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Pharmaceutical Quality Management System: Current Concept

Neetu Dubey[1,*], Himanshu Gupta[3], R.K. Sharma[2], Nitin Dubey[1], Nidhi Dubey[4]

1. IPS Academy, Indore, Madhya Pradesh, India.
2. Prestige Institute of Management, Indore, Madhya Pradesh, India.
3. Pioneer Institute of Management, Indore, Madhya Pradesh, India.
4. School of Pharmacy, Indore, Madhya Pradesh, India.

*Corresponding author: nitindubeympharm@yahoo.com

ABSTRACT:

Pharmaceutical industry is amongst most astringently regulated manufacturing units. Quality management system affects the ultimate quality of the finished product. The article represents and explains the current thinking and harmonized guideline of pharmaceutical regulatory authorities with especial reference to United States food and drug administration. The understanding and implementation of appropriate quality management system model enables a pharmaceutical organization to fulfil its ethical as well as regulatory responsibility of including management of identity, quality, safety, purity and efficacy of finished medicinal product. It makes good business sense.

Key words: Quality management, Pharmaceutical industry, Pharmaceutical management.

INTRODUCTION:

The concept of current pharmaceutical quality management system is based on a internationally harmonized guidance ICH Q10 , which is developed by the Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and USFDA and in final phases for adoption by the regulatory bodies of the European Union, Japan, and the United States is which describes a model for a pharmaceutical quality system that encourages the use of science- and risk-based approaches and can be implemented throughout the different stages of a product lifecycle. [1-4] It serves as an effective *quality* management system for the pharmaceutical industry. It integrates the fundamentals of good manufacturing practice (GMP) regulations, International Organization for Standardization (ISO) quality concepts, and complements ICH "Q8 Pharmaceutical Development" and ICH "Q9 Quality Risk Management. It is an

additional guidance as part of technical requirements for registration of pharmaceuticals for human use (ICH) which is not mandatory in nature. It enhances the quality and availability of medicines around the world. It helps to facilitate *innovation* and *continual improvement* and strengthen the link between pharmaceutical development and manufacturing activities.

Pharmaceutical quality management system

It is applicable to drug products, including biotechnology and biological products, throughout the product lifecycle the systems supporting the development and manufacture of pharmaceutical drug substances. [5] It includes:

1. Pharmaceutical Development
   A. Manufacturing and development of APIs.
   B. Manufacture of medical kits and devices for investigation.
   C. Development of medical delivery systems.
   D. Pilot plant scale-up activities
   E. Manufacturing process of formulation
   F. Development of medical devises for accurate dosing

2. Analytical method development
   A. During manufacturing process
      - Acquisition and control of materials
      - Provision of facilities, utilities, and equipment
      - Production (including packaging and labeling)
      - Quality control and assurance
      - Release
      - Storage

   B. During product technology transfer.
   C. During product discontinuation
      - Retention of sample and related documentation
      - Continued product assessment and reporting

Objectives:

Three main objectives are as follows:

1. Achieve Product Realization
2. Effective control over variables
3. Continuous Improvement

Elements of Pharmaceutical Quality System:

Fundamental elements for effective pharmaceutical quality systems are as follows:

- Managerial review of process performance and product quality
- Process performance and product quality monitoring system
- *Corrective action* and *preventive action* (CAPA) system
- Change control management system

The objective is to establish, implement, and maintain a system that allows the delivery of products with the desired quality attributes. Quality risk management also help in developing effective monitoring and control systems for specified process performance that in turn establishes the capability of processes. It is useful for identifying and prioritizing areas for continual improvement in terms of quality attributes, process technology and other technical aspects. These objectives ultimately contribute to the betterment of end product quality and better process understanding [6].The design, organization, and documentation of the pharmaceutical quality system should be appropriate and exhaustive enough in order to facilitate common understanding. The quality manuals should be prepared in line with the quality policy of the organization.

Management responsibility: Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system. Management has the responsibility to achieve quality related goals as per the quality policy. There must be a clear understanding and unambiguous set of authority and responsibility at all levels including individual and collective role. Strict commitment toward the quality objectives should be demonstrated. Management should participate in the design, implementation, monitoring, and maintenance of an effective pharmaceutical quality system. Quality audits should be performed periodically for appropriate improvement in process performance. Training needs of staff should be effectively identified and follow up system should be established to ensure proper training. Adequate resource management, effective communication between all levels of management and periodical review of the quality system helps to achieve desired pharmaceutical quality system governance.

Continuous improvement in process performance and product quality: Product quality depends on appropriate design of quality attributes during product development phase. Technical knowledge or specification, control strategy and validation approaches should be effectively transferred within or between manufacturing sites for commercial

manufacturing. Product discontinuation aspects include retention of relevant documents, samples and review of product assessment, complaint handling and stability related problems as per regulatory provisions. [1]

Objectives of quality management system may be achieved by following means:

A. Knowledge Management
B. Quality Risk Management

The technical aspects of the process, peculiarity of the product design and problems during product life cycles helps to create a knowledge database and should be systematically documented. ICH Q9 provides principles and examples of tools for quality risk management and approach to identifying, scientifically evaluating and controlling potential risks to quality. Innovation, continual improvement the outputs of process performance and product quality monitoring and CAPA drive changes. It facilitates continual improvement of process performance and product quality throughout the product lifecycle. Developing a new pharmaceutical quality system or modifying an existing one requires careful assessment of size and complexities of the company's activity; Identification of management responsibilities; systems, responsibility and specifications for contract manufacturing activities; Change control measures; identification and establishment of performance indicators. Quality risk management strategy should identify attributes for measurement and analysis of state of control with various approaches including statistical indicators. [4] Appropriate analytical tools should be available to verify the process performance and product quality. External or internal audits should evaluate problems indicators such as complaints, failures of batches, deviations, FDA warnings or recalls.

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