Larix Publications

Journal of Pharma Research
https://jprinfo.com/
Vol. 9, Issue 7, 2020 ISSN: 2319-5622
USA CODEN: JPROK3

Review Article

Elements of Pharmaceutical Quality System

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Received on: 30-05-2020; Revised and Accepted on: 07-07-2020

ABSTRACT

A *harmonized pharmaceutical quality system is applicable across the life cycle of the product emphasizing an integrated approach to quality risk management and science. The main objective behind the establishment of a Pharmaceutical Quality System is to establish, implement and maintain a system that allows the delivery of products with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities (including compliance with approved regulatory filings) and other internal and external customers. Identification and implementation of the appropriate product quality improvements, process improvements, variability reduction, innovations and pharmaceutical quality system enhancements, thereby increases the ability to fulfil quality needs consistently. ICH Q10 describes one comprehensive model for an effective pharmaceutical quality system that is based on International standards Organization (ISO) quality concepts. The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage.*

Keywords: *ICH Q10, Quality, Quality Risk Management, Process Improvement, ISO*

1. INTRODUCTION:

ICH Q10 was adopted in the year 2008 to establish and implement an effective QA system in order to comply with GMP. ICH Q10 demonstrates industry and regulatory authorities' support of an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities. ICH Q10 is a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle. Implementation of the Q10 model should result in achievement of Product Realization, establishment and maintain a state of Control and facilitate continual improvement. A Quality Manual or equivalent documentation approach should be established and should contain the description of the pharmaceutical quality system.

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DOI: https://doi.org/10.5281/zenodo.3933359

2. PHARMACEUTICAL QUALITY SYSTEM ELEMENTS

These elements should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of, each stage. Throughout the product lifecycle, companies are encouraged to evaluate opportunities for innovative approaches to improve product quality.

The Pharmaceutical Quality System should ensure that the Product and Process knowledge should be managed throughout the lifecycle and are in a state of control. The Q10 model's intent is to enhance these below mentioned elements in order to promote the lifecycle approach to product quality.

a. Process performance and product quality monitoring system;
b. Corrective action and preventive action (CAPA) system;
c. Change management system;

d. Management review of process performance and product quality.

3. PROCESS PERFORMANCE AND PRODUCT QUALITY MONITORING SYSTEM

Pharmaceutical companies should plan and execute a system for the monitoring of process performance and product quality to ensure a state of control is maintained. The process performance and product quality monitoring system should:

a. Use quality risk management to establish the control strategy. This can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control. The control strategy should facilitate timely feedback / feed forward and appropriate corrective action and preventive action;

b. Provide the tools for measurement and analysis of parameters and attributes identified in the control strategy (e.g., data management and statistical tools);

c. Analyze parameters and attributes identified in the control strategy to verify continued operation within a state of control;

d. Identify sources of variation affecting process performance and product quality for potential continual improvement activities to reduce or control variation;

e. Include feedback on product quality from both internal and external sources, e.g., complaints, product rejections, non-conformances, recalls, deviations, audits and regulatory inspections and findings;

f. Provide knowledge to enhance process understanding, enrich the design space (where established), and enable innovative approaches to process validation.

4. CORRECTIVE ACTION AND PREVENTIVE ACTION (CAPA) SYSTEM

The pharmaceutical company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, in line with ICH Q9. CAPA methodology should result in product and process improvements and enhanced product and process understanding. Investigations should identify true root causes of deviations or any non- conformances.

Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures. One of the most important quality system elements is the corrective and preventive action subsystem.es.

5. CHANGE MANAGEMENT SYSTEM

A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities, systems, equipment or processes. The intent is to determine the need for action to ensure and document that the system is maintained in a validated state.

Written procedures should be in place to describe the actions to be taken if a planned change is proposed to a starting material, product component, process, equipment, premises, product range, method of production or testing, batch size, design space or any other change during the lifecycle that may affect product quality or reproducibility. In order to evaluate, approve and implement these changes properly, a company should have an effective change management system. The change management system ensures continual improvement is undertaken in a timely and effective manner. It should provide a high degree of assurance there are no unintended consequences of the change.

Quality risk management should be utilized to evaluate proposed changes. The level of effort and formality of the evaluation should be commensurate with the level of risk.

Prospective evaluation criteria for a proposed change should be set. Proposed changes should be evaluated by expert teams with the appropriate expertise to ensure the change is technically justified. Changes should be evaluated after implementation to ensure the change objectives were achieved and that there was no deleterious effect on product quality.

6. MANAGEMENT REVIEW OF PROCESS PERFORMANCE AND PRODUCT QUALITY

Management review should provide assurance that process performance and product quality are managed over the lifecycle. Depending on the size and complexity of the company, management review can be a series of reviews at various levels of management and should include a timely and effective communication and escalation process to raise appropriate quality issues to senior levels of management for review. Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system. Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality. The quality policy should include an expectation to

comply with applicable regulatory requirements and should facilitate continual improvement of the pharmaceutical quality system.

(a) The management review system should include:

1. The results of regulatory inspections and findings, audits and other assessments, and commitments made to regulatory authorities;

2. Periodic quality reviews that can include:

I. Measures of customer satisfaction such as product quality complaints and recalls;

ii. Conclusions of process performance and product quality monitoring;

iii. The effectiveness of process and product changes including those arising from corrective action and preventive actions.

3. Any follow-up actions from previous management reviews.

(b) The management review system should identify appropriate actions, such as:

1. Improvements to manufacturing processes and products;

2. Provision, training and/or realignment of resources;

3. Capture and dissemination of knowledge.

Management Review of Process Performance and Product Quality Results in appropriate actions, such as:

i. Improvements to manufacturing processes and products

ii. Training and/or realignment of resources

iii. Capture and dissemination of knowledge

7. CONCLUSION

The Pharmaceutical Quality System covers the entire lifecycle of a product including pharmaceutical development, technology transfer, commercial manufacturing, and product discontinuation. ICH Q10 is not intended to create any new expectations beyond current regulatory requirements. This internationally harmonized guidance is intended to assist pharmaceutical manufacturers by describing a model for an effective quality management system for the pharmaceutical industry referred to as the pharmaceutical quality system. Consequently, the content of ICH Q10 that is additional to current regional GMP requirements is optional. The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognizing the differences among, and the different goals of each stage. The enablers viz., Knowledge management and Quality risk management support the PQS goals of achieving product realization, establishing and maintaining a state of control, and facilitating continual improvement.

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Article Citation:

Authors Name. Deepthi Suri. Elements of Pharmaceutical Quality System. JPR 2020;9(7): 79-82.
DOI: https://doi.org/10.5281/zenodo.3933359