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Review Article

A Review on Eight System Inspection Model

Jagtap Sneha R*, Bhusnure Omprakash G., Mujewar Imran N., Marewad Mayur R., Gholve Sachin B.

Department of Quality Assurance, Channabasweshwar Pharmacy College (Degree), Kava Road, Basweshwar Chowk, Latur, Maharashtra, India-413512

ABSTRACT

The FDA's Drug Manufacturing Inspection Compliance Program, which constitutes instructions to FDA personnel for conducting inspections, is a systems-based approach for inspections and is very consistent with the robust quality systems model presented in this guidance. 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. The quality systems model described in this guidance does not treat the five manufacturing systems as discrete entities, but instead integrates them into appropriate sections of the model. Those familiar with the six-system inspection approach will see organizational differences in this guidance; however, the inter-relationship. Generally, the term quality unit is used in this guidance. However, quality control unit is used when directly quoting parts. United States Food and Drug Administration (USFDA) propose Six System Inspection Model for the audit of pharmaceutical organization for minimization of regulatory submission. Author studied this system, then added and modified this to Eight System Inspection Model to make this more useful and user friendly for the pharmaceutical organization which wants to go for USFDA or other international audits. While doing this author added two additional systems (Management/Regulatory) and four additional points (Validation, HVAC System Validation, Water and Steam System Validation and Vendor Certification).

Keywords: Six system approach, six system models, Quality systems. CQMS; USFDA; CGMP; Six System Inspection Model; Eight System Inspection Model

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***Address for Correspondence:**

Jagtap Sneha R, Department of Quality Assurance, Channabasweshwar Pharmacy College (Degree), Kava Road, Basweshwar Chowk, Latur, Maharashtra, India-413512

Introduction

United States Food and Drug Administration (USFDA) in September 2004 announced pharmaceutical Current Good Manufacturing Practices (CGMP) for 21st century [1]. Their intention was to integrate quality system and risk management with existing CGMP guidelines to encourage adopting modern and innovative manufacturing technology. Also to harmonies the USFDA CGMP regulatory requirement with other international CGMP regulatory requirement [2, 3] and other quality management systems like International Standard Organization (ISO-9000) etc. The concept of Comprehensive Quality Management System (CQMS) is emerging from the USFDAs pharmaceutical CGMP for 21st century. The material in this paper is interpreted by the author from the Draft guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations [1].

Here, USFDA propose Six System Inspection Model for Food and Drug Administration (FDA) personnels for conducting inspection. By referring this model we developed Eight System Inspection Model which is a part of CQMS from the auditor and auditee or pharmaceutical organization point of view. It consists of two more systems i.e. regulatory/management and engineering. Here, we consider quality system as separate section which comprises the quality assurance and other quality related aspects. This system covers not only the 20 points referred by USFDA but also the other important aspects of CGMP i.e. 21 Code of Federal Regulations (CFR) Parts 210 & 211.

The CQMS is designed to help manufacturer of pharmaceuticals to meet the requirements of the FDAs CGMP regulations and to reduce the frequent regulatory submissions for minor changes. The principal objective of CQMS is to ensure consistent production of a quality product (identity, strength, safety, purity & efficacy) and those activities are sustainable. The robust CQMS will promote process consistency by integrating effective knowledge building mechanism into daily operational decisions.

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7 Critical FDA Concepts for Pharmaceuticals Quality Systems

From the discovery of penicillin in the late 1920s to the breakthrough anti-cholesterol and anti-HIV drugs being manufactured today, the pharmaceutical industry has always been in the front line of developing new technologies. But the industry has yet to fully embrace modern quality systems operations.

The FDA recently finalized a guidance to help pharmaceutical companies operate modern quality systems that are fully compliant with Current Good Manufacturing Practice (CGMP) regulations. The guidance is meant to encourage industry adoption of new technological advances and integrated quality systems, according to Dr. Janet Woodcock, FDA deputy commissioner and chief medical officer. The final guidance, which applies to manufacturing of drug products and components, was issued by the agency last September.

Called "Guidance on Quality Systems Approach to Pharmaceutical CGMP Regulations," the document is meant to bridge the gap between the 1978 CGMP regulations and current quality systems and risk management approach. By following the guidance, manufacturers will be able to make technological advancements in their operations more readily, with appropriate regulatory oversight. More importantly, the FDA is hoping that by following the guidance, manufacturers will be able to produce drugs more efficiently and at a lower cost.

Seven critical concepts

The guidance identifies seven concepts critical for modern quality systems:

Quality: Refers to the strength, purity, and other quality characteristics meant to ensure a drug product's safety and effectiveness.

Quality by Design and Product Development: Designing and developing a product and associated manufacturing processes that will be used during product development to ensure that the product consistently attains a predefined quality.

Quality Risk Management: This includes assessing the risks of quality issues, selecting and implementing risk management controls commensurate with the level of risk, and evaluating the results of the risk management efforts.

Corrective Action and Preventive Action (CAPA): Focuses on investigating, understanding, and correcting discrepancies while trying to prevent their recurrence.

Change Control: Managing change to prevent unintended consequences.

Quality Unit: A group within an organization that promotes quality in general practice.

Six-System Inspection Model: A model that can help pharmaceutical manufacturers comply with CGMP regulations. The six systems referred to in this inspection model are: quality, production, facilities and equipment, laboratory controls, materials, and packaging and labeling.[3]

SIX SYSTEMS APPROACH TO PHARMACEUTICAL CGMP REGULATIONS

The FDA has enacted several pharmaceutical cGMP regulations. These are key concepts that are critical to quality systems. Some of the concepts by which the FDA and other regulatory bodies ensure cGMP regulations are Quality, Quality by Design (QbD) and product development, Quality Risk Management, Corrective and Preventive Action (CAPA), Change Control, and the Six Systems Approach. [4], the six-system inspection approach is a systems-based approach to cGMP and is aimed at ensuring a robust quality system model for pharmaceutical products. Each of drug regulatory bodies across the world aspire practices to encourage and assist high-tech industries. Risk based prioritization in manufacturing inspections should instigate risk-based evaluation -making on a practical, each unit operation level throughout the manufacturing business. Implementation of the comprehensive Quality System Mode would ensure greater understanding of total operations leading to a more robust and updated Quality System that is fully compliant with cGMP regulations.

Six System Model [4-5]

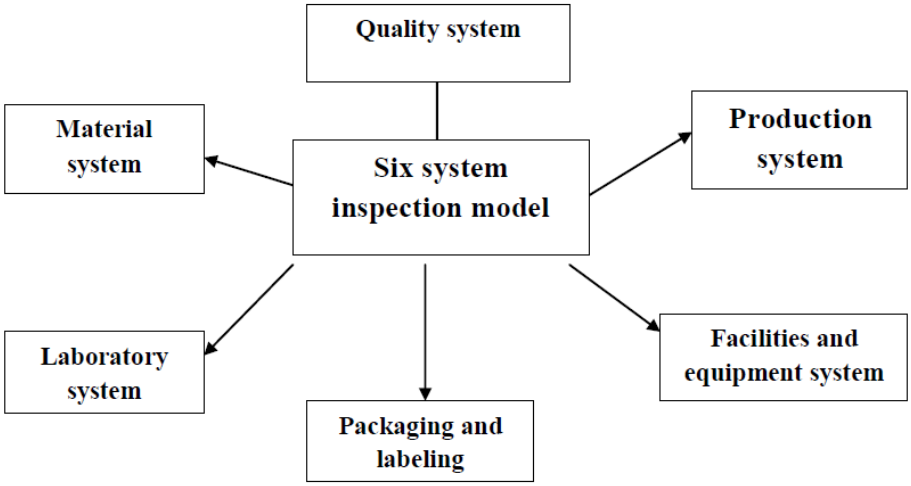

Fig 1: The diagram shows the correlation ship amongst the six systems: the quality system and the five manufacturing systems, which appear to be closely interrelated and inseparable during operations.

The concepts of GMP do not treat the five manufacturing systems as discrete entities, but instead integrates them into appropriate sections interlinked with each other. The interrelationships between processes should be quite apparent. One of the important themes of the systems-based inspection compliance program is to be able to assess whether each of the systems is in a state of compliance. Pharmaceutical manufacturers should implement modern quality systems with risk management approaches to meet the requirements of the Agency's current good manufacturing practice (cGMP) as per regulations (2l CFR parts 210 and 211). The guidance based on comprehensive quality systems (QS) model, highlighting the model's consistency with the CGMP regulatory requirements for manufacturing human and veterinary drugs shall be of great help.

1. Quality System:

This system assures overall compliance with cGMP and internal procedures and specifications. The system includes the quality control unit and all of its review and approval duties (e.g., change control, reprocessing, batch release, annual record review, validation protocols, and reports, etc.). It includes all product defect evaluations and evaluation of returned and salvaged drug products. See the cGMP regulation, 21 CFR 211 Subparts B, E, F, G, I, J, and K.

2. Facilities and Equipment System:

This system includes the measures and activities which provide an appropriate physical environment and resources used in the production of the drugs or drug products.

It includes:

a) Buildings and facilities along with maintenance;

b) Equipment qualifications (installation and operation); equipment calibration and preventative maintenance; and cleaning and validation of cleaning processes as appropriate. Process performance qualification will be evaluated as part of the inspection of the overall process validation which is done within the system where the process is employed; and,

c) Utilities that are not intended to be incorporated into the product such as HVAC, compressed gases, steam and water systems. See the cGMP regulation, 21 CFR 211 Subparts B, C, D, and J.

3. **Materials System**: This system includes measures and activities to control finished products, components, including water or gases that are incorporated into the product, containers and closures. It includes validation of computerized inventory control processes, drug storage, distribution controls, and records.

   See the cGMP regulation, 21 CFR 211 Subparts B, E, H, and J.

4. **Production System:** This system includes measures and activities to control the manufacture of drugs and drug products including batch compounding, dosage form production, in-process sampling and testing, and process validation. It also includes establishing, following, and documenting performance of approved manufacturing procedures. See the cGMP regulation, 21 CFR 211 Subparts B, F, and J.

5. **Packaging and Labeling System**: This system includes measures and activities that control the packaging and labeling of drugs and drug products. It includes written procedures, label examination and usage, label storage and issuance, packaging and labeling operations controls, and validation of these operations. See the cGMP regulation, 21 CFR 211 Subparts B, G, and J.

6. **Laboratory Control System**: This system includes measures and activities related to laboratory procedures, testing, analytical methods development and validation or verification, and the stability program. See the cGMP regulation, 21 CFR 211 Subparts B, I, J, and K. [6-7]

Quality Systems

Change management and change control

Change control within quality management systems (QMS) and information technology (IT) systems is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. It reduces the possibility that unnecessary changes will be introduced to a system without forethought, introducing faults into the system or undoing changes made by other users of software. The goals of a change control procedure usually include minimal disruption to services, reduction in back-out activities, and cost-effective utilization of resources involved in implementing change.

Change control is currently used in various products and systems. For IT systems it is a major aspect of the broader discipline of change management. Typical examples from the computer and network environments are patches to software products, installation of new operating systems, upgrades to network routing tables, or changes to the electrical power systems supporting such infrastructure.

Out of Specifications (OOS):-

Out of Specification (OOS) means the test result that falls outside the specifications or acceptance criteria which has been specified in the official compendia monographs or the finished product.

It provides agency's current thinking on out of specification and test results. Purpose of this document is it includes results of all tests that fall under outside of the specification which are established in drug application, official compendia and drug master files or by the manufacturer.

It also applies for all in process tests and chemistry based laboratory testing. Traditional testing and release methods are directed. Laboratory testing are performed under the active pharmaceutical ingredient, other components like in-process materials and finished product materials apply to the extent of current good manufacturing practices regulation and food and drug cosmetic act 1.

FDA Guidelines for OOS:-

This guidance covers the following:

1. Finished products & active pharmaceutical ingredients

2. Biology and biotechnological products

3. Human drugs

4. Veterinary drugs

5. Combination of product

6. Type medicated articles

7. Medicated feed 8. Dietary supplements

9. Transplantation of human tissues under 361 section out of specification in registration dossiers.

Out of Trend (OOT):-

OOT results are defined as a stability result that does not follow the expected trend, either in comparison with other stability batches or with respect to previous results collected during a stability study.

A time dependent result which falls outside a prediction interval or fails a statistical process control criterion.

A trend is a sequence of temporal procedures, e.g. for the manufacture of different batches of a product.

Seven Critical Concepts of the FDA's Quality Systems Guidance

FDA Issues Final Guidance on Quality Systems Approach

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The FDA recently finalized a guidance to help pharmaceutical companies operate modern quality systems that are fully compliant with Current Good Manufacturing Practice (CGMP) regulations. The guidance is meant to encourage industry adoption of new technological advances and integrated quality systems, according to Dr. Janet Woodcock, FDA deputy commissioner and chief medical officer. The final guidance, which applies to manufacturing of drug products and components, was issued by the agency last September.

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Basis of CQMS:-

It is based on the philosophy that,

"Quality should be built into the product, and testing alone cannot be relied on to ensure product quality."

This statement is supported by one incident which was happen with Boehringer Knoll Laboratories Ltd. There was production of an Antibacterial drug containing active ingredient as antibacterial agent along with other excipients. But due to failure in dispensing practice the dispensing officer dispensed Glibenclamide as one of the excipients along with antibacterial agent. In final Quality Control testing all test parameters were acceptable. But the incident of wrong addition of Glibenclamide came in focus, only after the complaints related to hypoglycemic effect are reported. This incident gives an idea that there are lots of such parameters which could not ensure the quality of product only by the final testing. That means the quality should be built through out the material and process flow and not only by the final testing of the product.[6]

FDAs 20 points

1. Provide leadership

In developing robust quality management system, the higher authority or senior management has to define organizations mission and strategies. They have to take active participation in system design, implementation, monitoring and review, Committing necessary resources visibly support the quality system. They have to develop internal communication in the area of research development, regulatory affairs, manufacturing, quality unit, personnel and other related issues.

2. Structure the organization

When designing a CQMS, the management has the responsibility to define organizational structure and document it and also to determine the jobs (employee roles), responsibilities and authorities within the system, to empower employee to detect and resolve the problems affecting quality of product.

3. Build your quality system to meet requirement

The CQMs provide system help to ensure compliance within the regulations related to identity, strength, safety, purity and efficacy, to control the outsourcing. It also defines standards of quality (specifications) and implementation of quality policies. The developing, implementing, monitoring and revising quality procedures is one of the major aspects of CQMS

4. Establish policies, objectives and plans

In developing CQMS, the senior management articulates their vision of quality through implementing the policies, objectives and plans. They provide strong commitment to quality into the organizational mission. They are responsible for developing quality manual, quality policies and to communicate policy at all levels of the organization, to make all employees and all other relevant people to understand it in letter and spirit also to revise these policies as and when needed.

The Quality objectives are created at the top level of the organization (and other level as needed) through a formal quality planning process. Use quality planning process to identify resources and define methods to achieve the quality objectives.

5. Review of the system

System review is required to continuing suitability, adequacy and effectiveness of the robust quality system. Such review should typically include both, an assessment of the product as well as customer needs. The quality system review should cover the points like, quality policy and objectives, result of audit and other assessment, customer feed back including complaints, trend analysis, actions to prevent a potential problem or a recurrence, follow up action from previous management reviews.

The review outcomes typically include improvements to the quality system and related quality processes, improvement to manufacturing processes and products, realignment resources. The review result must be recorded, planned actions should be implemented using corrective and preventive action and change control procedures.

6. General arrangements of resources

The following resources should be provided in adequacy,

Building and facilities

Equipment

Materials

Defined manufacturing and packaging process

Facilities for laboratory analysis and related resources

7. Develop personnel

The CQMS recommends qualified and trained personnel to do an assigned work properly, without overruling the CGMP regulations. The senior management defines qualification for each position, also gives the training to personnel in CGMP and specific job.

The training programmers should include at least following points,

Identification of training needs

Provision for training to satisfy their needs.

Evaluation of effectiveness of training

Documentation of training and retraining

Use of skills learned in training, in day to day activities.

8. Facilities and equipment

FDA officers expertise can be used to identify and select the proper facilities and equipment. (Pre inspection approval may be sought). These facilities and equipment must be qualified, calibrated, cleaned and maintained to prevent contamination and mix-ups. Equipment should include both process as well as testing equipments i.e. manufacturing, utilities and testing instruments or equipments etc.

9. Control outsourced operations

While outsourcing for operational processes to a second party, the Quality agreement should clearly describe materials and services, quality specifications responsibilities and communications mechanisms. Contract giver should satisfy him self about the adequacy and ability of the contract acceptors in terms of his quality systems and its implementation.

10. Design and development of product and processes

In CQMS the product characteristics are defined from design to delivery and exercise change control, and also the manufacturing, quality process and procedures are defined. It also establishes responsibilities for designing or changing products, documenting processes will ensure that critical variables are identified. This document should include resources and facilities needed, procedures to carry out processes, identification & control of critical variables, validation activities including operating ranges and acceptance criteria etc.

11. Monitor packaging and labeling processes

The CQMS recommend planning and documentation of all packaging and labeling procedures. These Procedures should outline Quality Control (QC) activities and responsible position, specifications and controls for packaging and labeling materials should also be determined before commercial production.

In CQMS, a design plan should include authorities and responsibilities; design and development stages; and appropriate review, verification and validation. Change control should be maintained throughout the design process.

12. Examine inputs

In CQMS models, the term “input” refers to any materials that goes into a final product, no matter, whether it is traceable or not in the finished product and also whether the materials is purchased by the manufacturer or produced by the manufacturers for the purpose of processing. Materials can include items such as components (e.g. ingredients, process water etc).container and closures etc. Quality system should address receipt, production, storage and use of all products.

All input must be tested or use of certificate of analysis of manufacturers may be accepted under suitable conditions. But even in the case of use of certificate of analysis, identification of the materials is needed. Materials produced in house should also go under the same acceptance criteria and testing procedures as other purchased materials (e.g. purified water, N_2 gas etc.)

13. Perform and monitor operations

In the CQMS, areas of process weaknesses should be identified and factors that are influential on critical quality attributes should receive increased scrutiny. The process should be validated and sufficient testing data should be provided a system for continuous improvement of operations should be developed and implemented. The entire life-cycle should be addressed by the establishment for continuous improvement mechanism in the CQMS

The procedure of review and evaluation should be in place to anticipate change control and monitor it. The deviations control procedures should also be in place. This deviation

control should cover personnel, materials, equipment and facilities. Product release record must be in place.

The critical Process parameters monitored during production are as follows

1. Process step should be verified by using validated computer system or a second person; these records must be maintained simultaneously.
2. Procedures should be in place to prevent objectionable microorganisms in finished product that is not required to be sterile and to prevent microbial contamination of finished product purported to be sterile, sterilization process should be validated.
3. The procedure should be developed to monitor, measure and analyses the operations
4. Procedure should be in place to ensure the accuracy of test result.
5. The system should address how to deal with "Out of Specifications" results.
6. The CQMS should address product distributions issues.

14. Address non conformities

A key component in any CQMS is handling of non conformities / or deviations. It includes, Defining and classifying non conformities (e.g. Critical, Major & Minor)

Developing document system for identifications, investigation and corrective action to be taken against non conformities.

Planed action for remedial purpose to avoid the recurrence in future and segregation of product currently facing non conformities.

15. Analyze data for trends

It involves collecting data from monitoring, measurement, complaint handling and other activities. This information is useful for detection and prevention of problems as early as possible.

16. Conduct internal audits

CQMS approach call for audits to be conducted at planned intervals to evaluate effective implementation and maintenance of the quality system and to determine if processes and products meet established parameters and specification.

The entire system should at least be audited once the year in staggered or planned manner. The managers who are responsible for the areas audited to take timely actions to resolve audit findings and ensure that follow up actions are completed, verified and recorded.

17. Risk assessment

The management should assign priorities to activities or actions based on the consequence of actions or inaction otherwise known as risk assessment. The risk assessment is used as a tool in the development of product specifications and critical process parameters used in conjunction with process understanding, risk assessment helps anticipated, manage and control change.

18. Corrective action

The corrective action is a reactive tool for a system improvement to ensure that significant problems do not occur. The procedure is to be developed and documented to ensure that the need for action is evaluated relevant to the possible consequences, the root cause of the problem is investigated, possible actions are determined, selected action is taken within the defined time frame and effectiveness of the action taken is evaluated. It is essential to maintain records of corrective action taken. The management can gather information from following sources for taking corrective action,

a. Nonconformance report and rejection

b.Complaints

C.Internal and External audit

D.Data and risk analyses related to operation and quality system processes

e.Management review decisions

19. Preventive action

The preventive action is an essential tool in quality system management.

The Preventive action may involve areas like, succession planning, training, capturing institutional knowledge, planning for personnel, policy and process changes. The selected preventive action should be evaluated and recorded and the system should be monitored for the effectiveness of the actions

20. Promote improvement

The effectiveness of the quality system can be improved through the quality activities described as above in CQMS. It is critical that senior management be involved in the evaluation of this improvement process.

AUTHORS POINTS

1. *Validation*

Initially pharmaceutical industry was heavily depended on controlling the quality, over a period of time this concept has changed to assuring the quality of product [3].

Pharmaceutical validation is the major activity under the quality assurance. Validation assures the desired performance of,

Buildings

Equipment

Materials

Processes etc

Hence, without validation we can not think of assuring desired quality attributes in any product.

2. Heating, Ventilation and Air conditioning (HVAC) system validation

Air is one of the major constituent in the creating the desired environment including storage and processing. This environment includes requirements related to temperature, relative humidity, class of air, differential pressure; number of air changes etc. and this entire thing is taken care by a suitably designed, operated, monitored and maintained HVAC system.

3. Water and steam system validation

All the regulatory requirements including pharmacopoeia monographs give lot of importance to quality of pharmaceutical water. Particularly USP, not only describes different monographs on pharmaceutical water, but also describes in detail validation system for pharmaceutical

water. Pharmaceutical water is to be considered as one of the major raw materials particularly in case of most of the liquid formulations either sterile or non sterile. Hence, generation, storage, distribution, use and disposal of pharmaceutical water are considered as one of the major activity of assuring the quality of the pharmaceutical product and hence it is very important from point of view of regulatory compliance.

4. Vendor certification

USFDA and other drug regulatory authorities world over insist on consistency of quality of all the inputs into manufacturing of pharmaceutical product or hence, certification of vendors becomes a very important activity in assurance of quality of pharmaceutical product. One can depend on certified vendors for consistency of quality, commitment of deliveries and other technical & commercial aspects related to purchase of inputs. Vendor certification is a team activity, consisting of representative from purchase, quality assurance, production, Research and Development (R&D) and engineering etc. Hence, this activity must be considered as one of the major activity under quality assurance.[9]

CONCLUSION

While thorough study of this Six System Inspection Model the author found that the 20 points proposed by USFDA are not get appropriately fitted into the Six System Inspection Model. For this reason the author modified the 6/20 concept to 8/24 that means Eight System Inspection Model which not only covers all 20 points proposed by USFDA but also other 4 points which are very important and other regulations are also emphasized on this 4 points.

In this Eight System Inspection Model, these 24 points fitted in such a way that it is found to be very useful for both Auditor and the Audittee i.e. pharmaceutical organizations. The pharmaceutical organizations which are going to be implementing the CQMS are found to prepare for the any type of audit that means either USFDA or any regional audit. One more and most important advantage of this CQMS is that, if in first inspection of USFDA, if FDA inspectors convinced that the CQMS is implemented and followed by the organization then in next inspection of USFDA they should remark that any small changes in facility, equipment or process etc are not required a regulatory submission after any small changes.

For Auditor, this system is useful by means of reduction of time required for the inspection of pharmaceutical organization which can decrease the work load on the inspector and which is ultimately beneficial for the customer getting a quality product for distribution.

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