Internal Audit Program - Quality Inspection in the manufacturing process to identify improvements in quality control"

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Abstract

Implement a preventive operations in-process auditing system with final inspection points at Company J, that monitors product, packaging configuration, and documentation execution to assure product manufacturing specifications are being met throughout the entire manufacturing process. This will be a preventive Quality Assurance approach. The internal audit program assure that the quality system maintains compliance with internal quality to assure that the quality systems are effective in achieving quality and business objectives.

Key Terms *- Internal Audit, Quality, Inspection, Manufacturing Operations*

Introduction

Quality assurance is critical in the pharmaceutical sector since patient health and well-being are at risk. Maintaining quality in production becomes more challenging as product design complexity and throughput rise. Improving quality control (QC) is required for manufacturers to fulfill rising market demands while maintaining acceptable standards. Company J has in place extensive systems and processes to give its staff the foundation and tools required to sustain a successful quality management system.

Problem Statement

This project was developed to show the efficiency of company J in the quality control inspection and audit procedure of the manufacturing areas to identify improvements in quality control, since it does not have an internal audit program. Implement an in-process audit system of preventative operations with final inspection points at a manufacturing company that oversees product, packaging configuration, and documentation execution to ensure product manufacturing specifications are met throughout the process of manufacture. This project will focus on the planning and implementation of instructions and Checklists, to identify areas in the Operations Department that require further attention. Such sites include facilities, equipment, procedures, safety, quality, compliance, failures, or observations related to good documentation practices, dress practices, in-process manufacturing (product), final audits in the product manufacturing process, and employee.

Methodology

Project needs or requirements will be examined and determined using a variety of tools. When carrying out a field study, such as carrying out an internal audit of the company, checklists are used as the main tool, where qualitative data is collected to describe the state of the company's operations. Field research involves selecting an event, condition, or circumstance to examine. The initial sample is made based on manufacturing processes in different areas and shifts. Three process audits will be carried out per area, with a weekly frequency per shift. Starting from a document created as instructions for a preventive audit system in operations processes with final inspection points. This inspection will verify that the manufacturing specifications of the product are met throughout the manufacturing processes by monitoring the product, packaging design and execution. Then some checklists will be done, where the feasibility will be reviewed. The project will be executed with the previous tools following the Project Management Life Cycle (PMLC) practices.

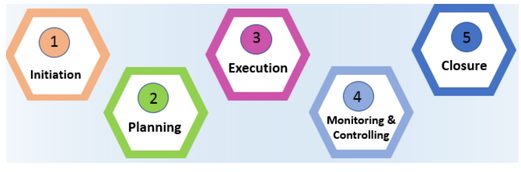


Figure 1: Project Management Life Cycle (PMLC)

Results and Discussion

Three types of audits of operations in the process will be carried out by quality auditors/technicians, such as General Audit, Audit of manufacturing in process and Audit of Final Manufacturing Inspection Points. A general audit includes, but is not limited to, the following: Audit purchase orders, logbooks, audit line clearance process, audit solvents and solutions, visual aids, audit facility, equipment condition, and controlled room gowning practices in manufacturing areas. In process audits the quality auditor/technician will verify acceptance activities, identification, and traceability, labeling and packaging, handling and storage, and manufacturing records for adequacy, completion, and compliance with established manufacturing procedures. The Manufacturing Final Inspection Points Audits are performed, at or after the final inspection operation, are met per established procedures, required to audit product families and operators randomly. An instructions document was created to execute said quality inspection and checklists for this audits to evaluate different topics.

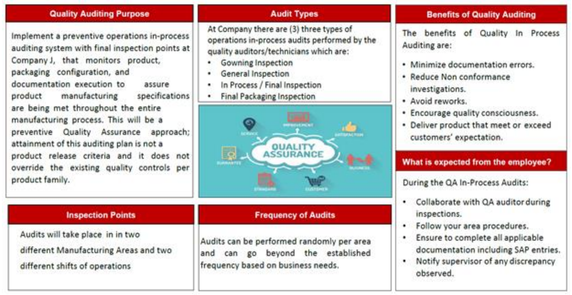


Figure 2: Quality Audit process

TITLE: QA INSPECTION AND AUDITING INSTRUCTIONS MANUFACTURING AREAS

1.0 PURPOSE:

1.1 To implement a preventive operations in-process auditing system with final inspection points at Company J that monitors product, packaging configuration, and documentation execution to assure product manufacturing specifications are being met throughout the entire manufacturing process. This is a preventive Quality Assurance approach; attainment of this auditing plan is not a product release criteria and it does not override the existing quality controls per product family.

2.0 RESPONSIBILITY:

2.1 Quality Assurance (QA) In-process Auditors/Technicians

3.0 EQUIPMENT:

3.1 Personal Computer

4.0 SOFTWARE:

4.1 SAP (System, Application, and Product)

5.0 INSTRUCTIONS:

5.1 Operations In-Process Audits

5.1.1 At Company J there are (3) three types of operations in-process audits performed by the quality auditors/technicians which are:

- General Audit
- Manufacturing In-Process (Product) Audit
- Manufacturing Final Inspection Points Audit

Figure 3: QA Inspection and Auditing Instructions Manufacturing Areas

TITLE: *QA GENERAL INSPECTION CHECKLIST*

Quality Technician: | Date/Time:
Area: | Shift:

Random Inspection Items Checklist	Pass	Fail	N/A
Product Identification & Traceability			
1. Materials and Product are identified, adequately stored, physically segregated under correct storage conditions (adequate temperature, etc.) and locked at required stages.	☐	☐	☐
2. Reagents and Solutions are properly stored, identified and, within expiration date.	☐	☐	☐
Production and Process Control			
1. DHR (Device History Record) or eDHR (Electronic Device History Record) and product related documentation complies with Good Documentations Practices (GDP) and applicable Standard Operating procedure requirements.	☐	☐	☐
2. System is available to all employees and associates demonstrate the knowledge to access the system and procedures.	☐	☐	☐
3. Area and equipment are identified, up to date, clean and organize. No signs of rust, chipped paint, dirt, or tape residues. Cleaning of the workstations are performed and documented.	☐	☐	☐
4. Conditions of the ceiling, walls and floor are in compliance (seal integrity, no scratches and no holes in the wall).	☐	☐	☐
5. Utilities systems are properly identified and in compliance (valves not leaking, returns not blocked, airflow per design and hoses not left in sinks).	☐	☐	☐
6. Equipment identification PM (Preventive Maintenance) within due date and legible label.	☐	☐	☐
Calibration			
1. Equipment is properly identified and within due date.	☐	☐	☐
2. Equipment with calibration at time of use is performed and documented (if applicable) (Logbooks).	☐	☐	☐
Control of Non-Conforming Product			
1. Products affected with NC are properly identified and segregated.	☐	☐	☐
2. Scrap components, products and/or materials are properly identified, segregated and in locked cages or carts.	☐	☐	☐
Labeling and Packaging			
1. Product meet packaging configuration and labeling requirements.	☐	☐	☐
Safety			
1. No safety issues identified.	☐	☐	☐

Comments: ☐ N/A

Figure 4: QA General Inspection Checklist

TITLE: CLASSIFIED AREA OR NON CLASSIFIED AREAS GOWNING PRACTICES CHECKLIST

Classified Area / or Non Classified Areas Gowning Practices Checklist

Assessment By: _____ Date/Time: _____
☐ Classified Area ☐ Non Classified Area: _____ Shift: _____

Item	Gowning Practices	In Compliance YES / NO / N/A
1	No eating, drinking, chewing gum, cosmetics, jewelry, nail polish particles, open shoes or sandals.	☐ / ☐ / ☐
2	Classified Area /Non Classified Area gowning are adequately placed.	☐ / ☐ / ☐
3	Gowned per sequence established in Gowning process.	☐ / ☐ / ☐
4	No personal belongings inside clean room area.	☐ / ☐ / ☐
5	Washed hands and nails with soap for Classified Area as applicable and Hand Sanitizer for the Non Classified Area.	☐ / ☐ / ☐
6	Head / hair covers and beard covers (facial hair) are used. Types of head / hair covers used at the facility include a hood, and/or a bouffant cap. No hair or beard is exposed.	☐ / ☐ / ☐
7	Sanitized hands with -Approved Sanitizing agent after having contact with potentially-unclean surfaces such as waste containers, under tables, under equipment, on top of equipment or floor. If wearing gloves, cleaned gloves with an Approved Sanitizing agent or re-gloved before resuming work in the station.	☐ / ☐ / ☐
8	Equipment/Tools entered into the Classified Area /Non Classified Area are cleaned or sanitized.	☐ / ☐ / ☐
9	Avoided contact with potentially unclean surfaces.	☐ / ☐ / ☐
10	Limit use of papers, notebooks, and other office materials that are not necessary for Classified Area documentation purposes.	☐ / ☐ / ☐
11	No contact between the Classified Area / Non Classified Area garment and the floor.	☐ / ☐ / ☐
12	Classified Area / Non Classified Area gowning snap button clips completely closed and that neck and wrist snaps securely fastened.	☐ / ☐ / ☐
13	Apply Isopropyl alcohol 70% over the gloves. If gloves are torn or become soiled, they must be changed immediately. Gloves must be changed every time the employee leaves and returns to the manufacturing area.	☐ / ☐ / ☐
14	When exiting the Classified Area or Non Classified Area remove Gowning per sequence.	☐ / ☐ / ☐
15	Organization of gowning room, used gown placed in the appropriate container.	☐ / ☐ / ☐
16	Verification of gowning room organization, supplies availability and proper dispose of used gowns.	☐ / ☐ / ☐

Comments ☐ N/A

Figure 5 : Classified Area or Non-Classified Areas Gowning Practices Checklist

TITLE: QA AUDIT FORM IN- PROCESS PRODUCT

Quality Technician(print name): _____ Shift: _____ Date/Time: _____
Operator: _____ Procedures: _____
Operation / Area: _____ PO: _____ Model: _____ PO / Lot Qty: _____
Material Segregation/Identification: ☐Pass ☐Fail ☐N/A Line Clearance: ☐Pass ☐Fail ☐N/A System Access: ☐Pass ☐Fail
Procedure vs Practice: ☐Pass ☐Fail ☐N/A

In Process Inspection Audit

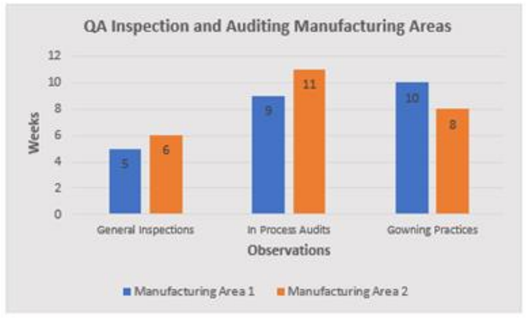
Num	Order / Serial / Batch or Lot No.	Pass/Fail	Comments ☐ N/A
1		Pass ☐ Fail ☐	☐ N/A
2		Pass ☐ Fail ☐	☐ N/A
3		Pass ☐ Fail ☐	☐ N/A
4		Pass ☐ Fail ☐	☐ N/A
5		Pass ☐ Fail ☐	☐ N/A
6		Pass ☐ Fail ☐	☐ N/A
7		Pass ☐ Fail ☐	☐ N/A
8		Pass ☐ Fail ☐	☐ N/A
9		Pass ☐ Fail ☐	☐ N/A
10		Pass ☐ Fail ☐	☐ N/A
11		Pass ☐ Fail ☐	☐ N/A
12		Pass ☐ Fail ☐	☐ N/A
13		Pass ☐ Fail ☐	☐ N/A

Pass/Fail	Comments ☐ N/A
☐ Pass ☐ Fail	

In Process Audit Result

Figure 6: QA Audit Form In-Process Product

All observations are evidence of opportunities for improvement, risks, or future non-conformities if they do not work for the audited processes.



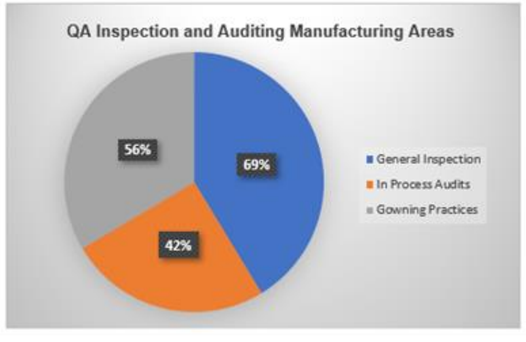


Figure 7: QA Inspection and Auditing Manufacturing Areas Observations

Conclusions

At a general level, it was observed that the processes lacked such audits, which generated non-conformities that could not be corrected, and the product ended up being discarded. An audit process has been put in place that proactively confirms that current controls and practices are being followed in manufacturing areas through procedures. This will be considered a preventative Quality Assurance approach and a risk mitigation measure that is not intended to replace existing quality controls. The processes need to be audited to identify discrepancies or non-conformities that, when detected, could be an opportunity for improvement, allowing a quality product to reach the market with a satisfied customer. Through the implementation of audits, it allows to improve the control and monitoring system in the Company. The benefits of the Quality Audit in Processes are: Minimize documentation errors, reduce non-conformity investigations, avoid rework, promote quality awareness, and deliver a product that meets or exceeds customer expectations.

Figure 8: Benefits of Using Quality Control in Manufacturing

Acknowledgements

I thank the Polytechnic University of San Juan and all the professors for giving me the opportunity to grow as a person and professional through this academic training, as well as my tutor for guiding and supporting me during this project.

I want to thank my family for all their help during the learning process of my specialization, since with their help I was able to get ahead in this important stage of development for me.

I thank all my coworkers for all their teachings in each of the subjects and topics transmitted during the specialization, since they were a constant support during the process of degree work, sharing their knowledge and all their attention for the realization of this Project.

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