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; attainment of this auditing plan is not a product release criteria and it does not override the existing quality controls per product family. The internal audit program assures that the quality system complies with internal quality to assure that the quality systems achieve quality and business objectives; and to identify areas of continuous improvement.*

Key Terms *— Inspection, internal audit, manufacturing operations, quality.*

INTRODUCTION

Company J is a global pharmaceutical company committed to improving healthcare standards and providing access to high-quality medications and health care products. Quality assurance is critical in the pharmaceutical sector, since patient health and well-being are at risk. As a result, we think that quality is everyone's responsibility. Company J has extensive systems and processes in place to give its staff the foundation and tools required to sustain a successful quality management system.

Product quality in manufacturing refers to how a measured set of product qualities compares to a desired set of product attributes. Maintaining quality in production becomes more challenging as product design complexity and throughput rise. Part of the reason for this is the increased possibility of machining and human errors, as well as maybe insufficient resources for quality inspection. Improving quality control is required for manufacturers to fulfill rising market demands while maintaining acceptable quality standards.

The American Society for Quality defines *quality control* as "a component of quality management focused on satisfying quality criteria" [1]. Quality control (QC), in other terms, is the endeavor to maintain a degree of quality during the manufacture or usage of an object. The benchmark against which a product is generally drawn from a similar product that is judged to be ideal or in good condition. If a product's qualities stray from the norm, it may be visually unappealing, have a shorter shelf life, and/or fail to perform effectively. QC is critical for every production process in any firm.

PROBLEM STATEMENT

This project was developed to show Company J's efficiency in the manufacturing areas' QC inspection and audit procedure in identifying QC improvements, to implement a preventive operations in-process auditing system with final inspection points at a manufacturing company that monitors product, packaging configuration, and documentation execution to ensure product manufacturing specifications are met throughout the manufacturing process. This is a preventative quality assurance strategy; compliance with this auditing plan is not a product release criterion and does not override existing quality controls per product family.

The production and process audit are a thorough and impartial examination of all steps of a manufacturing process to assess whether the pre-established quality and productivity criteria are respected, influential, and relevant in connection to the pre-established standards. Quality audits are the most effective way for a firm to ensure that its

quality system is adequate and effective. Inspection and manufacturing process audits boost output by minimizing the time needed to move a system through the manufacturing process. Production and process control audits ensure that when a design is released for manufacture, it is accompanied by the necessary travelers, operation sheets, and product-specific process instructions.

LITERATURE REVIEW

An audit is an "on-site verification activity, such as inspection or examination, of a process or quality system to guarantee compliance with requirements." An audit might cover an entire business or focus on a single function, process, or manufacturing step [2]. A quality audit is a verification effort to determine the degree of compliance of a product, design, process, or system to a standard specification or method [3]. Audits are essential for evaluating the performance of processes, products, and systems, whether existing or newly implemented, to deliver the most significant advantage to a company [4].

Advantages of Quality Auditing

There are various benefits to correctly conducting quality audits in companies. Quality audits boost organizational productivity; promote product consistency; decrease errors; and not waste personnel, machines, and resources. Quality audits encourage employees to reveal areas for improvement in understanding essential quality criteria.

The Auditor's Function

The auditor may be an employee who knows but is not actively involved in the process, product, or system being audited, or someone from outside the company who understands the business and industry standards [5].

Quality audits are classified into three kinds:

- **System audit:** It verifies that functional system elements are appropriate and effective and have been developed, documented, and implemented by specified requirements [1].
- **Process audit:** It analyzes whether an organization's procedures operate within predefined parameters [4].
- **Product audit:** It determines if a given product or service meets the required specifications, client needs, or performance. [4]

Quality Inspection

Quality inspection is verifying, measuring, or testing one or more product or service features and comparing the results to specific criteria to certify conformity. A successful inspection system standardizes quality, eliminates paperwork, and increases floor productivity [6].

The Key Types of Inspections

Quality inspection examines for quality and identifies solutions to decrease production costs, scrap losses, and defects. Three types of inspections are used to ensure product quality and consistency, and control systems to ensure quality and efficacy [6] (figure 1).

Figure 1
The Key Types of Inspections

- **Pre-production inspection:** Critical to lowering quality risk, since inputs may be evaluated before the manufacturing stage [6].
- **In-process inspection:** It happens when the line’s first product is inspected for conformance [6].
- **Final inspection:** Also known as pre-shipment inspection, it involves counting the total number of items and randomly drawing

samples of finished products. It occurs once everything is done and ready for distribution, and the results of final inspections are more dependable [6].

Quality Control

To assure product consistency, the manufacturing industry relies on QC. Maintaining the quality of the product or service to guarantee that clients receive the best product. Is critical to ensuring client satisfaction and providing high-quality products or services according to the company's standard operating procedures [6] (figure 2).

Figure 2
Benefits of Using Quality Control in Manufacturing

The Importance of Inspection in Manufacturing Processes

Inspections are crucial to achieving manufacturing quality, both for goods and processes, successfully simplifying your inspection processes may affect business success and client trust in your brand [7]. Product inspections are essential in the manufacturing industry for generating perfect items. During manufacture, transportation, and distribution, product quality is assured. Reputable manufacturers do quality tests to guarantee that their products are of the most excellent quality [7].

Inspections can be broadly classified into two different categories:

- **Product Quality Inspections:** Product quality inspections are an essential aspect of QC and are performed on-site at various phases of the manufacturing process and shipment [7].
- **Process Quality Inspections:** An in-process inspection can occur at any time during production. During in-process inspections, the end product's quality is assured by following the procedure before proceeding to the next step [7].

The inspectors who check for in-process inspections ensure that items match client specifications. If the product is found deficient after examination, the corporation determines whether to accept it.

Customers anticipate and want high-quality items. When clients obtain excellent products, it will increase customer loyalty, gain repeat business, gain new customers through recommendations, maintain or increase your market position, improve safety, reduce liability risks, and contribute to the overall positive branding of your product. Manufacturers who use QC methods are considerably less likely to experience product recalls or endanger customers with defective products [8]. Quality audits are a company's most effective continuous improvement tool to ensure that its quality system is adequate and effective [5].

METHODOLOGY

Various tools will be used to examine and identify the needs or requirements for the project's design and development. The Qualitative Descriptive research approach was used in this work, which strives to create a data-based view of the condition or situation. Descriptive research assists in describing the status of the company's processes, for which qualitative data is collected in a field study, which in this case is the execution of the audit in the company, the key instrument being the list of checkups. Field research entails selecting an event, condition, or circumstance to examine, that is, the selected method of "design and execution of testing," as well as observation and engagement in the configuration of the field of study [9].

The audit of operations in process will be carried out in the manufacturing areas of Company J. For that reason, they will work directly with personnel in the manufacturing area where the development of the products is carried out.

The initial sample is based on the manufacturing processes in different areas and shifts. By area, there will be three process audits, on a weekly basis per shift.

Design or Research Study Type

For the development of the problem question, a series of data obtained directly from the field work developed with the work team will be collected and researched, to evaluate both internal and external factors that help determine possible recommendations that may be given at the time of the audit. During this research, there will be accurate and efficient information that will allow recognizing the relevance of performing the audit in a participatory way with the company's administrative and operational employees. This research will begin with the use of a checklist in collaboration with the staff, in which viability will be reviewed. The data collected will allow the production of the appropriate suggestions to carry out changes in the company's design and testing processes [10].

Work Phases

The following work depicts the progression of actions to attain the objectives stated in the audit project. A system has been built with stages that logically display the process: exploration, implementation, and evaluation.

Considering the stated objectives, the technique began with identifying the processes; the risks were identified based on these processes and the theoretical references previously supplied. Based on this diagnostic, a meeting was organized to describe the audit process by the Quality and Operations Departments, after which the implementation process was defined, as well as the controls that must be implemented [10].

The project will be executed following the Project Management Life Cycle (PMLC) practices. The process is divided into four main parts: the initiation phase; the planning phase; the execution phase; and the monitoring, control, and closing phase (figure 3).

Figure 3
Work Phases

RESULTS AND DISCUSSION

A previously implemented procedure in the company was used as a reference, considering the changes and demands in the manufacturing processes. Four meetings were held with individuals from the departments of Operations and Quality for one month. The previous procedure was discussed in the company where the experiences were known. They could react to execute the audit process again with an inspection system that everyone could follow and understand. The most vulnerable process continued to be the operators' visual fatigue because the manufacture of the product requires a lot of labor and training for employees assigned to the different processes due to manufacturing volume increase and working pattern changes. That is why we recommend quality assurance presence in the manufacturing areas, that is, to add quality inspectors to the lines to monitor processes and procedures vs. practice to ensure the highest quality experiences for the patients.

The process was evaluated following the process flow (figure 4).

Figure 4
Process Flow Manufacturing Product

Process flow maintained the same production patterns. The in-process audits in the manufacturing process are performed in Building #3 in two different areas: Process Room 3 and Cleaning Inspection and Insertion Room 3. The manufacturing rooms where the audit in the process is performed, as well as the cleaning and sealing, have their controls; a gown is used in both areas, as established in the company procedure. A color was assigned to each box based on risk: green for low to no risk, yellow for medium risk, and red for high risk of an event that could affect product quality. Based on the process flow, there is a low-medium risk of an effect on critical quality attributes, since the process is redundant. Those visual-dependent, recurring tasks and/or continuous processes are identified to start in:

- **Building 3:** On continuous line, linear process with no rotation, visual inspection – visual-dependent.
- **Packaging/ Boxing:** Labor-intensive and visual-dependent.
- **Final Inspection and Labeling:** Manual process, and visual-dependent.

Even there is low-medium risk of affecting quality and compliance, the process can be improved to eliminate the non-conformances and investigations through the process caused mainly by human factors. For this reason, Company J needs to add quality inspectors to the lines with emphasis in monitoring high-risk process like visual inspection, first pack, and boxing. Continue monitoring NCs and complaints to establish any trend between working patterns and quality events. New ideas on identifying observations, rectifying them, and following up on them were presented. PMLC and its different four phases were also used:

- **Initiation:** A meeting was held to introduce the manufacturing area quality inspection project and audit process. A commitment was received to begin the project (table 1).

Table 1
Project Charter

QA INSPECTION AND AUDITING INSTRUCTIONS MANUFACTURING AREAS

Company J
Daphne Jimenez

Mon, 8/9/2022
22

Dec 26, 2022 | Jan 2, 2023

TASK	PROGRESS	START	END	DAYS
Meeting Departments of Operations and Quality	100%	8/9/22	8/31/22	31
Reference Document collection	100%	8/2/22	8/31/22	30
Establish quality team	100%	8/9/22	9/30/22	61
Describe Process Flow Diagram	100%	9/9/22	10/31/22	61
Generate schedules for audits	100%	9/30/22	10/13/22	14
Define Audit Plans and revise Written Procedures	100%	10/13/22	11/12/22	31
Develop Audit Checklists	100%	11/12/22	11/22/22	11
Develop Instruction document for the audit process	100%	11/12/22	11/15/22	4
Provide Audit training activities	100%	11/22/22	11/30/22	9
Preparing Audit Activities	100%	11/30/22	11/30/22	1
Implementing the Audit Program	100%	12/1/22	1/30/23	61
Reviewing and Improving the Audit Program		1/30/23	2/3/23	5
Completing the Audit program		2/3/23	2/3/23	1
Present Report with Conclusions		2/3/23	2/9/23	7

In this stage, the audit's objectives, scope, and resources are defined for its implementation and follow-up. Identify where the current and potential risks and problems. Determine audit schedule, type, content, and team appropriate for the auditee.

- **Planning:** Worked with the design stage of the audit process, in which the plan of what to do and how to comply with the proposed time of three months was defined. This proposed time was required due to the high incidence of non-conformities and thus being ready for external

audits. Three types of audits of operations in the process will be carried out by quality auditors/technicians: General Audit, Audit of Manufacturing in the Process (product), and Audit of Final Manufacturing Inspection Points. These audits and inspections will be carried out weekly per shift and with a frequency established according to the needs of the business (table 2). Determine the type of audit necessary based on the maturity of the facility. Establish maturity of facility and rank operations based on potential risk. Define corrective actions per scenarios (table 3).

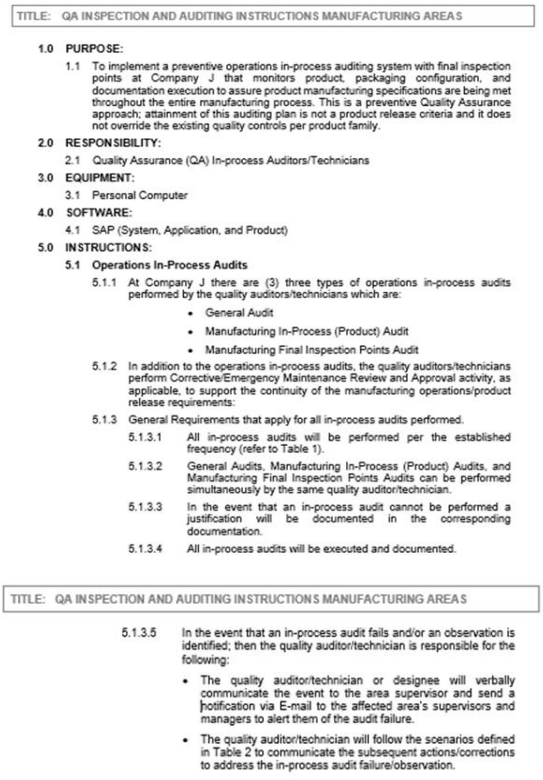
Table 2
In-Process Audit Frequency

In-Process Audit Type	Area/Operation	Frequency Recommended	In-Process Audit Form
General / Gowning	Process Rooms	Weekly Randomly (includes all shifts)	QA General Inspection Checklist
	Cleanrooms		
	First Pack Cleanrooms		
	Boxing Areas		
	All Gowning Rooms	Weekly per Gowning room (includes all shifts)	Classified Area or Non-Classified Areas Gowning Practices Checklist
Manufacturing In-Process (Product)	Process Rooms	Weekly per Shift, as applicable	QA Audit Form In-Process Product
	Clean, Inspect, Insert Cleanrooms		
	First Pack Cleanrooms		
	Boxing Areas – **All Operations**		
Final Inspection Points	Final Inspection Operations	Weekly per Shift, as applicable	QA Audit Form In-Process Product
	First Pack		
	Boxing Areas – **All Operations**	Per Sterilization Lot, as applicable	

Table 3
Audit Failure/Observation Scenarios/Actions

Scenario	Actions
General Audit Observations related to facilities or equipment. For example, damage to ceiling acoustics, chip paint, stains on the walls/ceiling/floors, rust, etc.	1. A corrective maintenance work order is required. 2. Impact to product will be evaluated as part of the corrective maintenance work order.
Audit Failures or Observations related to failures in good documentation practices.	1. Re-training the employee that did not meet the excellent documentation requirements, as applicable. 2. Awareness to area personnel that was issued the in-process audit observation. 3. Contact the area supervisor, to evaluate if further action is required. 4. Contact the area supervisor (or designee) in case of any observation related to the system.
Audit Failures/Observation related to gowning practices	1. Re-training the employee that did not meet with the gowning requirements, as applicable. 2. Awareness to area personnel that was issued the in-process audit gowning observation.
Manufacturing In-Process (Product) Audits failures. Examples: Identified that employee did not follow written procedures, Acceptance activities for a product do not meet procedure specification, product inadequately identified, incomplete manufacturing records, data documented does not meet procedural specification, etc.	1. Re-training the employee that did not meet with the procedural requirement, as applicable. 2. Awareness of the applicable procedure(s) to all area personnel for the area that was issued the audit observation/failure. 3. If there is a potential impact on product quality. Verify the previous production order of the employee issued the observation, as applicable. 4. Contact the area supervisor, to evaluate if non-conformance is required.
Manufacturing Final Inspection Points Audits that fail inspection.	1. Re-training the employee that failed the inspection. 2. Awareness of the applicable procedure(s) to all area personnel for the area that was issued audit failure. 3. Verify production order before and after the employee issued the audit failure, as applicable. 4. Contact the area supervisor, to evaluate if Non-conformance is required.
Safety Incidents/ Observations	1. Notify the Supervisor or Representative to evaluate risk.

- **Execution:** The inspection instructions were documented in the document "QA Inspection and Auditing Instructions Manufacturing Areas" (figure 5). Three checklists were created: QA Audit Form In-Process Product (figure 6), Classified Area (Controlled Room) or Non-Classified Areas Gowning Practices Checklist (figure 7), and QA General Inspection Checklist (figure 8), for internal inspection in Operations areas. These were carried out by the requirements and expectations of the Operations and Quality Management. A document was created to execute said quality inspection in the manufacturing process (figure 5).



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

5.1.2 In addition to the operations in-process audits, the quality auditors/technicians perform Corrective/Emergency Maintenance Review and Approval activity, as applicable, to support the continuity of the manufacturing operations/product release requirements:

5.1.3 General Requirements that apply for all in-process audits performed.

5.1.3.1 All in-process audits will be performed per the established frequency (refer to Table 1).

5.1.3.2 General Audits, Manufacturing In-Process (Product) Audits, and Manufacturing Final Inspection Points Audits can be performed simultaneously by the same quality auditor/technician.

5.1.3.3 In the event that an in-process audit cannot be performed a justification will be documented in the corresponding documentation.

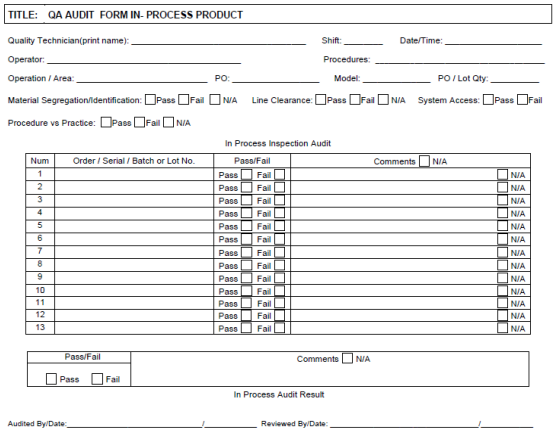
5.1.3.4 All in-process audits will be executed and documented.

TITLE: QA INSPECTION AND AUDITING INSTRUCTIONS MANUFACTURING AREAS

5.1.3.5 In the event that an in-process audit fails and/or an observation is identified; then the quality auditor/technician is responsible for the following:

- The quality auditor/technician or designee will verbally communicate the event to the area supervisor and send a notification via E-mail to the affected area's supervisors and managers to alert them of the audit failure.
- The quality auditor/technician will follow the scenarios defined in Table 2 to communicate the subsequent actions/corrections to address the in-process audit failure/observation.

Figure 5
QA Inspection and Auditing Instructions Manufacturing Areas



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

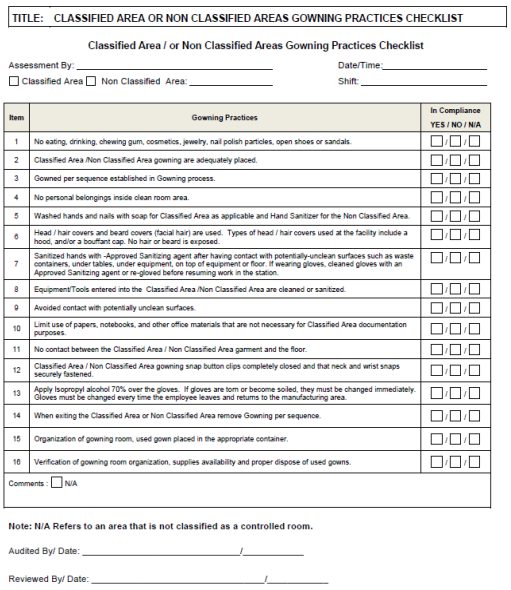
Pass/Fail	Comments ☐ N/A
☐ Pass ☐ Fail	

In Process Audit Result

Audited By/Date: _____/_____ Reviewed By/Date: _____/_____

Figure 6

QA Audit Form In-Process Product



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

Note: N/A Refers to an area that is not classified as a controlled room.

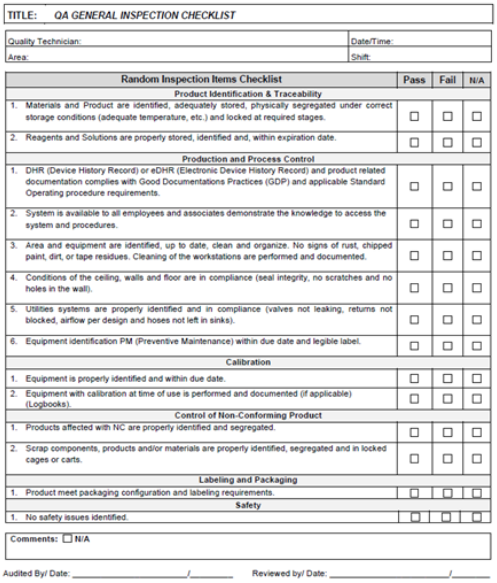
Audited By/ Date: _____/_____

Reviewed By/ Date: _____/_____

Figure 7

Classified Area or Non-Classified Areas Gowning Practices Checklist

The Audit and Internal Quality Inspection sheets were designed to evaluate different topics. A general audit is an in-process audit performed by manufacturing/packaging areas to ensure compliance. A general audit includes, but is not limited to, the following: audit purchase orders, logbooks, audit "good manufacturing practices," audit line clearance process and area cleaning, audit solvents and solutions, visual aids, audit facility, and equipment condition in manufacturing areas (equipment maintenance, label readability, and calibration dates). Verify controlled room dress practices for each manufacturing area and dressing room to ensure proper dress procedures are followed as established in the manufacturing process.



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

Audited By/ Date: _____/_____ Reviewed by/ Date: _____/_____

Figure 8

QA General Inspection Checklist

A manufacturing (in-process product) audit is performed to ensure that the execution of the manufacturing process follows written procedures at any stage of the process. 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. Audits are performed randomly per manufacturing/boxing area covering all shifts (as applicable). As part of the audits, samples can be taken from the manufacturing audits performed in manufacturing processes, including final packaging, and documented in the form "QA Audit Form In-Process Product."

The Manufacturing Final Inspection Points Audits are performed by the quality auditors/technicians to ensure that the product manufacturing requirements, at or after the final inspection operation, are met per established procedures, required to audit product families and operators randomly.

- **Monitoring and Control:** The Internal Audit Inspection Program will be carried out with the established frequency (weekly per shift) in a random manner according to the needs/continuity of the business (table 1). The program will be monitored and controlled by the plant's Quality Department. The collected data and the information obtained during the visits to different places by the audit team are analyzed. This analysis is done to identify the areas that need improvement. The findings will be documented in the Inspection Sheet. If an observation is identified during a general audit, an in-process (product) audit, and a final inspection point audit, the auditor /quality technician will follow the scenarios outlined on table 3.
- **Closing:** This will be done in collaboration with Quality and Operations Management for the subsequent phases of this program. Continue to enforce quality inspections in production processes to identify improvements in the company's quality control.

The program's expectations are for it to be dependable. Audit the relevant items at the relevant places. Individual and overall facility performance are program design requirements that must be met by quality auditors/technicians who match the audit type and audit team appropriate to the facility and auditee status, with standardized job aids for quality and compliance audit systems, decision criteria, and consistent scoring of findings. The audit of the manufacturing process enabled the identification of discrepancies in the development of the activities, which, when detected and addressed, may become possibilities for improvement in execution to maximize the quality of deliverables.

Discussion

Throughout the process, in audits carried out during eight weeks in two different manufacturing areas and two different shifts, the level of compliance in the observations aimed at improvement and risk management is evidenced. In general audits, 16 audits were carried out, of which 11 observations were focused on the lack of documentation in logbooks, showing that the information was not fully guaranteed, corrective measures were generated in facilities (unpainted walls, water leaks), lack of equipment safety in employees, unidentified equipment, labels with expired calibration dates, with a 69% result (figure 9).

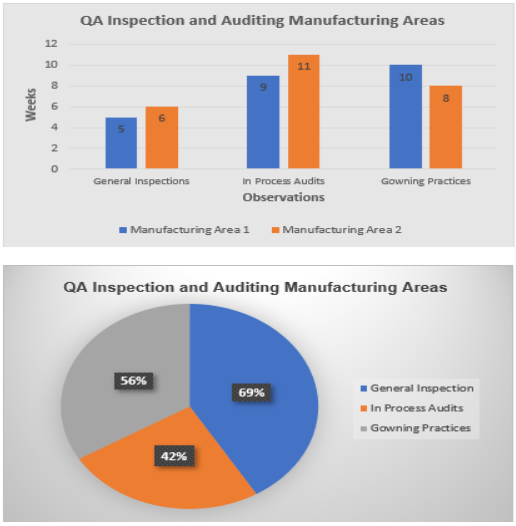


Figure 9
QA Inspection and Auditing Manufacturing Areas Observations

This was followed by a series of observations that were presented in the manufacturing audit in process, most of them focused on the lack of processes documentation, outside of process activities and failures protecting the information in the support system, resulting in the inability to guarantee information or manufacture of the product; 48 audits were carried out and 20 observations were obtained, with a 42% result (figure 10).

Finally, in verification of the Gowning Room of the Controlled Room for each manufacturing and gowning area, 32 audits were carried out with 18 observations, with a 56% result in relation to supply, organization, cleaning of the Gowning area and practical observations where proper dress practices were not followed (figure 9).

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

CONCLUSIONS

Once the project was completed, we noticed that the absence of the Internal Audit Program and Quality Inspection in the Operations area was a problem, and many non-conformities occurred. With this project, they have been controlled at different inspection points. An audit process was implemented that proactively confirms that current controls and practices are followed in manufacturing areas by procedures. The audit in the process of manufacturing areas incorporates an instructional document, and related forms, supporting business strategy in alignment with a proactive quality assurance approach.

The benefits of quality in process auditing are minimizing documentation errors, reducing non-conformance investigations, avoiding reworks, encouraging quality consciousness, and delivering a product that meets or exceeds customer expectations.

During ongoing QA audits, the auditor will expect the population to collaborate with the quality control auditor during inspections, follow the procedures for their area, complete all applicable documentation, including system entries and notify the supervisor of any observed discrepancies.

The purpose and objectives of the audits were established. To achieve manufacturing quality, products and processes were examined through a systematic review of all phases of a manufacturing process to assess whether the pre-established quality and productivity requirements were being followed. Creating an audit checklist helped the auditor carry out his duties logically and consistently.

The contribution of this project is to establish the minimum elements of the audit program in process and define the requirements for the programming, planning, execution, and reporting of process quality audits, issuance and monitoring of observations, and training guidelines for auditors/audit technicians.

Manufacturers should constantly strive to improve the quality of their goods and manufacturing processes. Improving Quality Control is an issue where the company sometimes needs to modify its organizational culture as it adopts new quality paradigms; it is a priority that gives a competitive edge in any sector and is vital for success at all levels.

At a general level, it was observed that the processes lacked such audits, which caused non-conformities that could not be corrected, and the product ended up being discarded. The processes need to be audited to identify discrepancies or non-conformities that, when detected, may 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 (figure 10).

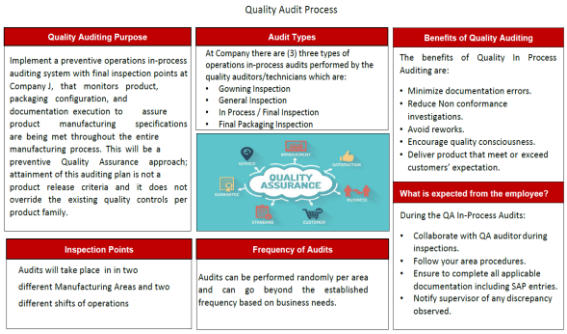


Figure 10
Quality Audit Process

RECOMMENDATIONS

The Company is expected to take on its own initiative the recommendations proposed by the auditors or quality technicians for the improvement of the audited processes and implement an improvement plan that allows continuing with the review of the other belonging processes.

At a general level, the project is well structured. A more structured guide should be standardized to support the audit process, to provide a better understanding of the processes, in addition to carrying out a more exhaustive follow-

up that contributes to measurements and controls for decision-making.

Finally, it is recommended to implement improvement plans by the process leaders, according to the results presented in the process audits, looking for measures of change in the organization to improve performance, with strategic planning to achieve a qualitative leap. in service and processes.

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