Review on ISO 9000 series requirements in Quality Management Systems

Naman Vohra*, Rajesh Kumar, Himani Rana, Amar Pal Singh & Ajeet Pal Singh

Department of Pharmacy, St. Soldier Institute of Pharmacy, Lidhran Campus, Behind NIT(R.E.C.), Jalandhar-Amritsar By Pass,Nh-1, Jalandhar-1444011,Punjab, India
Address of correspondence: Naman Vohra
Department of Pharmaceutics, St. Soldier Institute of Pharmacy, Lidhran Campus, Behind NIT(R.E.C.), Jalandhar-Amritsar By Pass,Nh-1, Jalandhar-1444011,Punjab, India
Email-vohranaman08@gmail.com

Abstract— *Quality of pharmaceuticals has been an issue for WHO since its establishment. In present world people are more concerned about quality, safety and efficacy of pharmaceutical products. Without assurance of meeting acceptable standards of quality, safety and efficacy of any pharmaceutical product, obviously quality of pharmaceutical product is compromised. For management of Quality, Safety and Efficacy, Quality Management System (QMS) comes in to the picture. Quality management in pharmaceutical industry is one of the most important aspects of pharmaceutical product development. It is because quality of a pharmaceutical product is directly related to the safety of consumer/ patient. For maintaining the quality, safety and efficacy companies follow several guidelines for example: USFDA, GMP, GLP, ICH, and ISO etc. This review mainly focuses on ISO 9000. ISO 9000 is a widely used quality management standard across the globe. Guidelines present in ISO 9000 are intended to increase business efficiency and customer satisfaction by establishinga quality management system, increasing productivity, reducing unnecessary costand ensuring quality and process and products. Main objective of this review is to highlight most important ISO 9000 requirements to produce an effective Quality Management System. This review also assembles ISO 9000 requirements in an effective way that will help scholars in their further research.*

Keywords— *Pharmaceutical Quality, Quality Management System (QMS), ISO 9000 Standard, Regulatory Guidelines, Product Safety and Efficacy*

Introduction

Pharmaceutical Quality Management System

A pharmaceutical quality management system helps pharmaceutical organizations ensure the quality of products and process improvement. It is applicable to drug products including biotechnology and biological products throughout the product life cycle.

Elements of a pharmaceutical quality management system

Fundamental elements for effective pharmaceutical quality management systemare as follows:

1. Process performance and product quality monitoring

2. Corrective action and preventive action (CAPA) system

3. Change monitoring system

4. Management review of process performance and product quality.

Applicable Pharmaceutical QMS Regulations

Int. J. Forest Animal Fish. Res.
www.aipublications.com/ijfaf

Page | 45

Some key regulations used in Pharmaceutical Quality Management System are written below:

1) ISO

2) cGMP

3) ICH guidelines Q10 on Pharmaceutical Management System

4) 21CFR (part211)

ISO (International Organization for Standardization)

ISO is a non-government organization founded on 23 February 1947. This organization develops and publishes a set of rules (a standard) worldwide.

These rules are universally recognized and accepted when these are implementedin a proper manner. It gives customers confidence that suppliers/organizations can consistently meet their needs.

ISO is an international standard setting body set by representatives of various national standard organizations and works in 165 countries.

Some of best known and most widely used standards of ISO are:

- ISO/IEC 27001- Information Security Management

- ISO 45000 Family- Occupational Healths and Safety

- ISO 14000 Family- Environmental Management

- ISO 17025 Testing and Calibration Laboratories

- ISO 20121-Sustainable Events

- ISO 22000-Food Safety Management

- ISO 31000 – Risk Management

- ISO 3166 – Country Codes
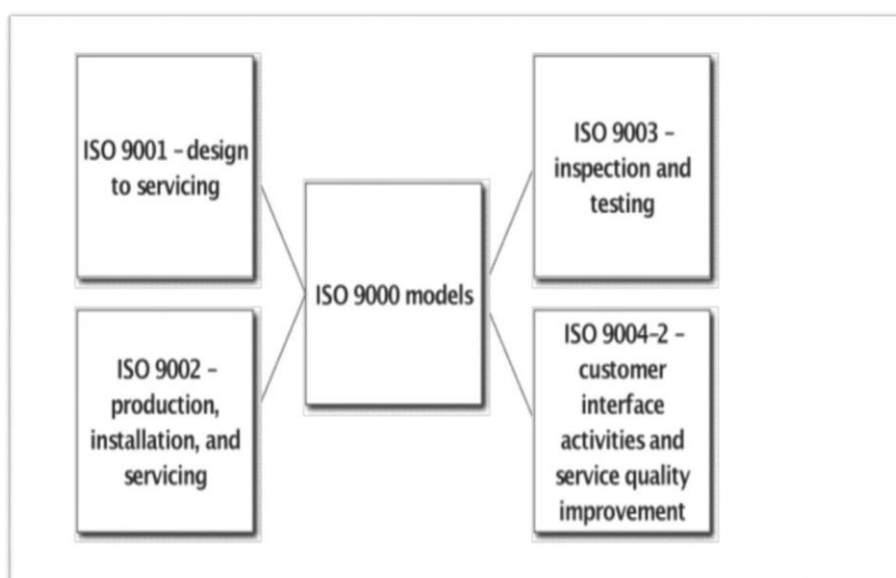
- ISO 50001 – Energy Management

ISO 9000

ISO 9000 is a series of international standards on Quality management and Quality assurance-guidelines which can be adopted by all types of organizations involved in production and supply of all kind of products and services.

Standards in the family are: ISO 9000

    ISO 9001

    ISO 9002

- ISO 9000 Family – Quality Management

    ISO 9003

    ISO 9004

The four model of Quality management system

ISO 9001: It covers model for Quality assurance in design development, production, installation and servicing.

ISO 9002: It covers Quality systems- Model for quality assurance inproduction, installation and servicing.

ISO 9003: It covers Model for quality assurance in final inspection and testing.

ISO 9004: It covers quality management and quality systems element- guidelines for quality management, planning, implementation and performance improvements.

Core Principles of ISO 9000

The seven quality management principles are:

QMP 1 – Customer focus

QMP 2 – Leadership QMP QMP 3 – Engagement of people QMP 4 – Process approach QMP 5 – Improvement

QMP 6 – Evidence-based decision making QMP 7 – Relationship management

PRINCIPLE OF ISO 9000 Quality Management

ISO 9000 requirements

Management responsibility

Organization's management shall create its quality policy. This quality policy shall be relevant to organization's organizational goals and consumer needs. It is sole responsibility of management to understand this quality policy, implement and maintain it at all the levels of organization.

Quality system

The supplier/ Organization shall establish document and maintain the quality system. It shall also ensure that product quality is maintained as per specified in the quality system document.

Contract review

Contract review is an important step before submission of a contract. Organization shall ensure that contractor has capability to meet the contract requirement and deliver it in specified time. Contract requirements shall be adequately defined and well documented as well.

Design control

Supplier/Organization shall prepare plan for each design and development and also should define responsibilities for their implementation. Design development should be well document and shall be updated along with progress in design development. All modifications in design shall be identified, documented and reviewed by authorized person. Design validation also should be performed to review and ensure that it fulfills the expectations and needs of consumer.

Document and data control

Document and data control is set practices to make sure documents are created, reviewed, distributed and disposed in a systemic and certifiable manner. The supplier/organization shall maintain a vibrant documentation and data control system. Supplier/Organization shall also ensure that documents and data required in operations shall available on all location where it is obligatory

Purchasing

Purchasing can be simply defined as the act of buying the goods and/or services that organization/company/supplier needs to operate and manufacture products.

Organization shall establish and maintain a documented procedure for purchasing of requiredgoods. It shall also ensure that purchased goods/products meet the criteria of quality system.

Control of customer-supplied product

The supplier shall establish and maintain documented procedure for customer supplied-products. Marking, storage, handling and preservation of customer-supplied products shouldbe controlled along with its activities related to supplies. Any occurrence of loss, damage or deterioration of customer supplied products is reported back to customer.

Product identification and traceability

Product identification is a wide-ranging concept to labeling the products. It includes product traceability along the supply chain, brand protection in market and contains a lot of informationabout the product.

The supplier/organization shall establish and maintain documented procedure for identificationof products during production, supplying/receiving and installation. There shall also be a well- documented system to trace the products whenever required.

Process control

A process control in continuous production processes is ability to observe and adjust to get desired output. Supplier should control the processes that directly affect the quality of product. These processes should be carried out in controlled manner and under professional supervision.

Final inspection and testing

Supplier/organization shall carry out final inspection and testing process to ensure that finished product fulfils the requirements of quality system document. No product shall be dispatched until the completion of inspection and testing.

Control of inspection, measuring and test equipment

Inspection, measuring and test equipment shall be used in the manner to ensure that the measurement uncertainty is known. It should be consistent with required measuring capacity.

Purpose of this procedure is to provide a system and a set of instructions and to allocate responsibilities for inspection, identification, calibration and maintenance of measuring andtest equipment.

Control of non-conforming products

The products that do not follow specific requirements should not be used or installed. Organization should form a specific well documented procedure for control of non-conforming products. These products should be controlled through:

- The process of identification

- Documentation/record mechanism of non-conformities.

- Segregation

- Action to eliminate nonconformity

- Re-evaluation of corrected product

- A notification to concerned authority

By following above written steps we can control non-conforming products during manufacturing operations.

Corrective and preventive action (CAPA)

CAPA is a key for continuous improvement in organization. It basically consists of retroactive or proactive improvement. Any preventive or corrective action taken to prevent or correct

non conformities in the product should be of appropriate degree to magnitude of problem.

Handling, storage, packaging, preservation and delivery

Handling, storage, packaging, preservation and delivery shall be established and maintained through documentation by the organization. It shall be done according to proper planning and control.

Control of quality records

Quality records are used to demonstrate the conformance to specified requirements. Hundreds and thousands of regulated companies worldwide use master control document as the soul of Quality management system. These documentation procedures are used for Identification, Collection, indexing, access, filing, storage, maintenance and disposition. These documentation procedures shall be established and maintained by the organization. All quality records should be comprehensible and stored in such a manner that they are readily retrievable.

Internal quality audits

Quality audit is a key element in the ISO quality system standard. Quality audits are typically performed at predefined time intervals. These are carried out by internal or external quality auditor or an audit team. Internal quality audits are performed to determine the effectivenessof quality system. It is also done to verify quality activities and its results.

Internal quality audit should be done by an independent auditor/ audit team which is not directly involved in the process of quality management system. The results of audit should berecorded. If any shortcomings found during audit, then personnel responsible for that area should take responsibility and correct it.

Training

Personnel involved in the quality management system shall be qualified to perform their tasks. They should have appropriate experience, trainings, education required. They shall be trained well and records of training should be maintained.

Servicing

Where ever and whenever servicing is required organization should document the procedures of servicing verify it and report that servicing meet the criteria of specific requirements.

Statistical techniques

Statistical process control is a method of quality control which is used to monitor and control the process. Statistical techniques make sure that process operates efficiently and producing maximum specification conforming product with less waste.

Statistical process has five steps:

1. Design the study

2. Collect the data

3. Describe the data

4. Make inferences

5. Take actions

These all above steps shall be followed to work efficiently with statistical techniques.

Organization should have appropriate documented procedures to implement and control the application of the statistical technique and maintain it.

Impact

ISO 9000 requirements will put a great impact on organizations. If any organization aspires to be ISO 9000 certified or want to retain it, they should follow up the procedures and should improve the standards of their products according to ISO guidelines.These implementations of ISO 9000 quality system results in improvement of business performance. Execution of relevant standards in an organization will make a positive impact on customer satisfaction and product quality.

Implementation of ISO 9000 standards impact directly and positively on:

1. Quality

2. Competition

3. Customer satisfaction

4. Employees

Benefits

1. It establishes and enforces consistent quality control.

2. CAPA required in standards assist improvements in production process.

3. Standards give a confidence to customers and strengthen relations b/w organization and customers.

4. Internal audit management reviews analysis of organization level data and documentation of procedures helps organization in taking right decisions.

5. ISO 9000 is also powerful marketing tool for holding organization.

6. ISO 9000 registration gives universal credibility to organizations and helps in getting approval of export of products to European Union and beyond because products meet the criteria of EU requirement directives as well as requirements of other foreign countries as well.

7. It reduces the overall cost of quality. Though initially it costs a bit higher but it counter balances the cost of external and internal failures.

Steps to Avail ISO 9000 Certification

1. Obtain the Support of Higher Management

   - Meeting of the quality steering group for process evaluation

   - Top management is informed by the committee on ISO 9000 costs, schedule, etc.

   - Executives pledge to pursue ISO 9000 registration

2. Staff Training

   - Provide all workers with basic quality and ISO 9000 training

   - Choosing and preparing staff to serve as internal auditors

3. Create a Manual of Quality Policies.

   - Study and comprehend the requirements of ISO 9000 as they relate to your business

   - Outline the Quality Policy Manual in general terms

   - Finalize the quality policy manual's initial draft

   - Send the customer a copy of the manual if they want to comply with ISO 9000 (if necessary)

4. Create Operational Guidelines

   - Define obligations using the quality Manual as a reference

   - Have persons in charge of the function describe their processes

   - Interview management and make adjustments to processes

   - To ensure consistency, compare operating procedures to the quality manual.

5. Conduct Internal Review

   - Hold an internal audit comparing the ISO 9000 handbook and compliance.

   - Apply the audit's corrective action recommendations.

6. Choose a Registrar

   - Costs of research registrars

   - Assess potential registrars

   - Decide on a third-party registrar.

7. Complete the Registration Procedure

   - Register and submit an audit request

   - Together with the registrar, accept the audit process and other details

   - Pre-assessment audit on hold

   - Make any necessary alterations

   - Audit your ISO 9000 registration

   - Make any necessary alterations

   - Recheck as necessary

   - Make any necessary alterations.

8. Register for ISO 9000 Certification

Vohra et. al
International Journal of Forest, Animal and Fisheries Research (IJFAF)
8(1)-2024

This demonstrates to run a company in accordance with ISO 9000 standards

ISO 9000 Quality Management System Components

The ISO 9000 standards provide components for the following aspects of a company's quality control system:

MANGMENT OBLIGATION

1 Order entry

2 Design control

3 Document and information control

4 Purchasing

5 Control of products provided by customers

6 Product recognition and accessibility 7Process management

8 Testing and inspection control of test, measurement, and inspection equipment

9 Controlling the inspection and test status of nonconforming products

STEP FOR ISO CERTIFICATE

Avail ISO 9000 in Just Three Steps

Step 1: Reaching Out

Initially get in touch with expert team and get all your queries regarding ISO 9000 clarified. Experts will provide with a clear road map on how to obtain the certificate and explain the procedure and cost involved.

Step 2: Provide the entire Required Document

After the initial discussion you will have to provide all the required documents for our experts to verify. Subsequently they will apply for ISO certification.

Step 3: ISO 9000 Certification Process

Experts will guide you throughout the ISO 9000 certification process and help to complete the procedure and get certified.

Disadvantage

1 Not all countries accepted Iso register

2 Mainly for exporting firms.

3 Barrier to trade

4 Time consuming

5 Costly

6 Difficult for small firms for afford

7 Discourage free thinking and employee empowerment

8 It presumes that work can be best controlled by its specifying and controlling procedure

CONCLUSION

This review gives brief outline of Quality management System in Pharmaceutical industry along with requirements for ISO 9000 Standards Certification. ISO 9000 Certification will undoubtedlygive an edge and ease in business operations in comparison to uncertified organizations. ISO encourages a better work environment, high customer satisfaction along with growth of organization. Establishment of Quality System document and proper implementation is a key toexcel.

REFERENCES

[1]   Available from: https://www.iso.org/.

[2]   Available from: https://asq.org/quality-resource/iso-9000.

[3]   https://www.iso.org/popular-standards.html

[4]   International Organization for Standardization. The ISO survey of certification, 2009. Geneva, Switzerland 2011. Available from: https://asq.org/quality-resource/iso-9000

[5]   Available from: https://www.simplerqms.com/pharmceutical-quality-management-system/

[6]   Singh AP, Singh AP, Singh N. Quality management systems and ISO 9000 effectiveness: Areview, Indian J Pharm. Pharmacol 2020;7(3)142-146.

[7]   Dubey Neetu, Gupta Himanshu, et al. Pharmaceutical Quality Management Systems: Current concept, Journal of Advanced Pharmacy Education& research 2: 120-124(2011) ISSN 2.

[8]   Block, M.R, Marsh,R.I.(1999). Integrating ISO 14001 into a quality management systemMilwaukee, WI: ASQ Press

[9]   Burgess, N. (1999)The role of consulting in quality development Proceedings of the WorldQuality Congress, Helsinki

[10]   Casadesus, M(2000). The benefits of implementation of the ISO 9000 standard: Empiricalresearch in 288

Spanish companies. The TQM Magazine, 12(6), 432-

[11] Corbett, C. J., Montes, M. J., Kirsch, D& Alvarez-Gil, M. J. (2002). Does ISO 9000 certi cationDoes ISO 9000 cortication pay? ISO Management Systems