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Auditing in the Pharmaceutical Industry: A Critical Component of Quality Management

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Abstract: ***Auditing is an essential role in a pharmaceutical company. A quality audit aims to improve a quality system by reviewing and evaluating all or a portion of it. It's one way to look at pharmaceutical programs and make sure that the processes and payment systems meet legal and regulatory standards. A team assigned by management to carry out this task or external, independent experts typically perform quality audits. It is possible to expand these audits to include contractors and suppliers. An audit will evaluate the advantages and disadvantages of quality assurance as well as the processes involved in it. The findings of the audit will help to enhance procedures and create a more effective system that will benefit the business. The purpose of this article is to discuss quality auditing in the pharmaceutical sector and to highlight its planning, principles, objectives, significance, benefits, and potential flaws. This review follows the Google Scholar search engine and the following keywords to provide a well-organized summary of the several recommendations that are currently accessible. This review follows the Google Scholar search engine and the following keywords to provide a well-organized summary of the several recommendations that are currently accessible.***

Keywords: Quality auditor, Auditor, Internal audit, Audit Planning, Audit Procedure, Administrative, Audit Deficiencies

1. Introduction

Regularly assessing a system's quality is known as quality auditing, and it can be done by an external or internal quality auditor, or by a group of individuals chosen by management to this objective. It is possible to expand these audits to include contractors and suppliers. The primary goal of a quality audit is to analyze and enhance a quality system by evaluating and examining all or a portion of it. Since its founding, the World Health Organization's (WHO) top priority has been pharmaceutical quality.[1]

Audits are carried out to determine the accuracy and dependability of the data as well as to evaluate a system's internal control. It gives management data about the effectiveness of way the business manages the caliber of its operations and output [2].

To put it simply, an audit is the examination of a system or process to make sure it satisfies the needs of its intended purpose [3]. "Systematic, independent, and documented process for obtaining audit evidence and evaluating them objectively to determine the degree to which the verification criteria are met" is how the International Organization for Standardization (ISO) describes audits. [4]

Audits are a virtual tool used in the pharmaceutical sector to evaluate adherence to the set goals outlined in the quality system, so clearing the path for the ongoing enhancement initiative by giving management input [2]. Today's pharmaceutical companies need to be able to show that their products are produced with complete dependability, under ideal circumstances, and with exceptional homogeneity that permits precise replication [2].

Auditing for both compliance and performance is crucial in ISO and Food and Drug Administration (FDA) settings. Writing and editing validation policies, guidelines, and standard operating procedures (SOP) from project qualification to performance evaluation phases is part of my experience in pharmaceutical audits.[5]

2. Definition Of Internal Audit

An independent appraisal activity established within an organization as a service to it," is how an internal audit is described. It is a management tool that assesses the efficacy of every aspect of an organization's management and operations. It works by looking at and assessing the suitability and efficacy of other controls.

Similar definitions of internal auditing may be found in the Institute of Internal Auditors' (IIA) definition, which states that internal auditing is an impartial, independent assurance and consulting activity intended to enhance an organization's operations. By providing a methodical, disciplined approach to assess and enhance the efficacy of risk management, control, and governance procedures, it aids a business in achieving its goals.

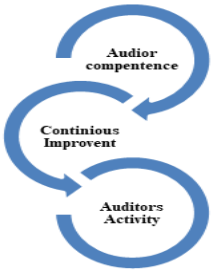

Figure 1: Protocol of Audit

According to these definitions, internal auditing has two distinct purposes:

first, it acts as a process that is carried out by the company's personnel and information technology systems to help the organization achieve its goals. Management tools: These track and assess how well a business manages its risks and its operational procedures [6].

Goals of audit

This intricate process has the straightforward objective of assessing current paperwork and activities to see if they adhere to the standards in place. The purpose of the audit is to assess the advantages and disadvantages of the quality control and quality assurance procedures. Based on the findings, we will be able to enhance the processes and construct a more robust system that will benefit the organization. Every pharmaceutical company's product contains qualities that need to be measured or validated by laboratory testing. The essential procedures that make up the pharmaceutical industry's control and balancing system are quality assurance and control.

If planning and preparation are done correctly, the audit should have no trouble accomplishing its goal. Building a brand reputation and preventing problems can be achieved through efficient auditing and adhering to standards.

Every product that a pharmaceutical company produces has qualities that require laboratory testing to quantify or qualify. The essential procedures that act as a check and balance system in the pharmaceutical sector are quality assurance and control. They support the process of comparing a system, procedure, or output to performance benchmarks.

Audits assist in giving management information about how well a business is able to regulate the quality of its operations and output. Additionally, it might serve as a tool to support and strengthen the consumers' faith and confidence.[7]

Objective:

1) To evaluate certain requirements to determine whether a quality system complies or not.
2) Verification of the effectiveness of the quality system that has been put in place to see if it meets the designated quality objective.
3) Giving the group members a chance to raise the standard of their system.
4) Complying with the rules is yet another primary goal.
5) To register the audited institutions' quality system.[8]
6) Assessing if requirements meet ISO 9001 standards; evaluating whether documentation complies with ISO 9001 standards determining whether implementation complies with documentation Assessing how well requirements and objectives are met.
7) Fulfilling any contractual or legal requirements pertaining to audits.
8) Offering a chance to enhance the quality management system.
9) Authorizing registration and listing on a list of registered businesses.
10) Assessing possible vendors.[4]

The following is the justification for starting an audit:

- An assessment of the supplier that requires the establishment of a contractual relationship.
- The contract structure includes ongoing supplier quality system verification to assess if the supplier's systems are implemented and meet specifications.
- To ensure that the organization's quality system was implemented in accordance with the standards, it should have also been verified.
- Evaluation of one's own system to determine how well it aligns with the industry standard for quality.[10]

1) Principle of auditing:

The basis for carrying out trustworthy and efficient audits is provided by the auditing principles. For audit processes to be consistent and honest, adherence to these guidelines is necessary. The following are the main ideas of auditing:

2) Integrity:

When performing their duties, auditors and audit personnel should act with professionalism, integrity, and accountability. Throughout the audit, they should maintain their objectivity, fairness, and competence while avoiding any factors that can skew their assessment.

3) Equitable Display:

Auditors are required to accurately and truthfully report the audit's findings, conclusions, and reports. Transparent disclosure of any issues found during the audit and disagreements between the audit team and interviewees is required.

4) Due Professional Care:

When performing audits, auditors should exercise caution and good judgment. They ought to understand the significance of their function and the audit client's confidence in them. In every audit scenario, rational and methodical judgment should be used.

5) Confidentiality:

Auditors are required to guarantee the safety of the data they acquire while conducting the audit. They should refrain from abusing audit information for their own benefit and make good use of it. This principle covers how to handle private or sensitive data appropriately.

6) Independence:

To guarantee objectivity and impartiality in audit conclusions, auditors should remain apart from the activity they are auditing. They ought to behave impartially and without favoritism. To ensure that findings and conclusions are only based on audit evidence, systematic criteria should be upheld throughout the audit process.

7) Evidence-Based Approach:

To provide repeatable and trustworthy audit conclusions, auditors should take a systematic and evidence-based approach. Verifiable audit evidence can be derived from existing information samples. Sampling ought to be used appropriately to bolster the audit's findings.

8) Risk-Based Approach:

Risk assessment and opportunities should be incorporated into audits using a risk-based approach. This methodology impacts audit preparation, execution, and reporting, guaranteeing that audits accomplish audit program objectives and concentrate on matters of importance to the customer. [10,11]

By following these guidelines, auditors can improve the efficacy, impartiality, and dependability of their audits while giving stakeholders useful and reliable information.

Type of audit:

Quality audit systems are mainly classified into three different categories type:

- Internal audit
- External audit
- Regulatory audit

Internal audit

Different Subtypes of Internal Audit:

- Quality system audit
- Management quality audit
- Process quality audit
- Data process audit
- Product quality audit
- Decision sampling audit
- Safety audit
- Facility audit
- Environmental audit

External audit

Different subtypes of external audit:

- Quality system certification
- Vendor audit
- Customer audit
- Laboratory audit
- Regulatory control audit
- Quality system improvement audit
- Product certification

Internal audit:

Another name for this kind of audit is a self-audit or a first-party audit. The organization both the auditor and the audited parties are a part of. [12] Giving advice to organizations on how to better accomplish their objectives is the professional activity of internal audit. When conducting an internal audit, a methodical approach is used to assess organizational issues or business processes and provide recommendations for improvement.

The main objectives of internal audits can be summarized as follows:

1) To support the system of internal controls.
2) Examine the functioning of organizational policies.
3) Confirm the legitimacy and correctness of mistakes and scams.
4) Error and fault detection and prevention.
5) Protecting the resources
6) The relevance of accounting principles.
7) Promotes the efficient operation of the internal check system.

When conducting an internal audit in a pharmaceutical facility, two key areas need to be examined: the work done by various departments and the records that these departments keep. A detailed document list and department-specific questionnaire must be created for this purpose.[13]

External audit:

This type of audit is also known as Second-Party Audit. It describes a client auditing a contractor or supplier. Even though this control is not subject to any stringent legal standards. It is usually a good idea to assess the level of skill of the contractors we use to manufacture our products, analyze our products, or do any other GMP-compliant task.[12]

Conducting these audits also provides significant business benefits.

1) Increased understanding and trust in the partnership agreement;
2) assurance that needs are recognized and fulfilled;
3) permission to scale back on some tasks (such as internal quality control (QC) testing of raw materials);
4) decreased chance of failure (and, consequently, associated expenses)
5) Numerous suppliers to the pharmaceutical business hold ISO 9001 or ISO 9002 certifications, and their certifying organization conducts routine audits of them Businesses that contract to manufacture or package pharmaceuticals will have to get licenses and be subject to regulatory audits.[13]

Regulatory audit:

Third-party audit is another term for this kind of audit. This kind of audit is not carried out by the supplier or the customer. A third party audit is carried out by an impartial organization or regulatory agency for registration, certification, or compliance needs.[12] These inspections are conducted by international regulatory agencies, including the Medicines and Healthcare Products Regulatory Agency (MHRA), UK, United States Food and Drug Administration (USFDA), Therapeutic Goods Administration (TGA), Australia, Medicines Control Council (MCC), South Africa, and others. A team made up of audit inspectors and a multidisciplinary company team is responsible for carrying out the audit.

Every department in the organization needs to be represented, including quality control, manufacturing, warehouse, maintenance, administration/people, and marketing/sales. Since manufacturers must always follow GMPs, these audits can be carried out without prior notice (MHRA presently conducts about 10% of its inspections in the UK in this manner). Companies may also be audited by regulatory agencies in other nations where goods are sold (for example, the FDA inspects manufacturers in Europe).

Regulatory inspectors are all very skilled, knowledgeable, and kind. All MHRA inspectors will be listed in the registers of people qualified to operate as qualified persons and lead auditors; they are all professionally qualified and have a minimum of five years of relevant experience in a production operation. suitably qualified to undergo an audit. Internal audits might offer benefits A manufacturing license or an import/export license may be restricted or revoked for not

approving a regulatory audit. (Financial companies that failed to comply with GMPs and respond appropriately to audit results have lately faced "punitive consensus decrees" from the FDA). As a result, organizations must have clear procedures for handling audits, and employees must have sufficient training in auditing procedures. Internal audits might offer beneficial practice opportunities.[13]

The benefit of audit:

Audits should be viewed as a management tool to evaluate the organization's internal quality management system, even if they typically have little bearing on regulatory inspections. Both external and internal audits can assist in achieving this objective. An efficient audit system's main advantages can be summed up as follows:

1) Managing a quality management system;
2) identifying unsatisfactory trends or situations to identify weak points in advance;
3) preventing quality failures by reviewing quality data;
4) informing senior management about the quality level of operations and/or facilities; standardizing audits will optimize output;
5) raising the audit's quality level (and, consequently, the quality of products and services) will ultimately result in a continuous improvement loop.
6) Standardizing audits will maximize output, raise audit quality standards (and hence, the caliber of goods and services), and ultimately create a feedback loop for continual development.
7) The auditee will comprehend that the purpose of the audit is to enhance the performance of the organization, not to monitor and critique his work. As a result, the audits will be accepted more widely. He will view audits as an opportunity to learn more and broaden his understanding of quality-related topics.
8) The auditee will be more accepting and save time if quality, safety, and environmental audits are combined. This will result in a large reduction in the number of audits.
9) The establishment of an industry-wide, high-quality audit system will raise the level of compliance.
10) Additional benefits can be obtained by pooling audits, such as Shared Third Party Audits. These efforts will lead to the partners developing mutual confidence and a better connection.[14]

Auditing procedure:

Notification: The initial stage of an audit is notification. This procedure notifies the party that will be audited of the audit's date and time. It enumerates the documents that must be examined in order to comprehend how an institution is organized.

Preparation: Before conducting an audit, the auditor follows a few procedures to pinpoint high-risk and concerning areas. It's called planning.

Opening assembly: A meeting of the auditing staff, directing personnel, and higher responsibility individuals from the recipient organization. The auditors will outline the intended course of action. The management will brief them on the consulting personnel's schedules and areas of concern.[15]

Field job: Fieldwork starts as soon as meeting reports are used to regulate terminal audit plans. The audit will be communicated to the staff. Plans will be made for the response of the audit staff. Following the acknowledgment of corporate procedures, the first investigation is launched. Key personnel interviews, testing of current company procedures using sampling, testing and evaluating of internal rules and legal practices for reasonableness,

Communication: Effective communication is essential for clarifying procedures and processes between the audit team and auditors. They can access documents as well.[16]

draft audit: This draft audit details the procedures and results. The document may also include a list of parties involved in getting preliminary results and concerns.[17]

Response from the management: Management will review the draft and make any necessary changes. They will also conduct a thorough inspection of the premises to remedy any errors. After making final changes, management receives all reports for feedback. After this, they are asked for their opinion on whether they agree with the faults identified, the corrections made, and the estimated date for all issues to be acknowledged.[18]

Finished and follow up: After an audit, it's necessary to hold a finished meeting to discuss observations and interpretations. Management representatives may provide commitments for corrective activities.

Clear communication among all parties involved is necessary to address any observed commitments and rectify actions. Auditing reports require a timetable for submitting observations and responses.

We will create appropriate timetables for any necessary corrective actions.

Periodic follow-up audits will be conducted based on observations and promises made over the term. We will create appropriate timetables for any necessary corrective actions.

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If a follow-up audit is not possible, corrective actions will be reviewed during subsequent audits.

Documenting the rationale for subsequent audits is crucial for future reference. Preventive activities assist avoid unfavorable events in the future.[19]

Key steps in audit inspection process

Management of audit:
A program for auditing may consist of one or many audits, contingent on the organization to be audited size, character, and complexity. The goals of these audits can vary, and they can also be combination (including quality management and environmental management systems) or joint (using several auditing agencies). Every task required to arrange the kinds and quantity of audits as well as to supply the tools needed to carry them out successfully and efficiently within the allotted time limits is included in the management of an audit program [fig. 2].

To oversee the audit program, senior management of the company should authorize it.

1) One should plan, design, administer, monitor, review, and enhance the audit program, according to the responsibilities allocated to program management.
2) Determine which resources are required and make certain.[14]

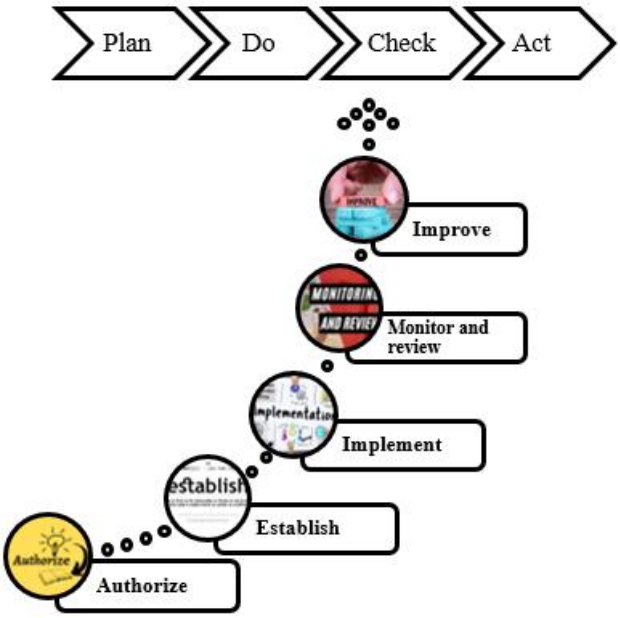

Figure 2: Process flow for managing an auditing program.

Information Gathering:
All that information consists of is facts or knowledge that has been acquired or given. It may be expressed explicitly in written or electronic documents, or it may be implicit in people's minds.[20]

Information on interfaces between functions, activities, and processes should be one of the many aspects of the audit that are pertinent to the goals, scope, and criteria. This information should be gathered through proper sampling and confirmed. Audit evidence can only consist of verified information, which needs to be documented.[4]

Any information that the auditor uses to assess whether the audited data complies with the specified standards and to reach the conclusions that form the basis of the audit opinion is referred to as audit evidence. Any data, information, process flows, bills, memos, contracts, or transactions are all considered forms of internal audit evidence.

The following would determine the evidence gathered for the internal audit:

- During the audit, instructions regarding the use of certain methods should be provided.
- The number of objects to be tested for every audit technique is known as the sample size.
- Items to choose: choose which items from the population to choose.
- Timing: There are differences in timing between the start and end of the accounting period. [6]

Method for gathering audit information
During an audit, information is gathered using six fundamental techniques. The Internal Auditor must decide which method—or combination of methods—should be utilized based on the kind of information that has to be acquired.

Interview:

Strong data collecting methods like interviews can be used both independently and in conjunction with other methods like observation. The Internal Auditor might decide what to look for based on the interviewee's insights. It can save a lot of time and confusion during an interview, therefore the most important thing to keep in mind is to always speak with the proper individual.
Effective communication is essential to any audit's success. Data will be acquired more successfully if the internal auditor interviews staff members. To obtain a thorough response, questions may be posed multiple times to various individuals, based on their level of responsibility (supervisor, operator, etc.).

Examinations:
It is best practice to begin an inspection with general observations and work your way down to more particular details. The internal auditor will survey the facility thoroughly
first, looking more closely at particular objects and making a note of anything that does not appear quite right. Throughout the examination, it's critical to raise questions. If an issue is discovered, the internal auditor must look into it more thoroughly to determine its scope.

Examining records:
Several methods are available to the Internal Auditor for examining firm records. Among these is random sampling. It highlights potential trouble spots and provides a broad assessment of the standard of record keeping. To draw reliable conclusions, however, one sample gathered over a specific period is typically insufficient.

Clarity is a crucial component of record keeping. No matter who reads a document, it should be obvious. Although specifics differ, all documents should have a title, an owner, and a revision status. Should any of this data be absent, the Internal Auditor ought to inquire as to why. It is necessary to compare the stated alterations with the master record. A person with the necessary authority must authorize, sign, and date any changes.

Observations

Observing a process in motion is the easiest way to verify its functionality. For a few hours, the Internal Auditor can watch how something is done in a typical situation by simply observing a usual action. Asking questions about what they observe is a good idea, but they must always be careful not to tamper with the procedures they are watching because that could make the staff members stop doing their regular duties.

Tracking vertically:

This technique, also known as "vertical auditing," entails concurrently reviewing every record created during the process while adhering to a predetermined path from start to finish. Using the vertical tracking technique helps the Internal Auditor see the wider picture by enabling them to see how different components of a program function together. However, it can also bring them to areas that were not originally part of the scope.

Exercises:
An exercise's purpose is to test something that is typically performed as part of the routine at the institution. Nonetheless, the test's timing and conditions are up to the Internal Auditor. The software, the equipment, or the staff may all be the focus of testing. An internal auditor should never conduct an exercise without the auditee's consent and knowledge. Unannounced acts may violate facility-specific rules or regulations that the Internal Auditor is not aware of, therefore doing so is likely to have negative effects.

Taking a note:
A competent internal auditor needs to have a streamlined method for taking notes. This is a crucial component of the work that cannot be disregarded. Along the journey, notes need to be evaluated and improved. When taking notes is difficult, one should employ a mental note-taking method. Throughout the audit, notes are utilized to help the internal auditor obtain accurate conclusions by organizing thoughts and observations. After every audit day, notes must be examined and completed.[14]

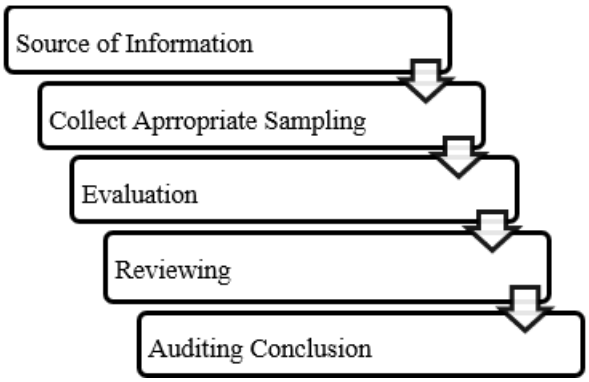

Figure 3: procedure for gathering data to draw conclusion from an audit. (4)

Administrative:
The main stakeholders that the internal audit team collaborates with must respect and believe in the team, and it must be regarded as a reliable source of guidance and assurance. This trust should not be taken for granted; rather, it can only be gained and retained through productive working relationships, prompt and excellent advice, and internal audit reports that are perceived as directly helping the organization fulfill its obligations.[14]

Different key stakeholders in internal audit are as follow:
- Chief executive
- Board of directors
- Audit Committee
- Senior management
- External auditor
- Other reviewers

Chief executive:
When internal audit reviews functionally to the audit committee, it is crucial that the head of internal audit has direct access to the chief executive, if needed. The internal auditor is referred to as a "partner" and the chief government officer (CEO) or chief financial officer (CFO) approves the internal audit function's budget and provides input for the internal audit strategy.

Board of Directors:
The head of the internal audit formally reports to the board of directors on the efficacy of the audit. In order to trade and observe, this efficacy is featured.13 Boards with a higher percentage of insider directors should be more knowledgeable to operate the company more effectively, which will improve performance.

Committee of Audit
An audit committee is an essential part of any organization's governance structure. It helps boards and chief executives determine whether important controls are strong and operating efficiently. Thirteen Three factors determine the quality of an audit committee: its size, independence, and experience.

Top level Administration:
Internal audit is necessary for senior management to make up for the loss of journal manipulation brought on by the organization's multiplied complexity.28 Internal auditors should establish a consistent basis of communication with

members of the senior management team, and through the distribution of useful, business-oriented, and reviews, reports, and advice that are generally predicated on respect, cooperation, and teamwork.

External auditor:
The development of the internal audit work plan and approach need the assistance of external auditors as well. The external auditor must assess the internal audit feature's work to determine its suitability for external audit purposes in order to prevent duplication.

Western-style external auditing standards, which are also being used in developing nations, support the dependence of external auditors on internal auditing for efficient repudiation. [21]

Deficiencies:
When an audit begins, certain circumstances may occur that point to a partial or complete failure of the quality management system; these circumstances are known as conformities or defects.

Reason for Nonconformities:
The specified procedure does not meet regulatory and GMP criteria. There has been no use of the define procedure in a describe manner. The anticipated outcomes are not met.

Classification of deficiencies:

1) **Critical defects:** Mostly appears as a negative physiological reaction in the customer. It has an impact on the product's strength, purity, safety, and effectiveness. Some major problems might arise from cross-contamination, incorrect labelling, or active substances that are not specified.
2) **Major defects:** It lowers the stability without endangering customers. Major defect causes include improperly calibrated equipment, neglected equipment maintenance, and operators unfamiliar with normal operating procedures.
3) **Minor defects:** They are unlikely to have an impact on the product's stability or quality. There are surface cracks in the walls, and the warehouse is not kept clean according to the SOP review schedule. This could be a possible cause of small flaws.[22]

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