planned KM system serves the overall business strategy of the organization. A knowledge management system can be made more robust through the contribution of all the stakeholders of the organization. By offering sound collaborative capabilities, a knowledge management system can provide the platform for helping the knowledge stakeholders share documents and project plans, find outside experts when needed, and know the status of a project even in complex situations.

The one key success factor for a knowledge flow management initiative that is above all the others is whole hearted support of all the stakeholders. Passionate commitment along with the skills would be an ideal option to survive the initial stages of KM initiatives in the organization.

Current research landscape given the challenges that the R&D organizations face today necessitate the work spread across various distributed project teams, tough timelines, coordination of complex and large scale efforts, Collaboration of teams Such demanding requirements pushed the envelope for the need for a variety of technologies to harness organization's intellectual capital.

All the pharmaceutical organizations work in groups and it is imminent that they have to work together With the need for multi-dimensional approach needed by the businesses the

number and scope of collaboration between the teams have grown rapidly in pharmaceutical research and development

The success of the KMS applications depends upon the collaboration between the researchers and the application developers and technical teams. The most common type of group work amongst the researchers is communication between individual researchers and the teams.

Information sharing is equally important if not more than the communication. . Information is commonly shared by the researchers by leaving a document or a note on a common platform so that other researchers can access it. Such KMS applications include discussion databases, bulletin boards and electronic news groups where documents and their responses are often grouped to follow the discussions.

The pharmaceutical industry is rapidly undergoing a revolution due to evolution of new health challenges together with social and economic challenges facing the current world. This has also caused evolution of R&D. Here, pharmaceutical R&D seem to rely more on technology use through which computers are employed to understand the biology of disease in 'virtual man' hence increasing the predictability of the effects of new drugs (Pharma 2020, 2013).

Now many companies are implementing easily configurable and flexible knowledge management systems that meet the requirements of the dynamic regulatory requirements. The robust, workflow-based knowledge management system allows for the automation of business processes, without programming or custom development. This would ensure that the systems meet today's regulatory requirements.

An enterprise content management system organizes documents, contacts and records related to the processes of a commercial organization. It structures the enterprise's information content and file formats, manages locations, streamlines access by eliminating bottlenecks and optimizes security and integrity. Enterprise content management systems which are part of KMS application portfolio play a very vital role in managing information pertaining to compliance to the regulatory standards. Document management systems (DMS) which is a computer system (or set of computer programs) used to track and store electronic documents. It is usually also capable of keeping track of the different versions modified by different usersare those Document management systems shall ensure that the documentation such as standard operating procedures (SOPs) and checklists are updated. DMS ensures that all the information is integrated with relevant repositories. DMS ensures that most of the document types are captured. DMS ensures that the documents such as SOPs are stored properly and maintained as per the desired storage duration. DMS also facilitates the retrieval of the documents as and when desired based on the Meta data which is so crucial when the researcher has to go through few thousands of pages of documentation. DMS also ensures that the critical documents are protected and are allowed to be accessed by those researchers to whom it is intended. DMS also ensures that rules based workflow would allow the documents sent to various people in the communication chain. Versioning part of the DMS would ensure that the documents that change over time and require updating can be Content management systems. Collaborative software or groupware is application software designed to help people involved in a common task to achieve goals. The design intent of collaborative software is to transform the way documents and rich media are shared to enable knowledge pertaining to compliance is shared more effectively and the teams distributed across the globe get benefitted through more effective team collaboration.

Collaborative software like lotus notes platform and Microsoft SharePoint facilitate action-oriented teams working together over geographic distances by providing features that support the researchers in communicating and collaborating the measures that have been taken to ensure compliance to regulatory and statutory requirements. The use of collaborative software in the pharmaceutical R&D creates a collaborative working environment. A collaborative working environment supports people in both their individual and groups thus ensuring that it gives competitive advantage to the organization by ensuring compliance.

KMS applications are principally designed to benefit and reward the workgroups rather than the individuals. It is very important to get the researchers use the applications as the applications rely on the usage by groups to be effective. In the high tech industry like pharmaceuticals the means for organizing knowledge is to develop it. One should maximize the functioning of research and development teams on knowledge creation and knowledge creation rather than for processing information.

KMS acts as a good source of knowledge creation and sharing as they enable data to be collected, stored and retrieved through any combination of forms thus meeting the requirements of the researcher and the teams.

A learning management system (LMS) is a software application for the administration, documentation, tracking, reporting and delivery of e-learning education courses or training programs

LMSs range from systems for managing training and educational records to support the researcher teams to learn collaboratively over the network software for sharing the knowledge about good manufacturing and good laboratory processes. As compliance to regulatory requirements it is essential that the researchers keep learning from each other among the teams and enrich each other's knowledge regarding compliance. Learning plans, scheduling the programs and the feedback systems toughly help the researchers to use learning management systems

The features of KMS have been enhanced allowing data to be interrogated, tabulated, checked, approved, stored and archived to comply with the latest regulatory guidance and legislation.

Conferencing solutions ensure that teams work cohesively and everything common between them can be share more efficiently and in real time as and when it is required. Use of Video conferencing products and online real-time presentation applications would certainly help researchers to collaborate and continue their research work in an interactive manner.

These seamless systems ensure that teams collaborate, information is stored centrally and the teams work on the applications as if they are working on them locally.

VIII. Conclusion

Compliance to regulatory and statutory requirements is seen as a necessary benchmark that all the pharmaceutical organizations have to abide by. Organizations have an option of looking at them as the guidelines that they need to comply to so that they exist and on the other side complying to those standards and adopting them earlier than other organizations would ensure that they have competitive advantage as the consumers would be more keen on buying products from those organization s which follow the guidelines. Knowledge management systems helps the researchers to collaborate and act as set of tools which not just let the researchers to collaborate together to produce better products. KMS tools like collaborative systems, content management systems, learning management systems ably support the research teams to share their knowledge especially the ones pertaining to regulatory compliance. Using these tools the researchers can carry out repetitive tasks easily

By far the technology tools, KMS being one among them have contributed to the collaboration aiding management of researchers in the organization.

The discussion above emphasizes that KMS have the capability of managing the knowledge of the R&D organization effectively through their collaborative features and their contribution is very important from the perspective of the researchers.

Organizations therefore need to accept the fact that KMS enhances the ability of the researchers immensely in facing the regulatory and statutory audits as these tools help them in retrieving the information in time and in full. KMS tools are only becoming more intelligent to meet the requirements and with predictive analytics built into such tools it come much easy for the companies to be compliant.

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AUTHORS

First Author – Joseph Kiran Kumar M, Eisai Pharmatechnology & Manufacturing Pvt. Ltd., Ramky Pharma City (SEZ), Parawada, Visakhapatnam- 531019, A.P. India , Phone: +917032919118, Email: josematcha@yahoo.comMy Name is Joseph Kiran Kumar working as General Manager – Information technology in Eisai Pharmatechnology and Manufacturing Pvt Ltd, in Visakhapatnam, India heading Information Technology function.
I am an MBA in Technology Management from Osmania University, Hyderabad, India and have around 20 Years of work experience. I have certifications in Project management (PMP), IT governance (CGEIT), IT Risk Management (CRISC) and Global CIO certification from Indian school of Business (ISB).
I am currently doing my Ph.D research from Jawaharlal Nehru Technology University, Hyderabad, India in Knowledge management systems and its impact on Pharmaceutical R&D.