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# QUALITY AUDIT: REGULATORY COMPLIANCE IN PHARMACEUTICALS

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## ABSTRACT

Quality audit is the process of systematic examination of a quality system carried out by an internal or external quality auditor or an audit team. It is an important part of organization's quality management system and is a key element in the ISO quality system standard. Quality audit is Periodic, independent, and documented examination and verification of activities, records, processes, and other elements of a quality system to determine their conformity with the requirements of a quality standard such as USFDA and GMP. It consists of systemic reviews to verify whether or not QC duties and responsibilities are being carried out in accordance with Specifications, Sops and the GMPs. Quality audits can be an integral part of compliance or regulatory requirements. Audits can also be used for safety purposes. Quality Audit can save organizations from quality disasters.

**Keywords:** Quality Audit**,** GMP, USFDA, Quality Assuarance , Quality Control.

## INTRODUCTION

Quality audit is defined as a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.[1]Quality audit means a systematic examination of a quality system. Quality audits are typically performed at defined intervals. Quality audit is Periodic, independent, and documented

examination and verification of activities, records, processes and other elements of a quality system to determine their conformity with the requirements of a quality standard such as USFDA and GMP.Any failure in their proper implementation may be published publicly and may lead to a revocation of quality certification. Also called conformity assessment or quality system audit.[2]

**SCOPE AND OBJECTIVES:**

Medicinal products have to be of high quality as people lives depend on it, although end product testing of samples from each batch is important, it is not enough to ensure quality which must be built into the manufacturing processes.[4] To ensure the quality, all pharmaceutical manufacturers are required to establish and implement as effective pharmaceutical QA system. To assess the effectiveness of these QA systems and to ensure it follows GMP, self-inspection and other regulatory audits must be performed.[3]

Pharmaceutical manufacturers commonly use audits as an effective mechanism to verify compliance with GMP regulation (GMP).

GMP audits with two important goals

- Audits are intended to verify that manufacturing and Control systems are operating under a state of control.
- Audits permit timely correction of potential problems.

Audits can be used to establish a high degree of confidence to remain under an adequate level of control by managements

**DIFFERENCE BETWEEN QUALITY AUDIT AND PERIODIC EVALUATION:** [5-9]

| Quality audit | Periodic Evaluation |
|---|---|
| 1. Quality audit is Periodic, independent, and documented examination and verification of activities, records, processes, and other elements of a quality system to determine their conformity with the requirements of a quality standard. | 1. Periodic evaluations are routine reviews and assessments of the quality standards of each drug product that are made to determine the need for changes in drug product specifications or manufacturing or control procedures. |

| | |
|---|---|
| 2. Auditors should not have direct responsibilities for the operations they review. | 2. Employees who are directly responsible for system under review normally perform periodic evaluations |
| 3. Audit is the function of Quality assurance. | 3. Periodic evaluation is a function of Quality control department, required by regulations (GMP) |
| 4. Verify whether or not the firm is properly carrying out its QC duties and responsibilities or to verify on a regular basis that a firms procedures and practices are in conformity with established SOPs and applicable GMPs. | 4. Periodic Evaluation determines the need for change in product, specification or control procedures and implements it if necessary. |
| 5. Auditors reviewed Sops, Employee practices and behavior to see how well they follow established SOPs. | 5. It plays a primary role in Day-to-Day decision-making process used by QC unit. |
| 6. Report is prepared by Q.C personnel | 6. Quality control management personnel usually prepared Periodic evaluations. |

## SELF-INSPECTION AND QUALITY AUDITS

### Principle

Purpose of self-inspection is to evaluate the manufacturer's compliance with GMP in all aspects of production and Quality control. The self-inspection programme should be designed to detect any shortcomings in the implementation of GMP and to recommend the necessary corrective actions.[11]

Self-inspections should be performed routinely, and may be, in addition, performed on special occasions, e.g. in the case of product recalls or repeated rejections, or when an inspection by the health authorities is concerned. The procedure for self-inspection should be documented.

**Items for Self-Inspection**[10]

(a) Personnel

(b) Premises including personnel facilities

(c) Maintenance of buildings and equipment

(d) Storage of starting materials and finished products

(e) Equipment

(f) Production and in-process controls

(g) Quality control

(h) Documentation

(I) Sanitation and hygiene

(j) Validation and revalidation programmes

(k) Calibration of instruments or measurement systems;

(l) Recall procedures

(m) Complaints management

(n) Labels control

(o) Results of previous self-inspections and any corrective steps taken

## TYPES OF QUALITY AUDIT [12]

The quality audit system mainly classified in three different categories:

1. Internal Audits
2. External Audits
3. Regulatory Audits

## INTERNAL AUDITS[12-15]

Internal audits are carried out by an organization on its own systems, procedures and facilities. Internal auditing involves the utilization of a systematic methodology for analyzing business processes or organizational problems and recommending solution which means vital from a business perspective. The organization of internal audits depends on the size and complexity of the organization. A procedure and programme of internal audits should be available.

Internal auditing activity is primarily directed at improving internal control like

- The efficacy of operations

- The reliability of financial reporting
- Deterring and investigating fraud
- Safeguarding assets and compliance with laws and regulations

Tier One

Audits carried out by the staff of a section or department on themselves. Audits will typically be short and limited in scope, focusing on 'visible', such as housekeeping and documentation auditors are usually selected on the basis of knowledge and experience of the area to be audited. Auditors should also receive some basic training on the reasons for audits and particular areas for examination.

Tier Two

Audits typically carried out by a local QA group, comprising staff independent of the department under audit. Such audits will typically be longer, but less frequent, and are likely to focus more on systems than housekeeping.

More extensive audit training will be required for tier two auditors, with more detail on quality systems and audit techniques.

Tier Three

Audits carried out by a corporate compliance group. Alternatively, external consultants may be used. Such audits are often carried out to assess readiness for a regulatory audit, but may also be used to obtain an expert view on a specific critical activity. Tier three auditors are likely to be highly-trained and experienced specialists, with an expert knowledge of GMP and other regulatory requirements for pharmaceuticals.

**Purpose of Internal Audit**

- Increase the potential for early identification of regulatory concerns based on FDA interpretations and current compliance focus.
- Identify compliance deficiency and deviations from industry standards and company requirements.
- Provide a benchmark of compliance with other companies and regulatory expectations.
- Inform management of compliance status, regulatory risk, and civil liability.
- Foster continuous improvement and forward quality.

- Provide a tool by which the company can stay ahead of rapidly increasing regulatory demands.

**Designing of the Internal Audit System**

In a pharmaceutical facility for internal auditing, you require to check mainly two things namely,

- Activities carried out 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.

**Implementing the Internal Audit System**

Ideally following steps should be taken to implement the audit system,

Constitute a small team of experts from various disciplines e.g. Q.A. / Q.C., Production, Validation, Engineering, Personnel etc.

- Provide initial training.
- Generally the head of Q.A. should be the chairman of this team.
- Fix an audit schedule (time table) and communicate to all concerned people.
- Carry out the audit of each area of activity at least once in six months.
- Report the audit findings to the concern department and seek their time bound compliance.
- Report to top management on observed deficiencies and corrective actions planned.
- Follow up and take further corrective actions if required.
- Repeat the audit as per pre-planned schedule.

**EXTERNAL AUDITS[16-18]**

External audits are audits carried out by a company on its vendors or subcontractors. There is no legal requirement to conduct such audits. Need is implicit, since manufacturers are required to have a thorough knowledge of their suppliers. Furthermore, if work is contracted out, they must ensure that contractors are competent to complete it, in accordance with GMP.

There are also strong business benefits to be derived from performing these audits:

- Building knowledge and confidence in the partnership arrangement

- Ensuring that requirements are understood and met
- Enabling reduction of certain activities (e.g. in-house QC testing of starting materials)
- Reducing the risk of failure (and, by implication, its costs).

The scope of these audits will vary, depending on the relationship between the two parties, which may range from a simple vendor-purchaser transaction to a strategic joint venture partnership. Regular audits will be carried out to assess compliance with agreed contractual standards, the frequency of which will depend on the initial findings and the criticality of the vendor and materials supplied.

As confidence in the vendor increases - through auditing,

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Reduce the level of external auditing.

External auditors typically have a broad practical experience of GMP and receive quality systems auditing training equivalent to that of ISO 9001 lead auditors Audit teams may also include specific technical experts, depending on the size of the facility and the scope of the audit Many pharmaceutical industry suppliers are ISO 9001 or ISO 9002-certificated and are regularly audited by their certification body

**Qualification of External Auditor:**

An external audit program require independent auditor to perform

- A full-scope finance audit
- Documentation audit
- An attestation of internal controls over operations reporting
- An effective external audit function often provides the board of directors and management with:

  ✓ Reasonable assurance about the effectiveness of internal controls over operating systems, the accuracy and timeliness in recording various activities, and the accuracy and completeness of required regulatory reports.

  ✓ Information useful to directors and management in maintaining a quality, operations and risk management processes.

**Scope of the external audit**

The management shall discuss with the external auditors the overall scope of the external audit, including

- Identified risk areas
- Any additional agreed-upon procedures
- Review the external auditor's compensation to ensure that an effective, comprehensive and complete audit can be conducted for the agreed compensation level.

## REGULATORY AUDITS[19-21]

These audits are carried out by regulatory bodies against relevant regulations for the manufacture and supply of pharmaceutical products. National regulatory bodies, such as the Medicines Control Agency (MCA) in the UK and Food and Drug Administration (FDA) in the USA, are statutorily responsible for carrying out such audits. These audits may be unannounced (MCA currently performs about ten per cent of its UK inspections like this) 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).Regulatory inspectors are extensively trained and are knowledgeable and professional. All MCA medicines inspectors are relevantly qualified and have a minimum of five years' appropriate experience in a manufacturing operation; they will be on the registers of persons eligible to act as qualified persons (QP) and lead auditors.

Failure to pass a regulatory audit can lead practical experience of GMP and receive to restrictions on (or the withdrawal of) a manufacturing or import/export license
Currently, different regulatory bodies have distinct audit styles and requirements, but to reduce costs and the audit burden on manufacturers, there have been moves towards sharing and mutually recognizing audit findings between these bodies.

The scheme retains and improves on the convention's main features:

- Networking and confidence-building between national inspection authorities
- Development of quality systems
- Training of inspectors and related experts

- Work towards global harmonization of GMP

Regulatory audits vary considerably in scope, frequency and duration. Audits by the national regulatory body are likely to be regular and to cover systematically all areas of a facility, over a period of time.

There may be additional audits (or visits) as a result of specific events, which may be company-specific (for example, the recall of a product) or industry-wide (a recent example being checks on compliance with transmissible spongiform encephalopathy's regulations by the MCA).Audits by the regulatory body of another country may be general or linked to a specific regulatory event: The pre-approval inspections of the FDA are linked to submission of a new drug application After a regulatory audit, a formal report will be delivered, the format of which will depend on the regulatory body concerned: MCA provides verbal feedback at the exit meeting, then a brief, action-orientated, written report shortly afterwards; FDA provides a 'form 483' at the exit meeting.

**ROLE OF GMP AUDITS IN QC AND QA PROGRAMMES:** [20, 22-24]

It consist of systemic reviews to verify whether or not QC duties and responsibilities are being carried out in accordance with Specifications, SOPs and the GMPs

What is to be audited:-

- Auditors review SOPs to insure they are complete, accurate and appropriate for the intended purpose Employee practices and behavior is observed to see how well they follow established SOP's. Compare master specifications against compendia and regulatory requirements
- Verify whether or not test data for in process and finished products confirm to specifications whether validation testing has been performed for all pertinent equipment and processed. Validation Test reports are compared against raw data and documents are reviewed to determine if conclusions are supported. Verify corrective actions taken in reaction to audit findings.

Deficient Practices that requires Regulation/or Administration:

1) Contamination or high potential for contamination with filth, objectionable microorganism, toxic chemicals or other drug chemicals
2) Failure to assure that each batch conforms to established specifications

3) Distribution of product that does not conform to establish specifications
4) Use of invalidated or inadequately validated test method
5) Deliverable blending of an adulterated batch with a good batch to obtain a batch that meets the minimum specification
6) Failure to assure batch conformity
7) Conducting packaging and labeling operations such a manner as to introduce a significant risk of mislabeling products
8) Failure to keep adequate batch records
9) Failure to record distribution by lot no. in case of recalls

**Benefits of GMP audits**

1) Assuring GMP compliance
2) Detecting potential problems
3) Effective program improvements
4) Increasing management awareness

**1) Assuring GMP compliance:**

The FDA conducts routine inspections of all pharmaceutical manufacturers to determine if manufacturing and control procedures conform to GMPs.FDA investigators make unannounced visits to the manufacturing facilities to examine facilities, equipments, personnel and records. They use systemic analysis approach where selected process is evaluated for GMP compliance.

For e.g. they cover following issues for these purposes:

- Review the design , construction and maintenance facilities
- Equipment facilities
- Batch production records
- Lab testing procedures
- Stability testing records
- packaging and label control
- complaint records

**2) Detecting potential problems:**

GMP audits find objectionable condition that is unknown to responsible production, QC, QA or management personnel.

For e.g. an auditor may observe an operarator at the aseptic filling machine, reaching over exposed vials. Operator may not realize his/her actions were a source of potential contamination

The auditor will see whether such actions are frequent or not .From this he can signal other GMP problems.

- ✓ Improper employee actions may result from SOPs not containing clear instructions
- ✓ Inadequate employee training
- ✓ Lack of adequate supervision

Audits can be effective mechanism to locate or identify problems which have gone undetected during the normal Day-to-Day QC review. The detection of unknown or unsuspected potential problems can be one of the most important benefits derived from an audit programmed.

**3) Effecting programmed improvement:**

Audit provides an effective mechanism for improving overall quality of QC and QA programmers

Such improvements may include the following

- Changing SOPs more properly
- Modifying manufacturing equipment or procedure
- Upgrading equipment or procedure
- Improving employee training programmed
- Developing new or revised documentary system

**4) Increasing management awareness:**

It is another benefit gained from GMP audits. For any given audits there are two outcomes, either problems are found or not

a. If the problems are found , management takes an appropriate step to eliminate the problem .A responsible management should also assess the likelihood that problems may also exist in other systems and steps should be taken to correct the problems

b. An audit is not finding any objectionable conditions

There are 2 reasons for that:

- Either there were no problems to be found
- Auditor failed to detect objectionable condition that were actually present

Here following are factors to be considered

- Objective of audit
- Did audit reports show the specific report to management for negative finding?
- Scope of audit
- Breadth and depth of the audit
- Experience and training levels of auditors

**ELEMENTS OF A SYSTEMIC AUDIT PROGRAM:** [25-28]

A systemic Audit program includes development of formal written documents, which must be designed and operated in a manner that permits conclusion and decision to have a scientific basis.

The success of audit programme depend upon

- Expectations being clearly defined
- Effective management review as per GMP system

**Key Elements:**

1) Expectations and Philosophies must be clearly defined by management
2) Audit Formats and Approaches
3) Checklist written criteria and Standard Operating Procedures
4) Planned Periodic frequency for audit

5) Specially trained personnel responsible for conduct a Audit
6) Finding Written Audit reports
7) Regular assessment for better performance of audit

**1) Expectations and philosophies**

Senior management establishes the fundamental expectations of audit and Upper level management must establish the realistic goals and objectives. One practical approach is use of "Formal Written Master Plan" approved by management. The master plan defines in an organized and systemic manner which has responsibility for the audit programme and Summary of documents represents overall philosophies and Expectations for the audit programme.

**2) Audit format and approaches**

Methods and Styles differ between companies and approach an audit differs by auditors to auditor depending upon experience.

Manual GMP audit methods can be divided in two categories

1. Checklist format
2. GMP regulation approach
3. Systems analysis method

I. Checklist format:-

Pharmaceutical manufacturers commonly use checklist as GMP audit guides and reporting finding. They are printed forms that have a series of questions or instructions that are grouped in to logical order. Blocks may be used to record answer and space may be provided to make comments. Questions on GMP requirements covering at least the following items

Advantages:-

- Simple, convenient and easy to use
- May be used for any desired subjected area
- Questions and guideline may be developed by knowledgeable personnel
- Questions are in logical order that help auditor to detect problems
- Report can be prepared in a minimum amount of time

Disadvantages:

1) Interpreting Questions:

Inherent difficulties arise to develop questions that are clear (unambiguous). Nearly every question may be interpreted in more than one way and auditor's actions or approaches may be influenced in unpredictable manner. Auditor's reaction will be determined not only by content of questions but also by factors such as experience, knowledge of the subject matter, attitude and motivation

Checklist questions may introduce bias or have hidden meanings and care needs to be that questions do not lead the auditor to answers that seem likely

E.g., have all master formula records been properly signed by a second person?

Did you find any instance where entries on the master formulas were not properly signed by a second person? (Careful examination of records to find improperly signed record)

2) Varied experience:

- Devising Questions that are meaningful and informative for personnel with different experience levels bias not an easy task. Clarity of the questions determined by the extent of scientific and technical terms used. Questions must be scientifically correct but should not be overly technical. Questions with too few scientific terms may lead to ambiguous. Elementary Questions that are helpful to inexperienced auditors may not be of much value to a senior auditor. More complex or detailed questions useful to highly trained personnel may be difficult to follow for those with limited knowledge of subject.
- Inexperienced personnel may not fully understand the intent of questions or may not recognize technical issues that are readily apparent to experience personnel
- E.g., are sufficient procedures in place to assure product sterility when sterilization cycled are interrupted? An inexperienced auditor may answer "yes" after finding an approved SOP for resterilization and verifying that every load during power failures had been resterilized per SOP requirement. Experience Auditor responds "NO": resterilization itself being objectionable.

3) Limited content:

The amount and type of questions that are provided limited. Not every issue will be covered. Each auditor must apply sound judgment when evaluating system.

### II. GMP regulation format

Some firms audit systems by using GMP regulation as a guide. The basic elements are derived from the following subpart of regulations:

- Subpart B: Organization and personnel
- Subpart C: Building and facilities
- Subpart D: Equipments
- Subpart E: Production and Processing Controls
- Subpart F: Production and Packaging control
- Subpart H: Holding and Distribution
- Subpart I: Lab controls
- Subpart J: Records and Reports
- Subpart K: Returned and Salvaged drug

The language in GMP is not specific enough to serve as an audit.GMP regulation contain broad statements of what is expected to be accomplished, but language doesn't use usually describe how it is to be done.

### III. Systemic potential problem analysis

This approach involves systemic evaluation of the factors that are likely to affect product quality. Formal assessments are made to determine whether or not conditions or practices exit that may adversely affect assurance of product quality. This format includes several variations depending upon the basic approach use to evaluate the system. A number of FDA investigators are described the systemic audit techniques. They emphasized the importance of establishing a basic set of criteria to evaluate the cause and effect relationship of production and operations to final product quality. These FDA investigators describe the organized method for determining of potential problem may exist that may adversely affect the product quality.

**3) Written criteria:**

Formal written criteria need to be established defining which audit data or elements are to be considered in the assessment of program performance

For audit data review these variables like

- Reliability of vendors who supply raw materials
- Components

- Services

Need to be identified and formal criteria established.

If criteria valid and complete, management can make sound scientific decision.

Effective use of written criteria to ensure that conditions and practices remain under a suitable state of control.

**4) Written Standard Operating Procedure:**

Formal written SOPs should fully describe the details for carrying out the various audit functions. The number of SOPs should be sufficient to represent each of the major audit operations. SOPs should contain enough details to completely and clearly define what is expected to be done and by whom.

SOPs should establish

- The responsibility for audit data review
- Personnel responsible for recommendations
- Decisions concerning corrective actions.

**5) Independent Responsibilities**

The QA unit usually carried out the audit function if its primary responsibilities are clearly independent from those of production and QC.

**6) Planned Periodic Frequency**

It is an important element of systemic audit programme.

A written plan ensures that audits are done at regular periodic intervals, with allowances for flexibility.

Each firm must establish the optimum time interval between audits based on several important factors like

- Intended purpose
- Objectives, scope and depth
- Prior history of audit finding.

1) Announced Visits:-

Advanced notice is given before the audit.

It is not persuasive for two reasons:-

- The person makes major adjustment in their behavior in anticipation of audit. The improved behavior may be temporary.
- Reliability is diminished if the employee covers up the problem.

**Benefits**

- Audit efficiency is improved from advance notification.
- Necessary records may be organized and retrieved in the preparation for the audit
- Key personnel become available

2) Unannounced Audits:

To view conditions and practices that is normal or customary (representative) as possible. For observing employees behavior. For direct observation of equipments and facilities. Prior notification and personnel alter their behavior is not advisable.

**7) Specially Trained Personnel**

The following personnel factors deserve systemic attention

- Defining auditor Qualification
- Documentation training skills and experience
- Selecting audit

Defining Auditor Qualification:-

- Selected based
  - ✓ On their knowledge
  - ✓ Experience in manufacturing and QC principles as well as years of first hand experience dealing with GMP matters.
- Essential auditor skill is aware of
  - ✓ Firm's SOPs and Knowledge
  - ✓ Integrated by various departments.
- Minimum education requirements should be established to insure that auditors have
  - ✓ Sufficient technical knowledge to review
  - ✓ Educate complex systems.

**8) Documentation Training Skills And Experience**

**Two formats**

1) Scientific Principles:-

- Training under chemistry, engineering, statistical and pharmaceutics

2) GMP:-

- GMP training may include the cumulative knowledge from years of experience
- This knowledge comes from
  - ✓ Formal training sessions
  - ✓ Daily activities
- This approach is to prepare summary document showing
  - ✓ The nature
  - ✓ Level of training for the GMP elements

**9) Selecting Audit Teams**

Limitations of Personnel audit:-

- ✓ Experience and knowledge, which is individual.
- ✓ Emphasize on familiar issues as well as particular area

Team is required for major comprehensive audit that cover many different systems and large amount of data. Composition of team will vary depending upon the nature and scope of the audit. Persons having specialize experience or technical skill may join the audit team. Leader is required for the auditing team who will assess each member's auditing skill. Leader will monitor their process at frequent intervals. Leader is usually a senior auditor who has extensive knowledge of the firm's operations and exhibit strong leadership qualities.

Team size depends upon

1) Firm size
2) Total no of products manufacturing and control system
3) Breath and depth of the audit.
4) The Audit objective

**10) Maintaining Auditor Awareness Levels**

Auditors need specialized technical knowledge about many diverse subjects.

Knowing which laws, regulations or guideline may be applied to each situation requires considerable knowledge. Formal systems can be established to help keep auditors abreast of changing technologies, regulatory expectation and potential problems

- Retrieving GMP information:
  - ✓ By keeping personal files containing GMP information
  - ✓ Computerized method may be used for maintaining technical references and information about GMP matters

**11) Reporting Audit Finding**

Systemic audit programmers must establish reporting methods that finding to be documented effectively and efficiently. Management to assure that corrective action is taken to eliminate problems and to measure the overall adequacy of the audit program uses reports. Audit reports should contain complete details of the program detected.

There are two important reporting phases:-

1) Preliminary reports during the audit
2) Final report to the management

1. Preliminary reports during the audit:

There are many things that have to be kept in mind during audit. Even when obvious problems are found that requires no explanation. Important benefits can be gained from having dialogues with employees. Finding is communicated with affected personnel. Often problems that are obvious to an auditor may not been apparent to the employees, so discussed may help the employees to learn why problems happened.

2. Final report to the management:

There are various ways to report audit finding to responsible management. Usually reports describe the details of the audit. Management must review the final reports and determine what steps need to be taken to eliminate deficiencies. The audit reports may be shared with manger supervisor who may discuss finding with employees. The workers and supervisory personnel should be given the opportunity to explain their views and ideas about the audit findings.

Managers and upper management should use this information in a way that gains the employee support needed to achieve corrections.

## 12) Conclusions And Recommendations:

There are almost three management groups which use as a means to improve overall performance of GMP systems:

1) Production and QC managements.
2) Management responsible for administering the audit program.
3) Senior management responsible for the overall program.

**Audit report**[9, 14]

| |
|---|
| Activity/Aspect audited: |
| Section: Report No: |
| Audit Officer: Date: |
| Details of activities ,documents ,methods , procedures ,records, |
| Results and reports examine during audit |
| Non-compliance(s): Category: |
| Corrective action(s)and time scale |
| (Officer responsible for action): |
| Noted and agreed on behalf of(section): |
| Signature of representative: |
| Corrective actions: |
| Carried out by(name): |
| On (date): |
| Confirmed by audit officer: |
| Signature: |
| On (date): |
| Received and approved by quality manager: |
| Signature: |
| On (date): |

## CONCLUSION

Quality assessment programs must faster and support continuous improvement and quality performance. Nobody likes to be audited. It is a means to have continuous improvement. This is especially when it involves giving your company the license to manufacture or shutdown.

But, if a person is prepared and a functional quality system is in place, one can see it as a way for continuous improvement.

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