Pharmaceutical Quality Management System Software: A Review and Its Importance in Pharmaceutical Industries

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Abstract:
Maintaining the quality of medication and pharmaceuticals has always been an area of major concern in today's world. The process is very complex and therefore needs to consider different types of rules and guidelines such as GMP and GLP. Quality management has emerged to be an important subject of matter in pharmaceutical industries [1]. Hence many laboratories and pharmaceutical industries are now giving more importance on proper implementation of an effective Quality Management System. Pharmaceutical Quality Management System (QMS) generally refers to procedures and practices which help in contributing to the overall quality of product. It ensures effective and efficient execution of tasks within organization [1]. Implementation of a proper Quality Management System is very important as it can help a pharmaceutical organization in fulfilling its responsibilities like quality, safety, efficacy of pharmaceutical product. A well developed QMS can easily assimilate the procedures and it can help in effective improvement of quality in all pharmacy related areas as well as satisfaction of customer, reduction of errors, variability and therefore improving the healthcare outcomes. Various software systems are available in the market for effective implementation of QMS. It comes with various features like auditing, documentation, corrective and preventive action (CAPA), training management, investigation management etc. This review paper focuses on different types of QMS Software and its importance in Pharmaceutical industries.

Keywords: QMS, CAPA, SOP, Installation Qualification (IQ), Operation Qualification (OQ)

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Introduction:

Pharmaceutical Industries have a very significant and vital role in Healthcare management system. It deals with manufacturing, marketing of pharmaceuticals medical devices and biological products which are used in the diagnosis and treatment of diseases and conducting research for innovation and development of new products which can be used for the welfare of mankind [2]. In recent times, Quality Management System (QMS) is a critical element in building the product and service quality. Delivering the products of high quality, proper safety and high efficacy to the market and consumes is the most important need of Pharmaceutical Industry, failing to adhere can lead in losing the loss of "integrity" and "Brand image" of the organization [3 -6]. Each Pharmaceutical Industry needs to follow certain standards by which

they can sell their products in respective country. "International Conference on Harmonization" Q10 model is one such standard which elaborates the elements required in efficient working of pharmaceutical quality management system and continual improvement [6-7]. Industries are facing many challenges for implementation of QMS Software. Organizations and Quality professionals require a quality management system which quickly adapts to the changes and helps in continuous improvement of quality. Many Industries and Organizations are integrating Quality management with QMS Software into their enterprise [9]. Maintaining the "quality" of the products and formulations is very necessary for prevention of various hazards related to health. If the products do not have proper quality then it can result in severe side effects and in some cases even the death of the consumer or patient [2]. Many industrial organisations and laboratories are implementing Quality Management Software Systems with a desire to improve the overall quality and efficacy. Effective implementation of QMS Software in organizations can provide support in enhancing the quality expectations, continuous improvement using innovation throughout the product lifecycle. It can help in forming association between manufacturing activities and pharmaceutical development. Thus, a well designed and implemented QMS Software can help in enhancing and ensuring quality improvement in all pharmacy sectors, enabling pharmacists to meet the ever increasing demands for better services and providing customer satisfaction. Other benefits include – better utilisation of resources, continuous improvement in product and process lifecycle through regular monitoring, management of internal audits, encouragement of the staff through effective team work, effective risk management and reduction of wastes.

Quality in Pharmaceutical Industry:

As per ISO, "Quality" refers to the extent with which certain parameters are set for achieving requirements. Quality of pharmaceutical products has been a major area of concern for many industries and regulatory agencies across the globe for maintaining the therapeutic effectiveness and total quality management for pharmaceuticals [10]. Depending upon the level of satisfaction, the quality of a product can be divided into three categories such as "excellent", "good" and "poor" [11]. Quality can also be defined as conformance to certain standards and specifications of the product [12]. The standards and specifications vary from product to product depending upon its efficacy, potency, therapeutic effect etc [13]. Quality can be categorised into two categories:

1. **Specification quality**: Specification quality is generally defined from consumer's point of view. It generally explains as to how every consumer compares quality of different products in the market.
2. **Conformance quality**: Conformance quality refers to the evaluation of certain factors by which a product or service is produced in a proper manner. As per pharmaceutical industry, quality can be defined as conformance to specifications of a particular product [13].

Quality cannot be defined in a particular manner; it varies from individual to individual in different ways [14]. However the parameter which is common to all is the "satisfaction". Pharmaceutical industries and organizations are required to maintain high quality standards and should not compromise with it as these products will be further used for mankind.

Various standards and guidelines suggest certain specifications and rules which are required to be followed by each and every pharmaceutical organization. Thus, Safety, Purity, Identity, Efficacy and Quality of a finished product are required to be maintained properly [15].

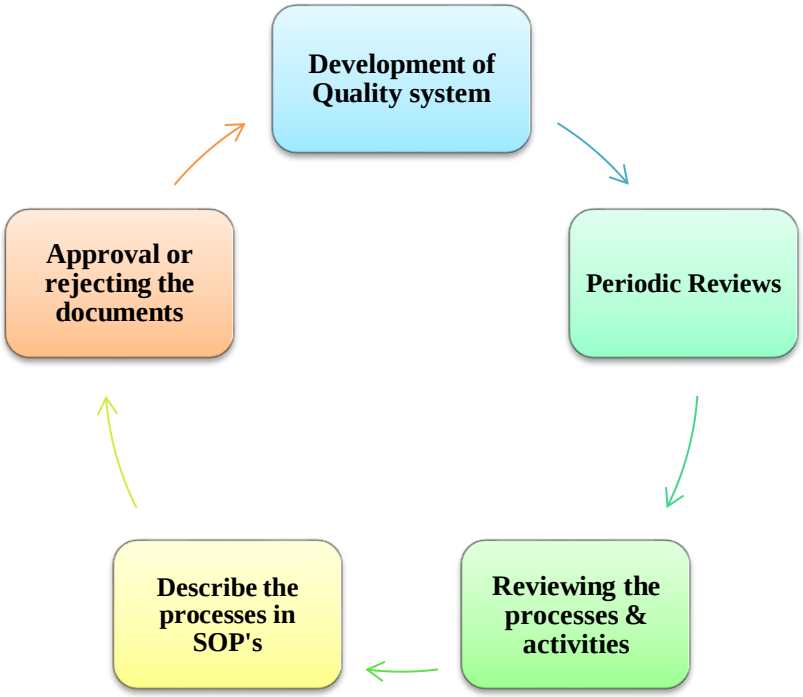

Figure 1: Responsibilities of Pharmaceutical Quality unit

Quality Management System:

Quality Management System can be defined as the most important aspect of management function which helps in implementing and determining the overall process and the direction in which the organizations will work to improve the quality of the product. It implements "quality policy" [16]. Quality management plays a very important role in pharmaceutical industries and organization as the formulated drugs and products have significant effect on various functions the body system of customers. Hence, it is important to maintain the identity, purity, safety, quality and efficacy of the products [6-8]. Effective implementation of quality management system helps in ensuring proper functioning of each process which is required to meet the standard regulatory compliance. Quality management system helps the organizations in regulating the quality parameters. It covers all the processes in detail related with the product processing such as drug sampling, objectives and policies, drug analysis, reporting of the samples, procedures in formulation of drug etc [3-5].

Quality Management system generally includes four elements –

1. **Quality planning**: Quality planning deals with the process of implementation of various guidelines into the manufacturing processes and set of procedures for accomplishing certain goals and objectives.

2. **Quality assurance**: Quality assurance generally deals with well scheduled and systematic activities which are performed as a component of a quality system for satisfying the quality of product.

3. **Quality control**: Quality control deals with the process of checking, controlling, and correction of various processes, procedures, and product, so that certain standards set for achieving quality are being fulfilled properly.
4. **Quality improvement**: Quality improvement is a process which deals with proper assessment of performance and taking precise, logical and systemic actions for its improvement [17-18].

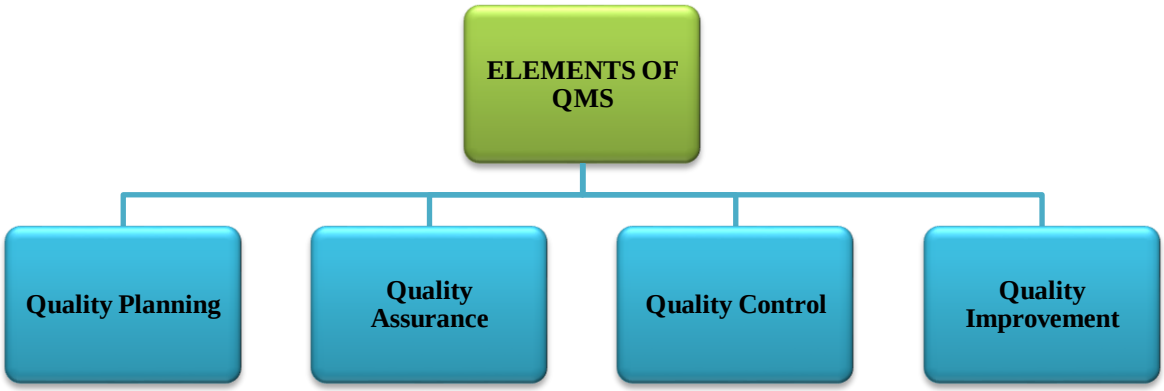

Figure 2: Essentials of Quality Management System [19]

Pharmaceutical Quality Management Software System:

Pharmaceutical Quality Management Software System can be defined as information management system which can help in proper management of quality policies and Standard Operating Procedures (SOP's). It includes: auditing procedures, manufacturing, ISO requirements, protocols and specific regulations related to industry. QMS Software provides a controlled manner in which quality, efficacy of a product can be managed properly throughout product lifecycle [20]. Properly organized (QMS) Software can help in ensuring continuous improvement of quality and proper management of various processes and tasks. It generally includes:

1. Documentation of various processes, policies and systems.
2. Implementation of controls and procedures.
3. Proper management of the whole system.
4. Audit management.
5. Resolution of complaints of customers.
6. Corrective and preventive action (CAPA) management [9].

Use of QMS Software helps in increasing productivity and helps in integration of various processes from all the parts of an organization [9].Thus, a proper implementation of QMS Software can bring compliance with industry standards, scope for continuous improvement, new innovations, proper decision making, and enhancement of product, processes and system [20].

Procedure for implementing QMS:

The process involved in the implementation of Quality Management System also controls its financial performance as well as effectiveness in pharmacy sector. Steps involved in implementation are as follows:

1. Identification of essentials and their integration into QMS after development of procedures
2. Development of important procedures and determination of basic activities like purchasing, delivery and customer services.
3. Identification of activities which are important for managing primary activities.
4. Supporting and developing the processes.
5. Generation of assurance processes as well as verification of activities for monitoring the efficiency of the processes.
6. Development of sub- processes and its identification on the basis of 'entry' and 'exit'.
7. Comparison of processes according to standards, performing the analysis and finding out the missing process.
8. Identifying and addressing the gaps.
9. Generation of QMS Model and its application in developing procedures and flow charts.[21]

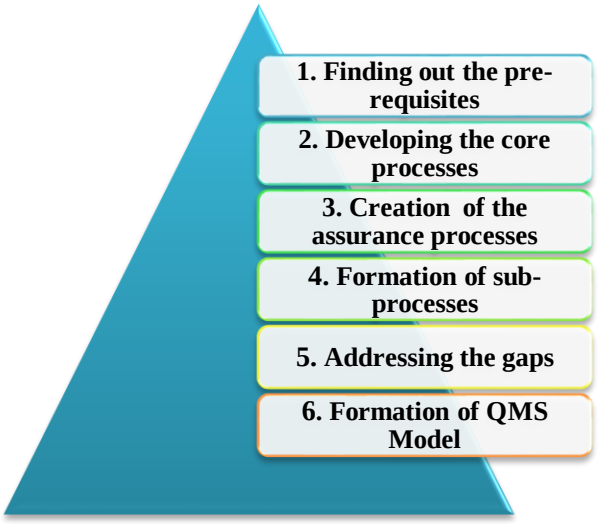

Figure 3:- Steps involved in designing Quality Management System [21]

Benefits of Implementing QMS Software:

Implementation of QMS Software in industries and organizations brings significant benefits as it helps in improving not only the quality and effectiveness of a product but can reduce the risks by complying with the performance standards.

1. QMS Software helps in proper arrangement of documents of various procedures and processes in one particular location and therefore results in improved documentation.
2. It gives in depth information about the whole manufacturing process which helps in pointing out the causes related to delaying of production.
3. Ensuring greater consistency in development of process and product which helps in better utilization of resources and helps in developing an effective end product.
4. QMS Software allows companies to maintain better relationship with customers by interconnecting with the customers and identifying their complaints. Information can be shared between customer service, sales and manufacturing executives.
5. Helps in establishing a proper layout for each process to be carried out in a unified manner.
6. Maximizes organizational efficiency by creating a set of Standard Operating Procedures (SOP's) which minimizes risks of non conformances [21-22].

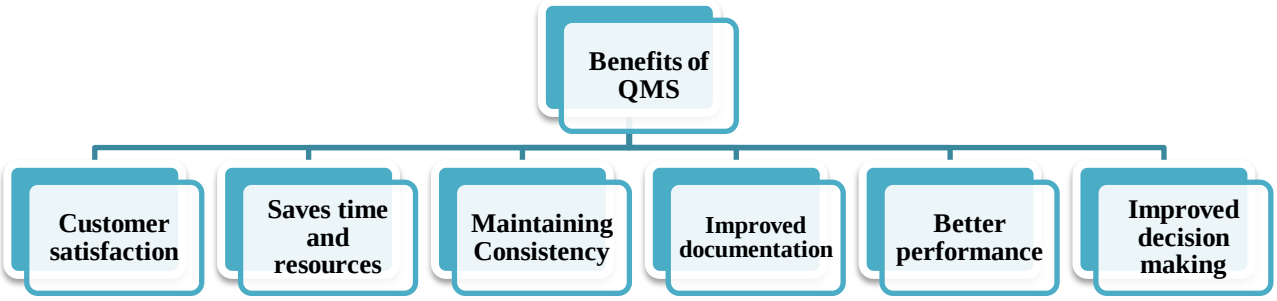

Figure 4:- Benefits of Quality Management System Software

Personnel who can profit from Pharmaceutical Quality Management Software Systems:

1. **Research and development managers –** R&D Managers can use QMS software for clinical and pre-clinical studies. They can effectively organize and search various research documents within a centralized secure system.
2. **Document authors –** A QMS Software can provide the author documents from various types of compliant templates so that it is convenient for authors to work without wasting their time to match the templates. The authors wouldn't face the difficulty of searching here and there for finding the location of a particular document, its revision and approval as all such tasks can be performed within the same system.
3. **Industrialized department –**QMS Software helps in tracking down the details of the various processes, specifications, deviations throughout the development cycle of the product. It helps in improving the overall quality of the product. The system helps in locating training records without any difficulty.
4. **Clinical Personnel –** As software systems are electronic and automated, searching various documents becomes very convenient and easy. Computerized copies of documents, e-mails, protocols, IRB information from various locations is easily available within a proper unified system.
5. **Administration –** A QMS Software can help in implementation management and maintenance of quality within an organization which can help in better utilization of resources, and can provide comprehensive solutions to problems such as requirement of assistance, or specific training requirement for a particular system's functionality [23].

Things to consider when implementing QMS Software:

An effective QMS Software can help the industries and organizations in producing products and formulations of high quality standards. Proper implementation of a QMS Software can dramatically improve the overall product quality and an entire quality process starting from the inspection till the final approval and shipment of the product.

The following parameters are considered for successful implementation of a QMS Software -

1. Validation of Software: The software trader should provide services related to validation and confirmation of software which can assist in meeting the requirements of the following- Installation qualification (IQ) and operational qualification (OQ) which are set out

by the FDA. The trader should also provide the essential set of records related to IQ and OQ with every software release.

2. Security: The QMS Software should come with a multilayered security model which will help in ensuring whether your intellectual property (IP) protected properly or not. It should have access controls to further protect product information and privacy.

3. Recovering lost data: The QMS software should come with built-in redundancies design which can help in quickly recovering the data from a wide range of system failures.

4. Execution and Training: There should be a proper list regarding the resources which are required from the trader and your team to complete the software execution. Also time which will be needed in implementation, configuration, and testing of the software should be taken into consideration as well as trader's approach towards training. It should also be considered whether the training will be given by live or in the form of recordings.

5. **Customer Satisfaction:** The organizations should consider whether they have adequate access to educational resources after going live and the dedicated supporting staffs (e.g., representatives or coaches related to customer service) who are ready to solve queries which can further lead to successful growth and extension of the QMS platform.

6. Adaptability: The QMS Software should be designed in such a manner so that it is easily able to accommodate various additional users, suppliers, as the company continues to grow.

7. Effective management of expenses: Management of expenses should include cost of software as well expenses related to maintenance. Extra expenses required for annual maintenance as well as new software should be determined. Identification of any costs related with training and customer service should be taken into consideration. Customer support must be included as an important part of the software subscription [23].

Types of Quality Management System Softwares:

1. **MasterControl –** This software has been particularly designed for helping industries which deal with pharmaceuticals for managing regulatory- related processes, records, and training in a single system. It helps the companies to make faster reach of their products in the market and thus improving compliance.

Features of MasterControl's Quality Management Software Systems –

MasterControl Software helps in quick and faster launching of products to the market by enabling the entire organization to perform the tasks more effectively with the help of various tools which are already known and employees are already capable. Benefits of MasterControl TotalPharma which can help in making reach of the products faster to the market include:

- It helps in creation of documents more quickly with the help of templates which are already approved for each document type.
- It comes with the ability of creating PDFs containing bookmarks watermarks, and computerized signature.
- It enables proper management of documents related to clinical trials.
- The software system has a web-based interface.
- It helps in creating various association booths which are having the ability to engage several departments.

- It helps in speeding up of various projects related to documents and process.
- It helps in reducing organizational overload by using automation.
- Several library templates are available which requires little changes in configuration, and therefore it results in faster implementation time.
- MasterControl helps in managing the delays caused in submission of documents due to their misplacement or due to submission of incorrect document.
- It helps in preventing the submission of the documents which lack bookmarks.
- The system helps in gathering all the information related to quality and product development at a single place.
- Regulatory personnel can involve themselves in the lifecycle of development of product and can easily use documents for other purposes as well as for regulatory submissions.
- This software system comes with the facility of importing e-mails which enables important communication with regulatory authorities as well as management of suppliers so that they can be connected to the system and documents can be easily tracked.
- The software system can easily work in integration with other systems like Microsoft Word so that each and everyone are able to take part in the process [23].

2**. Qualio -** Qualio is a software system which is specially designed for the needs of starting up small to mid-sized business in Pharmaceutical industries. Qualio helps in providing intuitive user experience and its implementation is simpler which helps in producing products with better quality and promotes faster growth of the organization. Qualio mainly focuses on quality document management with built-in features to create documents such as policies, SOPs, and other required documentation. It provides a proper balance of flexibility and control with various tools like document versioning, training tools, and customized notifications. It also comes with additional features such as CAPA, customer complaints, audits, and various aspects of the Pharma quality management lifecycle. Qualio offers strong document management capabilities and global association.

Features of Qualio Pharmaceutical Quality Management Software Systems –

- It comes with automatic quality and has all-in-one platform which helps in effective management and addition new drugs, departments and suppliers
- It promotes teamwork by effective association with workers and supportive staff.
- It helps in creating and accomplishing workflows for document approval and training.
- It helps in proper management of suppliers, customers, internal audits and controlling your entire business.
- Implementing Qualio is a very simple and fast process which makes it easy for team members and staff.
- It helps in digitalization of all the necessary documents.
- It helps in quickly generating the documentation with just a single click.
- It helps in making the document management more efficient and proper cooperation with each other on files with an in-system web editor.
- It generates a detailed report on training, completed and due activities, audit trails, and change control.
- It also helps in meeting specific requirements of FDA, ICH and ISO.

- It assigns CAPA-related tasks and track to completion.
- It helps in speeding up your route to market with the help and support from quality experts [24].

3. NOVA-QMS – NOVA QMS software solutions are specifically designed to target the pharmaceutical, biotech and other health-care industries. They are easy to use and come with features specialized modules that helps in managing all aspects of quality with less effort and time as maintaining consistent quality of product and its process is very difficult in recent manufacturing environment, so in these cases a robust quality management system is needed.

Features of NOVA Quality Management System Software –

- Quality Management - NOVA-QMS enables organizations in ensuring compliance, improving quality and reducing costs by integration of all quality processes, such as managing and finding out the various errors which result in deviations, customer related services such as managing their complaints, supplier quality, auditing, change control, taking right measures, training supervision, etc. It comes with the ability to deal with all the problems within a single unified system.
- Management of Deviations and its Investigation – With the help of NOVA-QMS errors which can result in various deviations are noted down properly and evaluated to determine the main cause. It helps in reducing the cost of quality and improves productivity.
- Customer related services – This software helps the pharmaceutical industries by implementing a centralized perspective of managing complaints related to customers and reporting of unfavourable events and thus permits the users in taking advantage from a single interface.
- Control of Audits – This software enables the organizations in developing better quality, proper management of expenses, and recognizing functioning risks by providing the proper controlling and execution of audits and thus making sure that issues are sorted out on time in efficient manner.
- Change Control – This software helps the companies in improving the effectiveness, increasing control, and reducing various defects by executing an efficient change control program, which merges well with other elements of the quality management system.
- Corrective and Preventive Action (CAPA) - Novatek software helps the organizations in enhancing the quality, decreasing the expenses by automation of the entire process using a unified approach.
- Training Management - Nova-QMS software system helps the organization in reducing the risk and increasing the working efficiency of employees by improving various training strategies. It helps in providing a unified, automated, and computerized software system which helps the industries in having proper control.
- Document Management - Novatek helps the companies with minimizing the costs and controlling the performance by providing various solutions for fully unified Quality Management Systems (QMS) [25].

4. AssurX – AssurX Quality Management System Software is specifically designed for supporting the standards and requirements of Pharmaceutical industries. AssurX is suitable

for industries which are related to pharmaceuticals, biotechnology and manufacturing. The AssurX Software comes with IQ/OQ validation templates. This software enables the organizations in identifying the risk and fixing it which further prevents the problems associated with quality and compliance, thus promotes continuous improvement.

Features of AssurX Quality Management System Software –

- It comes with single interface by which one can improve the quality, ensure compliance, manage the risk effectively, and streamline workflow.
- It is very simple and easy to install, configure, use, and modify.
- It helps in tracking activities, sharing data and information to the suitable user.
- It comes with various analytical tools.
- It helps in identifying and solving the problems quickly using risk-based approach.
- It promotes proper management of various operations while detecting, correcting, and preventing potential causes.
- The software is specifically designed to meet cGMP, HHS and other FDA regulations.
- The risk assessment features such as CAPA and proper risk management system enables to meet the ISO standards in quality management systems.
- Enables HIPPA Compliance.
- It helps in automatically resolving, tracking various documents and issues related to products which are generated from any source.
- It helps in effective management and control of costs and thus makes a better quality product.
- It is fully compliant with 21 CFR Part 11 and Part 820 as well as flexible enough to keep us updated with changing cGMP requirements [26].

5. Origami – Origami enables to meet the requirements of various industries and organizations in building a custom of quality management, managing data integrity, managing suppliers, and making sure overall conformity is maintained. The Origami Quality Management System (QMS) helps in developing a risk-based CAPA process, which helps in ensuring that the team is efficiently trained and is performing to their best, managing suppliers, and investigating various lab results and thus supporting quality metrics and reporting. The Origami QMS also helps in scaling up to new people, divisions, and processes as they get added in your organization. Origami also provides all-inclusive modules at low costs and high speed.

Features of Origami Quality Management System Software –

- Origami enables automation of entire audit process, scheduling of audits, conducting audits and reviewing actual audit scores against targets.
- Origami helps in efficient management of regular document review processes, thus saving time and money. Origami automates all stages of document management; hence reviews, changes, approvals and training are all managed properly.
- The training management software enables proper functioning of training and certifications according to the industry regulations, SOP revisions, and others. It is compulsory for individual employees to be certified. By using this software the audit of your workforce goes effortlessly by completing necessary certifications on time.

- The CAPA management software works on the risk management. Based on the type of failure and fault in information, the system helps in adjusting the workflow pattern, thereby handing over high-risk problems to the particular concerned team.
- The origami software helps in identifying and keeping focus on the premium suppliers. It can also be used for supplier (re)qualifications, supplier self-assessment reporting.
- Origami gives you integrated quality management abilities which helps in achieving the targets of organization, ensuring that the team mates are properly trained to follow the procedures.
- Origami software helps in recording complaint information such as the type of complaint like product installation, packaging and shipping as well as the source of complaint. It also helps in ensuring that the organization tracks and manages communication with authorities [27].

6. Intelex: Intelex QMS helps in providing a cloud- based interface for quality, safety, health, environment and its management. It manages people, processes, customer report, and essential information, ensures conformity, manages various risks and further improves operational performance. It helps in encouraging data driven decision making for optimizing suppliers, effective cost management and customer satisfaction. Intelex caters to the needs of various industries such as automation, construction, education, healthcare and manufacturing.

Features of Intelex Quality Management System Software –

- It helps in proper management of documentation, scheduling, auditing and reporting of information.
- It enables in setting certain standards and objectives related to quality across a variety of dimensions.
- It helps in defining all the processes and procedures which are involved in manufacturing a product.
- It also assists its services for resolving the issues and complaints of the customers to provide them satisfaction by determining the root cause of complaint.
- It enables proper planning and execution of quality management processes and controls.
- It enables proper implementation of various strategic plans and best practices for continuous improvement of quality.
- The software makes it easy to manage proper training of individuals through various training programs and also manages training data of your organization in a secure web based platform.
- It helps in saving time, money and resources by tracking down the supplier data in a unified and single online database which is accessible to every individual across the organization.
- The software system systematically reduces risks, increases various opportunities and innovation and thus promotes continuous improvement in maintaining the quality of the product.
- The software is specifically designed to gather information related to non-conformance, analyzing the root cause of the problem and thus taking corrective and preventive actions [28].

Conclusion:

In today's highly competitive world, the industries have a certain pressure of maintaining high quality of products and making its rea.ch to market more rapidly as well as meeting the requirements of customer as well as regulatory authorities. Therefore the selection and implementation of proper quality management system software is very crucial and it requires a series of steps. An effective implementation of quality management system (QMS) in workplace is very important for helping the organizations in achieving their product development milestones as well as commercial success. Effective pharmaceutical QMS software helps the industries to sell and maintain safe and effective products that consistently meet or exceed customer expectations [29-30].

List of abbreviations:

QMS – Quality Management System
CAPA – Corrective and preventive action
IQ- Installation qualification
OQ - Operational qualification
ISO- International Organization for Standardization
ICH – International Council on Harmonisation
cGMP – Current Good Manufacturing Practices
SOP – Standard Operating Procedure
IP – Intellectual Property
HIPPA - Health Insurance Portability and Accountability Act
CFR - Code of Federal Regulations
HHS – Health and Human Services
FDA - Food and Drug Administration
NOVA – Novatek International

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