

## Pharmaceutical Quality Assurance & Control

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### INTRODUCTION

Life is short, and the art long; the occasion fleeting; experience fallacious, and judgment difficult. The physician must not only be prepared to do what is right himself, but also to make the patient, the attendants, and externals cooperate." Thus, Hippocrates, the father of modern medicine, epitomized the art of the physician. "To do what is right" in terms of quality control and prevention has far-reaching implications, not only for physician, but for "the patient, the attendants, and externals." In keeping with this sublime philosophy, this article focuses on the assurance of Quality as a part of regulated Pharma industry.

The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control. A significant portion of the CGMP regulations (21 CFR 211) pertain to the quality control laboratory and product testing. Similar concepts apply to bulk drugs.

### Quality Assurance

Quality assurance covers all activities from design, development, production, installation, servicing and documentation. This introduced the rules: "fit for purpose" and "do it right the first time". It includes the regulation of the quality of raw materials, assemblies, products and components; services related to production; and management, production, and inspection processes.

One of the most widely used paradigms for QA management is the PDCA (Plan-Do-Check-Act) approach, also known as the Shewhart cycle. Quality control is a process employed to ensure a

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 provided meet specific requirements and are dependable, satisfactory, and fiscally sound.

Essentially, quality control involves the examination of a product, service, or process for certain minimum levels of quality. 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 them. Once such problems are overcome, the product, service, or process continues production or implementation as usual.

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

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are some basic differences. Quality control is concerned with the product, while 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.

#### *Quality Control:*

The term quality control refers to 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 particular pharmaceutical substance (thin layer chromatography, infrared spectroscopy, etc.), to more complicated requirements of pharmacopoeial monographs. Activities extend to the area of quality control laboratories (good laboratory management practices, models, e.g. for certificate of analysis and lists of laboratory equipment, and an external assessment scheme.

It is defined as all measures to be taken during manufacturing designed to ensure the uniform outputs of pharmaceutical products conforming to established specifications of identity, strength, purity and other characteristics such as potency, safety, and toxicity.

#### *Quality Assurance:*

QA is defined as a procedure or set of procedures intended to ensure that a product or service under development (before work is complete, as opposed to afterwards) meets specified requirements. QA is sometimes expressed together with QC as a single expression, quality assurance and control (QA/QC). Quality assurance, or QA for short, is the activity of providing evidence needed to establish quality in

work, and that activities that require good quality are being performed effectively. All those planned or systematic actions necessary to provide enough confidence that a product or service will satisfy the given requirements for quality.

For products, quality assurance is a part and consistent pair of quality management offering supposedly fact-based external confidence to customers and other stakeholders that a product meets needs, expectations, and other requirements. QA claims to assure the existence and effectiveness of procedures that attempt to make sure - in advance - that the expected levels of quality will be reached.

#### *Failure testing*

A valuable process to perform on a whole consumer product is failure testing, the operation of a product until it fails, often under stresses such as increasing vibration, temperature and humidity. This exposes many unanticipated weaknesses in a product, and the data is used to drive engineering and manufacturing process improvements. Often quite simple changes can dramatically improve product service, such as changing to mould-resistant paint or adding lock-washer placement to the training for new assembly personnel.

#### *Statistical control*

Many organizations use statistical process control to bring the organization to Six Sigma levels of quality, in other words, so that the likelihood of an unexpected failure is confined to six standard deviations on the normal distribution. This probability is less than four one-millionths. Items controlled often include clerical tasks such as order-entry as well as conventional manufacturing tasks. Traditional statistical process controls in manufacturing operations usually proceed by randomly sampling and testing a fraction of the output. Variances of critical tolerances are continuously tracked, and manufacturing processes are corrected before bad parts can be produced.

#### *Total quality control*

Total Quality Control is the most necessary inspection

control of all in cases where, despite statistical quality control techniques or quality improvements implemented, sales decrease.

The major problem which leads to a decrease in sales was that the specifications did not include the most important factor, "What the customer required". The major characteristics, ignored during the search to improve manufacture and overall business performance were:

1. Reliability
2. Maintainability
3. Safety

As the most important factor had been ignored, a few refinements had to be introduced:

1. Marketing had to carry out their work properly and define the customer's specifications.
2. Specifications had to be defined to conform to these requirements.
3. Conformance to specifications i.e. drawings, standards and other relevant documents, were introduced during manufacturing, planning and control.
4. Management had to confirm all operators are equal to the work imposed on them and holidays, celebrations and disputes did not affect any of the quality levels.
5. Inspections and tests were carried out, and all components and materials, bought in or otherwise, conformed to the specifications, and the measuring equipment was accurate, this is the responsibility of the QA/QC department.
6. Any complaints received from the customers were satisfactorily dealt with in a timely manner.
7. Feedback from the user/customer is used to review designs.
8. Consistent data recording and assessment and

documentation integrity.

## **PACKAGING MATERIAL TESTING**

Where a drug product is presented in an inadequate package, the entire effort put into the initial research, product development and manufacturing control is wasted. Drug quality is directly dependent on packaging quality. In many cases (e.g., metered-dose aerosols), packaging quality is critical to the overall performance and effectiveness of the drug product. Faults in the packaging and labelling of a drug product continue to be a major cause of drug recalls. Packaging materials are required to be tested or examined prior to their use in a packaging operation to ensure that materials of acceptable quality are used in the packaging of drugs required to be tested or examined prior to their use in a packaging operation to ensure that materials of acceptable quality are used in the packaging of drugs