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Review on Six System Inspection Model

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ABSTRACT

Inspection is a key to auditing. First, we want to check visually, and every system focuses on safety and effective manner. Each system fixes the quality of the drug product mainly self-inspection should be conducted before auditing, step by step, the process must inspect from starting material to the finished, approved product. Labels, equipment's, materials to be checked as per GMP guidelines. The Principles of quality management system was demonstrated by GMP. The inspector follows the guidelines accurately in the system; we want to check the personnel, hygiene, quality, scale-up activity and overall quality functions. In production system guidelines demonstrate the critical manufacturing test area check properly by the inspector in the field weighing, sieving, are performed in the system IPQC (In-process Product Quality Control) and FPQC (Finished Product Quality Control) conducted test to be check properly it follow as per GMP guidelines. In the facility and equipment system not, only equipment also inspects manufacturing, processing and production activity. In the laboratory and control system, check the stability test area and quality control area. The material systems order to monitor the component status accurately. In the packaging and labelling system, check the labels, storage control and mix-up area study properly. Finally, the regulatory inspector submits the report to Pharmaceutical Inspection Co-operation Scheme. This article focuses on six system auditing models and the guidelines for regulatory inspectors.

SIX SYSTEM INSPECTION MODEL

The six-system auditing is a lengthy process, and it should carry out step by step process. Flow of quality management system to package and labelling system are helps to satisfy the quality.the six systems have given below

Six system auditing

WHAT IS A QUALITY MANAGEMENT SYSTEM (QMS)?

- A quality management system (QMS) is defined as a system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.
- A QMS helps co-ordinate an organization's activities to meet customer and regulatory requirements and improve its effectiveness.

BENEFITS OF QUALITY MANAGEMENT SYSTEMS

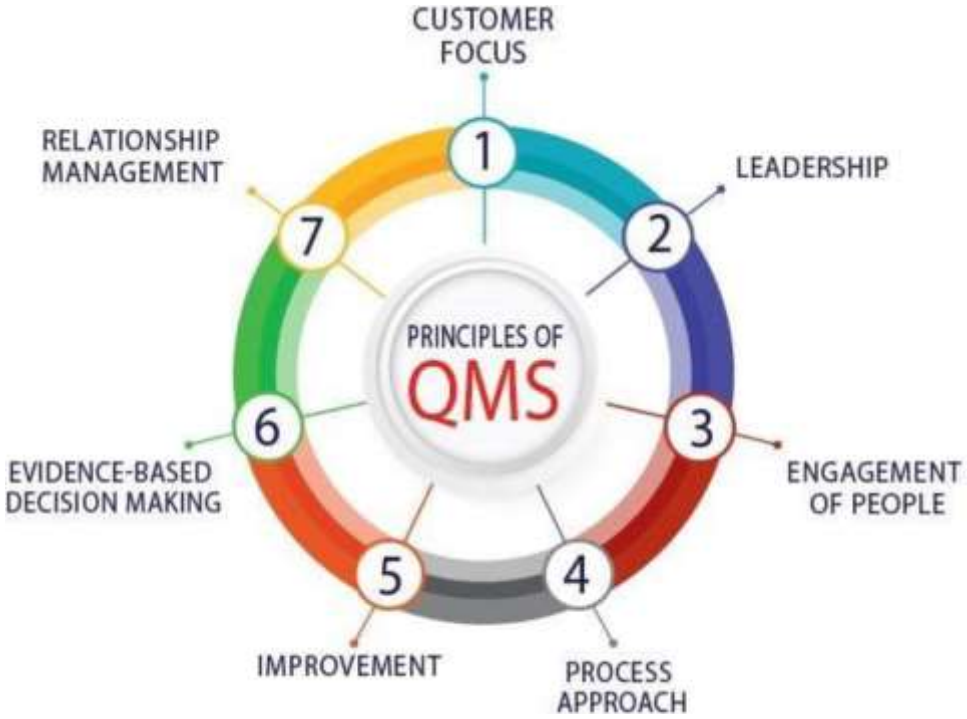
Implementing a quality management system affects every aspect of an organization's performance. Benefits of a documented quality management system include:

1. Meeting the customer's requirements, which helps to instil confidence in the organization, in turn leading to more customers, more sales, and more repeat business
2. These benefits gives additional advantages, including:
3. Defining, improving, and controlling processes
4. Reducing waste
5. Preventing mistakes
6. Lowering costs
7. Facilitating and identifying training opportunities
8. Engaging staff
9. Setting organization-wide direction
10. Communicating a readiness to produce consistent results

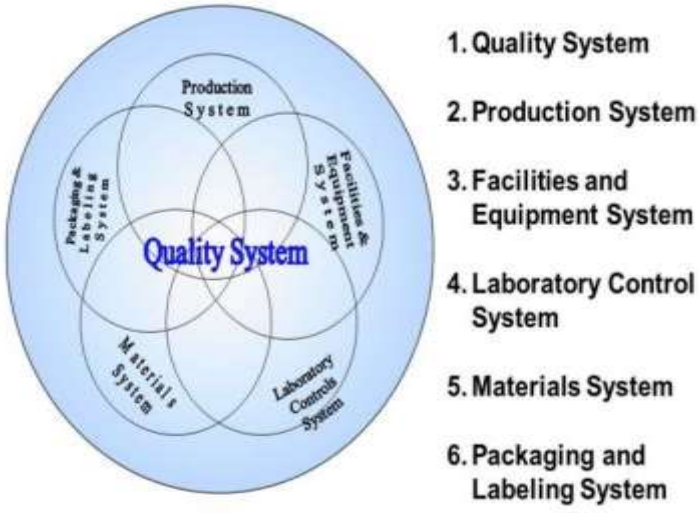
ELEMENTS AND REQUIREMENTS OF A QMS

The diagram shows the relation ship Between the six the quality system and the five manufacturing systems, which appear to be closely interrelated .verifies quality policy, management review, quality manual and quality audit procedures, quality plan and system procedures and instructions have been defined, tested and documented.

He also determines whether management reviews, including review of the suitability, safety, preventive measures and effectiveness to check the contractor and the product details of the certified contractor and the tender details, check the regular meeting details and the topics on the meeting, verification on quality improvement activities, check scale-up events and also check the manufacturing control and quality system.



The six systems referred to in this inspection model are:



Quality Management System

It is a structured collection of process, procedures and documented policies and evidence are constructed to upgrade the system. CAPA (corrective and preventive action) plays the primary role to know the defectiveness of the product and helps to improve quality and safety. The regulatory inspector is looking for weak spots in a firm's manufacturing operation. Inspector normally focuses on management control, production/process controls and corrective/preventive actions. The inspector review management procedures/high-level quality system procedures. Quality manual, quality plan and designing documents must to view and preview before the auditing. In the inspector's review of any section, he does an overall view of subsystems and understanding the subsystems. The inspector must view if the system complies with GMP. To ensure the quality system (product development system) is functioning correctly. The inspector

Production System

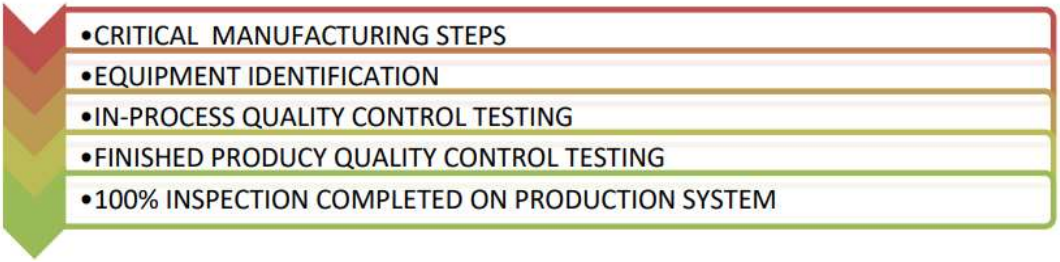
Critical manufacturing steps Critical manufacturing steps are selection, weighing, measuring, identifying and addition of components during processing. From batch records, mixing time, sieving time and testing, the inprocess material deviation should be recorded. The inspector determines whether such critical steps are being done by a responsible Individual after the finishing second responsible individual must check it properly. The processing by controlled by manual, automatic, mechanical, or electrical equipment performance verified. The record should be verified incorrect manner. To check the signature of the test performed person and cross-check them.

Equipment identification

The inspector determines all type of containers and equipment are used to manufacture a drug product. Identifying the label content including batch number and stage processing and verify the batch production and stored to prevent mix-ups or contamination. All of the activities should record on the BMR (Batch Manufacturing Record) or MMR (Master Manufacturing Record).

In-process testing

To check the weights, dissolution, and disintegration time of tablets, filling with liquids, adequacy of mixing, homogeneity of suspension, clarity of solution. The inspector alert to verify pre-recording of test result such as tablet weight determination. The inspector must visit an on-going test procedure and verify which type of specifications followed for the test.



Production system Auditing

Finished product testing

To check the product from the production area, equipment and apparatus for FPQC (Finished Product Quality Control) should check properly and to evaluate the method of the process done the FPQC test

Facility and Equipment System

Building and facility

The inspector typically reviews the layout, exit poll, construction, size, structure and location of the plant. He would be looking out for adequate lighting, sanitation, ventilation, screening and all physical barriers like dust, temperature, humidity and microbiological control. To check they followed SOPs or not, monitor the pest control activity and inspect the water purity, HEPA filters (High-Efficiency Particulate Air), HVAC system (Heating, Ventilation and Air Conditioning system), and compressed air system must be at hand for review by the inspector. He also looks at an adequate locker, toilet and hand washing facilities.

To prevent contamination, need to following procedure.

- Receiving, sampling, and storage of raw materials
- Manufacturing, primary and secondary packaging, and product and final labelling.
- Room for the container, primary and secondary packaging materials, product and final labelling, and finished products.
- Drug product Production and control of laboratories.

Equipment

The inspector reviews the design of the instrument, the capacity of the machine, construction of the device and the location of material used in the production field, flow line for the manufacturing process is in given below

Figure 4: Manufacturing Flow Diagram

He checks the equipment to protect the identity (visual examination), content capacity, quantity, strength (flexibility), assured the quality or purity of the drug. Check the validation report, quality unit, FAT (Factory Acceptance Test) and SAT (Site Acceptance Test) installation.

Inspector specifically looking for

- Equipment installed in the perfect place, and it is suitable for easy cleaning, maintenance and adjustment
- To prevent contamination from other formulation or disease from others (previous formulation)
- Equipment cleaning and maintenance status usually documented in a logbook (evidence purpose) with calibration details

Laboratory Control System

It covers all components like in-process and finished products and should include specifications. They confirm appropriate standard of identity of the instrument, the strength of the system, quality and purity, and evaluate all records.

Packaging and Labelling System

The inspector reviews the label to prevent drug and label mixtures. He determines to assure that all the content in labels is correct. Labelling and packaging areas have adequate physical separation from the manufacturing process. Do not allow without the Labels are checked manually against the master label content before released to the product. The inspector determines the responsible person for the label review. Storage area is separated from one another to avoid mix-ups Inventory of label stocks. The eligible individuals are responsible for the labels and he issues all the labels under his knowledge. Receipt of these departments, the record should be showing the number of labels needed for a single batch. Adequate controls of the quantity

of labelling issued, labelled, and remaining are returned (excess labels place in a separate place with documented evidence). Mistaken labels must utterly destroy without any missing. As per the specification, Inspector visits the labelling section correctly to ensure that all previously used labels destroyed or not. To assure that all production batches well monitored during packaging. Under controlled conditions to follow packaging necessary for drug packaged and no labelling should be issued. To prevent cross-contamination and the labels mix-up also stopped. What is the way to know similar labels should follow and labelled containers to prevent mix-up? Quarantine finished packaged products to be tested for examination or testing of a representative sample to be safely tested and shift into approved one incorrect manner. An outside contract packer is distributing labels and control all the labelling content; it is a qualified label or not. He requires an explanation of how the finished package control number relates and how it is used to find the identity of the original batch. He may also like to ensure that the label batch number is the same as the control number on the finished package.

Purpose of Inspection

- To distinguish good lots from bad lots.
- To distinguish good pieces from bad pieces.
- To determine if the process is changing.
- To determine if the process is approaching the specification limits.
- To rate quality of product.
- To rate accuracy of inspectors.
- To measure the precision of the measuring instrument.
- To secure products-design information
- To measure process capability.

CONCLUSION

The auditing should be held in a planned way unless we get confused; each step fixes the quality of the product. The quality was not satisfied it is not good. The auditing helps to know our self-quality and it is the beginning of the audit. The product quality was depending upon the way of selection of raw material, manufacturing, packaging. Each step to be crucial, it only assures the quality. By way of auditing, we know the quality level of the product. The product marketing is depending on PIC/S approval.