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PHARMACEUTICAL QUALITY AUDIT AMIDST THE COVID - 19 PANDEMIC - A REVIEW

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ABSTRACT

Auditing is a critical function in the pharmaceutical industry, encompassing internal, periodic, and marketing audits. Internal audits assess risk management, control, and governance within companies, identifying noncompliance and weaknesses for improvement. Periodic audits monitor and enhance operational processes like manufacturing and quality control, aiming for continuous improvement.

Remote/digital auditing was introduced by ISO 19011:2018 Annex A1 and is an alternative compliance method for applying teleconferencing, emails, and calls. Due to COVID-19, it gained prominence, with ISO updating guidance in 2020. Feasibility depends on technology, data security, and digital documentation. Remote audits require proper agreement and consideration of data quality.

Marketing audits evaluate marketing strategies based on the 4Ps: product, price, place and promotion, optimizing efforts and targeting the right audience. The primary objective is to ensure compliance with regulations and improve quality management systems, demonstrating product safety and gaining trust from regulatory authorities and stakeholders.

Audits identify nonconformities within quality management systems, allowing companies to enhance processes, minimize risks and improve overall quality. Audit programs provide a structured framework for consistency and effectiveness, while auditors play a crucial role in

assessing compliance and finding areas for improvement. Stakeholders benefit from the assurance provided by audits regarding compliance and quality.

Internal auditing impacts accounting information technology and effectiveness in publicly traded pharmaceutical companies, maintaining the accuracy of financial information, preventing fraud and identifying financial risks.

Remote audits using advanced communication technologies offer benefits like cost and time savings, flexibility and reduced travel requirements. However, ensuring their rigor and effectiveness are on par with traditional on-site audits is crucial.

In conclusion, auditing is vital in the pharmaceutical industry to assess compliance, meet regulatory standards and improve quality management systems. It involves internal, periodic and marketing audits, addressing key areas and resolving nonconformities for enhanced operations. Internal auditing also influences accounting information technology and effectiveness in publicly traded pharmaceutical companies. The implementation of remote audits provides opportunities for efficient auditing practices.

Audit effectiveness is largely dependent on the quality of internal audits. The amount of experience of the team and the proper level of audit that is planned, carried out and communicated are all factors that affect audit quality, as illustrated in **Figure 1**.

Keywords: Quality audit, Remote audit, COVID-19, Audit Benefits, Audits overview, Audit Action, Audit Procedure

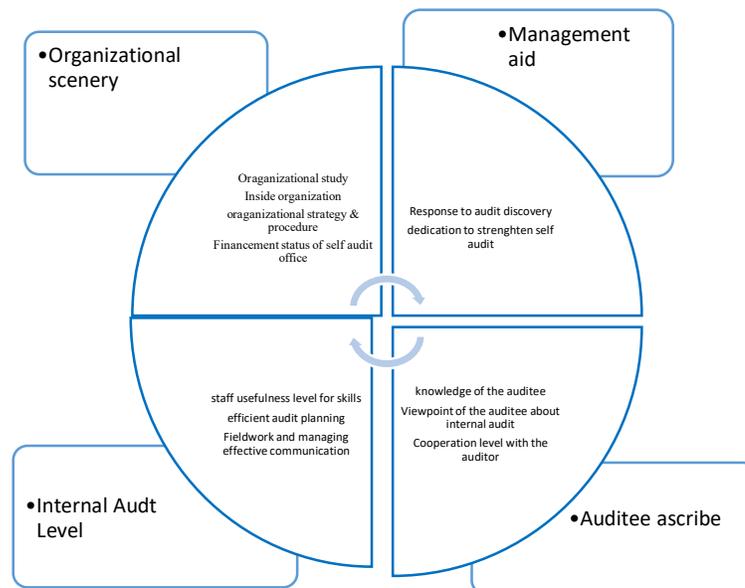


Figure 1: Factors influencing internal audit effectiveness by Mihret & Yismaw

2. PERIODIC AUDIT

ICH10 gives achievement of the three main objectives:

- Product realization success,
- monitoring and control and
- Continuous improvement essentials.

These objectives play a major role in Auditing.

- Purchase high-quality materials from the provider and submit them for Prove through audits to increase product performance. For state-of-control implementation and monitoring, regular assessments of operations and procedures are required. These reviews can be carried out with the help of auditing.
- Reviews regularly differences in programs for ongoing progress.
- ICH Q10 highlights reasons to promote internal and external lists:
 - Incorporating both inside and outside audits comes about as a portion of the method execution and item quality.
 - observing framework.
 - Take corrective and preventive actions (CAPA) after audit examinations.
 - Include audit findings in the evaluation of the quality management system.

- Reviewing both internal and external feedback will help you develop continuously [3].

3. THE MARKETING AUDIT'S REACTION TO THE 4PS MARKETING MIX

An organization's marketing plans, goals, strategies, actions and organizational structure are all evaluated systematically in a marketing review. This method has been used for a very long time in marketing planning and management. To provide clear criteria for marketing managers to adopt this approach, researchers evaluate and control marketing mix plans for small and medium-sized firms (SMEs). Before 1980, studies on marketing organizations concentrated on their function in putting marketing theories into practice. The Science Centre established the 4ps marketing mix, which emphasizes product, price, location and advertising as key elements in successful product promotion [4, 29].

4. AUDIT AND ITS CONTENTS

4.1 AIM:

Assessing the exercises and existing documentation to determine whether or not they satisfy certain standards is the fundamental goal of this complicated handle. A review evaluates quality control and assurance processes, identifying strengths and weaknesses, to improve processes and create a stronger framework

for the company's success [1]. Pharmaceutical products undergo laboratory tests for quantification, with quality control and assurance being crucial check and balance systems [5].

The results of an audit help management make choices by evaluating a company's quality assurance, legitimacy and consumer trust [6]. Planning and preparation in advance help audits achieve their objectives and put remedial measures in place to get rid of nonconformities and stop them from happening again.

Effective audits and compliance management protect a brand's reputation and avert unwanted outcomes including penalties, bad press and legal action. They provide real-time visibility and guarantee adherence to internal and external standards, rules of conduct and procedures. This enables planning, testing and programming as well as finding nonconformities and monitoring progress [7].

4.2 OBJECTIVES OF AUDIT

- To judge compliance or non-compliance by the quality system to meet specified requirements [8].
- To meet regulatory requirements [8].
- Enroll the quality system of the audited establishment [6]
- To must need a qualifying potential supplier [7].

- Assessing congruity of documentation to ISO 9001 [6]
- To determine the effectiveness of performance targeting the specified Quality Objectives [7]
- Providing a chance to upgrade the quality management system [7].
- Assessment of conformity of requirements with ISO 9001 [6]
- Authorization to register and acquiesce to the subscriber list companies [8]
- Arrangement of an opportunity for the group of individuals for moving forward quality in the framework [7]

4.3 AUDIT AND REGULATORY STANDARD

Manufacturers and other types of firms are encouraged to carry out quality audits by the ISO, a Head in the establishment of worldwide Quality.

In 1987, the ISO 9000 standards were published. The First Part Audit of the quality system is required by significant standards like ISO 9001: 2000, ISO 14001: 2004, and ISO 13485 nowadays. In the case of ISO 14001: 2004, internal audits are also required of the environmental management system. According to these principles an audit is a tool for assessing and boosting quality [25].

The Food and Drug Administration enforces numerous rules based on the Quality System

Regulation (21 CFR) to ensure safety and effectiveness.

Medical device manufacturers are required to undertake audits to verify sure their quality control procedures adhere to Part 820 and cGMP standards for drugs, blood and blood components. The need for auditor advice is also emphasized in the guidance for blood banks and pharmaceutical companies, including First Part audits and supplier audits. An extensive analysis of the quality assurance approach is required by the standards for quality assurance in blood institutions [8].

4.4 BENEFITS OF AUDIT

A company's internal quality management program is evaluated through audits, which affect regulatory inspections and internal and external quality assurance [9].

Auditing can assist in achieving this objective. A successful audit system offers numerous advantages.

- Implementing a quality management system successfully.
- Recognizing potential weak Notes by identifying unfavorable patterns or circumstances
- Standardizing audits enhance production, quality and ongoing product and service development, resulting in higher quality and better outcomes.

- Preventing quality failures based on reviewing quality Information.
- Communicating facility and operations quality to Senior Management.
- The auditee is aware that audits are conducted to boost organizational effectiveness, which promotes a greater understanding of and acceptance of quality-related issues. They see audits as chances to learn more about quality-related subjects and to enhance their knowledge [9].
- Audit frequency is decreased, auditee acceptance is raised and time is saved when quality, safety and environmental audits are combined.
- Pooling audits, such as Shared Third Party Audits, can result in additional advantages.
- The degree of compliance will rise if an industry-wide, high-quality audit system is established. These efforts will result in the partners' relationship improving and their confidence rising [7].

4.5 AUDIT COMPONENTS

The following five audit components are included:

- Risk Assessment analyses significant risk variables that pose a challenge to an organizational sector and weighs their relative significance.

- The overall statement describes the audit's objectives, explanation, outcomes and criteria for success.
- A document defining the goals and procedures of an audit is called an audit program [3].
- Auditing protocols outline particular actions that auditors must complete to collect, evaluate and record information during audits.
- Records of audit program interviews and tests are kept in work papers [10].

4.6 PRINCIPLE OF AUDIT

Specific concepts are used in audits to support management policies and practices. Respecting these rules enables accurate findings, impartial cooperation and comparable outcomes under similar circumstances.

- Professionalism is grounded in integrity; auditors and audit program leaders should fulfill their responsibilities with ethics, accountability, diligence, competence, adherence to regulations and awareness of potential factors influencing their judgment
- Fair presentation necessitates the provision of accurate and genuine information, reflecting the audit's activities faithfully in its findings, conclusions and reports while emphasizing important audit-related

matters and unresolved conflicts transparently and impartially through open, honest, prompt, concise and comprehensive communication.

- Data security and privacy auditors must handle acquired statistics with care, refraining from personal gains or endangering the auditees' legitimate interests, while also encompassing the proper management of sensitive or confidential data within this framework
- Independence ensures impartiality and unbiased judgment in audits, requiring that auditors be free from conflicts of interest and autonomous from the operational executives of the audited entity. This ensures that auditors can remain objective throughout the review process while working to reduce bias and promote impartiality in first-party audits. By following a methodical procedure, depending on verifiable evidence, and utilizing suitable sampling techniques for limited time and resources, an evidence-based approach assures credible audit results.

4.7 CATEGORY OF AUDIT

4.7.1 INTERNAL AUDIT OR FIRST PART AUDIT

- Internal auditing, often known as self-auditing, includes both auditing and

being audited by members of the same organization.

- The work of internal auditors a variety of audit methods, mostly concerning the efficacy of internal controls over financial reporting within the organization.
- To minimize pressure to provide positive evaluations, internal auditors of publicly listed businesses must report directly to the board of directors or a subcommittee rather than management. This makes sure they aren't viewed as being impartial towards the business they audit [10].
- The powers of communication, the chances for growth brought about by technological advancements and the increasingly complicated and sophisticated nature of global corporate operations all have an impact on the characteristics of internal audit [2].

Three stages of assurance in the internal audit

- The First Part auditor's objective evaluation of the data is part of the assurance services and is used to form views or draw conclusions about a system, operation, function or other topic. An assurance engagement's kind and scope are determined by the

internal auditor. In assurance services, three parties typically participate:

- The term "process owner" refers to the person or group who is directly connected to a certain thing (entity, activity, function, process, system, subject matter).
- In the First part auditors carry out evaluations.
- The person or group using the assessment is known as the user [11].

4.7.2 EXTERNAL OR SECOND PART AUDIT

- A client auditing a supplier or contractor is referred to as a second-party audit.
- A second-party audit can be carried out by a medical device company that hires a lab for sterility testing to confirm compliance with QSR rules and show it to FDA investigators.
- To ensure that a components supplier complies with ISO 9001 or ISO 13485 requirements, the same business may audit the supplier.
- Although some auditors contend that the procedure resembles a supplier survey, an audit may also be used to evaluate potential raw material suppliers [10, 12].

4.7.3 REGULATORY OR THIRD-PARTY AUDIT

- This kind of audit is not carried out by a supplier or a customer.
- Such audits are carried out either for agency certification or registration or for compliance purposes.
- Such activities may also include an autonomous body. This category includes current GMP inspections carried out by the FDA in a pharmaceutical manufacturing facility.
- Third-party audit is another term used to describe the examination and inspection process used to accredit institutions and universities.
- Instead of assessing conformity themselves, ISO delegates this responsibility to local regulatory or private sector organizations. Due to this decision, both second and third-party audits are considered external audits [12].
- factories are required to follow GMP, audits are carried out by regulatory inspectors and corporate personnel, often without prior notice. Companies, like European manufacturers, may also be subject to audits by regulatory organizations from other nations, including the FDA.
- If a regulatory audit is unsuccessful, production may be restricted, a facility may be shut down, a product batch

may be recalled, or an import/export license may be revoked. Internal audits must be managed by a team, and staff members must be auditing-trained [13].

INTERNATIONAL DRUG REGULATORY AUTHORITIES

1. WHO [world health Organization]
2. TGA (Australia) [therapeutics goods administration]
3. MHRA (UK)
4. USFDA [U.S] [14]

4.8 AUDITOR RESPONSIBILITY

10 MOST IMPORTANT AUDITOR FOLLOW THEIR ROLE

- Assist in team selection and communication.
- Plan and oversee all aspects of the audit.
- Engage in audit team conversation with auditee.
- Manage disagreements and tricky circumstances.
- Coordinate and oversee meetings with the auditee team.
- Make choices on the quality system and auditing issues.
- The audit results must be reported without delay.
- The primary difficulties faced must be reported.
- Critical non-conformances must be reported right away.

- possesses strong communication capabilities. [8]

4.9 CONDUCT AUDIT PROGRAM

- Depending on the size, complexity, and nature of the organizational structure, the audit program may consist of multiple audits. These audits, which have a variety of goals, can be joint or combined (with Quality management and Environmental management systems). Planning, coordinating, and assigning resources for efficient and on-time audit completion is all part of managing an audit program [1].
- Top management of the company should permit to manage the audit program.
- The administrators of the audit program are in charge of designing, establishing, executing, overseeing, reviewing and enhancing it.
- They must ascertain the resources that are needed and guarantee their availability [8].

5.1 AUDIT ACTION

5.1.1 STAGE :1 INITIATING THE AUDIT

- Designate the team leader of the audit
- Choosing the audit member
- Establishing contact with the auditee
- Preliminary visit

- Escort doc review

5.1.2 STAGE 2: PREPARING FOR THE ON-SITE AUDIT ACTIVITIES

- Audit strategies
- audit plan Preparation
- Auditees responsibility
- work delegation to audit team
- Preparing Word doc

5.2 INFORMATION GATHERING

Acquired facts or knowledge are referred to as information, whether they are expressed explicitly in written materials or implicitly in people's brains. Information about the interfaces between functions, activities and processes should be gathered during audits and validated to be pertinent to the goals, parameters and standards. Only validated information should be documented and utilized as audit-proof [15].

5.3 AUDIT EVIDENCE

To determine whether the audited data complies with the standards set out and to reach the findings upon which the audit opinion is based. Any information, data or analysis used during an internal audit transaction, process flows, bills, memoranda and vouchers.

The following would affect the internal audit evidence gathered:

- Specific auditing processes should be outlined for audit participants' teaching.

- Sample size or the number of objects to test for each audit technique.
- Choose which items from the sample should be used in the selection process.
- Timing - The timing from the beginning of the period of accounting to its end might alter [14].

5.4 ADMINISTRATION

The internal audit team must cooperate with important stakeholders who value, trust and have faith in their capacity to offer sound advice and assurance. This confidence may be increased by effective collaboration, prompt, competent counsel and internal audit reports that directly aid the company in upholding its duties.

5.4.1 EXECUTIVE DIRECTOR

Internal audit provides functional reports to the Audit Committee, but it is critical that the CEO may be reached directly by the head of the First part audit when necessary. Today's businesses are recognizing the advantages of having the CEO get direct reports from the head of First Part audit. Additionally, it makes it simpler for the Chief Executive and internal auditor to interact often. This not only demonstrates the importance of internal audits. In addition to discussing the role

that the Chief Executive anticipates the First part audit to play inside the organization, this session should be utilized to learn more about the organization's new and evolving risks and challenges.

5.4.2 COMPANY OF DIRECTOR

The performance of the internal audit function, which is frequently delegated to the Audit Committee, a subcommittee of the Board, may be reported to the Board of Directors by the Head of Internal Audit. The Head of Internal Audit should have direct access to the Chief Executive Officer and the Chair of the Board whenever necessary.

5.4.3 AUDITING COMMITTEE

The audit committee is an essential part of the governance framework of an organization, aiding Chief Executives and Boards in deciding whether important controls are necessary and operating effectively. The relationship between the internal audit and the committee is crucial, with several factors to take into account.

- Discuss internal audit plans with the Chief Executive;
- Coordinate work programs for internal and external audits;
- Review audit content to identify concerns and suggest improvements;

- Examine and accept internal audit findings, as well as support the charter and suggest programs be approved.
- Act as the key client of the internal auditing division and forge effective working connections with the team's members, both collectively and individually;
- Assess the effectiveness of the First part audit function using internal audit reports and their overall interactions with the internal audit team.
- Maintaining open lines of communication with the Audit Committee is crucial, especially with the Chair. The Head of Internal Audit should be available to members for open discussion of problems and having private sessions with the Head can increase internal audit autonomy [26].

5.4.5 SENIOR EXECUTIVES

Internal audit must have a professional and cooperative connection with the organization's senior management to carry out its duties successfully. Internal auditors should communicate with senior management team members frequently and establish cooperative, respectful relationships by providing them with reports and advice that are valuable, business-focused and practical. Meetings with management should be utilized as a chance to get an

update on important business developments and the dangers they pose to the company. These sessions should also be used to gather unofficial input regarding the effectiveness of internal audits and to help determine how internal audits can best support the management of the organization. So, if needed, the internal audit team would advise managers to request their guidance and help informally or formally.

5.4.6 EXTERNAL AUDITING FIRM

- While external auditors assist in the development of the internal audit strategy and work plan, the internal audit team encourages management to seek guidance.
- Both audit teams must concentrate on the crucial financial and operational processes that underpin the company's financial statements to avoid duplication of compliance and assurance. To prevent such duplication, the external auditor needs to assess the work of the internal audit team to determine whether it is sufficient for external audit objectives.
- The internal audit department may be given the responsibility of communicating with external auditors on behalf of the

organization. In such a capacity, knowledge of both present and planned external audit coverage may be useful to an internal audit team. Therefore, effective communication between the two auditing groups makes it easier to carry out external audits. When the need arises, the internal audit team will urge managers to ask for their guidance and support informally or formally. Only with transparent interaction between the internal and external audit teams can such a task be completed. To promote frequent exchange of data, this can be accomplished by setting up official meetings between both the internal and exterior audit teams.

5.4.5 OTHER AUDITORS

Managers are encouraged to ask for guidance and help as needed, both formally and informally, from an internal audit team. The business should set up regular contact among review committees to guarantee cooperation and complementarity. The sharing of ideas and information can be facilitated by formalizing procedures, particularly when working with other organizations as a result of interagency cooperation agreements. ^[16]

5.5 INFORMATION OF AUDIT IN THE FOLLOWING STEPS

5.5.1 INTERVIEW

Interviewing is a potent method for gathering data that functions well on its own and is frequently used in conjunction with other methods, like observation. The First Part auditor's decision-making regarding what to observe can be influenced by the interviewee's insights. The most crucial thing to keep in mind when conducting interviews is to always speak with the appropriate individual. Managers are encouraged to ask for guidance and help as needed, both formally and informally, from an internal audit team. The business should set up regular contact among review committees to guarantee cooperation and complementarity. The sharing of ideas and information can be facilitated by formalizing procedures, particularly when working with other organizations as a result of interagency cooperation agreements.

5.5.2 INSPECTION

Before concentrating on specific details, begin with general observations. The internal auditor needs to go around the building carefully, make inquiries and look into things further if problems are found [17].

5.5.3 REVIEWING DOC

A variety of techniques, including random sampling, are used by the internal auditor to review corporate records to spot possible problems and gauge the standard of record keeping. Each document must have a title, owner and modification status since clarity is essential. The auditor should check for any missing information and compare the original document to any modifications to ensure that a specific person approved, signed and date the changes [12].

5.5.4 OBSERVATION

Observing a process in operation is the simplest approach to determining how it functions. The Internal Auditor may have the chance to see how something is done in typical conditions by spending a few hours watching a routine activity. He or she should inquire about what they see, being careful at all times to avoid interfering with the activities they are watching as this could prevent the staff from performing their duties as usual.

5.5.5 VERTICAL TRACKING

This technique, also known as "vertical auditing," entails tracking a particular development from the start to the finish while concurrently reviewing all the records that are generated in the process. By examining how program

components work together, the vertical tracking approach gives internal auditors access to areas that weren't formerly in their purview.

5.5.6 EXERCISES

An exercise's purpose is to put something that is routinely done at the facility to the test. However, the test's timing and environment are entirely up to the Internal Auditor. The employees, the program, or the equipment might all be the subject of testing. Without the auditee's consent and knowledge, an internal auditor shouldn't conduct an exercise. Since the Internal Auditor is uninformed of any facility-specific rules or regulations, taking such action is likely to have unfavourable effects.

5.5.7 TAKING NOTE

To organize thoughts and observations and draw accurate conclusions during audits, a trustworthy internal auditor has to have a mental note-taking technique. Throughout the trip, this approach should be assessed and refined and after each day, the notes should be checked and finalized [18].

6.1 INTRODUCTION OF AUDIT PLAN

The Plan of Audit: To lower audit risk to an acceptable level, the auditor should create an audit plan. The audit plan, which is more specific than the overall audit strategy, outlines the

types, timing and scope of audit procedures that will be carried out by the engagement team to gather enough relevant audit evidence to lower audit risk to an acceptable level. The audit plan's documentation also acts as a record of the correct preparation and execution of the audit processes, which may be examined and approved before the execution of additional audit procedures [14].

6.1.1 AUDIT PLANNING PROCEDURE FOR BASICALLY 6 STEPS

The process of preparing an audit includes creating a detailed strategy as well as the direction, scope, methodology and program for the audit.

- Determine the best methods to carry out the audit's goals.
- Help to oversee and manage the auditing activities.
- Ensure that the time needed to complete the audit's most important tasks is allocated properly.
- Encourage the audit's swift conclusion.
- Make the audit work's evaluation easier.
- Support the audit team members in receiving the proper tasks and liaise with outside experts.

For a quick recap, audit planning entails strategic decision-making, effective

resource allocation and coordinated efforts to ensure the successful execution and evaluation of the audit [13].

6.1.2 MAIN OBJECTIVES OF AUDIT PLANNING

The auditor's job is to set up the audit in a way that will allow it to be completed effectively. Audits may be complicated, risky and expensive processes. Engagements need to be planned to guarantee that the auditor:

- ensures that audits are focused on important areas,
- quickly addresses issues,
- plans and oversees audits,
- chooses team members with the necessary skills,
- and directs and supervises the group to ensure effective performance [24].

6.1.3 THE STAGES IN PLANNING AN AUDIT INCLUDE (PLANNING PROCEDURES).

- First, clients describe the nature of the engagement and auditors meet with key individuals or new hires. Timing and the audit's scope are discussed.
- Create an audit program plan by analysing the material from the previous auditor or accounting firm.

- Check for changes in the audit by looking at recent firm growth, mergers and product lines.
 - The assessment of interim financial statements identifies accounts and transactions that differ from forecasts, such as budgets or prior quarters. To find accounts that have been misstated and demand extra attention, analytical techniques are required for audit preparation.
 - In accounting businesses that provide services like tax preparation, seek out and speak with non-audit staff to learn customer information.
 - Set up the audit team and the engagement meeting. The order of the different audit techniques should be decided.
 - Identifying the need for outside assistance, employing specialists and involving the client's internal auditor.
 - Update audit procedures and accounting concepts for thorough industrial audit programs.
 - Set up a schedule and collaborate on events with your clients [19].
- personnel are present, it provides an opportunity to obtain commitments for implementing corrective measures. It is crucial to ensure that all parties involved understand the observations and any commitments made for corrective actions. Additionally, timelines should be established for the release of the audit report and the provision of responses to the observations.
- Corrective actions need to be completed within a specified timeframe.
 - Depending on the observations and commitments made for corrective actions, a follow-up audit may be necessary.
 - If a decision is made not to conduct a follow-up audit, the corrective actions should still be evaluated in future audits.
 - It can be beneficial to document the reasons for not conducting a follow-up audit unless the audit procedure explicitly states when follow-up audits are or are not required, as this documentation can be valuable for future audits.
 - To address negative perceptions, it is important to take both preventive and corrective actions. Preventive measures aim to strengthen the quality

6.2 CLOSE-OUT AND FOLLOW-UP ON THE AUDIT

- At the end of the audit, it is important to conduct a close-out meeting to discuss the findings. If management

system to prevent the recurrence of similar negative observations [3].

6.3 AUDIT PROCESS

An audit is a dispassionate examination and assessment of a business's operations to make sure they adhere to predetermined criteria. It can perform several tasks, including financial and regulatory audits. Depending on the nature and standards controlling the auditor's job, many audit methodologies exist. The audit adheres to guiding concepts including moral behaviour, appropriate presentation, professional care, independence, objectivity, impartiality and neutrality as well as assessments that are supported by evidence and are capable of working together and being trusted. Since quality management is a component of the management system, auditors should be familiar with the company, its procedures, its products, how they interact with others, the ISO 19011 standards, as well as their background and training. Along with the capacity to do audits, auditors should have a working knowledge of audit methodologies [6].

6.4 STAGES OF THE AUDIT

THREE STAGES OF AUDIT

1. The first stage is the engagement plan.

- Create a methodology for auditing.
- Specify objective measurements and documents for use in determining compliance.
- Create suitable sampling strategies.
- Use measures for measuring the accuracy of computer systems.

2. Plan for the second stage of auditing

- Develop an audit process, including objective measures and documentation that may be used to judge compliance.
- Create suitable sampling strategies.
- Utilize measures to assess computer system accuracy.

3. Third stage activities: fieldwork

- Distributing computerized records.
- Policies and procedures.
- A record of provider payments.
- Quality control plans [7].

Authors should mention if they sought missing information from investigators or sponsors, stating who was contacted and what unpublished information was acquired clearly and concisely [20, 27].

6.5 PROCEDURE OF AUDIT

The audit process consists of ten steps [8]

6.5.1. NOTIFICATION: The audit process starts with notice, which includes a list of needed documents and

information about the audit date and time to better understand the structure of the firm.

6.5.2. PLANNING: Auditors identify risk areas and concerns before audits to ensure compliance.

6.5.3. FIRST MEETING A meeting with auditing staff, senior management, and administrative staff will discuss the procedure, areas of concern and employee schedules for consultation.

6.5.4. FIELDWORK Field work begins after meeting results revise audit plans, notified employees, and staff schedules are created. An initial investigation is launched after learning business procedures, interviewing key personnel, sampling practices, reviewing laws and testing internal rules for reasonableness.

6.5.5. COMMUNICATION Regular communication between the audit team and the corporate auditor is crucial for clarifying processes and accessing records and procedures.

6.5.6. DRAUGHT AUDIT The draught audit prepares preliminary findings and a distribution list of stakeholders after the audit's conclusion, detailing the findings and actions

6.5.7. MANAGEMENT RESPONSE The draft is evaluated, edited and suggested improvements for

management. After final revisions, the report is delivered for the seventh stage, management response. Management is asked to agree on the raised issues, plan to address them, and determine the resolution date.

6.5.8. LAST MEETING Final meeting aims to resolve issues, discuss management response and clarify the audit scope.

6.5.9. REPORT DISTRIBUTION in the ninth phase, the audit report is distributed to officials, both internal and external, in the region.

6.5.10. THE FINAL STEP IS AUDIT FEEDBACK, the audited organization implements proposed adjustments, while auditors examine and test their quality, adherence and consequences. This process repeats until concerns are resolved and the next audit cycle begins [10].

RESOLVE NONCONFORMITIES CQMS involves handling nonconformities by defining, categorizing, and creating a document system for identification, investigation and corrective action. This includes planning corrective action to prevent future recurrence and isolating products encountering nonconformities [21, 28].

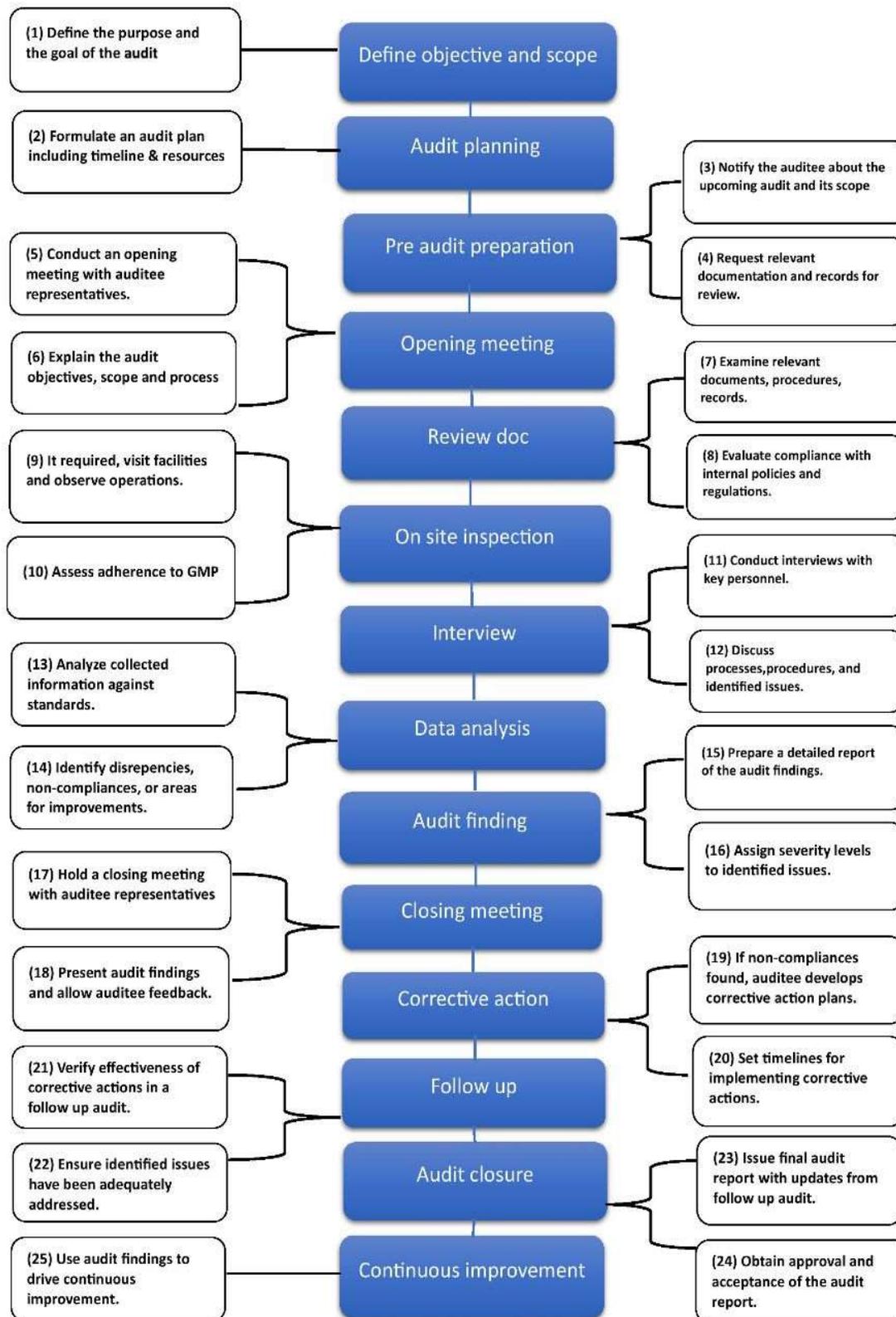


Figure 2: Overview of Audit In Pharmaceutical Industry

6.7 REMOTE AUDIT IMPLEMENTED IN PHARMA INDUSTRY

The ISO 19011:2018 Annex A1 outlines remote auditing as an audit method. However, the COVID-19 pandemic led to the release of the new ISO 9001 Auditing Practises Group Guidance on Remote Audits (ISO, 2020), providing more advice on remote auditing. The document explains issues to consider and discusses potential risks and limitations of remote auditing.

Every pharmaceutical industry conducts audits so an audit is the heart of the industry correcting the non-conformities in the 2019 COVID period major downside of doing the audit in the industry so time pharmaceutical industry implements remote audits. According to GMP regulations, conducting an audit and also providing the legal necessity for an audit to assure product safety, quality and efficacy. As a result, they did not use the traditional technique of onsite auditing at the time. Therefore, the organization is a little bit embracing the remote audit. As a result, the pharmaceutical industry was published and the industry coped with the circumstances it found itself in. Global pandemic unprepared regulators and businesses for auditing impact, affecting contingency measures and affecting auditing activities. To address some of the industry's concerns, regulatory authorities responded quickly and released Q&A materials.

The disadvantages of remote auditing are as follows

- Lack of advice due to traditional onsite auditing
- No evidence has been gathered since they are unaware of the pandemic.
- Carelessness
- Inadequate handling
- Maybe Sharing information should not be considered confidential.
- Difficulties in determining a company's overall impression via remote audit

Advantages of remote auditing

- Live video demonstrating whether or not the product's manufacturing process is safe.
- Lowering transportation costs
- Enter the evidence into the computer database.
- Easily assess nonconformities and provide CAPA
- Easily complete the doc in the database.

In conclusion, remote auditing is quite difficult to execute in the pharmaceutical sector, hence they use remote auditing. Remote auditing is safe in a pandemic situation, but they do not know the industrial facilities in offline mode, and they do not examine the product at direct analysis, and in case sample analysis report should be hidden due to manufacturing flaws. So

remote auditing has many disadvantages and few advantages, but by 2023, many pharmaceutical industries will be approaching both traditional and remote auditing methods [22].

6.8 PROBLEM OF STUDY

The effectiveness and dependability of information technology play a part in the public joint stock pharmaceutical industries sector and internal audit has an impact on this through the following questions:

- How does internal auditing impact accounting IT in the publicly traded pharmaceutical industry sector?
- How does internal audit impact how effectively the public joint stock pharmaceutical industries sector relies on accounting information? [23]
- The major problem in Auditing
- Lack of Audit Techniques such as sampling and analysing.
- Lack of Communication skill
- Lack of identifying the problem and also lack of implementing the corrective action
- Carelessness during the audit
- Use the doc for personnel gain. [8]

CONCLUSION

In summary, the content presents a comprehensive overview of the audit process and its various components. It emphasizes the significance of careful

planning, thorough information gathering and efficient administration in conducting successful audits. The key points covered include the initial stages of audit initiation, the importance of preparing for on-site activities, the gathering and validation of relevant information, the role of audit evidence, and the importance of effective collaboration with stakeholders. The content also discusses the stages of the audit process, including engagement planning, fieldwork and communication, drafting the audit report, management response and final meetings. It highlights the implementation of close-out measures and the potential need for follow-up audits. Furthermore, the content explores the challenges and benefits of remote audits, particularly in the pharmaceutical industry. It acknowledges common issues faced during audits and highlights the need for strong audit techniques, effective communication skills, problem identification and the implementation of corrective actions. Lastly, the content highlights the influence of internal auditing on the effectiveness and reliability of information technology in the pharmaceutical industry and identifies the impact of internal audits on the reliance on accounting

information as a topic of study. Overall, the content provides a comprehensive overview of the audit process and underscores the importance of effective communication, planning and follow-up for successful auditing outcomes.

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