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Research Article

A BRIEF REVIEW ON: PHARMACEUTICAL AUDIT GUIDE

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A R T I C L E I N F O

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A B S T R A C T

Nowadays, auditing is a important part of a pharmaceutical industry. Quality audit is a review and evaluation of all or part of a quality system with the specific purpose of improving it. We can evaluate different programs of pharmacy and can make sure that the process and methods comply with the regulatory authorities. This audit can be performed externally or by professional expert team who solely performs the function of auditing. Audit not only deal with manufacturers but also done with different channels like supplier and contractors. By performing audit evaluation of quality assurance department and its different process is evaluated, and results came up with this used for improvement in methods and can be used to perform best for company benefits. This article focuses on Evaluating conformity of requirements to ISO 9001, Evaluating conformity of 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 and Qualifying potential suppliers. This review comprises a well-organized summary of various guidelines available till date using the Google Scholar search engine and the keywords listed below.

INTRODUCTION

Audit in simple terms could be defined as the inspection of a process or a system to ensure that it meets the requirements of its intended use. International organization for standardization (ISO) defines the audits 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."

Audits are conducted to ascertain the validity and reliability of the information; also to provide an assessment of the internal control of a system. It provides management with information on the efficiency with which the company controls the quality of its processes and products. The simple goal of this complex process is to evaluate existing activities and documentation and determine if they meet the established standards.

Every product manufactured by a pharmaceutical company has characteristics that must be quantified or qualified by laboratory tests. Quality control and quality assurance are the necessary processes that play the role of control and balance system in pharmaceutical industry. In the pharmaceutical industry, audits are virtual means for assessing compliance with the established objectives defined in the quality system and thus paving the way for the continuous improvement program by providing feedback to management. 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.

In food and drug administration (FDA) and ISO environments, auditing of both compliance and performance is essential. Pharmaceutical audit experience includes the drafting and revision of validation policies, guidelines and standard operating procedures (SOP) from project qualification to performance evaluation phases . If implemented correctly; it can be one of the most effective means of improvement.

Objective

- Evaluating conformity of requirements to ISO 9001
- Evaluating conformity of 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 suppliers

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Glossory

Pharmaceutical Ingredient (API)

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

Aide Memoire:- Document supporting the auditor(s) to conduct a structured audit.

Audit:- A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which criteria are fulfilled.

Auditee:- Persons from an organisation or organisational unit being audited.

Auditor:- A person with the competence to conduct an audit.

Audit Team:- One or more auditors conducting an audit.

Audit Unit:- An organisation or organisational unit (e.g. departments, plants sites) to be audited.

Communication:- Is a process of exchanging information between two or more persons. Communication can be verbal and/or non-verbal. Competence The demonstrated ability to apply knowledge and skills.

Compliance, GMP:- Applying to national/international GMP regulations.

Compliance, regulatory:- Applying to statements made in the organisations own documents submitted to the authorities.

Critical Quality Attribute (CQA):- A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

Critical Process Parameter:- A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the processproduces the desired quality.

Manufacture:- All operations of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage, and distribution of APIs and related controls.

Material:- A general term used to denote raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs and packaging and labelling materials.
Outsourcing:- Activity (laboratory, production, service) that is executed by another company on behalf of the original manufacturer.

Process:-Set of inter-related or interacting activities which transforms inputs into outputs.

Quality Manual:- Key document specifying the Quality Management System of an organisation.

Quality Unit(s):- One or more organisational units independent of production which fulfils both Quality Assurance and Quality Control responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organisation.

Quality Management System:-A management system to direct and control an organisation with regard to quality

Questionnaire:-Document asking for specific information.

Senior Management:- Management that is not involved in the day-to-day business, but is in a position to implement changes or improvements.

Supplier:-An organisation or a person that provides a product.

Audits and Regulatory Standards

The ISO, a global leader in the development of international standards, is instrumental in boosting interest in quality audits among manufacturers and other types of businesses when it published the ISO 9000 standards in 1987.

Today, popular standards such as ISO 9001: 2000, ISO 14001:2004, and ISO 13485 all require internal audits of the quality system (or the environmental management system in the case of ISO 14001: 2004).

Under these standards, audit serves as a mechanism for evaluating and improving quality. The same principle is reflected in a number of regulations enforced by the Food and Drug Administration. Under the Quality System Regulation (21 Code of federal regulations [CFR] Part 820), medical device manufacturers are required to conduct audits to ensure that the quality system is compliant (Sec. 820.22).

The current good manufacturing practice (CGMP) regulations for pharmaceuticals (21 CFR Parts 210-211) and for blood and blood components (21 CFR Part 606) include general requirements for regular evaluation of quality standards.

Guidance for the pharmaceutical industry and blood establishments also emphasize the importance of audits. For example, the "Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations" recommends internal audits and supplier audits.

The "Guidelines for Quality Assurance in Blood Establishments" call for a comprehensive
audit of the quality assurance programme.

Qualification and Attribution Of Auditors

Auditors should be qualified by education, training and experience in auditing techniques. Incorrect statements or interpretations of regulations can be extremely costly and prejudicial to a company. Therefore the auditor should be fully knowledgeable in the understanding and interpretation of applicable regulations. They should also have excellent communication skills as it is of paramount importance, not only that all observations are well understood, but also that no conflict situations arise in the course of the audit.

Training, Experience, Education, Background Education

Because of the nature of API manufacture, it is recommended for the auditors to have a good educational knowledge of chemistry. Qualifications as Pharmacist, Medical Doctor, Chemical Engineer, graduate or Ph.D. in Chemistry, Biology or related fields as Agrochemistry etc., are appropriate. A good understanding of biochemistry and of analytical techniques and practices is a definite advantage ISO 10011, Part 2 requires at a minimum secondary education. Because GMP

audits may include the in depth review of complex systems/techniques as water systems, impurity profiles, verification of compliance with notified information etc. A higher requirement is given in this guide, corresponding to a minimum of secondary education.

With the exception of Pharmacists whose university courses may include modules on GMP Regulations, a good knowledge of applicable regulations is usually obtained through training and experience.

Training

Training should start with collecting, reading and understanding the applicable GMP (ICH Q7) and other related reference and guidance documents. It is sound practice to participate at regular intervals (e.g. once a year) to recognised seminars and conferences where regulations and trends are explained and interpreted. The auditors should also be trained in auditing techniques including planning, organising, questioning, communicating and reporting. For example, in the APIC Audit Programme, a five day training programme combining GMP knowledge and training in auditing techniques is a pre-requisite for APIC Auditor Certification.

Experience

A career within the Pharmaceutical Industry for example in Production, Technical Support, Quality Control or Quality Assurance may contribute to the appropriate qualification by experience. ISO 10011 requires a minimum of 4 years of practical workplace experience of which 2 year in QA activities. Experience is also obtained through participation to audits, either as auditee, or as coauditor. ISO 10011 requires at a minimum participation to four audits for at least 20 working hours

Mental Stability

Because of the need to obtain the proper information and because of his educational role, the auditor should be able to prevent any conflict situation and to create a positive, constructive environment. The audit should always be conducted in an amiable atmosphere, with tact, honesty, diplomacy and persuasiveness. Therefore the auditor should have a very stable character, be able to restrain himself from emotional, aggressive or discouraging declarations in the course of the audit.

During the audit, the auditor role is to collect the information in an objective manner, keeping the auditee informed as the audit proceeds. In this way serious misunderstandings in the Closing Meeting can be avoided.. In the Closing Meeting or review of Audit Report phase, the auditor should resist to any pressure from the auditee to revise or reclassify the audit findings unless of course a clearly explained error in the accuracy of the findings has occurred and is accepted by the Lead Auditor.

Conflict Situations, Compatibility

Whenever a conflict situation arises, the auditor should never resort to threats, intimidation or strong arm tactics. In most cases, a calm, patient, sympathetic or persuasive attitude will overcome the persons reluctance or hostility. If the above fails, further actions will depend on the nature of the audit.

Social Competence

All auditors (lead auditors and co-auditors) should exhibit a proper social behaviour to ensure no conflict situations or improper attitudes arise in the course of the audit. Auditors shouldrealise the auditees may be stressed and feel challenged or undermined aggressed by the attitude, remarks and comments of the auditors.

There are no educational requirements for social competence. However, management should assess the social behaviour of candidates before nomination as auditor. Unsociable or unstable individuals do not qualify as auditor.

Communication Skills

Because of the key role of an audit for the company, it is of utmost importance that all remarks are well understood and accepted. Therefore, the auditor should, at any time, explain in a didactic manner, why he believes a situation is not acceptable or should be improved. Training in communication skills is a definite requirement for an auditor. It is beneficial if one of the auditors is fluent in the language of the auditee. If this is not possible, then a responsible individual (e.g. the quality assurance manager) should be designated to translate and explain the questions, comments and remarks of the auditor as well as the responses of the auditee. The auditors should try to assess whether or not the translator provides a faithful translation

Flexibility

The GMP reference is given by the ICH Q7 document which is by nature more a « what to do rather than a « how to do » guide. Therefore alternate approaches to reach these standards are permissible, provided they result in the same level of assurance for product quality. The auditor should not impose his solution to a given problem and be receptive to alternate solutions. An auditor should also not expect that all functions are available all the time at the time he dictates. Whenever appropriate, he should outline who and when he expects to see those, in order to create minimum disruption to the auditee's facilities

Requirements for Lead Auditor

The lead auditor takes a key role in the auditing process with a number of tasks and responsibilities. He should:

- Inform the auditees of the purpose of the audit and agree the audit agenda
- ensure that the agreed-upon audit agenda is followed,
- co-ordinate the activities of the other auditors, in particular, when the auditing party subdivides into distinct parties,
- Ensure consistency throughout the audit, e.g. prevent non-productive nick-picking side discussions,
- Consolidate all findings present the audit findings and classification to senior management at the conclusion of the audit because of the possible major consequences of his decisions, the lead auditors must be extremely competent in GMP standards and auditing techniques. As a minimum, he/she should :
- Be independent from production or economic constraints in his role as auditor
- Be recognised as having the required competence by senior management

- Have the required authority to take hard decisions if required by the findings of the audit (in-house audits only)

Types of Audits

The quality audit system mainly classified in three different categories:

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

Quality audits are performed to verify the effectiveness of a quality management system.

Internal Audits

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. Internal audit is a professional activity that consists of advising organizations on how to achieve their goals in a better way. The internal audit involves the use of a systematic methodology to analyze business processes or organizational problems and recommend solutions. The main objectives of internal audits can be summarized as follows:

1. To assist the internal control system.
2. Review of organizational policies and their operations.
3. Verify the accuracy and authenticity of errors and frauds.
4. Detection and prevention of errors and faults.
5. Safeguarding the assets.
6. Applicability of accounting policies.
7. Helps in smooth functioning of the internal check system.

For this purpose, a department-wise questionnaire and document list is required to be prepared in detail.

External Audits

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] Although there are no strict legal requirements for this control. It is always advisable to evaluate the competence of the contractors in which we produce our products or carry out the analysis of our products or any other activity according to GMP. Performing these audits also offers important commercial advantages:

- Develop knowledge and confidence in the partnership agreement
- Ensures that requirements are understood and met
- Allow the reduction of some activities (e. g. in-house quality control (QC) testing of starting materials)
- reduce the risk of failure (and, by implication, its costs)

Many pharmaceutical industry suppliers are ISO 9001 or ISO 9002- certified and are regularly audited by their certification body. Pharmaceutical contract manufacturing or packaging companies will need to be licensed and will be subject to regulatory audits.

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.

International regulatory bodies such as Medicines and healthcare products regulatory agency (MHRA), UK, United States food and drug administration (USFDA), Therapeutic goods administration (TGA), Australia, Medicines control council (MCC), South Africa, etc. Are responsible for carrying out these checks. The company must have representatives from each of the following departments: production, quality control, warehouse, maintenance, administration/personnel and marketing/sales. These audits can be performed without warning (MHRA currently performs around ten percent of its inspections in the UK in this way) as manufacturers are required to always comply with GMPs. Regulatory bodies in other countries where products are sold can also audit companies (e. g. FDA audits European manufacturers) are professionally qualified and have a minimum of five years of appropriate experience in a production operation; they will be in the registers of persons eligible to All regulatory inspectors are extensively trained, competent and professional. All MHRA inspectors act as qualified persons and lead auditors.

Failure to approve a regulatory audit may result in restrictions (or revocation) of production or import/export license. (The FDA has recently imposed "punitive consensus decrees" on financial companies that did not respond adequately to the audit results and comply with the GMPs). Therefore, it is essential that companies have defined processes for managing audits and staff should be adequately trained for being audited. Internal audits can provide valuable opportunities for practice.

Steps in Managing the Audits

Introduction

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. As with most issues involving people, clear and effective communication with the relevant stakeholders is essential if business benefits are to be maximised through strengthening all aspects of the customer/supplier relationship. Issues for remedial action will be a prominent feature of the audit report. If these are ignored the audit will have incurred a significant failure (and lost opportunity) cost to both auditor and auditee.

Pre-audit Information

The collection, collation and analysis of relevant information is an essential prerequisite for successfully planning a quality audit. It is important to clearly establish the reason for performing the audit (e.g. new supplier; outsourcing; defect/recall investigation; routine re-audit; remedial action follow-up; etc.) in order to determine the type, scope and specific objective(s) of the audit. There should also be a clear business benefit to justify the cost, to both auditor and auditee, of undertaking the audit. This may, for example, be to satisfy a regulatory requirement, or to gather information to justify reduced analytical testing upon future receipt of a raw material (Clarification: This in no way absolves the manufacturers (supplier and receiver) from performing all necessary tests prior to release and dispatch).

Experience of previously received product, particularly problem deliveries (in the case of a supplier audit), together

with earlier audit reports (if they exist) can add value to the preparation for a quality audit.

Preparation

Dependant on the scope of the audit the audit team can be composed of one or more auditors. If special expertise is required the team can be expanded by the inclusion of (a) specialist(s). If there is more than one auditor a lead auditor should be assigned and responsibilities should be agreed. It is advisable to interchange auditors from time to time for a given area in internal audits. This will combine the benefits of a detailed understanding of the areas/activities with the broader expertise and experience of different auditors.

Contact with the auditee should be made well in advance of the audit to allow adequate time for the necessary arrangements to be made, and initial information gathering to take place. A Primary Contact within the Quality Assurance department of the Auditee should be defined at the outset for a Customer or Third Party Audit and regulatory inspection. The lead auditor or Inspector will then be in direct communication to make the necessary arrangements and agree the agenda in advance of the audit.

When a pre-audit questionnaire (appendix B) is used, and this is strongly advised, responses should be studied carefully by all relevant stakeholders, and clarification requested as appropriate. This will allow the audit proper to concentrate on areas of uncertainty and/or perceived weakness thereby saving time and reducing inconvenience, to the benefit of both auditor and auditee. Previous audit reports are another valuable source of information.

Similarly, discussing experiences, good and bad, with recipients (e.g. internal customers in the case of an internal audit; your raw materials testing laboratory in the case of an external raw materials supplier audit) can provide useful information such as batch/lot numbers for challenging traceability etc.

The agenda for the audit should be communicated to, and agreed with, the auditee. This could also identify key reference documents (e.g. GMP; Quality Manual, etc.) and relevant working documents such as checklist(s), etc. to be used during the audit. The auditor should be aware of any sensitive issues, for example Highly Confidential information and, should any conflict arise during the audit, the auditor should take care to handle the issues in a way that will not jeopardise the relationship with the auditee.

Performing the Audit

The audit should commence with an opening meeting to introduce auditor(s) to relevant auditee staff and Senior Management Representatives (especially relevant for an external audit or inspection); review scope and objectives, and finalise and agree the agenda and timetable. The opening meeting also provides an opportunity to explain the audit rationale, clarify the audit plan, agree communication channels and clarify ambiguous replies in the pre-audit questionnaire.In the case of an external audit the opening meeting also provides an ideal opportunity for the auditee to explain Company rules concerning e.g. safety, taking photographs, confidentiality of information, taking samples, talking with operators, making recordings, etc. The auditor should decide in advance whether to use a detailed checklist or (less detailed) 'Aide Mémoire' (see annex 2), or simply rely on memory and experience. If the former, then it is a courtesy to explain this approach to the auditee. The Aide Memoire has the advantage of maintaining focus by providing structure to the questioning sequence and ensuring that all listed issues are covered. However the auditors should feel free to spend more time on specific topics where compliance issues are becoming apparent and so should used the Aide Memoire as a guide from which the auditors can deviate if a concern arises over an issue not covered by the checklist.

During the audit it is usual to walk through relevant parts of the facility to observe the operation at first hand, to gather information, to assess the cleanliness and condition of facilities and the risk of potential contamination. Some auditors prefer to undertake a brief 'tour', following the introductory meeting, in order to familiarise themselves with the size and complexity of the operation and achieve a clearer understanding of workflow and relative location of different activities. They may subsequently re-visit relevant areas to review GMP/systems compliance in greater detail. During the audit evidence of compliance, or otherwise, will be obtained through observation, questioning, examining documentation and records, and challenging issues of concern. All relevant observations should be recorded clearly and concisely together with supporting evidence. Concerns should be discussed with the auditee as they arise to avoid surprises in the Closing Meeting. The closing meeting is particularly important since it allows the auditor (or audit team) to communicate the audit findings and conclusions in a logical and co-ordinated manner to the auditee's management. It is, therefore, useful to provide a simple agenda and a short written summary of observations. It is important to emphasise the good news as well as highlight the areas for improvement together with supporting evidence. Audit deficiencies should also be classified to highlight the priority for actions to the auditee and their Senior Management.

The Audit Report Template (Appendix D) includes a Classification definition based on the EU GMP Inspection Report Format and this is used as standard in the APIC Audit Programme.

Deficiencies are classified as follows

1. Product Quality / Patient Safety Related deficiency (Critical)
2. Significant cGMP Deficiency but with no direct impact on Product Quality /Patient Safety (Major)
3. GMP deficiencies that are either considered to be minor isolated examples or there is insufficient information to classify them as Major (Other)

As stated above, the deficiencies should contain no surprises for the auditee, as all concerns should have been raised during the audit. The auditee should be given the opportunity to clarify and fully understand the evidence for the deficiencies. In this way there will be an acceptance of the findings and the auditee can then plan to fully address the audit findings rather than replay the audit. While it is the auditors role to identify what needs to be achieved when a problem is identified, in the case of Second or Third Party Audits he/she should not be prescriptive in 'how' to achieve it, although advice may be offered, if specifically requested.

Reporting the Audit and Auditee Response

The single most important product of an audit is the audit report. It provides a record which identifies and may be useful for prioritising (e.g. Critical, Major, Other) areas for improvement. The audit report should be drafted, and the final version issued, as soon as possible after completion of the audit for reasons of both accuracy and effectiveness.

Suggested timings are within a maximum of 3 weeks. It is recommended that a draft of the report be supplied to the auditee for comment and check on the factual accuracy and to avoid misunderstandings arising over observations and recommendations.

Confidentiality of internal audit reports are subject to company policy. These reports are normally not made available to external auditors and inspectors from regulatory authorities. Follow Up Of **Progress with Remedial Actions**

The timely implementation of corrective actions, and verification of their effectiveness, is essential to the concept of continuous improvement. The efficiency and comprehensiveness with which agreed remedial actions are progressed is often a good reflection of the auditee management's true commitment to quality. While minor remedial actions may be followed up at the next routine audit, progress with major issues should be reported within an agreed timeframe. It may also be necessary to re-audit to ensure that serious remedial action hasbeen satisfactorily completed for Critical or Major deficiencies.

Failure of the auditee to actively progress major and/or serious actions should be referred to senior management (in both companies in the case of an external audit). Responsibility for Follow Up and to decide timing of next audit lies with the customer or stakeholder responsible for initiating the audit and specifically with the QP of The Manufacturing Authorisation Holder for Human and Veterinary Medicinal Products in the case that the audit is done as part of ensuring effective GMP Compliance for Active Substances used in the manufacture of Medicinal Products in Europe.

Possible Audit Breakdown

The breakdown of an audit should be an exceptionally rare occurrence. However, it may be the result of poor planning/preparation, failure to clearly define and agree scope and objectives, an inadequately trained auditor or one lacking the appropriate personal characteristics, poor communication before and during the audit; and/or lack of commitment/co-operation/understanding on the part of the auditee. In such circumstances the scope for action to improve the situation is usually limited to either trying to identify and resolve the root cause (usually with the help of senior management) and endeavouring to continue with the audit or, as a final resort, to abort the audit.

The Audit Plan

The auditor should develop an audit plan for the audit in order to reduce audit risk to an acceptably low level. The audit plan is more detailed than the overall audit strategy and includes the nature, timing, and extent of audit procedures to be performed by engagement team members in order to obtain sufficient appropriate audit evidence to reduce audit risk to an acceptably low level. Documentation of the audit plan also serves as a record of the proper planning and performance of the audit procedures that can be reviewed and approved prior to the performance of further audit procedures.

Planning objectives

"The objective of the auditor is to plan the audit so that it will be performed in an effective manner." Audits are potentially complex, risky and expensive processes. Although firms have internal manuals and standardized procedures, it is vital that engagements are planned to ensure that the auditor:

- Devotes appropriate attention to important areas of the audit;
- Identifies and resolves potential problems on a timely basis;
- Organizes and manages the audit so that it is performed in an effective and efficient manner;
- Selects team members with appropriate capabilities and competencies;
- Directs and supervises the team and reviews their work; and Effectively coordinates the work of others, such as experts and internal audit.

The purpose of all this is to ensure that the risk of performing a poor quality audit (and ultimately giving an inappropriate audit opinion) is reduced to an acceptable level.

The steps in planning an audit include (Planning Procedures 1.):

1. Basic discussions with the client about the nature of the engagement are performed first, and the auditor meets the key employees or new employees of a continuing client. The overall audit strategy or the timing of the audit may also be discussed.
2. Review of audit documentation from previous audits performed by the accounting firm or a predecessor auditor (if the latter makes these audit documentation available) will assist in developing an outline of the audit program.
3. Ask about recent developments in the company such as mergers and new product lines which will cause the audit to differ from earlier years.
4. Interim financial statements are analyzed to identify accounts and transactions that differ from expectations (based on factors such as budgets or prior periods). The performance of such analytical procedures is mandatory in the planning of an audit to identify accounts that may be misstated and that deserve special emphasis in the audit program.
5. Non-audit personnel. of the accounting firm who have provided services (such as tax preparation) to the client should be identified and consulted to learn more about the client.
6. Staffing. for the audit should be determined and a meeting held to discuss the engagement.
7. Timing. of the various audit procedures should be determined .
8. Outside assistance needs should be determined, including the use of a specialist as required and the determination of the extent of involvement of the internal auditors of the client.
9. Pronouncement. on accounting principles and audit guides should be read or reviewed to assist in the development of complete audit programs fitting the unique needs of the industry.

10. Scheduling with the client is needed to coordinat activities.

CONCLUSION

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. 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.

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