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Review on Process Management and Regulation in Pharmaceuticals

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ABSTRACT: -

A technique or collection of procedures known as quality control (QC) is designed to make sure that a service or product is made in accordance with a specified set of quality criteria or that it satisfies the needs of the client or customer..

The overall purpose of quality control is to make sure that manufactured goods adhere to relevant criteria. It entails identifying and eliminating faults and deviations from the established standards of quality.

Scope of MANAGEMENT AND REGULATION

There are three broad areas where quality control should be applied in manufacturing industry.

1. Supply quality assurance. A contract with the supplier of raw materials and components is known as supplier quality assurance (SQA). In accordance with this contract, the manufacturer guarantees that all incoming components and materials will be of a consistent and respectable quality. The process of regularly policing and maintaining the quality of expensive components and materials is also known as "incoming material control.".

2. In-process control. Random product samples are taken during the processing stage, and their quality is assessed in accordance with specified criteria of quality. These tests might highlight several production-related flaws. To ensure that the right quality items are produced, corrective measures are done. Process control aids in ensuring that the final product maintains the desired level of quality and helps to stop the creation of subpar goods.

So long as a process continues to generate items of the desired quality and design, it is regarded satisfactory or under control. Process control approaches include evaluating process standards such as rework, scrap, dimensions, rejection, and so on. Process control encompasses all of the techniques used to analyse, maintain, and enhance quality standards at various stages of manufacturing.

3. Post-mortem inspection. It is consumed following the creation or completion of the goods. It is a method for determining a product's quality and grouping the units into acceptably good and rejectably bad categories. Quality assurance is another name for inspection controls. Reliability is the name for design controls applied after the items leave the factory

Concept And Scope of Regulation:-

The term "component of quality management focusing on giving confidence that quality requirements will be fulfilled" is quality assurance. Quality assurance boosts management's confidence both internally and externally, to consumers, authorities, regulators, certifiers, and other parties.

Scope of Management And Regulation in pharmaceutical

- To eliminate errors by concentrating on the procedure.
- To make development and testing procedures better so that errors do not occur.
- Create a good quality management system and evaluate its effectiveness with ongoing monitoring.
- The prevention of quality issues by organised, methodical operations. https://asq.org/quality-resources/quality-assurance-vs-control

Good Laboratory Practice(GLP):-

The planning, carrying out, monitoring, recording, archiving, and reporting of non-clinical health and environmental safety investigations are the focus of the GLP quality system.

GLP principles include:-

- Organization and Personnel
- Management-Responsibilities
- Sponsor-Responsibilities
- Study Director-Responsibilities
- Principal Investigator-Responsibilities
- Study Personnel-Responsibilities
- Quality assurance program
- Quality Assurance Personnel
- Facilities
- Test System Facilities
- Facilities for Test and Reference Items
- Equipment, reagents and materials
- Test systems
- Physical/Chemical
- Biological
- Test and reference items
- Standard operating procedures
- Performance of study
- Study Plan
- Conduct of Study
- Reporting of results
- Archival - Storage of Records and Reports **(This November is Wikipedia Asian Month)**

❖ In pharmaceutical laboratories, GLP should be followed. Following are the main points those should be considered under GLP.

• The laboratory should be located designed, customized and maintained to suit the performance of all Q.C. test and analysis required.

Conveniently located to service the Mfg. Dept. but preferably separate to avoid vibration, dust, internal and external traffic to protect the delicate instruments.

• As far as possible there must be separate wings instruments, for analytical, microbiology and sterility etc. and all wings may be interconnected with the internal door.

• There must be an effective airlock, provisions for A.C. and fumigation chamber, the laboratory should be so designed that not only adequateprovision of space but provision for utility, water, solvent storage, extraction dust collection etc. were covered.

Laboratory furniture so designed to provide for adaptability, tabletop must be covered properly resistant to acid, alkali and solvent etc. The floor should be smooth, easy to clean and adequate drainage facility.

Equipment:-

Each instrument must have a written standard operating protocol. The instrument needs to be kept clean at all times and should be kept in a separate room with a sufficient amount of space and a controlled temperature. Also, the surroundings needed to be cleansed.

The instrument needs to be calibrated, maintained, and temperature-controlled with extreme caution, and it needs to be kept spotless at all times. Also, the surroundings needed to be cleansed.

The calibration and maintenance/ service record must be kept and must be done periodically.

• The glassware must be calibrated with certified one before use. Particularly the glassware which is supposed to be measuring purpose calibration necessary before utilized must use.

• The light should be adequate.

• The electrical system in the laboratory must not be overloaded.

Chemicals and Reagents:-

• Chemicals and reagents should be stored in a way that involves their use, and all of their containers need to be appropriately labelled. Chemical transfers must be handled with extreme caution. A prepared solution and all analytical reagents need to be labelled. Records of Molar Solutions entered into the corresponding register.

Documentation:-

• The paperwork is essential to a successful laboratory. Practice documentation is the established technique for storing data for later use. Protocols, logbooks for equipment use, maintenance, and calibration, and well-established SOPs are the essential documentation that must be provided.

The following are some of the information that is routinely recorded in a laboratory: Receipt and storage of samples.

- Sampling
- Analytical testing
- Validation
- Calibration
- Data recording
- Operation of instruments
- Reagent preparation
- Training Records
- Organizational charts
- Sampling Procedure
- Analytical testing methodology
- inventory/list
- Instrument calibration Data
- Methods validation data
- Analytical testing results and reporting.

Records and reports:-

All graphs relevant to IR, HPLC, etc. should be preserved alongside the raw data in the laboratory's records of all tests run. Access to records should be limited to authorised individuals for ease of reference, and they are best kept locked away.

Auditing Procedure:- (pharmaguideline.com)

The quality Assurance Department of the laboratory should constitute a committee who has to regularly audit their facilities to ensure compliance with GLP requirement.

Good Manufacturing Practices (GMP):-

• Every laboratory must keep track of all tests run, and graphs for IR, HPLC, and other tests should be kept with the raw data. Access to records should be limited to those who are permitted, and they should ideally be kept under lock and key for rapid reference.

Principle of GMP:-

1) Design and construct the facilities and equipments properly

2) Follow written procedures and Instructions
3) Document work
4) Validate work
5) Monitor facilities and equipment
6) Write step by step operating procedures and work on instructions
7) Design, develop and demonstrate job competence
8) Protect against contamination
9) Control components and product related processes
10) Conduct planned and periodic audits

GMP Categories:-

- Sale
- Premises
- Equipment
- Personnel
- Sanitation
- Raw Material Testing
- Manufacturing Control
- Packaging Material Testing
- Finished Product Testing
- Quality Control Department
- Records
- Samples
- Stability
- Sterile Products

Why GMP is important:-

Unintentionally added harmful chemicals may be found in low-quality medications. A medication won't work as intended therapeutically if it contains little to no of the advertised component.

Current Good Manufacturing Practices(cGMP):-

- In order to ensure that a drug complies with the requirements of the act, has the identity and strength, and meets the quality and purity characteristics that it is claimed to possess, current good manufacturing practises are the procedures to be used, the facilities to be used, or the controls to be used.
- cGMP refers to Current Good Manufacturing Practices regulation enforced by US FDA
- cGMP provides system that assures proper design, monitoring and control on manufacturing process and facilities.
- cGMP regulation assure the identity, strength, quality and purity of drug product by requiring that manufacturer of medication adequately control manufacturing operations.
- This includes establishing strong Quality Management System, obtaining appropriate quality of raw material, detecting and investigating product quality deviations and maintaining reliable testing laboratories.
- cGMP adequately put into practice to prevent instance of contaminations, mix ups, failure and error.
- These assures product meet their quality standard.

Regulatory Authorities:-

A) Food and Drug Administration(FDA) -

The Food and Drug Administration (FDA) is in charge of ensuring the security, safety, and efficacy of biological goods, medical devices, our country's food supply, cosmetics, and radiation-emitting products in order to safeguard the public's health. The FDA also offers the general public precise, fact-based health information.

B) United State Food and Drug Administration (USFDA)-

Located under the Department of Health and Human Services, the Food and Drug Administration (FDA or USFDA) is a federal organisation. The FDA is in charge of ensuring the safety of food, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed[4], and veterinary products in order to protect and advance public health.

C) World Health Organization (WHO)-

The United Nations has a dedicated agency for worldwide public health called the World Health Organization (WHO). [2] "The attainment by all peoples of the highest attainable degree of health" is the primary goal of the WHO, according to its constitution. [3] It has 150 field offices worldwide, six regional offices, and its main office in Geneva, Switzerland.

D) Medicines and Healthcare products Regulatory Agency(MHRA)-

The United Kingdom's Department of Health and Social Care's executive agency, the Medicines and Healthcare Products Regulatory Agency (MHRA), is in charge of making sure that drugs and medical equipment function as intended and are safe enough to use.

Scope:-

- IP rights cover a wide range of things, and there are two ways to classify them depending on whether they are copyright or industrial property. Patents or inventions, trademarks, trade names, biodiversity, plant breeding rights, and other commercial interests are all examples of industrial properties.
- Intellectual property rights have a wide range of applications and cover a variety of areas. Because of the ongoing changes in technology, globalisation, and IP regulations, defining intellectual property rights is challenging. In general, the concept of intellectual property refers to a collection of legal provisions intended to safeguard the ownership of patents, trademarks, inventions, and literary and artistic creations.

Importance:-

- Strong and Effective Protection of Intellectual Property Safeguard families and consumers. Solid IP rights enable customers to make informed decisions regarding the security, dependability, and efficiency of their purchases. Intellectual rights support the assurance and comfort that customers want and markets need.

- Businesses rely on strong protection for their patents, trademarks, and copyrights, while consumers need IP to make sure they buy products that are safe and reliable. An IP asset is like any other physical property offering commercial benefits to businesses.

Trademark:-

A trademark is a symbol that can be used to separate the products or services of one company from those of other companies. Intellectual property rights provide protection for trademarks.... This suggests that the trademark may be used solely by its owner or may be licenced to a third party for use in exchange for payment.

Types of Trademark –

1) Arbitrary and Fanciful Trademarks.
2) Suggestive Trademarks
3) Descriptive Trademarks