International Journal of Pharmaceutical Research and Applications
Volume 9, Issue 4 July-Aug 2024, pp: 1524-1533 www.ijprajournal.com ISSN: 2456-4494

Exploring Auditing Practices in Pharmaceutical Microbiology Laboratories: An Overview

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Date of Submission: 15-08-2024 Date of Acceptance: 25-08-2024

ABSTRACT: This comprehensive review looks at the development and important aspects of auditing procedures in laboratories that study pharmaceutical microbiology. It begins by tracing the historical development of auditing from the 1950s, highlighting the initial implementation of quality control measures designed to ensure the accuracy and reliability of microbiological testing. The review underscores the significance of regulatory guidelines introduced in the 1970s and 1980s, along with the significant impact of ISO 9001:2000 quality management systems in the 1990s, which brought auditing to the forefront of quality assurance. The paper delves into various types of audits—internal, external, and regulatory—emphasizing their objectives and principles and discusses the skills and responsibilities of an auditor, along with a detailed explanation of steps or processes performed while auditing. The review identifies key challenges in auditing these laboratories including navigating regulatory complexity, documentation, addressing technical complexity, conducting audit follow-up, maintaining laboratory practices, risk management, and ensuring personnel competency. It also discusses modern advancements in microbiology laboratories, such as automation, biosensors, microbial colony assessment, Surface-Enhanced Raman Spectroscopy (SERS), Laboratory Information Management Systems (LIMS), and artificial intelligence. Through this analysis, the paper provides a comprehensive understanding of the evolving landscape of pharmaceutical microbiology laboratory audits and their critical role in maintaining compliance with current Good Manufacturing Practices (cGMP).

KEYWORDS: Internal audits, External audits, Auditing practices, Regulatory guidelines, Quality management systems, current Good Manufacturing Practices (cGMP), Automation.

I. INTRODUCTION:

Definition of Audit: An impartial, methodical assessment known as a pharmaceutical quality audit will help you determine whether the operations your business conducts adhere to accepted industry standards.

Audits are carried out to determine the data's validity and reliability and evaluate a system's internal oversight. It gives management data on the effectiveness with which the pharmaceutical industry controls the quality of its production methods and products. The audit's findings and the corrective measures ensure that all the concerned parties know that the program works according to established rules of practice. Audits are a virtual tool used in the pharmaceutical industry to assess compliance with the objectives specified in the quality system. Thus, paving the way for continuous improvement by providing feedback to management. To understand the concept of auditing, let's study various insights into it.

Key elements of auditing: The key elements that should be kept in mind while using the term audit are that:

a. It must be systematically conducted and must be carried out by a third party who is not involved in the operations.
b. Auditing must be documented.
c. To support the audit's findings, evidence must exist.
d. The auditor must determine the degree to which the audit requirements have been met (mostly complying with Current Good Manufacturing Practices.

The audit is defined as a systematic, in-depth examination of any department that provides manufacturing or support services to a

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Volume 9, Issue 4 July-Aug 2024, pp: 1524-1533 www.ijprajournal.com ISSN: 2456-4494

pharmaceutical manufacturing company to ensure compliance with the Current Good Manufacturing Practice (cGMP). [1,2] Medical device makers are required under the Quality System Regulation (21 Code of Federal Regulations (CFR) Part 820) to carry out audits to confirm that the quality system is compliant (Section 820.22). General requirements for routine review of quality standards are included in the current good manufacturing practice (cGMP) regulations for pharmaceuticals (21 CFR Parts 210– 211) and blood and blood components (21 CFR Part 606). [3]

Objectives of an Audit: The main objectives of auditing are as follows:

- To determine conformity and non- conformity of the quality system i.e. assessing conformity with ISO 9001 [4]
- Evaluating conformity of implementation to documentation
- To determine the degree of effectiveness of the implemented system in meeting specified quality objectives
- Providing an opportunity for improvement in the quality management system
- To provide managers with information

Principles of Auditing:

i. **Integrity:** Maintain fairness, honesty, and accountability when running audits and managing audit programs.
ii. **Fair presentation:** Deliver audit findings and conclusions with correctness, completeness, timeliness, objectivity, and integrity.
iii. **Professional care:** Use reasonable judgment and due diligence in every audit circumstance.
iv. **Confidentiality:** Protect audit information sources, especially those that are private or sensitive.
v. **Independence:** Throughout the audit process, make careful judgments that are fair and without bias.
vi. **Evidence-based methodology:** Base the audit findings and recommendations on verified data and adequate sample sizes.
vii. **Risk-based methodology:** Utilize risk-based strategy by incorporating opportunities and hazards throughout every stage of the audit process, from planning to communication. [5,6]

Various types of Audits: Auditing is studied under three main categories:

i. Internal Audits
ii. External Audits
iii. Regulatory Audits

i. **Internal Audits:** They are also sometimes referred to as First-Party Audit or Self-Audit. From the name only we can understand that in this type of audit, an organization's auditing is conducted by a professional working in that same organization. Internal auditing is a profession that involves giving organizations advice on how to more effectively accomplish their objectives. Internal audit is a methodical approach to evaluate organizational issues or business operations and make recommendations accordingly to resolve them.

ii. **External Audits:** These are also referred to as Second-Party Audit. This type of audit is conducted by someone who does not belong to that organization. Most often, an audit of a contractor or supplier is carried out by a customer. It is always advisable to assess the skills of the contractors we use to make our products, analyze those products, or do any other GMP-compliant activity.

iii. **Regulatory Audits:** These are also referred to as Third-Party Audit. It is conducted by an audit inspector who is appointed by a regulatory agency or independent body for compliance or certificate or registration of the organization. The term auditor is used for the person who is auditing while the one whose organization is being audited is referred to as auditee. This audit can be conducted without the manufacturer's prior knowledge as they must always comply with GMPs. These checks are carried out by regulatory authorities named as Pharmaceutical Inspection Convention (PIC). [7,8,9]

Skills required by auditors: Microbiology expertise and specialized training are required for auditors. The functions that auditors are auditing should not affect them in any way. A good auditor will make sure their questions are addressed and that they fully comprehend the situation before assessing what they have heard and observed. They

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are persistent without being harsh. Some skills needed to be a good auditor are:

- **Fairness:** The very first and most important quality that a good auditor must possess is being unbiased.
- **Technical expertise:** The auditor must have a good technical knowledge of the areas to be audited.
- **Effective interviewing and questioning techniques:** The auditor must prepare a good questionnaire to get a fruitful result of auditing the particular area.
- **In-depth knowledge of Good Manufacturing Practices:** One of the basic skills required for auditing is knowledge of Good Manufacturing Practices.
- **Confidentiality:** The auditor must never disclose the privacy of an organization. [10,11]
- **Communication:** Strong questioning and interviewing skills.
- **Considerate areas:** In addition to searching for flaws, auditors ought to draw attention to the area's positive points.

Figure 1: Process of Gathering Audit Evidence

Responsibilities of an auditor: So far, we have understood how important an auditor is for an organization, as he/she manages the quality of an organization. To maintain such type of standard quality, one has to understand and follow the responsibilities of an auditor, which are as follows:

- Help in selecting the team and keeping them informed
- Planning and supervising every stage of the audit
- Introducing the auditee to the audit team
- Handling disagreements and tough circumstances
- Deciding audit-related matters and the quality system
- Reporting audit findings without delay
- Identifying and reporting major issues
- Reporting of critical non-conformance as soon as possible
- Possessing effective communication skills

Procedure for conducting audit: 10 steps are followed to perform an effective audit. [12] These audit processes are listed below:

i. **Notification:** The first and foremost step in the audit process begins with notifying the organization to be audited about the date and time of the process. This notification also includes the documents to be reviewed for a better understanding of the organization.
ii. **Planning:** The planning is done before auditing and focuses on the skills of the

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auditor to plan out the audit. It is done to pinpoint key areas of risk and concerns.

iii. **Opening meeting:** The meeting is done among auditing staff, senior management of the respective auditing target, and administrative staff. This meeting is done to discuss and propose the auditing process that the auditor will undertake. Also, the management will outline their areas of concern as well as the schedule of the employees who must be conducted.

iv. **Fieldwork:** Fieldwork is conducted on the scheduled day and the employees are informed about the audit. [13] Investigation begins and key employees are interviewed, sample testing, examining the law, and to determine if the internal policies and procedures are fair.

v. **Communication:** Good communication should be built with the audit team to avoid any kind of misunderstanding during the auditing process. The corporate auditor of the organization and the audit team should communicate regularly to acquire access to records, explain procedures, and clarify processes.

vi. **Draft audit:** Following the completion of the fieldwork at the organization, a draft of the audit is prepared. This draft audit contains details of issues found, a distribution list for parties to get preliminary results, and an explanation of what was done and discovered.

vii. **Management response:** The prepared draft is given to the management of the organization to review, edit, and suggest changes to concerning areas specified in the draft audit and also to rectify the errors. In response to the report, management is asked if they agree with the issues documented in the draft, the plan of work as to how they are going to correct the issues, and the expected date by which all the problems will have been addressed. [14,15]

viii. **Final meeting:** The purpose of this final meeting is to close loose ends, to have a discussion on the management response to the draft audit, and to address the scope of the audit.

ix. **Report distribution:** This step involves sending the complete audit report to the relevant authorities including both inside and outside the audit region.

x. **Feedback:** This is the last step and involves audit feedback whereby the audited organization puts the recommended changes into practice while the auditors evaluate and assess the effectiveness, consistency, and quality of the adopted changes. This process continues until issues are adopted and the next audit cycle begins.

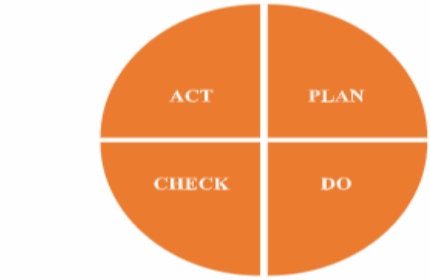

Figure 2: Managing Audit Program

Benefits of auditing and compliance:

To ensure the quality, safety, and efficacy of pharmaceuticals, the pharmaceutical business relies heavily on auditing and compliance. Frequent audits lower the risk of product recalls and protect patient health by assisting in the identification and correction of possible problems in manufacturing processes. Adhering to regulatory norms cultivates confidence among regulatory agencies, medical practitioners, and patients, thus augmenting the organization's standing and appeal. A strong auditing system can also result in cost savings, operational efficiencies, and the avoidance of legal problems, all of which contribute to the pharmaceutical company's overall success and sustainability. Some benefits are enlisted below: [16-19]

- **Respect for set guidelines**: adhering to guidelines will result in a product with fewer defects, which will raise customer compliance with the product on the market and boost the company's revenues.
- **Employee satisfaction:** A rise in staff satisfaction
- **Auditor independence:** An unbiased decision would be made by the independent person conducting the audit.
- **Assessment of compliance:** Measuring the degree of adherence to the standards is

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Volume 9, Issue 4 July-Aug 2024, pp: 1524-1533 www.ijprajournal.com ISSN: 2456-4494

important and plays a key role in an organization's ongoing development.

- **Verifying risk assessment models**: Risk assessment is essential for maintaining any facility, and audits offer an opportunity to verify the risk assessment models that a business is using.
- **Identifying emergent issues**: If a new issue arises, it may be resolved right away before it gets out of hand. [20]

Historical Overview of Auditing in Microbiological Laboratories:

Auditing in microbiological laboratories has a rich history dating back to the 1950s and 1960s. During this era, quality control measures were initially implemented to ensure the accuracy and reliability of microbiological testing. As the critical role of microbiological testing in public health and pharmaceuticals became more recognized, the need for robust auditing as a quality control measure became increasingly evident.

In the 1970s and 1980s, the introduction of regulatory guidelines and standards highlighted the essential role of auditing in microbiological laboratories. This period saw the establishment of protocols and frameworks that laboratories had to adhere to, ensuring consistent and reliable testing outcomes. The advent of ISO 9001:2000 quality management systems in the 1990s further underscored the importance of auditing in quality control and assurance, focusing on the accuracy, reliability, and safety of microbiological testing processes. The evolution of auditing practices has continued with advancements in technology and the increasing complexity of regulatory environments. Modern auditing now integrates digital tools and data analytics to enhance the precision and efficiency of audits. There is a growing emphasis on continuous improvement and risk-based auditing approaches, which aim to proactively identify and mitigate potential issues before they impact laboratory outcomes. The ongoing development of international standards and best practices ensures that auditing remains a dynamic and integral part of maintaining high-quality microbiological testing in laboratories worldwide. [21,22]

Pharmaceutical Microbiology Laboratory:

Pharmaceutical Microbiology deals with the study of particular microorganisms associated with the development, production, scale-up, and manufacture of pharmaceuticals, as well as the subsequent reduction or elimination of several microorganisms in the constituent environment. A crucial aspect of quality control in the pharmaceutical manufacturing process is the removal of microorganisms and microbial by-products, such as endotoxin and exotoxin, from water and other starting materials to guarantee the sterility of the final pharmaceutical products.

The research and development of anti-infective agents, the use of microorganisms to identify potential drug mutagenic and carcinogenic activity, and the use of microorganisms in the production of pharmaceuticals like insulin and human growth hormone are additional facets of pharmaceutical microbiology. [23,24]

Auditing of the pharmaceutical microbiology laboratory:

Till now we understood the concept of auditing and the different aspects related to this term. This part of the study will deal with the application of auditing performed in the microbiology laboratory. Below are the points one must focus on before auditing a microbiology laboratory.

i. Personnel:

The laboratory must have a sufficient number of trained staff. Written procedures must be available defining the training of microbiological staff in both cGMPs and microbiological techniques. This also includes regular laboratory procedures entering cleanrooms and collecting samples for environmental monitoring. A training procedure, strategy, and training records for every employee should be available from the laboratory.

ii. Laboratory layout and flow of sample:

It is implied in the current GMP rules that microbiological laboratories must be large enough to accommodate all of their operations. This must address all facets of sample handling and storage, as well as specific testing spaces for various materials and media handling, incubation, and preparation of microbiological cultures as well as the removal and disposal of biohazardous waste. Certain tasks, such as the identification of microbes, endotoxin testing, and interpreting environmental monitoring sample data, might need to be done in designated spaces. Testing for sterility must always be done in a specially designated testing facility. Along with good premise area design, auditors expect to see a logical flow of samples through the testing procedure and sufficient control to guard against unintentional contamination of the samples and activities.

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iii. Handling of the sample:

The auditor's responsibility is to closely examine the sample receipt, handling, storage, and documentation. Sample labels must be checked for identity, source, quantity, batch number, or other unique code. The auditing procedure must confirm that the numerous microbiological samples have expiration dates and rigorous storage guidelines. There might be more paperwork available to specify the tests that need to be run on the sample, the storage circumstances, the deadline for finishing the tests, or other details.

iv. The culture media:

The quality of the culture media determines the quality of work produced in the microbiology laboratory. As such, quality assurance and media preparation are crucial components and are critical areas to be audited. As is customary in laboratories, when it comes to media, reagents, chemicals, and other procedures outlining reception, preparation, labeling, storage, and usage must be in place before accessing the microbiological laboratory.

A complete batch record or recorded history of the process must be available in the case of media culture. This should contain information about the media batch that was used, the type of water that was used, the responsible analyst, weight records, autoclave cycle records, pH adjustments (including the use of a pH meter), growth promotion (if applicable), and the batch number. [25,26] It is anticipated that every medium or reagent sterilization procedure will be thoroughly validated. If the media was obtained outside, a certification about these specifications needs to be on hand.

v. Maintenance of reference media:

Microbial cultures, biological indicators, endotoxin standards, and antibiotic standards are examples of microbiological reference standards. There must be controls on the receiving, storage, preparation, and usage of each of these standards. These standards typically come with a certificate of analysis, which needs to be examined.

vi. Maintenance of stock cultures:

One of the most often used standards in microbiology labs is microorganisms. Stock cultures need to be managed and kept in check. To protect their purity and identity, cultures should be managed from the moment they are received until they are used and stored.

The preparation, handling, and storage of cultures will be examined during an audit. This has to do with worries about misidentification and the possibility of viability loss due to improper storage. There should be no more than five transfers (passages) from the original culture for long-term storage. [27] This is required to prevent phenotypic variations.

vii. Record keeping and documentation:

A paper-based or electronic (Laboratory Information Management System, or LIMS) system may be used for the actual control and information regarding sample handling. If the system is electronic, it must make sure that all applicable system validation requirements are satisfied. The audit trail and password access must be the auditor's main concerns.

Laboratory notebooks, equipment files, and log books will all be inspected. Training files are a relevant and significant category of documentation. These are always requested during an audit, and each employee of the microbiology lab must be able to provide proof that they have received the necessary training and evaluation for the duties they perform regularly.

viii. Equipment used:

The result of test data in a microbiology laboratory depends upon the performance of the instrumentation used like incubator, autoclave, etc. All equipment should have an inventory that includes information on the type of instrument, its serial number when it was first brought into the lab, the calibration and validation procedures, and a schedule for preventive maintenance. It is intended that in the laboratory, the instrument's condition must be confirmed by labeling whether it is in calibration or maintenance. Every piece of equipment must have a log book that details the samples tested on or with it, the maintenance that was done, and other details. Investigating after an instrument or sample failure can benefit from this. Calibration certifications are frequently requested by auditors; therefore, they must be thoroughly examined and authorized.

Different kinds of equipment need different amounts of calibration and validation. The criticality of the instrument decides this along with a URS (User Requirements Specifications) assessment. [28,29] Temperature mapping is crucial for equipment like water baths, incubators, and refrigerators, both during qualification and regular maintenance. Temperature probes and

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operating thermometers can be traced back to national standards.

ix. Sanitization:

Cleaning and disinfecting the space and its furnishings is one method to prevent cross-contamination. Additionally, the media preparation space in the laboratory, if it exists, needs to be kept in good condition. Among the tools needed for media preparation are spatulas, glassware, weighing, and mixing containers. Such components should have written, verified protocols for storage and cleaning.

x. Testing of microbial limits:

When it comes to auditing, the auditor must look over the following aspects:

- Development or growth promotion and suitability using <100cfu of each organism as an inocula level. [29]
- Need to compare the results to the previous batch of media
- Addition of 'nutritive' and 'selective' media, which means that the media must show that it not only recovers the target organism but also inhibits other organisms
- Enrichment schemes, such as using soybean-casein media instead of lactose broth for testing Salmonella and Escherichia coli
- Are the test organisms incubated at the proper temperature?

xi. Sterility testing:

The sterility test validation procedure must be examined in detail by the auditor during an audit. Since it is anticipated that the testing facility will be of a caliber comparable to that of the product's manufacturing facility, it is expected to be closely examined. Consequently, Personnel and material flows must be specified for the production of sterile goods, and the test should be carried out in isolators or cleanrooms under unidirectional circumstances. The methods used to move media, test equipment, and samples into the testing environment must be evaluated by auditors. The findings of test controls, sterility test failures, and environmental monitoring should also be reviewed by auditors. Each of these reports provides some information regarding the condition of the test environment. Media made up of different non-sterile items, such as blood, serum, glucose, antibiotics, or any other non-filterable or heat-labile substance solutions that could then need to be dispensed aseptically, would necessitate stringent sterility control to the extent that the entire batch is incubated for three days; if identified. If contamination is more than 10%, the entire batch needs to be thrown away. [29,30]

xii. Antibiotic assays and efficacy test of preservatives:

Routine testing requires validation of neutralization when preservatives are used in pharmaceutical preparations. Testing the preservative system's efficacy as part of stability and product development initiatives can be necessary.

Written protocols should be followed while doing antibiotic testing. During an audit, specific requirements would be examined, including medium preparation, temperature control, assay technique and reference standard control, concentration, and material amounts utilized. It would be necessary to have a solid understanding of the computations used to determine potency. To merely enter the data into a computer program and accept the outcome without understanding the context of the review process is insufficient for the analyst.

Advancement in microbiology laboratory:

Technological advancements in the microbiology lab can automate workflows to manage complex tests, execute numerous workflows concurrently, and shorten the most laborious steps, such as sample preparation. Automation is a stepping stone towards development in microbiology labs. [32] The five key opportunistic areas for automation are as follows:

i. Usage of Biosensors which are compact, miniaturized platforms based on chips that can be used to detect various organisms instantly and evaluate their interactions with various substances using small quantities of analytes.
ii. Evaluating microbial colonies is a tedious and time-consuming procedure. Several methods, such as digital photography of cellular autofluorescence to identify and count developing microcolonies and the application of light forward-scattering and learning algorithms, are aimed at enabling a quicker reading of agar plates. An alternate choice is the variety of automated colony counting available technologies while advancements such as hyperspectral imaging technology have made gains in those areas where some of the devices have

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had difficulty reliably counting mixed cultures.

iii. Surface-Enhanced Raman Spectroscopy (SERS) study is of great importance for future advances in identification technology. With the help of this type of Raman Spectroscopy, which works by passing light through a sample to see how it scatters, recent developments indicate that the accuracy of different bacteria in different conditions classification can reach up to 98%.

iv. Tools like LIMS (Laboratory Information Management Systems) are utilized to decrease data mistakes and accelerate the analysis process. LIMS technology needs to be improved to take into account improvements in laboratory analytical tools and to allow for the extraction of more comprehensive insights from data. This next-generation LIMS is compatible with a wide range of laboratory automation components, such as robotic arms, automatic control units, sensors, and high-definition cameras.

v. Artificial intelligence, or AI, can examine large amounts of data and identify trends and revelations that could advance knowledge. Two AI-based Software-as-a-Service (SaaS) programs, Glooko and OsteoDetect, which use artificial intelligence to offer digital pathology systems and outcome predictions, have received FDA approval.

Challenges during auditing of pharmaceutical microbiological laboratories: [33,34]

Table 1 describes various types of challenges that are faced during the auditing of any pharmaceutical microbiological laboratories.

Table 1: Key Challenges in Auditing Pharmaceutical Microbiological Laboratories

S. No.	Challenges	Descriptions
1.	Regulatory Complexity	-Evolving Regulations: Keeping up with changing regulations from different bodies (FDA, EMA, WHO, etc.)
2.	Documentation and Record-Keeping	-Volume of Documents: Managing and reviewing large volumes of documentation (SOPs, reports, records)
3.	Technical Complexity	-Specialized Knowledge: Deep understanding of microbiological testing methods and equipment
4.	Audit Follow-Up	-Corrective Actions: Ensuring identified issues are addressed with

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Volume 9, Issue 4 July-Aug 2024, pp: 1524-1533 www.ijprajournal.com ISSN: 2456-4494

		appropriate corrective and preventive actions (CAPA)
5.	Laboratory Practices	-Inconsistent Practices: Variability in lab practices can complicate auditing
6.	Risk Management	-Risk-Based Approach: Implementing a risk-based approach to identify and prioritize high-risk areas
7.	Personnel Competency	-Training and Competency: Evaluating training programs and staff competency -Staff Turnover: High turnover can lead to inconsistencies in training and practices.

III. CONCLUSION

Auditing pharmaceutical microbiology laboratories is a multifaceted process essential for maintaining the integrity, accuracy, and reliability of microbiological testing. This review highlights the historical progression of auditing practices, the implementation of stringent regulatory standards, and the significant advancements in technology that have shaped current auditing methodologies. Despite the challenges posed by regulatory complexities, extensive documentation, technical intricacies, and the need for ongoing personnel training, effective audits are crucial for identifying non-conformities and driving continuous improvement in laboratory practices. The integration of advanced technologies such as automation, AI, and enhanced data management systems promises to streamline audits and enhance their effectiveness. Ultimately, robust auditing frameworks are vital for ensuring that pharmaceutical products meet stringent safety and quality standards, thereby safeguarding public health and maintaining regulatory compliance. This review underscores the necessity of adaptive and forward-thinking auditing strategies to address the dynamic challenges in pharmaceutical microbiology laboratories.

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