ISSN 0976 – 3333

Available Online at www.ijpba.info.

International Journal of Pharmaceutical & Biological Archives 2011; 2(3):828-830

REVIEW ARTICLE

Quality Control And More

Jaya Agnihotri*and Anubha Khale

M.E.S. Instititute's , H.K. College Of Pharmacy, Pratikshanagar, Jogeshwari (W) Mumbai 400102, India

Received 16 Apr 2011; Revised 24 May 2011; Accepted 07 Jun 2011

ABSTRACT

In today's scenario as new and better medicinal agents are being produced at an accelerated rate,the role of quality control chemist becomes challenging one. The quality control department becomes an important link in data analysis for newly launched products by a manufacturing company. To be effective, it must be supported by a team effort. Production failure causing rejection or recalls after market introduction are serious and can be easily detected and minimized by an effectively administered quality control system. Quality control system must be comprehensively designed, correctly implemented, fully documented and effectively monitored. Though the product is successful at research level, there are many constraints in scale up. At the same time more exacting and sophisticated analytical methods are being developed for evaluation. As a handful of data is available with quality control department, consistent and predictable performance of the product is expected.The current article reveals duties and responsibilities of quality control department.

Key words: Quality Control, Data Entry, Quality assurance, Total Quality Control.

INTRODUCTION

The concept of quality control (QC) programme refers to the process of striving to produce a perfect product by a series of measures requiring an organized effort by the entire company to prevent or eliminate errors at every stage in production. It is a process employed to ensure certain level of quality in a product or service. It may include whatever actions a business deems necessary to provide for the control and verification of certain characteristics of a product or service. The basic goal of quality control is to ensure that the products, services, or processes provide to meet specific requirements and are dependable, satisfactory and fiscally sound [1].

Essentially, quality control involves the examination of a product, service, or process for certain minimum levels of quality. A systematic effective quality control programme includes raw material testing, in-process tests drug product containers packaging and labeling material consideration to ensure that the container closure system provide functional protection of product against environmental factors[2]. The goal of a quality control team is to identify products or services that do not meet a company's specified standards of quality. If a problem is identified, the job of a quality control team or professional may involve stopping production temporarily. Depending on the particular service or product, as well as the type of problem identified, production or implementation may not cease entirely. Usually, it is not the job of a quality control team or professional to correct quality issues. Typically, other individuals are involved in the process of discovering the cause of quality issues and fixing

***Corresponding Author:** Jaya Agnihotri**, Email:** scientific.cell@hkcollege.ac.in

them. Once such problems are overcome, the product, service, or process continues production or implementation as usual. In principle, quality control for analytical performance consists of two complementary activities: internal QC and external QC.

The internal QC involves the in-house procedures for continuous monitoring of operations and systematic day-to-day checking of the produced data to decide whether these are reliable enough to be released. The procedures primarily monitor the bias of data with the help of control samples and the precision by means of duplicate analyses of test samples and/or of control samples. These activities take place at batch level (second-line control).

The external QC involves reference help from other laboratories and participation in national and/or International interlaboratory sample and data exchange programmes (proficiency testing; third-line control).

Quality control can cover not just products, services, and processes, but also people. Employees are an important part of any company. If a company has employees that don't have adequate skills or training, have trouble understanding directions, or are misinformed, quality may be severely diminished. When quality control is considered in terms of human beings, it concerns correctable issues. However, it should not be confused with human resource issues.

Often, quality control is confused with quality assurance. Though the two are very similar, there are some basic differences. Quality control is concerned with the product, where as quality assurance is process–oriented. Even with such a clear-cut difference defined, identifying the differences between the two can be hard. Basically, quality control involves evaluating a product, activity, process, or service. By contrast, quality assurance is designed to make sure processes are sufficient to meet objectives. Simply put, quality assurance ensures a product or service is manufactured, implemented, created, or produced in the right way; while quality control evaluates whether or not the end result is satisfactory.

Requirment of Quality Control of Pharmaceuticals

Manufacturers in the pharmaceutical industry are always working to balance the demands of meeting global regulations and production costs, in an effort to produce the most innovative research and development while also producing safe, reliable prescription drugs. Quality control is an essential operation of the pharmaceutical industry. Drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. New and better medicinal agents are being produced at an accelerated rate. At the same time more exacting and sophisticated analytical methods are being developed for their evaluation.

Responsibilities of Quality Control Department of Pharmaceutical industries

The quality control department shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products. They will review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control department shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company. Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control department. The quality control department shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. The responsibilities and procedures applicable to the quality control department shall be in written form such written procedures shall be followed. Each person engaged in the quality control department shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that all employees remain familiar with CGMP requirements applicable to them. There shall be an adequate number of qualified personnel to perform and supervise all operation in quality control department.The staff is responsible for the examination of returned preparation to determine whether such preparation should be released, reprocessed or destroyed;adequate record of the distribution of

such preparation should be maintained[3]. System and procedure in a quality control laboratory Good laboratory practice include:

- General procedure for analysis abstracted from IP/BP/USP.
- Current approved and authorized specifications and standard test procedures.
- Authorised document for analysis.
- Retention of analysed sample.
- Laboratory safety guidelines.
- Validation (instruments,personnel and analytical procedures).
- Periodic validation of analytical method in use.
- Continous upgrading of quality system.

Continous upgrading of quality standards.

Prospects in Quality Control Dept

Pharma quality control remains extremely important and specialists in this field will continue to be needed, because of automation, More tasks that once fell to quality assurance engineers can be handled by production workers. There are probably more opportunities in other sectors of the economy, particularly in healthcare where quality assessment is a relatively new idea. Remuneration has now become the central issue for attracting and retaining employees across industries. The compensation structure within the pharma industry has also undergone a sea change over the past couple of years due to the phenomenal growth in this sector.

☐ Some of the specific career areas that fall within the scope of QC area include:

- Quality control technicians or analysts
- Quality control managers
- Quality Researcher
- Quality control Engineer
- Quality control Specialist
- Quality control Assistant
- Quality Control Inspector
- Quality Control supervisor
- Health and safety officer
- Quality control Auditor
- Laboratory Analyst

REFERENCES:

1. Lechman Leon,Liberman H.A.,Kanig J.L.,Quality control and Assurance,:In The Theory and Practice of Industrial pharmacy,Published by Varghese publishing house,Third edition Page no 804.
2. Quality assurance of Pharmaceuticals, A compendium of guidelines and related materials,Volume 2,Updated edition page no 111
3. Sethi P.D.,quantitative analysis of drugs in pharmaceutical formulations,Third edition, CBS Publishers and distributors 2008,page 32-33