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Role of Quality Control in Pharmaceutical and Chemical Industries: A Review

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ABSTRACT

One of the crucial divisions of any pharmaceutical company is quality control. A sizable workforce is employed in the QC department after R&D. The goal of a qualitative analysis by a chemist is to determine the constituents of the sample. In a quantitative analysis, the amount or concentration of a certain substance in the sample is sought to be ascertained. A qualitative analysis might involve determining whether a sample of salt contains the element iodine, whereas a quantitative analysis might involve calculating the proportion by weight of any iodine that exists in the sample**.** Before the raw material is sent to the stores department and once it has entered the factory grounds, the QC department will inspect it for quality. The QC department authorizes the raw material if the quality is in accordance with the standards. Analyzing raw materials is what it is termed. Basic tasks will be carried out by the concerned QC chemist with the group leader or manager's approval.While the product (chemical or formulation) is being prepared or manufactured, the in-process analysis will be carried out. After the product or material is produced, an analysis of the finished product will be conducted. This Research article is an effort for the researchers, focused on research and development unit.

Keywords- research and development, quality control, pharmaceutical, drugs, protocols.

I. INTRODUCTION

The World Health Organization (WHO) defines the term quality control as, "The sum of all procedures undertaken to ensure the identity and purity of a particular pharmaceutical. Such procedures may range from the performance of simple chemical experiments which determine the identity and screening for the presence of a particular pharmaceutical substance (thin layer chromatography, infrared spectroscopy, etc.), to more complicated requirements of pharmacopoeial monographs."[1]

The Indian Drugs and Cosmetics Act and Rules defines a QC system as follows:

It shall be ensured that all quality control arrangements are effectively and reliably carried out the department as a whole shall have other duties such as to establish evaluate, validate and implement all Quality Control Procedures and methods."

Drug producers are obliged to build up own QC labs and hire people who are qualified and trained to conduct the relevant tests. The department needs enough room to carry out all the studies, store the data necessary for them, and keep reference samples from each shipment of the company's products. Chemical, instrumental, biological, and microbiological testing are the four main categories under which quality control labs operate.

Being autonomous from all other departments is one of the essential needs for the Quality Control department. The Quality Control Head, not the Production Head, must answer to the highest authority.

The different Instruments used in QC department :

UPLC,HPLC, GC, UV, FTIR, AAS, XRD, Particle size analyzer, KF Tritator, MV Tritator, Melting Point apparatus, Muffle Furnace, Polarimeter, Friability Apparatus

Disentrigation Apparatus, TLC (Thin Layer Chromatography), Water Bath Dissolution apparatus

Responsibilities of Quality Control:[2]

Responsibilities of quality control are as follows :

1. Preparing specifications for all raw materials, packing materials, finished products, intermediates and solvents, and reagents used in analyses.
2. Inspecting, sampling, and testing of all starting materials including packaging materials, intermediate and finished products as per

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procedures defined in the Standard Operating Procedures (SOPs).
3. Performing stability testing to assess product stability.
4. Monitoring environmental conditions are met as per current Good Manufacturing Practices (cGMP) requirements.
5. Preparing analysis reports for the tested samples, and recording and investigating any results that are Out Of Specifications (OOS).
6. Approving product batches for sale after ensuring it meets quality, safety and efficacy standards prescribed.
7. Calibration of all laboratory instruments and devices used in the testing.
8. Validation of analytical methods used in the testing.
9. Retaining reference samples from each batch of products released to the market.
10. Reviewing the batch manufacturing and packing records and assessing the test reports to ensure products are of the desired quality and have been properly packed and labeled.
11. Participating in any investigation that follows market complaints about the quality of a product.

Types of quality control

Just as quality is a relative word with many interpretations, quality control itself doesn't have a uniform, universal process. Some methods depend on the industry. Take food and drug products, for instance, where errors can put people at risk and create significant liability. These industries may rely more heavily on scientific measures, whereas others (such as education or coaching) may require a more holistic, qualitative method. [3]

At its core, quality control requires attention to detail and research methodology.

So, what is quality control? There are a wide range of quality control methods, including

Control Charts:

A graph or chart is used to study how processes are changing over time. Using statistics, the business and manufacturing processes are analyzed for being "in control."

Process Control:

Processes are monitored and adjusted to ensure quality and improve performance. This is typically a technical process using feedback loops, industrial-level controls, and chemical processes to achieve consistency.

Acceptance Sampling

A statistical measure is used to determine if a batch or sample of products meets the overall manufacturing standard.

Importance of Quality Control in the Pharmaceutical Industry

Drugs are critical to human health and well-being, so their quality is critical. When dealing with consumable products that people rely on, poor quality control measures can lead to devastating consequences.

One of the most notable examples is the 2008 Chinese melamine milk scandal, in which many infants were hospitalized due to kidney damage after consuming infant formula that had been adulterated with melamine. While that particular incident didn't take place in the pharmaceutical industry, it does underscore the importance of quality control in any industry where products have the potential to cause harm.

In the case of pharmaceuticals, there are a few reasons why quality control is so important:[4]

- To ensure patient safety—obviously, the primary concern in the pharmaceutical industry is patient safety. All drugs must meet certain safety standards before they can be approved for use, and it's the job of quality control to make sure those standards are met.
- To comply with regulations—the pharmaceutical industry is one of the most heavily regulated industries in the world. Quality control is essential for ensuring compliance with all regulations, both in the country of manufacture and in the countries where the drugs will be sold.
- To protect the company's reputation—in an industry where public trust is so important, a company's reputation can be easily tarnished by even a single quality control lapse. This is why pharma companies go to great lengths to ensure that their products meet the highest possible standards.

These are the three main steps that are involved in quality control in the pharmaceutical industry. Of course, there are many other sub-steps and procedures that are carried out at each stage, but these are the three main ones.

GLP (Good Laboratory Practice) in Quality control

- Quality Control Laboratory Area & equipment should meet the general & Specific Requirements for Quality Control Areas given in Chapter 3. Laboratory equipment should not be routinely moved between high risk areas to avoid accidental Cross-Contamination.

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- In particular the microbiological laboratory should be arranged so as to minimise risk of Cross-Contamination.
- The personnel premises, and equipment in the laboratories should be appropriate to the tasks imposed by the nature and the scale of the manufacturing operations. The use of outside laboratories, in conformity with the principles detailed in Chapter 7, Contract Analysis, can be accepted for particular reasons, but this should be stated in the Quality Control records.

Documentation of Quality control Department[5]

Minimum Availability in of Documents In Quality control department as per given below ;

- Specifications.
- SOP for Sampling, Testing, Records (Including test worksheets & Laboratory notebooks format), Recording and verifying ;
- SOP for calibration/qualification of instruments and Maintenance of Equipment also department should maintain Records of the same.
- SOP of investigation of out of specification and out of Trend results.
- Testing reports and/or certificates of analysis.
- Data from environmental (air,water & other utilities) monitoring, where required;
- Validation records of test methods where is applicable.

Laboratory Inspection

The specific objective will be spelled out prior to the inspection. The laboratory inspection may be limited to specific issues, or the inspection may encompass a comprehensive evaluation of the laboratory's compliance with CGMP's. As a minimum, each pharmaceutical quality control laboratory should receive a comprehensive GMP evaluation each two years as part of the statutory inspection obligation.[6]

In general these inspections may include

- the specific methodology which will be used to test a new product
- a complete assessment of laboratory's conformance with GMP's
- a specific aspect of laboratory operations

Activity of Quality Control Department

II. CONCLUSION

Quality Control is concerned with sampling, specifications, testing, documentation, release procedures which ensure that the necessary and relevant tests are carried and that the materials are not released for use, nor products released for sale or supply until their quality has been judged to be satisfactory. It is not confined to laboratory operations but shall be involved in all decisions concerning the quality of the product. Overall management of the laboratory work, its staff, and the evaluation of the results of analysis are important elements in the evaluation of a control laboratory. Span of supervisory control, personnel qualifications, turnover of analysts, and scope of the laboratory's responsibility are important issues to examine when determining the quality of overall management and supervision of work. Individually or collectively, these factors are the basis for an objection only when they are shown to result in inadequate performance of responsibilities required by the CGMPs

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