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Importance of Quality in Pharmaceutical Industry: A Review

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In the pharmaceutical industry, "quality" refers to how well a drug substance or product fulfill its inherent features and is suitable for its intended use. Important characteristics including the drug's identification, potency, and purity are included in this brief overview.

A drug's quality is essential to both patient safety as well as effective therapy. A drug may be harmful to patients if it is contaminated or not pure. In the same way, a medication may not work as intended to treat a problem if it is not effective enough.

Quality comprises with Quality Assurance and Quality Control Department.

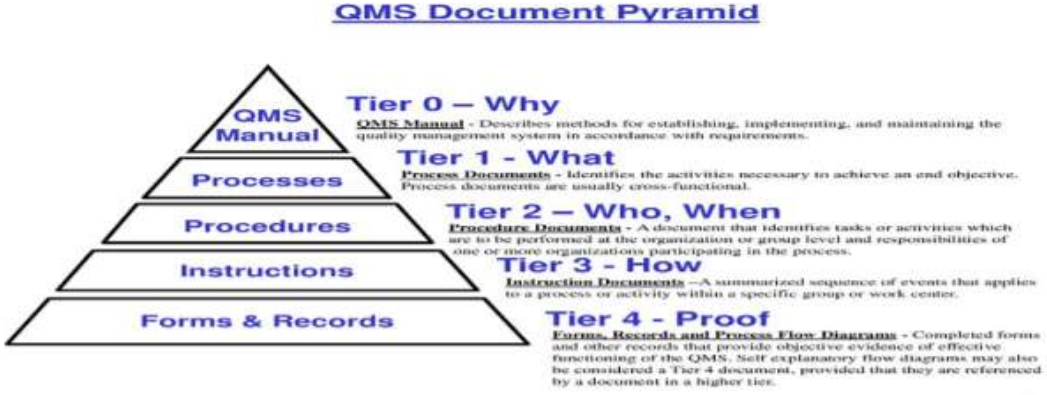
Quality Assurance: QA focuses on establishing and maintaining a robust system of processes, documentation, and standards to prevent quality issues in the first place. It encompasses not only product quality but also the quality of the entire pharmaceutical manufacturing and distribution process.

Quality control:QC involves systematically examining and testing pharmaceutical products at various stages of production to identify and rectify defects or variations. It ensures that each product meets the specified quality standards before reaching the market, safeguarding patient safety.

QA and QC are indispensable for ensuring pharmaceuticals' safety, efficacy, and consistency.

The quality documents:

The quality documents consist of Company policies, quality management plan, SOPs, working instructions, conventions, guidelines, forms, templates, logs, tags and labels. They are established by consensus and approved by a nominated body, and they provide for common and repeated use, rules, guidelines or characteristics for activities or their results with a view to promote transparency, consistency, reproducibility, interchangeability and to facilitate communication. The hierarchy and types of quality documents relevant to quality systems will depend upon Company business objectives and business model. SOPs are Level 2 quality documents and, along with other relevant quality documents, ensure the effectiveness and efficiency of quality systems.



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Pharmaceutical Quality Management System:

The goal of the Pharmaceutical Quality Management System (QMS) is to guarantee and uphold consistent and superior quality in the manufacturing of pharmaceutical products through an all-encompassing set of guidelines, protocols, and practices.

The pharmaceutical company's specific needs as well as any applicable legal obligations must be reflected in the QMS. Pharmaceuticals may reduce risks, boost customer happiness, and accelerate quality procedures by implementing a strong Pharmaceutical Quality System (PQS) that complies with current regulation.

The pharmaceutical quality management system includes several processes, such as

- Training management
- Document management
- Change control
- Audit management
- Deviation management
- CAPA management
- Validation

The quality system sets a strong emphasis on quality system documentation to keep track of all issues and their solutions. It employs monitoring techniques like quality assurance to prevent quality deviations.

The following is an outline of the most prevalent rules and guidelines that apply to the pharmaceutical QMS:

1) International Organization for Standardization (ISO)
2) Pharmaceutical Inspection Co-operation Scheme (PIC/S)
3) ICH Guideline Q10
4) 21 CFR Part 11

1) **International Organization for Standardization (ISO)**

The ISO is an International Organisation that creates standards for a variety of industries, including the pharmaceutical industry. ISO 9001:2015, which was previously known as ISO 9001:2005, is the current standard for Quality Management Systems (QMS) and is used by some pharmaceutical companies to ensure that their QMS meets quality requirements and improves performance.

2) **Pharmaceutical Inspection Co-operation Scheme (PIC/S)**

In the area of Good Manufacturing Practice (GMP) for pharmaceutical goods intended for human or veterinary use, international regulatory authorities have an informal, non-binding agreement known as the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

A pharmaceutical quality management system is one of the standards for pharmaceutical companies that are outlined in guide documents published by the PIC/S, such as the PIC/S GMP Guides.

PIC/S GMP standards are used by pharmaceutical companies to offer a framework for manufacturing processes, control systems, and quality management systems that guarantee the safety, efficacy and high quality of products.

The guides cover various aspects of GMP compliance, such as:

- Premises and equipment
- Personnel
- Documentation
- Quality control
- Complaints and product recall
- Self-inspection

3) ICH Guideline Q10

According to Swiss law, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a non-profit organisation. It seeks to harmonise pharmaceutical needs more globally. The Quality criteria are denoted by the combination of the letter Q and particular numbers, such Q8, Q9, and so on. The Pharmaceutical Quality System is governed by the Q10 guidelines.

It provides a unified framework for the quality processes based on accepted norms, laws, and regulations, such as ICH Q8 (Pharmaceutical Development & ICH Q9 (Quality Risk Management), etc.

4) 21 CFR Part 11

In order to verify compliance with regulatory requirements and quality control measures, a pharmaceutical company's processes, procedures, and systems are systematically examined through a quality audit. These audits are essential for evaluating and improving the quality and safety of pharmaceutical products. They encompass various aspects, such as

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- Good Manufacturing Practices (GMP)
- Good Laboratory Practices (GLP)
- Good Clinical Practices (GCP)

Types of Audits in the Pharmaceutical Industry

The Pharmaceutical Industry conducts various types of audits to improve the quality aspect and subsequently implements an ongoing improvement approach as follow:

GMP Audits: Pharmaceutical product quality is dependent on manufacturing procedures according to Good Manufacturing Practices standards, which are made ensured of by these audits.

GLP Audits: Pharmaceutical research and development depends on Good Laboratory Practices audits to make sure that laboratory activities adhere to defined protocols and maintain data integrity.

GCP Audits: Good Clinical Practices audits are essential for clinical trials for ensuring patient safety, data accuracy, and regulatory compliance.

Vendor Audits: These audits evaluate the quality of components and raw materials given to pharmaceutical companies.

Regulatory Audits: To make sure companies are adhering to legal standards, regulatory bodies like the FDA conduct audits. They scrutinise each and every step of the manufacturing process of pharmaceuticals.

Essentially, they serve as a quality assurance mechanism to identify and rectify deviations from established quality standards. In the pharmaceutical industry, a regulatory audit is a specialised quality audit carried out by regulatory bodies such as the FDA to guarantee adherence to national and international regulations.

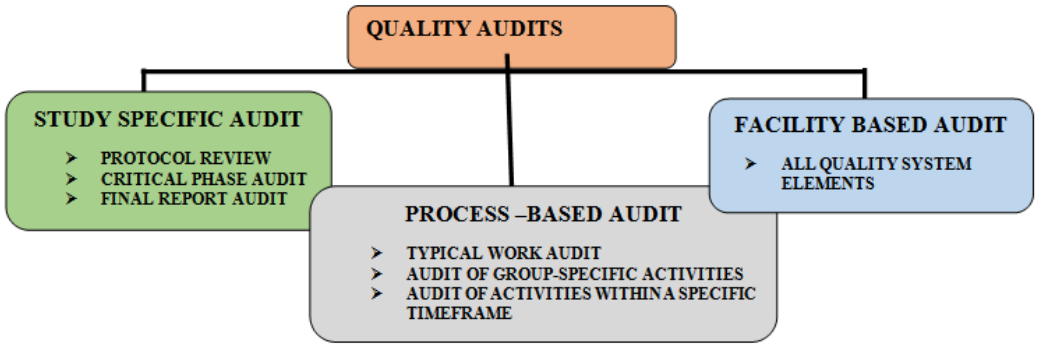
- **Good Laboratory Practice (GLP)** Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Following GLP is crucial for regulatory compliance and decision-making processes, as well as for promoting trust in scientific research data.

GLP provides reassurance on the validity, accuracy, and sound integrity of study data presented to government assessors. The QA Professional monitors GLP compliance by conducting audits of the facilities, of ongoing work being done there, and of relevant documentation. In the pharmaceutical sector, internal audits are essential tool for guaranteeing adherence to regulations, pinpointing opportunities for enhancement, and safeguarding patients. Internal audits are crucial, but too frequently they are viewed as a checkbox exercise that doesn't offer the depth and value they ought to.

As requirements are compared with actual circumstances during internal audits, auditing is a crucial tool for the QAU to employ in ensuring that a facility is in compliance.

Three types of internal audits should be carried out by the Quality Assurance Unit: system inspection, process-based audits, and study-specific audits. These internal audits are a means of determining if a GLP compliance program is operating appropriately. The data acquired from these audits can also be utilized to help with the development of a new GLP compliance program. Internal audits can be a helpful tool for maintaining compliance and encouraging ongoing development as the GLP compliance program gets more experienced.

There are three major types of Quality Audits:



The GLP regulations require that QA conduct audits of the following types

- **Facility audits** – to assure the facility is fit for purpose and documents to support processes are in place

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- **Process and Study audits** – observing personnel in the laboratory to assure they are following relevant procedures and working in compliance with GLP
- **Study Plan reviews** – review of the document which outlines the work to be conducted
- **Study Report reviews** – review of the report to check it accurately reflects the data generated during the study and contains everything required under GLP
- **Computerised Systems used to generate study data and facility records**– review of documents associated with validation of new systems plus audits of ongoing maintenance and validation status of the system

Proactively contributing to improvements in departmental rules and procedures is another aspect of the role. Each employee in every organizational unit is in accountable of trying to make sure that their work procedures are effective and constantly evolving.

It is also examined how these audits might be strategically and effectively used to support the creation and ongoing enhancement of a compliance program. It is imperative that the audit results and findings are promptly communicated to the facility management and study director.

- **Risk based QA Program:**

Risk is defined as the total likelihood of issues or problems arising in the system that affect the data's integrity and the study's overall compliance. By including the concept of a risk-based inspection program, the quality assurance (QA) focus will be increased on using resources efficiently and proportionately to the recognized risks related to studies, facilities, and the quality system.

QA should involve in risk identification, assessment, evaluation, control and risk management.

For example in GLP Facility, According to the OECD's guidelines for GLP, QA conducts internal audits in compliance with ISO and GMP in addition to study, facility, and process based inspections. The process of identifying and improving the risks within the testing facility is ongoing. The testing facility adheres to a systematic risk management program and a constant risk identification strategy. Management makes ensuring that the test facility has a thorough risk assessment program that complies with OECD GLP guidelines. At the test facility, the quality risk management program is implemented and followed.

Internal audits in the Test Facility (study-based, process-based, and facility-based) are carried out by the risk-based QA program independently. QA conducts routine audits to help identify potential risks in the test facility. Study Director/ Management then reviews the applied CAPA.

Finding areas for process, equipment/instrument, study- and facility-based improvement is made easier by the results of the quality risk management programme implemented in accordance with SOP, which also includes internal audits conducted by QA. Additionally, the Test Facility's quality systems will be enhanced by QA and Management ongoing review of any CAPA or processes that have been established.

- There are several approaches to conduct an internal audit.

1) Prepare a plan of action to avoid high-risk areas. Thus, a company can address them before a regulatory inspection and enhance the quality & effectiveness of its company operations.
2) Develop a structure for the audit program that takes a risk-based approach.
3) Conduct periodic training for the audit team to keep up with regulatory changes, observation trends, and risk areas.
4) Have an opening meeting with all the functional teams at the beginning of the audit so that an auditee can get the time to prepare for the audit operationally.
5) Finish the audit with a close-out meeting to present the audit findings and conclusions.
6) Prepare an audit report to communicate the result of the investigation.
7) This report also provides accurate data for addressing important organizational issues effectively.

Use of audits during development of a new GLP compliance program:

- A QAU uses internal audits as a vital tool to confirm a facility compliance. It is believed that the period of time between a new QMS's first adoption and maturity is typically challenging for an organization to set up its rules and processes. As a result, it is critical that a QAU evaluate, compile, and apply internal audit findings in order to support the expansion of a new compliance program.

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- Improving SOPs
- Identifying best practices
- Enhancing a mature GLP compliance program
- Pattern and trend analysis
- Taking a risk-based approach
- Following regulatory development:

It is highly advantageous for auditors to be up to date on the latest developments in regulatory auditing and to utilize this information when developing audit plans. This makes it possible to guarantee that the compliance program is kept abreast of any new regulatory requirements.

- **The benefit of optimising the Pharma Audit procedure using audit management software:**

The complexity and frequency of audits rise in line with the evolution of the pharmaceutical industry. Software for audit management is advantageous in this instance. Such software has a number of benefits, such as:

Efficiency: The audit process is streamlined by audit management software, which reduces the amount of manual paperwork and administrative effort.

Data Security: It offers a safe environment for handling and keeping track of confidential audit data.

Real-time tracking: In real time, auditors may monitor the status of their audit, it's findings, and its corrective action.

Report Generation: By automating report generation, the programme facilitates the communication of audit findings.

- Best Practices while Performing Internal Audits in the Pharmaceutical Industry:

Nowadays, the majority of quality system plans involve analysing manufacturing procedures as an integral part for pharmaceutical companies. An internal audit assists in evaluating a system's internal control and determining the efficiency of the quality system.

Through the provision of vital information regarding identified problem areas or the prevention of issues before they become non-conformance or compliance concerns, internal audit practices enable an organisation to continuously improve its operations. When conducting an internal audit, auditors need to evaluate and improve the efficacy of risk control and governance procedures using a systematic, disciplined approach.

- **Significance of Audits in the Pharmaceutical Industry:**

- Audits are an integral component of quality management within pharmaceutical companies. It is crucial part of assurance of quality procedures.
- The company conducts these audits in order to assess its own operations, identify non-compliance issues, and put corrective actions in place. They are a proactive measure to prevent regulatory non-compliance, product recalls, and possible patient injury. They also ensure that procedures are in line with set quality standards. Pharmacy companies are implementing audit software more and more to streamline this process and increase its effectiveness and efficiency.

CONCLUSION:

- Quality is one of the most important management principles for any organization regardless of industry. This is particularly true for the pharmaceutical sector, maintaining quality product standards is essential for the prevention and treatment of numerous medical disorders.
- In order to "assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations," the QAU will be able to gather enough information. The data acquired from internal audits can also be utilized to help with the creation of a new compliance program and to support the ongoing enhancement of an existing one. Complies with regulatory regulations in addition to having each protocol audited and each report examined. The ability to support an ongoing process of improvement that all staff members, and the QAU specifically, may utilize, is of utmost significance.
- There are several regulations that govern the pharmaceutical industry.
- The applicable regulations may change based on the kind of product and the target market as per Pharmaceutical standards such as ICH Q10, EU and PIC/S GMP, and ISO 9001:2015, etc.
- Pharmaceutical Companiesshould concentrate on problem-solving& continuous improvement approach by implementing internal audits for evaluation and CAPA,so that it can speed up and enhance quality aspect of QMS procedures to save time and facilitate compliance.

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