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How To Face Quality Audit's (A Case Study)

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Abstract
During my 16 year career journey, I faced various Regulatory audits like USFDA, TGA, MHRA, WHO & Customer audit like MERCK, PIREXEL in pharmaceutical industries. Academic approval inspection like PCI & UGC also faced during my academic experience. In both the field what I learn from audit and proactive approach for handling of any audit is expressed in this article. I focused here only regulatory audit preparation. Academic audit preparation will be cover in upcoming case study. In the pharmaceutical industry, audits are an essential part of the institutions' quality management system ensuring compliance with regulatory expectations, supporting products quality assurance and customer satisfaction. Depending on the category of the audit, it is usually performed by the qualified group of professionals assigned by management for this intention, external or regulatory agency. This review covers the main view points of auditing in the pharmaceutical industry including its goals, objectives and benefits, mandatory regulatory standards and principles of auditing along with the role and responsibilities of the auditor and their code of conduct during an audit. It outlines the management of an audit program with the main methods of gathering audit information and the key stakeholders of the quality audit. It also emphasizes a five-phase process which includes audit planning and preparation, conducting fieldwork, audit reporting, and following up on corrective action plans. In brief, this is a structured summary on the entire process of an audit and the importance of creating an environment of good relationship between stakeholders, employees and auditors in delivering values to audit activities of any size.

Keywords: Quality audit, pharmaceutical industry, audit agenda, audit planning, academic & industrial inspection.

I. INTRODUCTION

Auditing is an important activity and a critical function conducted to ascertain the validity and reliability of the information about how effectively the company controls the quality of their processes and products

(1). The general definition of an audit is an inspection of a process or a system to ensure that it meets the requirements of its intended use

(2). According to the International Organization for Standardization (ISO), the audit is defined as "systematic, independent and documented process for obtaining audit evidence and evaluating them objectively to determine the degree to which the verification criteria are met"

(3). The understanding of the existence and scope of the internal audit can also be increased by investigating academic research on this topic

(4). Therefore, the purpose of this review is to cover the main viewpoints of auditing in the pharmaceutical industry and its contribution in achieving corporate goals, by using simple and relatable language, supported by facts, recommendations and references.

II. MATERIAL AND METHODS

The methodology for this research concerns analysis of review articles, original articles, actual audit faced during industry and academic, guidelines, standards concerning the phenomena internal audit and quality control systems in pharmaceutical industry, audit agenda for product approval & academic grant. A bibliographic- research is done using the following databases: PubMed, EBSCO, Scopus, Sage, Science Direct and Google Scholar, audit & observation page from regulatory body website. Articles and papers were searched on the keywords: internal audit, quality audit, pharmaceutical industry, and audit program, audit planning. In addition, references in collected articles linked to other related articles are taken into account. Only articles in English language are selected. Internal audit in the pharmaceutical industry Quality audit (control mechanism as an integral part of pharmaceutical institutions' quality management system) aims in resulting corrective actions, clear directions, guidance, clear observations, good recommendations, ensuring all the involved parties that a program has consistency withpharmaceutical regulatory requirements. A company that produces drugs today must be able to demonstrate that it does

so with absolute reliability, in optimal conditions and with extreme uniformity, that allows accurate reproduction(1). A complete report of the correctly implemented audit does not only ensure compliance with regulatory expectations, but most importantly supports improving products quality assurance and customer satisfaction. Board of director's instruction and QCM data also used for this research.

Type of audits and quality audit system

There are three categories of quality audits in pharmaceutical industries:

- **Internal audit**

This type of audit is also known as First-Party Audit or self-audit. Those auditing and those being audited all belong to the same organization (1). According to regional legislations, the internal audit is defined for EU members as "self- inspection" and as "measurement, analysis and improvement" according to ISO 9000:2000 (5). As for the Institute of Internal Auditors (IIA), 'Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes' (6). The qualified group of professionals who perform various and it procedures, do not pretend to be the regulatory authority but to support and advice the management of the company on how to achieve the goals and to solve potential issues. Therefore, a well-established organization manages to maintain balance between the audit function and the departments being audited.

Several main objectives makeup the concept of a successful audit, such as:

✓ Reviewing the organizations system of control,

✓ Verification of compliance with all relevant procedures, policies, regulations and legislation, monitoring risk assessment and management,

✓ Overcoming the possibilities for errors and frauds of organizations assets,

✓ Identification of opportunities for constant improving of quality control system.

Auditing is always a sampling activity, and therefore it is important that the auditor gets a good overview about the company's quality management system by going through selected issues thoroughly (7, 8). In a pharmaceutical organization, these selected issues mainly consist in checking activities performed by different departments and documents maintained by these departments. For this purpose, a department wise questionnaire and document list is required to be prepared in detail (9).

- **External audit**

This type of audit is also known as Second-Party Audit. It refers to a customer conducting an audit on a supplier or contractor(1). Even though there is no strict legal requirement to conduct such audits, it is recommended for the manufacturers to access and evaluate the competence of the suppliers and to ensure that contractors are competent to complete the contracted work, as per the GMP guidelines.

These kind of audits also offer important advantages:

✓ develop building knowledge and confidence in the partnership arrangement,

✓ ensure that requirements are understood and met,

✓ enable reduction of certain activities (e.g. in-house QC testing of starting materials),

✓ reduce the risk of failure(9).

The scope and the frequency of these audits will vary, depending on the relationship between the two parties involved and on the initial findings, and they will be carried out to assess compliance with agreed contractual standards (9).

- **Regulatory audits**

This type of audit is also known as Third-Party Audit. Neither customer nor supplier conducts this type of audit. A regulatory agency or independent body conducts a third party audit for compliance or certification or registration purposes(1). Highly trained, knowledgeable and professional regulatory inspectors and company representatives from different involved departments perform the audit. These audits may be unannounced as manufacturers are expected to be complying with GMP at all times. Regulatory bodies from other countries in which products are sold may also audit companies (i.e. FDA audits European manufacturers) (9). Failure to pass a regulatory audit may result in restriction of production or closing down, recalling product batches or revocation/withdrawal of import/export license. Therefore, it is crucial that companies have team of staff able to manage internal audits and at the same time, adequately trained staff for being audited.

Auditing goals and objectives

The simple goal of this complex process is to: a) evaluate the activities and existing documentation and determine if they meet pre- determined standards; b) evaluate the strengths and weaknesses of the quality control and quality assurance processes; c) call for corrective action (10). Corrective action aims at eliminating the causes of nonconformities by focusing on the systematic investigation of the root causes of non-conformities so that their recurrence can be prevented (11). Effective auditing and proper compliance with the standards will help in building the brand reputation and avoiding the Adverse effects of non-compliance

like fines, bad PR, prosecution (12).
The following are the main objectives of audit:

- ✓ Evaluating conformity of requirements and documentation to ISO 9001,
- ✓ Judging conformity of implementation to documentation,
- ✓ Determining effectiveness in meeting requirements and objectives,
- ✓ Meeting any contractual or regulatory requirements for auditing,
- ✓ Providing an opportunity to improve the quality management system,
- ✓ Permitting registration and inclusion in a list of registered companies,
- ✓ Qualifying potential supplier

(13). **REGULATOR STANDARDS ON AUDITING**

GMP is mandatory for introduction for the manufacturers of medicinal products, but the addition of ISO 9001 to the already established GMP-system creates a better management of the system and provides additional benefits (5). Requirements for mandatory audits are set out in the standard ISO 9001:2015 «Quality Management Systems. Requirements» (paragraph9.2) and general recommendations for audits of management systems are given in the standard ISO 19011:2018 (14). The ISO standards play an important role in the European Union's industrial policy, both in relation to the promotion of the competitiveness of European industry, and with regard to the free movement of goods(5). Adoption of ISO's good practices in EU aims to comply with customers who require ISO certificate; to improve competiveness; to minimize repetitive auditing by similar and different customers, and to improve subcontractors' performance (5).

Benefits of auditing in pharmaceutical industry

Auditing plays an important role in pharmaceutical industries as it ensures that the product complies with the regulatory expectations of a quality product as well as with customer specifications for effectiveness and safety. If implemented properly, an effective auditing offers numerous benefits such as:

- ✓ Managing quality management system,
- ✓ Detecting in advance weak points, through identification of unsatisfactory trends or Situations,
- ✓ Preventing quality failures, on the basis of quality data reviewing,
- ✓ Informing Senior Management about quality level of facilities and/or operations (15).

The auditor within the audit system

An auditor is defined by ISO 9000:2015 as a person who conducts an audit. He/she should have general understanding of audit principles, management skills, as well as, technical understanding relevant to the activities to be audited (16).
The main responsibilities of the auditor include:

- ✓ Applying auditing techniques within regulation standards and policies, Selecting and assigning the audit teams and their roles and responsibilities,
- ✓ Effective and efficient planning of all audit phases and carrying out assigned responsibilities including the use of appropriate sampling methods,
- ✓ Performing the audit process while remaining true to the purpose without deviating, fear or favor,
- ✓ Preparing report(s) and arriving at acceptable conclusions based on results and documented observation of stated audits,
- ✓ Reporting the results of the audit, main obstacles and critical on-conformances to top management without delay,
- ✓ Maintaining audit records and ensuring documents and privileged information remain secure and confidential,
- ✓ Monitoring, reviewing and improving the audit program,
- ✓ Controlling conflicts and react effectively in stressful situations.

Basic principles of auditing

Audit has certain principles and rules that govern it, which are considered to make the auditing an efficient and reliable tool of supporting management systems and policies
(14). These principles list out the role and responsibilities of the auditor, their code of conduct during an audit as relevant for independent work of auditors and as well for reaching similar conclusions in similar circumstances.

Six basic principles of auditing that should be emphasized are**:**

- ➢ **Integrity of the auditors (14)**

Professional auditors should:

- ✓ Perform the audit diligently, honestly, and responsibly.
- ✓ Be objective and maintain calmness in cases of conflict.
- ✓ Have the competence to perform the audit.
- ✓ Remain unprejudiced and unbiased and maintain their objectivity and fairness in all dealings.
- ✓ Observe and comply with all applicable legal obligations.
- ✓ Be aware of any influence for fair judgment during an audit.

- ➢ **Truth fully and accurately reporting (14)**

The auditors should present the audit reports with all the findings and conclusions, truthfully and

accurately. Significant obstacles encountered during the audit or any unresolved disagreement between the audit team and the auditee should be sufficiently documented and reported with all significant difficulties faced during the audit(17).

- **Due diligence and judgment in auditing (14)**

Auditors should apply due diligence related to the importance of the task and the confidence placed in them by the audit client and other interested parties(17). An important factor of this principle is that an auditor must make reasonable judgments in all circumstances when carrying out their audit tasks.

- **Confidentiality of information**

The information that the auditors gain during an audit should be handled, protected and appropriately secured. Such information should maintain confidentiality and never be used for personal gain or in any way that is harmful to the audit client's legitimate interests (14).

- **Independence**

The auditor should be independent, objective throughout the audit process and should never interfere with the activity in the organization he is auditing. This will ensure that the audit and the audit findings are unbiased and based on verifiable evidence (14).

- **Audit evidence**

All audit evidence gathered by the auditors through a formalized process called audit sampling, should be easily verifiable (14). This process should ensure that a proper amount of sampling is made as it contributes to the level of confidence that can be put in the audit findings presented by the auditors (18).

PHASES OF AN AUDIT CYCLE

To achieve its' objective efficiently and cost-effectively an audit should be thoroughly planned, carefully structured, systematically performed, faithfully reported, and remedial actions progressed to a timely and satisfactory conclusion (19).

The whole process of audit engagement usually follows a five-phase process, which includes audit planning, and preparation, conducting fieldwork, audit reporting, and following up on corrective action plans.

Phase1-Audit planning

The objective of the auditor is to properly plan his work starting with establishing the audit strategy that consist of the general audit plan, developing audit program and scheduling audit procedures. Describing the program, in the form of a written plan with defined objectives and steps to meet the objectives for doing audits, constitutes the first step in establishing an auditing plan.

An audit plan should define:

- ✓ Audit frequency-All aspects of the quality system should be audited annually, regardless of whether they are organized to be conducted in one audit or spread out over several audits.
- ✓ Responsibilities of member teams for conducting audits.
- ✓ Management representatives responsible for reviewing the audit report.
- ✓ The benefit expected by the audit procedure.
- ✓ The criteria to be used for evaluation of audit observations. Depending on the audit objective, a basic GMP checklist may be used, or more detailed check lists or criteria may be developed that are specific to the operation being audited.
- ✓ Rating criteria applied to assign a score to audit observations. If the rating criteria used is qualitative, the severity of an observation is rated as critical, major, minor, or recommendation, or if quantitative, rating system is applied through criteria such as 1to5 (with1being full compliance and 5 being out of compliance) (20).

Some potential objectives might include:

- ✓ Identifying and devoting appropriate attention to important are as of the audit,
- ✓ Promptly identifying and resolving potential problems,
- ✓ Properly organizing and managing the audit so that it is completed expeditiously,
- ✓ Selecting competent and capable team members and assigning proper tasks,
- ✓ Coordinating the work done by outside experts,
- ✓ Facilitating review of the audit work,
- ✓ Obtaining the necessary audit evidences and forming reasonable judgement (21).

An audit programme contributes to the determination of the effectiveness of the auditee's management system and it can include one or more management system standards, conducted separately or in combination (18). The extent of an audit programme should be based on the size and nature of the organization being audited, as well as on the nature, functionality, complexity and the level of maturity of the management system to be audited (18).

These audits may have a variety of important objectives with in the management system and may also include the key characteristics of product quality related to health and safety, or significant environmental aspects and their control(18).Those assigned the responsibility for managing the audit program should:

1. Plan, establish, implement, monitor, review and improve the audit program.
2. Identify the necessary resources and ensure they are provided (17).

Phase 2-Audit preparation

While in phase of preparation for an audit, alead auditor should be appointed incharge for guiding of the audit team through planning, conducting, reporting and communicating with the team and the customer. The lead auditor will then be in direct communication with the auditee to establish the format of the audit ,ensuring it aligns with its objectives and initiate the agenda before the audit starts. The proposed audit agenda should be communicated, reviewed and agreed with the auditee and adequate audit working documents should be developed. This will allow the auditors to come prepared and allow the customer to begin retrieving documents (22).

If audit checklist is defined to be used, it is required inclusion of specific items appropriate of the topics defined by the audit type and focus. In pharmaceutical industry internal audit, there are several sections recommended to be, at the very least, included in the GMP audit checklist: Quality management, Personnel, Facility and Equipment System, Documentation, Production System, Packaging and Labeling System, Storage System, Laboratory Control System.

Evidence gathering methods in auditing

The auditor must gather sufficient, reliable, relevant and useful information about the particular subject matter, to achieve the engagement's objectives. Only verifiable information can be audit evidence which must be recorded (3). The collection of audit evidence would be dependent on the following:

- ✓ Audit procedures to use - specific procedures should be spelled out for instruction during the audit.
- ✓ Sample size to be tested.
- ✓ Items to select - determine which items in the population should be selected.
- ✓ Timing-can vary from the beginning of the accounting period to the closure of it(23).

To form their opinion, auditors collect and evaluate audit evidence using various evidence gathering methods that can be use date very stage of the audit. Depending on the information needed to obtain, one of the main evidence gathering techniques can be used:

- ✓ **Interviews -** Interviewing is a powerful data collection method with its objective to get the person to talk. The most important thing to remember when interviewing is to being prepared for interviews and to always talk to the right person. Questions may be asked several times in different ways or to different people depending on their level of-responsibility in order to get a complete answer. The more effectively the Auditor interviews personnel, the more useful information will be gathered (24).
- ✓ **Inspections** - As for the ISA 500.A14 "Inspection involves examining records or documents, whether internal or external, in paper form, electronic form, or other media, or physically examining an asset (25). Inspection of records and documents provides audit evidence of varying degrees of reliability, depending on their nature and source and, in the case of internal records and documents, on the effectiveness of the controls over their production" (25).
- ✓ **Reviewing documents** - Company records are historical facts of what has happened in the past. When reviewing company records, the Auditors usually use a random sampling ,and only current, valid and credible records are generally accepted as representation of the action that has taken place (17). In general, each document must contain a title, verifiable dates, evidence of the person who performed actions, results, subsequent actions and the same must be completely filled out, and if any information is left uncompleted, it must be justified or else the auditor should ask why (17).
- ✓ **Observations –** This is a way of providing audit evidence by observing how a process work under normal circumstances. In order to collect sufficient audit evidence this primarily visual method is usually followed by hearing, touching, smelling or other type of audit techniques.
- ✓ **Vertical tracking-**This method, which is also referred to as "vertical auditing", involves checking all the processes or procedures performed by a particular department and to see and judge how these different procedures and processes within that department, are impacting each other and interacting across the quality management system.
- ✓ **Taking notes-**This efficient method will enable the auditor to complete the observation in detailed and traceable evidences to reach accurate conclusion.

Phase 3– Field work

Field work is the execution phase of the audit, during which auditors conduct multiple activities identified in the planning process. Activities often include conducting interviews with key staff, reviewing laws, policies and best practice, on-site audit management, meeting with the auditee, assessing process and system controls and verifying that these controls work, communication among team members and with relevant parties within the organization (26).

Audit walk-throughs of the auditor is of high relevance for the possibility of observation of operations, information gathering, as well as for uncovering not evident problems unless the auditor is actually present (22) on the relevant parts of the company.

During this phase, the auditor should clarify all the inconveniences about a procedure or process with the auditee, all the information gathered, and relevant

observations should be supported by evidence and clearly recorded. Preliminary observations, potential recommendations or significant findings of each day throughout fieldwork, should be discussed during wrap-up meetings with management (22).

Phase 4-Audit Reporting

The audit report is an important product of an audit which outlines the results of an auditor's investigation, providing correct and clear data that along with recommendations will address corrective actions for improvement that need to be taken. The audit report should be summarized as drafted audit with findings based on clear, referenced evidence or regulatory requirements, categorized in a risk manner and accompanied by a recommendation for corrective action to be taken. Major and minor are two types of nonconformities identified through audits, that differ based on the infraction and the steps needed to correct it.

Minor non-conformance is a system weakness, that can easily be fixed and in less time, that it does not detrimentally affect the operation or quality control of the company. Major non-conformance is evidence of a significant failure in the management system that entirely prevents the company from operating at ISO 9001 standards.

The statement of nonconformity needs to be presented as a report that helps the management to take the necessary corrective action. It is recommended that a draft of the report be supplied to the auditee to review, check, edit and suggest changes to avoid misunderstandings arising over observations and recommendations (13). The audit process may end by issuing the final corrected and approved audit report to the auditee management.

Phase 5 - Follow up on corrective action plans

Corrective action plans and its implementation, is considered an effort for continuous improvement by the auditee management. Minor non-conformance does not cause any major consequences and the corrective actions required, may be followed up at the next routine audit, while major issues should be reported within an agreed timeframe. It may also be necessary to re-audit to ensure that serious remedial action has been satisfactorily completed for critical or major deficiencies (19).The auditee to the top leadership/process manager should report corrective action plans and their status.

III. CONCLUSIONS

Internal audit is an effective independent activity within a pharmaceutical industry quality management system. It ensures a thorough analyses and evaluation of the company activities and helps prevent, predict and detect mistakes and weaknesses in order to minimize losses. Internal audits help the organization achieve its goals and ensure all the involved parties that a program complies with regulatory and Good Manufacturing Practice (GMP) requirements. An effective and strong audit program whether internal or external, should have a clearly written defined definition, objectives and approved procedures. The objectives of all audits should be evaluation of the efficiency of an organization's quality system backed up with audit reports issued to management provided to make them continuously improve of the quality management system. Creating an environment of good relationship between stakeholders, employees and auditors will support the audit process and deliver values to audit activities of any size. A quality systems approach calls for audits to be conducted at planned intervals to evaluate effective implementation and maintenance of the quality system and to determine if processes and products meet established parameters and specifications. I observed picture about how to face audit is more prompt & clear in industrial employees as compared to academic employee. An audit performed by a well-trained and thoroughly prepared auditor can be highly beneficial by identifying areas for genuine improvement. An audit should not to be seen as interrogation with the auditee as permanent loser, it is a comparison of what is laid down to what is in place. Auditing is no goal in itself. Auditing in the pharmaceutical sector serves two different categories: regulatory compliance and business needs. When employees and managers begin to see audits as opportunities to improve, they begin to see auditors not as police officers but as productive members of the organization.

This execution phase should be concluded with a meeting between the auditor and auditee management, where audit findings, deficiencies and conclusions will be communicated.

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