



## Pharmaceutical Quality Management Tool: An Audit

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### ABSTRACT

Auditing is one of the important tools to evaluate quality management system (QMS) of pharmaceutical companies. Auditing aims to enhance quality of products by continuous improvement. Auditing inspects the companies and ensures that all the procedures, documentation, financial statements etc, is in compliance with the regulatory required standards or not. Thus, auditing serves as effective tool for quality management, quality improvement as well as for the survival of industries by the view of quality. This article focuses on several components of quality auditing in the pharmaceutical sector, including its concepts, goals, objectives, importance, benefits, types, management system and checklist.

**Keywords:** Goals of audit, management of audit, checklist, audit report template.

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### INTRODUCTION

Audits can be defined as inspection of the system or companies to ensure that all the process or attributes meets all the requirements within given standards or not.<sup>1</sup> Auditing also provides information to the management with which the industries can control the overall processes to meet the good quality of products efficiently.<sup>2</sup> As per ISO (International Organization for Standardization) audits are systematic, independent and documented processes carried out to evaluate, to determine degree to which verification criteria are met.<sup>3,4</sup>

The historical ancestry of audits is connected to the origin of statehood and the co-existing government authority on the tasks and the responsibilities of organizations. In the "Good Manufacturing Practice" of the World Health Organization (WHO), the in-company audit is represented as a measure of the quality assurance and quality control of pharmaceutical products. Taking into consideration the communal and economic importance of pharma industries, many countries endorse national strategies for drug medicinal products in accordance with which the manufacturing units are needed to adopt a quality control and quality assurance system, which also includes an audit.<sup>5</sup>

Quality audit is considered as a key tool for observing the suitability of an industry's quality assurance system. Conduction internal and external audits of drug supplying

agents and outsider operations are main features of a good quality management system. Auditing in the pharma industry serves two different aspects: regulatory conformance and business requirements. By developing a high standard quality auditing system all over the industry, the conformance level will rise.

Quality auditing is periodical process of supervising a system for its efficiency which is acknowledged by an in-house auditing agent or external quality audit officer or by a group of people assigned by the management for evaluation purpose. A quality audit includes an evaluation and supervision of all factors of a quality management system with aim of assessing and enhancing it.<sup>6</sup>

An audit can be of enormous benefit to all departments and above all it provides an excellent opportunity to promote the best type of quality- one based on prevention rather than detection of errors. An audit may involve a range of techniques for examination of activities, materials and records. In all cases the aim is to establish whether criteria have been met and are being met. Quality audit is mainly used to evaluate all aspects of quality as it is one of the pivotal factors for a company's success or failure. They must be conducted with utmost precaution and all the non-conformances observed should be pointed and corrected.<sup>7</sup> Where compliance plays a crucial role in healthcare, unlike any other fields a mistake once committed can cost more than just a recall or a potential market loss. It can cost a life. Audits also help us in determining whether a process or a facility is or is not following applicable rules. If rules are violated, the cause must be determined and ways to prevent future deviations must be recommended.

With earlier developments like India opening its drug inspection office in Beijing to check for compliance with good manufacturing practices (GMP), it seems quite



obvious that the need for audits and compliance is becoming an everyday need.<sup>8</sup>

### Goals of Pharmaceutical Audit

- Evaluation of activities and documentation :-

The simple goal of this complex process is to evaluate the activities and existing documentation and determine if they meet predetermined standards. An audit will evaluate the strengths and weaknesses of the quality control and quality assurance processes, the results of which will help us in improving the processes and build a better system for the benefit of the company.<sup>8</sup>

- Quality assurance and quality control :-

Every product that is manufactured by a pharmaceutical firm has characteristics that need to be quantified or qualified by laboratory testing. Quality control and quality assurance are the necessary processes that play the role of a check and balance system in a pharmaceutical industry. They help in examining a system, process or product against performance standards. Audits help in providing management with information about how effective a company is in controlling the quality of their processes and products.

- Increasing credibility :-

It can also act as a tool to help in increasing the credibility and substantiate trust and confidence of the customers.

- Corrective action :-

Given proper preparation and planning, the audit itself should achieve its intended purpose with ease. An audit calls for corrective action. 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. 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 public relation.<sup>8</sup>

- Providing real-time visibility :-

The Audit & Compliance Management can help in ensuring and demonstrating compliance with internal and external standards, codes of conduct and procedures while providing real-time visibility of the compliance profile of an organization. It also enables the scheduling, planning, and conducting of audits/assessments which in turn help us in identifying non-conformances and leading to triggering and tracking of recommendations for improvement.

The process of auditing is a significant part of any process which requires an improvisation in their quality. The FDA, cGMP essentially have a primary requisite for an internal audit to be performed by all industries that are included in

medicinal products which is a resolution of their effective action in quality system.<sup>6</sup>

### Audit Objectives:

1. To ensure a quality managing system's compliance or non-compliance by examination of certain parameters.
2. To fulfil the regulatory requirement.<sup>9,10</sup>
3. Success confirmation of executed quality administration to ensure whether they summon to required quality aims and objectives.
4. Allocation of enhance to the group members for improvising grade of quality in their administration.
5. To permit listing of the audited organization quality system in a register.
6. Presenting a chance to enhance the quality management system.<sup>4</sup>
7. Assessing the documentation's in compliance with ISO9000.<sup>2</sup>
8. Evaluating the implementation's adherence to the documentation.<sup>6</sup>

### Importance of audits:

Audits are crucial for determining the success of processes, products, and systems—whether they have been in place for some time or have just been implemented—as well as being a crucial component of compliance and regulatory obligations. They are also an essential instrument for confirming the veracity of objective evidence of processes and for presenting proof of any issue areas' decrease and eradication.

The process of growth and development prioritize issue of quality of the products in pharmaceutical industries, so they are starting to implement a new managing tool to acquire competitive attitudes on the global market in the form of pharmaceutical audit.

According to World Health Organization, up to 10% of the medicines in the international market, and about higher than 25% in developing nations, are of substandard quality or spurious with anti-biotic and anti-malarial being the most widely observed. According to WHO multi-nation study of the year 2002 on successful drug regulation, Uganda pharmaceutical plants audited had 60% GMP transgressions, which threw back serious issues related to GMP conformance and execution. The reason behind this is lack of high quality management systems amongst local pharma industries to produce good quality products.<sup>11</sup>

High infant death ratio in Uganda, amongst other aspects, are occurred due to low quality and spurious drugs, unavailability of essential medications, and providing medical services via unauthorised pharmacies and shops by unqualified practitioners. In an examination by Renschler in 2015, there occurred 120,000 deaths of kids under the age of five, per year, that might be related with



the consumption of low quality anti-malarial drugs in sub-Saharan region of Africa alone.<sup>12</sup>

#### Benefits of conducting audits:

1. By conducting audits at any organisation, industry it analyze whether the product is in adherence with particular standards it will lead to development of products with lesser defects.<sup>13</sup>
2. To improve customers focus.<sup>14</sup>
3. Increases profit and economic growth of an organisation.etc.
4. Due to detection of weak points, processes it reduces defects.<sup>13</sup>
5. Prevent quality failures by documentation review.

#### TYPES OF AUDITS:

The audits system for quality is classified into three different types.

- Internal audits.
- External audits
- Regulatory audits.

#### Internal Audits

Internal audit has been termed by the I.I.A. (Institute of Internal Auditors) as an individualistic and focused activity that provides accompanies assurance regarding its operations; it guides in the direction of improvising them and contributing by bringing augmented value. Along with this, internal audit provides solutions to improve efficiency and cover deficiencies by evaluating the management process, the governance and controlling process, and risks the organization is exposed to.

Internal audit is an activity that brings a long-term positive impact on the control and management processes of the company. These audits are conducted within the organisation to monitor or check whether the manufacturing as well as all processes are going on properly or not.<sup>15</sup> Thus, these audits are also said to be self-audits or first party audits.<sup>10</sup>

In internal audits the auditors are of same organization or belong to its own organization. Internal audits advices to organizations that how to reach goals in better way, how to prevent defects, errors etc. - By internal auditing the methodology of work, organisational problems, solutions to these problems, business process etc can be evaluate.<sup>5</sup>

Objectives of internal audits:-

- To evaluate the control system as well as working system of an organisation.
- To analyse whether the goods of manufacturing are followed by company or not.
- To advice the organisation about corrective and preventive measures during all processes.

- To avoid errors and defects.
- In pharmaceutical industries internal audits are carried out to check,
  - A. Documentation maintained by all departments.
  - B. Activities carried out by individuals.

- *Key elements* for internal audits:<sup>16</sup>

#### 5C of internal audit.

- Cause
- Consequences
- Corrective Action
- Condition
- Criteria

#### External Audits

- These audits are called as second- party audits.
- There is no any link between auditors and organisations.
- The external audits are conducted for suppliers or contractors.
- For conducting external audits no precise legal requirements are needed.
- These audits advices the organisation about different processes, activities in compliance with GMP.
- Objectives of external audits:
  1. To evaluate financial statements of companies.
  2. To check whether the reports of companies are up to date and trustworthy.
  3. To reduce the defects, errors in the process.

#### Advantages:

- 1 Increase assurance and expertise in the cooperation agreement.
- 2 Ensures that assumptions are made and requirements are found.
- 3 Reduce the possibility of failure.<sup>10</sup>

#### Regulatory Audits

Regulatory audits are conducted by independent body or authorities for inspecting the certification as well as registration purposes of organization or company. The regulatory authorities like United States food and drug administration (USFDA), medicines and healthcare products regulatory agency (MHRA), therapeutic goods administration (TGA), medicine control council (MCC). etc are responsible for conducting such audits.<sup>8</sup> During auditing process the company must have representatives belonging to different departments for inspection process. Revocation of regulatory audits may results in restrictions



in export licence, manufacturing licence of an organisation.<sup>5</sup>

- Objectives of conducting regulatory audits:-

1. To access the reliability and rationality of information.
2. To access certification processes of an organization.

### MANAGEMENT OF QUALITY AUDIT

The term "internal quality audit" refers to an audit that is conducted by qualified employees of the organisation. The other type of audit, an external audit, may also be carried out by paid auditors from outside the company.

The following sub headlines can be used to categorise the quality auditing process:

1. Initiation of the audit
2. Planning the audit
3. Audit execution
4. Audit report and follow up

#### 1. Initiation of the Quality Audit:-

The procedure of starting a quality audit is the initial stage. A preliminary meeting between the client, the auditee, and the auditing organisation is required to begin a quality audit. The three parties discuss about the planned audit's goal, the standards against which the paperwork and activities will be measured, and other topics during the meeting. The auditors to be engaged and the audit's duration are discussed. The client, the auditee, and the auditing organisation (or their representatives) must have the responsibility to speak for and make decisions on behalf of the accountable managers of their respective organisations, while the conference was being organised. The auditee and the auditing organisation can carry out their tasks in the best possible way if there is mutual understanding and agreement.

- PLANNING AND INITIATION

Clients Activities: - The client's responsibilities include starting the audit, specifying the reference criteria, receiving the quality report, and determining any necessary follow-up actions. The client starts the audit by interacting with the three functional parties—the client, the auditing company, and the auditee—to establish understanding and agreement on: The goal and benchmark for the quality audit.

The audit's timing and instructions for each party can refrain from interfering with the auditing in any way.

- Auditee Activities: - The following are the duties of the auditee with regard to the planning and execution of the quality audit:

- 1) Designating trustworthy people to collaborate with the auditor(s).

2. Providing the auditor with a workspace and services.

3. Ensuring that the auditor(s) have access to the required resources.

4. Interacting with the auditor at designated meetings (s) reviewing the audit results to confirm.

- Auditing Organisation:-The representatives of the auditing organisation interact with the clients and the auditee during the initial meeting, the names of the auditor(s) to be involved, the time needed to create any special working documents for the audit and information about the facilities and assistance that the auditee can provide.<sup>17</sup>

#### 2. Planning the Quality Audit

Prior to beginning, the tasks at hand should be planned.<sup>18</sup> In order to develop accountability and ownership of the performance that results, responsibilities must be set. It is important to determine the customer's needs and identity. Written documentation used to explain the work activity or the products ordered should include requirements. All of the specifications and papers serve as the benchmark against which quality is assessed.<sup>19, 20</sup>

#### Resources Needed For a Quality Audit

The type of audit and the relationship between the auditee and the auditor will both have a significant impact on the resources required for the quality audit. Typically, the materials required for the quality audit includes:

##### Personnel:-

Staff from the auditee will be needed for a variety of tasks throughout the quality audit, including:- accompanying the auditor(s) during their audit activities, responding to inquiries about the organization's quality system and standard, and participating in the pre- and post-audit auditing sessions and maybe delivering the good or service being audited.

##### Office Facilities:

The auditor's need throughout the audit is a private places where they can reflect on their observations and make plans. Since external auditor(s) typically prepare reports and corrective action requests at their home offices, they shouldn't demand the auditee to provide typing or word processing facilities. However, they do need access to a telephone. Internal auditors require such resources.

##### Plant Facilities:

Most quality system standards mandate that the auditee make specific verification facilities available to the customer's representatives so they can use them to check the contractor's data. This includes things like specialised metrology devices, calibration standards for metrology items, ambient factors, product tensile strengths, etc. Access to such facilities would be necessary for both internal and external auditors.



**Scheduling:**

Naturally, the complexity of the quality system being audited and the importance of the issues being examined will determine how long the audit will take. It is important to plan ahead and provide enough time to account for potential delays. It is desirable if the auditor(s) provides a duration period that reflects the amount of time the audit is most likely to take, as well as proposed minimum and maximum duration criteria.

**Working Paper:**

All the documentation needed for the audit activities, such as procedures, is referred to as working paper in audit standards. Workflow guidelines check lists, records, etc. Working documents provide memory joggers for the auditor(s), ensuring that no components are overlooked throughout the review and evaluation. Additionally, it contains thorough records of what was audited, where the audit's activities were conducted, and the conclusions for each audit activity. Regardless of the type of quality audit or the auditors, the general guidelines for the various working papers are the same. However, each audit type will have unique papers of its own.<sup>17</sup>

**3. Quality Audit Execution**

The process of conducting audits begins with the gathering of data to ascertain if the department in question is adhering to defined standards and quality control processes. The auditor conducts interviews at this point, eliciting information and taking notes. The audit plans and checklists may have their scope expanded and may be the subject of additional scrutiny, depending on the findings. Non-conformities, or circumstances that have happened that clash with standardised processes and procedures, will be recorded at this point.<sup>21</sup>

Thinking in terms of "what to look at" and "what to look for" is an excellent way to prepare check lists. For instance, it might be determined to examine papers, files, goods, gear, processes, etc. Checklists are frequently used by auditors to assess the effectiveness of the system when conducting audits.

Time should be set aside during the audit to review and confirm that the programme is operating in accordance with the plan and that necessary revisions do not render the original plan incorrect.

The non-conformities are noted and ranked in order of importance. They must be documented in the manner specified in the non-conformity report. The deviations could be classified as slight or substantial. Major non-conformities disclose the failure of entire systems or the absence of such systems, whereas minor non-conformities are those that represent an isolated witnessed instance of failure to comply with a procedure or quality management system need. Major non-conformities are when a lot of small non-conformities of the same kind taken together indicate a system failure.

The auditee organisation is then given the findings of the audit, and corrective action is suggested to make things better.

**4. Quality Audit Reporting and Follow-Up****Reporting:**

During the process of conducting the audit, accurate transcriptions of observations made, inspection or test results obtained, conformances and non-conformances identified, and other issues resulting from the quality audit shall be prepared in an appropriate manner and records. The records must be utilised to link each area of non-conformance to the precise area of control and activity where it was discovered and to generate a report of the whole audit findings at the audit's conclusion.

Following the audit it is required to schedule a meeting with the company's management or the management of a supplier organisation that is the subject of the audit. The audit's results must be presented and debated in order to reach consensus on the resolution or correction of any issues or areas of non-conformance found during the audit. It must be agreed upon when such modifications will occur.

The report is put together from the inputs of various auditors and scrutinises to make sure the conclusions are strictly legal requirements rather than auditor's opinion.<sup>18</sup> The audit report will subsequently be released and made available to the management of the supplier and the customer, as necessary, in order to strengthen both parties' confidence and improve the ongoing activity.

**Follow-Up:**

- The audit team must plan a second look at any nonconforming areas or anything that require rectification. This must occur on the same day as or immediately after the agreed-upon deadline for resolving such issues or insufficiently controlled regions. Then, just the items impacted by the remedial action will be examined during a partial audit. The final report of the audit is released after the follow-up audit issued; it must demonstrate the level of control discovered throughout the quality system audited. The final audit report will be released following the follow-up audit and will detail the level of control discovered throughout the quality system examined.<sup>17</sup>

**OVERVIEW OF AUDITING PROCEDURE:**

The audit process consists of a total of 10 steps:

- I. **Notification:** Notification is the first step in the audit process. The audited party is informed of the date and time of the process through the notification process.<sup>9</sup> The notification will also include a list of the papers the order wishes to examine in order to comprehend the structure of the business.
- II. **Planning:** Prior to the audit, the auditor will plan by identifying major areas of risk and areas of concern.<sup>22</sup>



- III. **Opening meeting:** Meeting between the administrative staff, senior management, and auditing target management. The auditors will outline the procedure they'll follow. Management will outline to them areas of concern and the availability of the staff that must be consulted.
- IV. **Fieldwork:** The meeting's outcomes are utilised to modify the final audit plans before fieldwork starts.<sup>9</sup> Employees are informed of the audit, schedules for the audit staff's activities are created, and an initial investigation is launched after learning about business procedures, speaking with key staff, testing current business practises using samples, reviewing the law, and determining the reasonableness of internal rules and procedures.
- V. **Communication:** The audit team should communicate with the corporate auditor on a regular basis to clarify processes, get documents, and clarify procedures.
- VI. **Draft audit:** After the audit is finished, the draught audit is prepared as the next stage. The draught audit includes a list of parties to receive preliminary results, a description of what was done and what was discovered, as well as a list of concerns.<sup>10</sup>
- VII. **Management response:** Management is given the document so they may examine, edit, and recommend improvements as well as look into any problem areas and fix any mistakes. The report is submitted to management for the seventh stage, the management reaction, once any necessary modifications have been made. Management is asked to respond to the report by indicating whether they concur with the issues raised, the plan to address those issues, and the anticipated deadline by which all issues will be resolved.<sup>23,9</sup>
- VIII. **Final meeting:** The purpose of the final meeting is to tie up any loose ends, go through the management reaction, and discuss about the audit's scope.
- IX. **Report distribution:** The final audit report is sent to the proper officials inside and outside the audit region in the ninth phase, which is the report distribution.
- X. **Feedback:** The audit feedback is the final step, during which the audited organisation implements the adjustments that were suggested, and the auditor assesses, tests, and evaluates the effectiveness of the implemented modifications. This keeps happening until every concern is addressed and the new audit cycle starts.<sup>24,10</sup>

## ADMINISTRATION

The internal audit crew should have the self assurance and believe of the key stakeholders it works with and viewed as a supply of advice and assurance. This self belief can be solely hooked up by and maintained by having effective working relationship, through turning in excellence and well timed recommendation and internal audit responses

and reviewed considered to be contributing in assisting corporation to its responsibilities.

### The key stakeholders in internal audit are:

- Chief executive
- Board of directors
- Audit committee
- Senior management
- External auditor
- Other reviewers

The significance of this character relationship is analyzed below.

#### a. Chief executive

It is important that Head of Internal audit has direct access, as and when required, to the Chief executive when internal audit reviews functionally to the audit committee. Chief government officer and (CEO) or Chiefs finance officer (CFO) approve the internal audit function's price range and furnish enter for the internal audit plan; and thinning about the internal auditor to be a "partner".<sup>25</sup>

#### b. Board of directors

The head of the additionally formally record to the board of directors for the effectiveness of the internal audit. This effectiveness is featured in order to trade and views.<sup>13</sup> Boards with greater insider directors ought to have extra know-How to higher function the firm, that reason contributing to higher company performance.<sup>26</sup>

#### c. Audit committee

Audit committee plays an indispensable function in the governance framework of organizations. It assists Chief executive and Boards to understand whether or not key controls are excellent and working effectively.<sup>13</sup> Audit committee quality is measured in three dimensions: its size, its independence, and its expertise.<sup>27</sup>

In this respect, the relationship between the internal audit and the audit committee is essential and has a quantity of dimensions which are noted below:

- I. Advise the chief executive about the internal audit plans of the organizations;
- II. Direct or coordinate work applications bearing on to inner and external audits;

Review the content material of internal audits or pick out significant things of concern, and to propose the Chief executive on good exercise or possibilities for improvement.

#### d) Senior management

Senior management needs internal audit to compensate for the loss of manipulate the journal ensuing from the multiplied organizational complexity.<sup>28</sup> Internal auditors ought to engage one regular foundation with participants



of the Senior administration team, and through the Shipping of practical, business-focused and beneficial reviews, reports and advise that is primarily based on cooperation, collaboration and mutual respect.<sup>13</sup>

**e) External auditors**

External auditors too need to assist in creating internal audit approach and interior audit work plan. To keep away from duplication, the exterior auditor needs to evaluate the work of the internal audit feature to decide the adequacy for external audit purposes.<sup>13</sup>

External auditing requirements that originated in the western world, which are additionally being utilised in creating countries, advocate external auditor’s reliance on internal audit to reap audit effectively.<sup>29</sup>

**f) Other reviewers**

Internal audit is one of a range of internal and external

assessment and assurance things to do that exist as phase of organizations governance arrangements. The organizations shall gain when all these activities, such as these carried out by way of the Ombudsman and regulators, Function in a coordinated and complimentary manner to the best extent possible. This requires ordinary formal and informal contact between assessments our bodies to decrease duplication and overlap.<sup>13</sup>

**AUDIT CHECKLIST:**

One of generally used equipments in pleasant administration is a checklist, which may also comprise a set of standards in opposition for efficacy of a technique is judged.<sup>30</sup>

To gathering objective evidences, information about documentation, implementation also enhances quality management system of organisation.

**QUALITY MANAGEMENT AUDIT REPORT TEMPLATE<sup>32, 33</sup>**

<b>REPORT NAME:</b> _____	<b>AUDIT DATE:</b> _____
<b>AUDIT TYPE:</b> _____	<b>AUDIT TEAM LEADER:</b> _____
<b>Audit Summary:</b>	
<b>Audit objective:</b>	
<b>Audit Participants:</b>	
<b>Checklist(s)/Guideline(s) Used:</b>	
<b>Documentation/Work Products/Activity Examined:</b>	
<b>Brief Descriptions of substandard issues:</b>	
<b>Impact of Issues:</b> <input type="checkbox"/> Serious <input type="checkbox"/> Critical <input type="checkbox"/> Major <input type="checkbox"/> Moderate <input type="checkbox"/> Minor <input type="checkbox"/> None	
<b>Audit Status:</b>	
<input type="checkbox"/> Substandard issues found	<input type="checkbox"/> Corrective Action Plan is needed
<input type="checkbox"/> No issues found	<input type="checkbox"/> Resolution, Without Any Changes
<input type="checkbox"/> Escalation to Senior Management needed for immediate attention	
<b>Audit Recommendations:</b>	
<input type="checkbox"/> Acceptable Process/Procedures	
Process/Procedures conditionally acceptable subject to addressing action items below	
<input type="checkbox"/> Unacceptable Process/Procedures	
<b>FINDINGS/ CORRECTIVE ACTIONS/ACTION ITEMS</b>	



The fundamental aim of the guidelines is to assist the auditor to make sure about continuity of an audit and also save time during the audit. This will help auditor to come to a knowledgeable judgement. Corporation conducting audits generally defines layout of audit Sample which is used for defining checklist. The information which require for auditor could comprise.

- Information from proceeding audits.
- Known satisfactory problems.
- Priorities of the management.
- Information about documents.
- Specifications and information about product/ services.

Based on knowledge and experience auditors own consideration.<sup>31</sup>

This preparations are advice auditors how to There will be a large wide variety of checklists organized for a large audit; in all likelihood one for every department, and the place one of a kind duties exist inside a (large) department, possibly similarly checklists for every team auditee system with what documents. The checklist is popularly known as the “aide memoir” and memory aid.

A properly information to the training of a guidelines is to suppose in phrases of “what to seem at” and “what to seem to be for”. The important purpose of checklist is remains as memory aid for an auditor.

#### Checklist Benefits:

- Identifies applicable samples
- Defines a formal audit process
- Requires useful research
- Helps hold the tempo of audit
- Keeps audit goals clear
- Gives historic reference as an audit record
- Reduces workload on auditor in the course of the audit
- Assures auditee of auditor professionalism
- Provide house for audit notes

#### Checklist disadvantages:

- Can emerge as a tick list
- Maybe full of yes-no questions
- May stifle initiative and system evaluation<sup>24</sup>

#### CONCLUSION

- The quality management systems (QMS) approach calls for audits to be performed in the planned schedule to evaluate the strength, effectiveness and maintenance of quality by quality system. As well as to inspect whether the products meets the required standard parameters and specifications or not. Audits are

performed by qualified auditors who work together and provide ways of prevention of errors during manufacturing as well as many other processes related to quality. By performing quality audits the continuous improvement of an organisation regarding quality will takes place which further helps in customer focus and further with the view of profit.

- Instead of just identifying non-conformance, process problems, and corrective measures, quality audits should highlight instances of good practice to guarantee maximum benefit for an organization. This will make it possible for other departments to exchange knowledge and modify their working procedures, leading to continual improvement.

#### REFERENCES

1. (Kaur J. Quality audit: Introduction, types and procedure [Internet]. Place Unknown: Pharma Pathway; 2017. Available from: <http://pharmapathway.com/quality-audit-introductiontypes-and-procedure>).
2. Kumar S, Tanwar D, Arora N. The role of regulatory GMP audit in pharmaceutical companies. *Int. J. Res Dev Pharm Life Sci.* 2013;2:493-8.
3. Quality management system procedure, by Development Academy of Philippines, Revision No. 08, August 16, 2016 , available from : <https://www.dap.edu.ph/wp-content/uploads/2017/09/QP-04-INTERNAL-QUALITY-AUDIT.doc-FINAL.pdf> .
4. Guideline ICH. Pharmaceutical quality system. Q10, Current step. 2008 Jun;4.
5. Nedelcheva Y. Internal Audit in the Pharmaceutical Sector: International and National Good Practices. *Journal Aktiv.* 2014 Apr 1:13-5.
6. Kannan S, Morais SR, Prema S, Chitra K. Auditing as a management tool in pharmaceutical companies. *International Journal of Pharmacy and Biological Sciences.* 2020;10(1):230-5.
7. George-Silviu C. Analysis of internal audit practices on FTSE100. *Procedia Economics and Finance.* 2014 Jan 1;15:1265-72.
8. Vedanabhatla SO, Gupta NV. A review on audits and compliance management. *Asian J Pharm Clin Res.* 2013;6(2):43-5.
9. Kumar S, Tanwar D, Arora N. The role of regulatory GMP audit in pharmaceutical companies. *Int J Res Dev Pharm Life Sci.* 2013;2:493-8.
10. Alfa A. Jain, Vishal B. Babar , Amol A. Kulkarni V. Review on audit in pharmaceutical industry ,*International Journal of Pharmaceutical and Chemical Analysis.*2021.
11. Gilbert, O., Benon, C. B., & Charlotte, M. Z. (2015). Decision making practices in the pharmaceutical sector: Implications for Uganda. *African Journal of Business Management*, 9(7), 323–345.
12. Lubowa N, Ekeocha Z, Byrn S, Clase K. Pharmaceutical Industry in Uganda: A Review of the Common GMP Non-conformances during Regulatory Inspections.2021





13. Agarwal PR, Mishra AM. Pharmaceutical quality audits a review. *Int J Appl Pharm.* 2019;11:14-22.
14. Mills J. Quality auditing. Springer Science & Business Media; 2012 Dec 6.
15. Gaikwad PH, Jadhav AG, Pathan VT, Gujarati NA. REVIEW ON VENDOR AUDIT MANAGEMENT. *Asian Journal of Pharmaceutical Research and Development.* 2018 Aug 23;6(4):92-6
16. Karagiorgos T, Drogalas G, Giovanis N. Evaluation of the effectiveness of internal audit in Greek Hotel Business. *International Journal of Economic Sciences and Applied Research.* 2011 Apr 11;4(1):19-34.
17. Dale H.B , Besterfield C.M, Besterfield G.H, Besterfield M .S , Urdhwareshe H, Urdhwareshe R. Total quality management, third edition 2012
18. Brandt C. Structured GMP Audits. A ROADMAP TO GMP COMPLIANCE PART 3. 2017:18.
19. . Mark Hammar , Five Main Steps in ISO 9001 Internal Audit. Available from: <https://advisera.com/9001academy/knowledgebase/five-main-steps-in-iso-9001-internal-audit/>
20. Arter DR. Quality audits for improved performance. Quality Press; 2003.
21. Becher .M The four key steps in quality audits. ISO 19011, ISO 9001. [internet] Available from :- (<https://blog.softexpert.com/en/the-4-key-steps-in-quality-audits/>)
22. Cahill LB. Preparing quality audit reports: Ten steps (and some leaps) to improve auditing. *Environmental Quality Management.* 1994 Mar;3(3):319-24.
23. Audit plan and process article by case western reserve university. available from [INTERNET] <https://case.edu/auditservices/audit-plan-process> .
24. Biswas P. ISO 9001. Internal audit [Internet]. Place Unknown: Word Press; 2015. Available from: <http://isoconsultantpune.com/iso-90012015-internal-auditby-pretesh-biswas-apb-consultant/>.
25. Christopher J, Sarens G, Leung P. A critical analysis of the independence of the internal audit function: evidence from Australia. *Accounting, Auditing & Accountability Journal.* 2009 Jan 26;22(2):200-20.
26. Zhou H, Owusu-Ansah S, Maggina A. Board of directors, audit committee, and firm performance: Evidence from Greece. *Journal of International Accounting, Auditing and Taxation.* 2018 Jun 1;31:20-36.
27. Krishnan J. Audit committee quality and internal control: An empirical analysis. *The accounting review.* 2005 Apr;80(2):649-75.
28. Sarens G, De Beelde I. The relationship between internal audit and senior management: A qualitative analysis of expectations and perceptions. *International Journal of Auditing.* 2006 Nov;10(3):219-41.
29. Mihret DG, Admassu MA. Reliance of external auditors on internal audit work: A corporate governance perspective. *International business research.* 2011 Jan 1;4(2):67-79.
30. Walker AJ. Quality management applied to the development of a national checklist for ISO 9001 audits for software. In *Proceedings of IEEE International Symposium on Software Engineering Standards* 1997 Jun 1 (pp. 6-14). IEEE.
31. Tricker R. ISO 9001: 2015 audit procedures. Routledge, 2016 Jul 1.
32. Quality Management Audit Procedure, by Program Management Office, available from: <https://www.state.nj.us/transportation/capital/pd/documents/QMAuditProcedure.pdf>
33. Seoane PJ. Use and limitations of checklists. Other strategies for audits and inspections. *The Quality Assurance Journal: The Quality Assurance Journal for Pharmaceutical, Health and Environmental Professionals.* 2001 Sep;5(3):133-6.

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