

## A REVIEW ON AUDITS AND COMPLIANCE MANAGEMENT

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### ABSTRACT

Audits are an inevitable part for a good management system. The audits represent one of the most interesting and challenging role of a quality assurance inspector. Audits manage and check whether the regulations are implemented efficiently to achieve set objectives. They help in measuring actions against requirements.

Compliance management is a smart and intelligent way of recording and managing the shortcomings so that they can never be repeated. This article stresses the importance of audits and the effective role of compliance management in improving our routine activities for a hurdle free system that in turn can help us in improving a company's profits. It also outlines the effective role of compliance management for the survival of an industry. This article also lays emphasis on the different stages that comprise an audit and the corrective steps that should be taken at every stage so that perfection is achieved in all aspects in a pharmaceutical industry. In short, it gives a briefing on the entire process of an audit and the effective role of compliance management in managing the audit findings for the overall development of an organization.

**Keywords:** Audit, Compliance.

### INTRODUCTION

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.

Looking at the example of an emerging market like India, it has characteristics that make it unique. Firstly, the market is dominated with branded generics, which make up for 70 to 80 percent of the retail market. Secondly, a dominant position is enjoyed by local players who are driven by formulation development capabilities. Thirdly, prices are low. While India ranks tenth in terms of value globally, it ranks third in terms of volume. These characteristics present their own set of opportunities and challenges [1]. As important as being among the top competitors globally, equally important is the 'factor' which enables it to sustain the severe competition from its competitors and still remain in the global market. This factor is nothing other than "quality"- a term most commonly used and also most commonly overlooked. So when it comes to scrutiny of quality, audits play a pivotal role in ensuring that the product meets the standards globally because quality cannot be imparted but it should be built from the start. Here comes the role of an audit which helps in checking every intricate aspect of a product.

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 [2]. It is at this point that compliance plays a very important role as 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 [2].

With recent 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.

### Goals of an Audit

The simple goal of this complex process is to evaluate the activities and existing documentation and determine if they meet pre determined 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 [3]. 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 [4]. Audits help in providing management with information about how effective a company is in controlling the quality of their processes and products. It can also act as a tool to help in increasing the credibility and substantiate trust and confidence of the customers [5].

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 non-conformities by focusing on the systematic investigation of the root causes of non-conformities so that their recurrence can be prevented [6]. 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. 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 [7].

Coming to compliance, assessing compliance might be a simple task requiring brief inspection to find out whether rules are being followed or not. Looking at the other extreme, making a judgment might require extensive research of regulatory requirements, interpretations before a valid decision is taken. However, measurement of compliance has presented challenges [8]. So, care should not only be taken while performing an audit, it is equally important to manage the next steps like evaluating the risks, arriving at a decision and managing the changes made for the successful completion of an audit [1]. To maximize the benefit of auditing process, findings can be categorized and summarized to allow for

trend analysis to provide a clear view on status of compliance and identify opportunities for improvement.

**COMPLIANCE MANAGEMENT**

The basic motive of compliance management is to ensure that all employees required for the smooth running of a facility act responsibly. Therefore, being vigilant about the standards can have a direct or indirect impact on the products produced. Because to sustain in the present market situation, it is more important to be pro active than reactive. Consequently, audits also help in protecting companies from potential criticism [6].

Compliance management is a central safety management component that can be effectively performed with integrated, automated data management tools. This is not rocket science. By acting diligently and creating complete transparency within an organization, many hidden risks can be discovered and resolved. The audit program and the corrective actions taken as a result assure that the company is operating according to established standards of practice [7].

A compliance program can assist in preparing for the associated rigors of audit. Just as important, a compliance program can help to improve employee morale and productivity, and overall business performance. An effectively run compliance training program can begin to build and foster a culture of respect, ethical behavior and compliance.

An audit checks for discrepancies between what is expected and what is delivered. The difference between these two is what can be called as "expectation gap". Compliance management enables efficient management of the short comings of an audit as every pharmaceutical company has a commitment to their customers to provide highest quality drugs.

Proper compliance management also allows easy tracking of non-conformance rectification thereby leading to corrective and preventive actions (CAPA). With extensive dashboard and drill-through reporting, we can easily and instantly report compliance breaches at a particular site. This is a dynamic practice, because it can and will change as the needs change [9].

Given below (fig. 1) are the numbers of audit violations found in the year 2011 of an undisclosed company during an audit. From this, it can be assessed that audits focus into the minutest details of a facility and hence a high degree of adherence to GMP's is required and the need for compliance management for the survival of an organization.

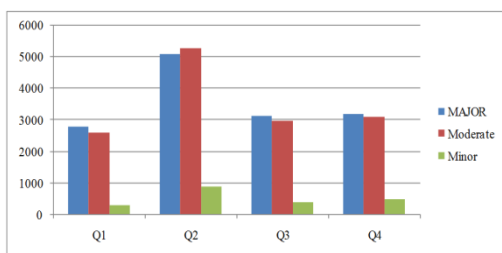


Figure1: Number of violations during 2011/quarterly [7].

**Reasons for an effective audits and compliance management system**

**Internal- in order to [10].**

- ✓ Determine level of compliance.
- ✓ Provide a stimulus for continual improvement.
- ✓ Build confidence in GMP and QA system.
- ✓ Recommend corrective action.

**External- in order to [10]**

- ✓ Establish and monitor capability of supplier or contractor to deliver goods and services that are fit for purpose.
- ✓ Build mutual confidence.

**Parameters for evaluation**

Before considering the parameters for evaluation, a study questionnaire was designed to assess the attitude and perception [11].

The following nontechnical parameters are checked as a part of audit [9]

NONTECHNICAL PARAMETERS	TECHNICAL PARAMETERS	OTHERS
Accuracy of data.	Instrumentation	Customer satisfaction
Action plans to correct problems.	Automation of analytical process	Employee health and safety.
Adequate training of analysts.	reliability of measurements	
Timely reporting of test data.	Proficiency esting	

**AUDIT STAGES**

Each stage of audit has its own set of objectives that are applied to individual programs with specific operating procedures. Whatever might be the uniqueness of each audit, all audits majorly consist of four stages [6,12]:

**First Stage - Engagement plan**

- ✓ Develop methodology to conduct audit.
- ✓ Specify objective measures and documentation that can be used in judging compliance.
- ✓ Design appropriate sampling techniques.
- ✓ Employ measures of judging accuracy of computer systems.

**Second stage-audit plan**

- ✓ Develop methodology to conduct audit.
- ✓ Specify objective measures and documentation that can be used in judging compliance.
- ✓ Design appropriate sampling techniques.
- ✓ Employ measures of judging accuracy of computer systems.

**Activities in third stage-field work**

- Check
- ✓ Computerized dispensing records.
  - ✓ Policies and procedures.
  - ✓ Provider payment records.
  - ✓ Quality control plans.

**Process of Audit and Compliance Workflow**

An audit process (fig. 2) begins with the verification of adherence with the regulations laid out by regulatory bodies which is followed by identifying the shortcomings and going for corrective action and finally followed by checking for compliance.

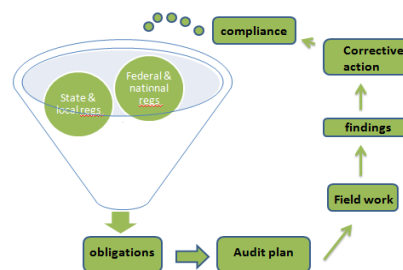


Figure 2: Audit and compliance management workflow [5].

The findings of an audit can be used to defend legal claims that the terms of contract are not abided by the company. And if an audit uncovers a lack of clarity in a company's procedure of operation, they can be used to improve the organization's performance and prevent any other future allegations [6]. For example, if an audit

finding states that improper documentation of purchase orders is found, it might be attributed to unscrupulous employees engaging in fraud.

#### FREQUENCY OF AUDIT

In general, the frequency for auditing does not exist. Table (1) gives an example of a list of criteria which can be used to determine how often to audit [9].

**Table 1:List of criteria for conducting an audit [9].**

Factor	High concern	Lower concern
Nature of testing		
• Health related	✓	
• Routine		✓
• Research	✓	
Test methodology		
• Custom or new	✓	
• Standard		✓
Performance history		
• Excellent		✓
• Average	✓	
Regulatory audits		
• Met requirements	✓	✓
• Did not meet requirements		

#### Benefits of audits and compliance can be said as [12]

- ✓ Adherence to established standards- following standards will lead to a product with less defects thereby increasing customer compliance to the product in the market which results in increase in profits to the company.
- ✓ Increase in employee morale
- ✓ Because an audit is performed by an independent person, his decisions would be unbiased.
- ✓ Compliance assessment- the level of compliance to the standards should be assessed which would play a vital role in the continuous development process of an organization.
- ✓ Validating risk assessment models- risk assessment is a pre requisite for sustaining any facility and audits provide a chance to validate the risk assessment models being followed by a company.
- ✓ Identifying emerging issues- any new issues if evolved can be solved immediately before it becomes a big issue.
- ✓ General deterrence  
As they say nothing's perfect, even audits and compliance is like a double-edged sword with its own set of drawbacks which may be said as:
- X It reveals the current performance of an organization which might scare off employees and customers if reported that the organization performance is declining consistently.
- X As it is the auditor's sole call, the decision is totally dependent on the auditor's opinion.
- X Resource costs: it refers to the labor and support costs that should be invested for conducting an audit.

#### CONCLUSION

While a letter to a company notifying an "audit" might not be the most welcomed news, an audit should be viewed as a management tool. From a bottom line perspective, audits not only help in the continual development of an organization but also the profession.

Audits are very much essential to verify the existence of evidence showing conformance to required processes, to assess how successfully processes have been implemented, for judging the effectiveness of any defined target levels and are a hands-on management tool for achieving continual improvement in an organization. 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.

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