Research Article

Comparative evaluation of quality management system in pharmaceutical industry

Venkatesh Chagi, S. B. Puranik

Department of Quality Assurance, PRIST University, Thanjavur, Tamil Nadu, India

Correspondence: Venkatesh Chagi, PRIST University, Thanjavur, Tamil Nadu, India. E-mail: venkatesh.chagim@gmail.com

ABSTRACT

Quality management system (QMS) in pharmaceutical industry is prime requirement of regulatory authorities and to investigate the gaps along with identification of root cause for gaps followed by corrective action and preventive action implementation to fulfill the product quality throughout its life cycle from infrastructure and personnel requirement, selection of vendors, vendor audit, and material procurement. Manufacturing and testing, documentation, Batch release, and dispatch to the market. Complaint handling and self-inspection to improve the quality system. In this study, different regulatory requirements for QMS are reviewed, compared, and compiled to identify the gaps between each regulatory guideline and efforts were made to make an idea to fulfill the identified gaps, which when followed suffice regulatory requirements of selected countries.

Keywords: Quality, Pharmaceutical Inspection Cooperation Scheme, quality assurance, Schedule M, United States Food Drug Administration, World Health Organization

Introduction

In the medicines industry at large, quality management is usually defined as the aspect of management function that determines and implements the "quality policy," i.e., the overall intention and direction of an organization regarding quality, as formally expressed and authorized by top management.[1] Quality management system (QMS) is an integral part of all the other manufacturing systems of pharmaceutical industry and interconnected. The diagram below shows the relationship among the six systems: The quality system and the five manufacturing systems. The quality system provides the foundation for the manufacturing systems that are linked and function within it.[2] Since the numbers of Food Drug Administration (FDA) 483s are received by pharmaceutical industries are related to not effectively implementing elements of QMS, hence the differences in requirements of QMS in different regulatory guidelines is essential to know for effective implementation to get the regulatory approvals. Figures 1 and 2 are the graphical presentation of data collected from FDA website from November 2014 to October 2015 on FDA 483s.

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This study is conducted to compare the major pharmaceutical guidelines on Good Manufacturing Practices (GMPs), *viz.*, and World Health Organization (WHO GMP) guide, Schedule M of Drugs and Cosmetics Act (India), the United States FDA (USFDA), Medicines and Health Care Regulatory Authority (MHRA), and Therapeutics Good Administration (TGA) or Pharmaceutical Inspection Cooperation Scheme (PIC/S) with respect to QMS and to identify the gaps between all these guides. Finally, the ideation has been developed to fulfill the identified gap in such a way that the follow of such ideation meets the requirement of these guides (Figure 3).

Materials and Methods

In this study, comparative evaluation of regulatory guidelines such as WHO GMP, Schedule M of Drug and Cosmetics Act, USFDA GMP, TGA/PICS GMP, and MHRA GMP was conducted with respect to QMS to determine the similarities and differences in these guidelines.

The comparison was conducted by selecting each topic of QMS and its way of description in the selected guidelines in the form of Table 1. Differences were identified and discussed in the discussion part and results were drawn.

Results and Discussion

Upon review of various elements of QMSs, it is evident from the above comparative evaluation table that the guidelines selected for the review cover all the elements of QMS, however some of the elements, *viz.*, annual product quality review, self-inspection or internal audits,

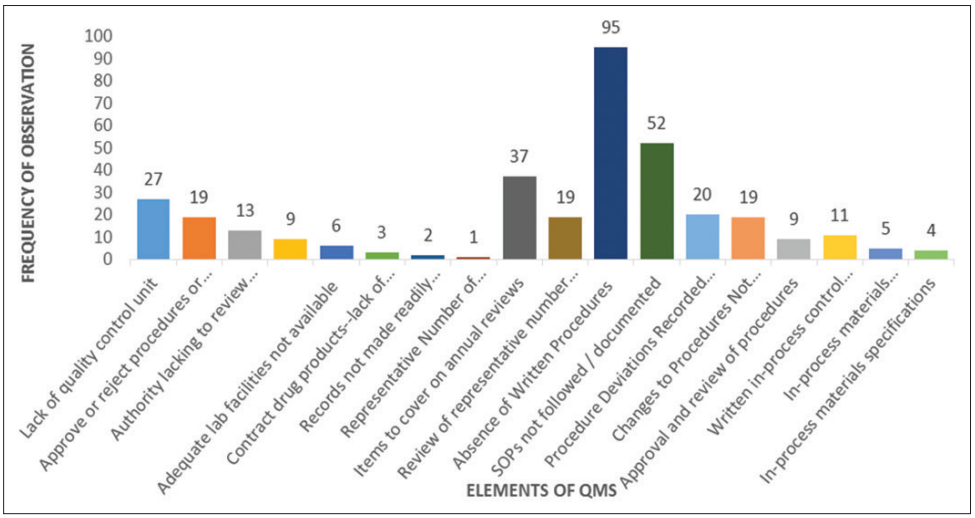

Figure 1: Presentation of data collected from the Food Drug Administration (FDA) website from November 2014 to October 2015 on FDA 483s

Figure 2: Diverging radial used to show the relationships to the central idea in the circle

quality risk management, and preventive action are not covered in all the guidelines.

Implementation of QMS elements mentioned under "topic" column by referring to any guideline which gives detailed information on the QMS will suffice the requirement of regulatory authorities, for example, implementation of QMS in pharmaceutical industry situated in India by following Schedule M will suffice the requirements of Indian regulatory. Implementation of annual product quality review, quality risk management, and preventive actions with the existing elements of QMS will suffice the requirements of all selected regulatory authorities with respect to QMSs.

Table 1: Quality management system in pharmaceutical industry

Topic	WHO GMP[1]	Schedule M of Drugs and Cosmetics Act[3]	USFDA[2,6]	MHRA/TGA/PICS[4,5]
Guideline	Annex 3 WHO GMPs for pharmaceutical products: Main principles	Part 1 GMPs for premises and materials	21. CFR Part 211 Current GMP for finished pharmaceuticals	Guide to GMP for medicinal products Part I
Quality assurance	1. Quality assurance	14. Quality assurance	211.22. Described as responsibilities of quality control unit	Chapter 1: Quality management Quality assurance
Personnel	9. Personnel	6. Personnel	Sub part B – Organization and personnel	Chapter 2: Personnel
Personnel qualifications	9.7 details about education qualification of personnel	Rule 71 of Drugs and Cosmetics act	211.25. personnel qualifications	2.1. General
Personnel health and hygiene	11. Personnel hygiene	7. Health, clothing and sanitation of workers	211.28. Personnel responsibilities	Personnel hygiene 2.13-2.14
Training	10. Training	6.6	211.25. Personnel qualifications	Training 2.8-2.12
Management responsibilities • Leadership • Structure • Build quality system • Establish policies, objectives and plans • System review	1.3.	Management responsibilities are not specified in the act, the activities related to other components are covered in section 14. Quality assurance	Leadership is not specified in parent guideline Remaining parts of the management responsibilities are covered	Covered under principles of quality management
Resource management • Building and facilities • Equipment	Premises are covered under section 12 Equipment is covered under section 13	Building and premises are covered under section 1.2 Equipment is covered under section 11	Building and facilities covered under sub part C Equipment is covered under sub part D	Premises and equipment are covered under chapter 3
Design and develop product and processes	Covered under 16. Good practices in production	Detailed in 8. Manufacturing operations and control	Covered under written procedures; deviations 211.100	Covered in Chapter 5 - Production
Examine inputs	This covered under 14. Materials and 17. Good practices in quality control	Covered in 10. Raw materials 22.4 testing	Subpart E – Control of components and drug product containers and closures	Covered under starting materials 5.25-5.34
Perform and monitor operations	Covered under 16. Good practices in production	Detailed in 8. Manufacturing operations and control and 22.4 testing	Covered under 211.100. Written procedures; deviations. 211.103. Calculation of yield 211.110. Sampling and testing of in-process materials and drug products 211.111. Time limitations on production 211.113. Control of microbiological contamination	Covered in Chapter 5 - Production
Address nonconformities	Explained under 5. Complaints and 6. Product recalls	This is details in 27. Product recalls 28. Complaints and adverse reactions	Discrepancy investigation: 211.22(a). responsibilities of quality control unit. 211.100. Written procedures; deviations. 211.115. Reprocessing. 211.192. Production record review. 211.198. Complaint files.	This is explained under chapter 8 complaints and product recall
Evaluation activities analyze data for trends	1.6. Product quality review	Annual product quality review is not covered in this guide	Covered under 211.180	It is covered in 1.4 product quality review
Evaluation activities conduct internal audits	It is detailed in section 8. Self-inspection, quality audits and supplier's audits and approval	It is covered in 15. Self-inspection and quality audit	Not covered in this guideline	Specified under chapter 9 self inspection
Evaluation activities risk assessment	Quality risk management is covered under sections 1.4 and 1.5	Not covered in this guideline	Not covered in this guideline	It is covered in quality risk management 1.5 to 1.6
Evaluation activities corrective action	Corrective actions and preventive actions are covered under 1.6 product quality review, 5. complaints 8. Self-inspection, quality audits and supplier's audits and approval	15. Self-inspection and quality audit 24. Reprocessing and recoveries	Covered under 211.22. Discrepancy investigation 211.192. Production record review	1.4. Product quality review Chapter 9 – Self inspection

(*Contd…*)

Table 1: *Continued…*

Topic	WHO GMP[1]	Schedule M of Drugs and Cosmetics Act[3]	USFDA[2,6]	MHRA/TGA/PICS[4,5]
Evaluation activities preventive action	Corrective actions and preventive actions are covered under 1.6. Product quality review, 5. Complaints 8. Self-inspection, quality audits and supplier's audits and approval	Preventive actions are details only for 24. Reprocessing and recoveries	Not covered in this guide	1.4. Product quality review Chapter 9 – Self inspection

GMP: Good Manufacturing Practices, USFDA: United States Food Drug Administration, MHRA: Medicines and Health Care Regulatory Authority, TGA: Therapeutics Good Administration, PICS: Pharmaceutical Inspection Cooperation Scheme

Figure 3: Quality system flow

It is also important that only implementation of QMS will not suffice to get the regulatory approvals, further review of each element of GMP to understand and interpret the same to effective implementation along with infrastructure is essential to get the required regulatory approvals.

This study covered the review of regulatory guidelines with respect to elements of QMS to identify the differences and similarities in different regulatory guidelines. In depth review, understanding and interpretation of each listed element is required for effective implementation of QMS.

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