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Quality Management and Quality Assurance in Pharmaceutical Development

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Abstract:

Quality of medicines refers to the gathering of essential specifications. The topic of quality management is very important in pharmaceutical industries along with the importance of identity, safety, purity and ultimately appropriate quality of product, because, the products of pharmaceutical or drugs are directly supplied to the customer's body system. The quality, safety and efficacy of pharmaceutical product are achieved by the concept of both quality assurance and quality control. The quality of the product can be maintained by taking the help of various guidelines such as GMP, GLP and many others, as it is a complex process. In every pharmaceutical industries, there is a quality assurance department who looks for the guidelines followed by the industries. In this paper, it is tried to discuss about the quality management system in the pharmaceutical industry and their elements. Along with the quality assurance, there is number of challenges, which has to be face in the pharmaceutical industries that are also discussed in this paper.

Keywords: *Quality Assurance, Total Quality Control, Total Quality Management (TQM), Pharmaceutical.*

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Introduction

The context of quality has become an important factor in the current state of the era. Nowadays people are very smart in choosing only those thing which ensures to fulfill their demands and needs. Quality can be precisely defined as the gathering or achievement of the essential specification of fast-changing world of the current scenario. Quality in reference to the pharmaceutical industry now becomes a non-ignorable issue. The topic of quality management is very important in pharmaceutical industries along with the importance of identity, safety, purity and ultimately the appropriate quality of the product, because, the products of pharmaceutical or drugs are directly supplied to the customer's body system. There are some kinds of rules and specification has been made by several laws and guidelines which has to be strictly followed by every pharmaceutical industry. Quality Management System is a system which is followed by every pharmaceutical industry for maintaining the quality of pharmaceutical products (Pandey and Anju, 2018). Quality assurance covers all matters which influence the quality of a product individually or collectively (Potdar, 2007). Awareness for the significance of the quality of the pharmaceuticals products has been growing since the launching of cGMP-current good manufacturing practices of FDA and practices and guides which are harmonized by the world. Several definitions represents this awareness which defines the quality, as exactly as it should be. The joint statement between the federations of international pharmaceuticals (FIP), and the International Federation of Pharmaceuticals Manufacturers Associations (IFPMA) is highlighted by the role of Governments provides the pharmaceutical industry as one of the most closely structured industries for more than 50 years by certifying the safety of medicinal products to protect the patients (Haleem *et al*., 2013).

Quality

Quality can be described very unclearly although it is a very commonly used term. The concept of quality is easy to visualize but it is very difficult to define. Quality is the definition of perspective dependent which varies from person to person. Many quality experts have defined the quality in their own ways such as delighting the customer, conformance to standards or specifications, fitness for use, meeting customer's requirement or expectations etc. therefore the quality is the defines as the sum of features and characteristics or service or product that bears on its skill to fulfill need.

The brands of a particular tablet are checked and compare before selecting and purchasing it on the basis of its therapeutic efficacy and side effects, color, and odors. Therefore the customer or user of a product compares the features of products, and during the quality compare, the presence of efficiency in the product is also checked and compared. There are two aspects of quality of a product or service, in which first aspects related to the features of the product and service, whereas, the second aspect concern about the presence of efficiency in the products and services.

For the success of the organization, the eight dimensions of quality are very important which are listed as follows.

- Performance: Primary operating characteristics of products
- Features: Basic functioning characteristics of product supplemented
- Reliability: During the specific period, the possibility of good functioning
- Conformance: The degree to which, established standards achieved by the design and operating characteristics of a product
- Durability: Measurement of life of a product
- Serviceability: Repairing ease and speed
- Aesthetics: Looks, feel, taste and smell of a product
- Perceived quality: Seen by a customer (Mazumder, Bhattacharya and Yadav, 2011)

The Top Ten Responsibilities of the Pharmaceutical Quality Unit

- Establishment of the quality system
- Auditing of compliance to the quality system
- Establish procedures and specifications
- establishment of manufacturing controls
- Performance of laboratory tests or examinations
- Review and approve or reject all things cGMP
- Ensure investigation of non-conformance
- Keeping management informed
- Description of responsibilities in writing
- To remain independent

Elements of Quality Management System

There are four facets which are typically involved in quality management systems

1. Quality Planning:

It is the process, use achieve measurable objectives and requirements by translating quality policy into processes, procedures, and instructions.

2. Quality Assurance:

It is the planned and methodical activities which provide confidence that process, product, or service requirements for quality on executed as a part of the quality system which is now being satisfied.

3. Quality Control:

It is an act of monitoring and appraising to ensure requirements for quality. It also corrects the process, product or service.

4. Quality Improvement:

It is the process of taking methodological and systematic actions by analyzing performance for improving it.

Quality Risk Management

All the products of pharmaceuticals have an inborn element of risk. There are many stakeholders in the industry of pharmaceuticals and also their corresponding diverse interest, therefore an effective quality risk management approach and a clear definition of risk are to be applied in an organization. In the agency and industries, the need for procedure and processes recognition for merging the use of risk management programs is noticed by FDA. After that, FDA has started publishing position papers. For the identification of risk, risk management plans should be used. A method for the communication, assessment, control, and review of risks to the quality of medicinal products is called quality risk management. In this process, the decision can occur at any stage of the process. In the guidelines of Medical Device Use-Safety, human factors engineering are incorporated into risk management through which it can be illustrated that how medical device use and hazards are correlated with each other, should be observed at a time of development of a device which is the part of risk management process.

Total quality management

Just like a technique, Total Quality Management (TQM) is the conception which involves everyone and everything in the organization to stress out a systematic, integrated, and consistent perspective. Customer-driven, a learning organization is provided by the TQM as it a management philosophy, in which continuous improvement in the effectiveness and efficacy of the organization and its corresponding processes takes place hence it is devoted to the total customer satisfaction. TQM is basically used for the quality improvement and for other purposes such as profit, productivity, market share, and competitive edge of organizations of various types (Haleem *et al*., 2013).

International Conference on Harmonization (ICH)

Both regulators and research-based industry initiatives are included in ICH initiative. These initiatives are from different countries such as Europe, Japan, and the US for the scientific and technical discussions of the testing procedures through which the safety, quality, and efficacy of the medicine can be assessed and ensured. For the registration of pharmaceuticals, technical requirements of ICH is needed for the human benefits and here ICH stands for International Conference on Harmonization.

Purpose of ICH

- International harmonization of Technical Requirements can be monitored, updated and increased by this.
- Medicines can be ensured with safety, efficacy, and quality which must be registered and developed in the most appropriate and cost-effective method.
- Public health can be promoted and protected by applying an international perspective.
- The unnecessary duplication of clinical trials in humans can be prevented.
- The use of animal testing can be minimized with the safety and effectiveness.
- Improvement of the efficiency of global drug development (Pandey and Anju, 2018).

Challenges in the Pharmaceutical Industry

The environment of the pharmaceutical industry is being increasingly complex and dynamic. In the pharmaceutical industry, a number of changes have been carried out since last many years which tends to continue. There are lots of factors which have increased the level of insecurity such as global competition, increased buyer-cost sensitivity, markets opening, and advancement in technology. The increase in cost is encountered by the unavoidable increase in the patient expectations, cost increment in health care and incapability of economics. Therefore, the cost can

be reduced by increasing the competition and accountability through the number of measures, which are introduced by the government. The loyalty of major branded drugs is threatened by the development of generic drugs, is the other major change in the field of pharmaceuticals. A product which is manufactured after the patent expiry by another manufacturer is called generic product which remains generally at a cheaper price. The success of technological advances in manufacturing new product leads to the growth of many organizations (Rana *et al*., 2009).

Review of Literature

Bell and Moore, (1998) worked on the topic of integration of quality assurance or quality control into quantitative analysis. Under the strict quality assurance and quality control guidelines, modern laboratories operate. They noticed that the incorporation of quality assurance and quality control is possible by utilizing blanks, replicates, knowns and spiked samples. The appropriate use of quality control and quality assurance involve the understanding of basic principles of the chemical as well as the strength of traditional laboratory exercises. The accurate conceptual value is a result of the transformation from the abstractions into concrete data with the involvement of the skill of student in numerous enhanced problem-solving.

Fernandez *et al*., (2009) studied to assess the impacts of implementing the ISO9001:2000 standard in the pharmaceutical industry. Different stages which are followed by the implementing the ISO9001:2000 systems are discussed in their review which is achieved by including this within the previous regulatory system of GMP. They concluded that joining of the SDM quality system into the improvement of the system was permitted by the ISO9001: 200 compliance in the GMP environment, which will improve the main objective of the SDM i.e., to satisfy the customer.

Rana *et al*., (2009) the perceptions about the impact of total quality management of employees are investigated in their paper and also their roles in the organization and the way of perceiving the effectiveness of the quality processes in Pakistan Pharmaceutical Industry. Here questionnaire was used as a tool for data collection in the survey method. The results have found many significant factors such as Employee performance, employee training, employee development, teamwork and quality process with the total quality management which are correlated with each other.

Mazumder, Bhattacharya, and Yadav, (2011) given a wide overview of the TQM concept and the management which leads to the quality improvement of pharmaceuticals. The most important goal of pharmaceuticals is to implement an effective quality assurance policy. An adequate quality assurance of the product can be obtained by controlling well organized, accurately performed, adequately staffed process and dosage before, during and after the production. It is concluded by them that, product quality should not be simply tested in the product but must be built.

Haleem *et al*., (2013) highlighted the guidelines and practices of quality in the pharmaceuticals industry. They identified many guidelines such as WHO guidelines, EU guidelines, and ICH guidelines. They also reviewed risk management, corrective actions and preventive actions, quality by design, process capability analysis, process analytical technology, lean manufacturing, Six Sigma, ISO series, total quality management, and HACCP. They find out that although there is a number of literature present it lacks describing applications which are much significant to the guidelines and recommended that new case studies should be done for proving the feasibility of such practices.

Ahmed, (2016) reviewed quality assurance and quality control in laboratories. For the brisk execution of the task, the general public of pathologist should have work shoulder with the permission of the ministry of health. Quality assurance and quality control are kept up for solid and fast true results within conceivable time. By this patient is treated earlier by the clinicians with the right findings that lead to the early recovering of the patient.

Wangchuk and Tashi, (2016) studied the quality assurance of the university medical education, hospital services and traditional pharmaceutical products of the Bhutanese So-we-rig-pa health care system. Their study is supported by the phenomenological understanding and content analysis of data. They cross-checked their information provided in their study which highlights the support of government and people taken by the BSM, development of the quality assurance system by implementing the traditional empirical knowledge and modern scientific protocols, administrative and functional organizations which provides the quality to the healthcare services in Bhutan and at last gave the guidelines for extensive standard treatment and BSM quality documentation system. It is concluded that Bhutan governments give the priority to the quality, safety, and efficacy of BSM.

Pandey and Anju, (2018) presented on the quality management system in the drug industry and their elements. The specification of the product manufacturing can satisfy the manufacturer and product fulfilling the requirement and need of the

consumer makes them happy. They concluded that quality is an unavoidable issue in the current scenario in context of the pharmaceuticals as it become a legal issue and it must be maintained in every pharmaceutical product. There are some aspects and need for the maintenance of quality through quality management system which is also discussed in their paper.

Conclusion

The professional, social and legal responsibility is of a great importance which is linked with the pharmaceuticals manufacturer, who gives the assurance of quality of the product. An adequate quality assurance of the product can be obtained by controlling well organized, accurately performed, adequately staffed process and dosage before, during and after the production. It is necessary to make judicious decision because the health of the consumer can be involve in the control decision and also involve the reputation of the pharmaceutical manufacturer. It is concluded that the quality of the pharmaceutical products must be maintained by incorporating the quality management system because the product may satisfy the consumer but their poor quality may disappoint the consumer and also may affect the reputation of the manufacturer.

References:

Ahmed, Md. Mazher. "Quality Assurance & Quality Control in Laboratories: A Review." *Research and Reviews Journal of Pharmaceutical Quality Assurance*, vol. 2, no. 1, Sept. 2016, pp. 26–31.

Bell, Suzanne C., and Jeff Moore. "Integration of Quality Assurance/Quality Control into Quantitative Analysis." *Journal of Chemical Education*, vol. 75, no. 7, 1998, p. 874.

Fàbregas-Fernández, Anna, *et al*. "Quality Assurance in Research: Incorporating ISO9001:2000 into a GMP Quality Management System in a Pharmaceutical R D I Center." *Accreditation and Quality Assurance*, vol. 15, no. 5, Oct. 2009, pp. 297–304.

Haleem, Reham M., *et al*. "Quality in the Pharmaceutical Industry – A Literature Review." *Saudi Pharmaceutical Journal*, vol. 23, no. 5, 2015, pp. 463–469.

Mazumder, Bhaskar, *et al*. "Total Quality Management in Pharmaceuticals: A Review." *International Journal of PharmTech Research*, vol. 3, no. 1, Mar. 2011, pp. 365–375.

Pandey, Priyambada, and Goyal Anju. "Quality Management System in Drug Industry: A Review." *Biomedical Journal of Scientific & Technical Research*, vol. 2, no. 1, 11 Jan. 2018, doi:10.26717/bjstr.2018.02.000653.

Potdar, Manohar A. *Pharmaceutical Quality Assurance*. Narali Prakashan, 2007.

Rana, Tariq Mehmood, *et al.* "Role of Quality Management in Pharmaceutical Development: Evidence from Islamabad and Lahore." *Indus Journal of Management & Social Sciences*, vol. 3, no. 2, 31 Dec. 2009, pp. 99–109.

Wangchuk, Phurpa, and Tashi . "Quality Assurance of the University Medical Education, Hospital Services and Traditional Pharmaceutical Products of the Bhutanese So-Wa-Rig-Pa Health Care System." *BMC Complementary and Alternative Medicine*, vol. 16, no. 1, Dec. 2016.

Wingate, Guy. "Moving from Quality Control to Quality Assurance." *Pharmaceutical Engineering*, vol. 34, no. 2, Apr. 2014.