Vol 3| Issue 2| 2013 | 89-92.

e-ISSN 2248 – 9142
print-ISSN 2248 – 9134

International Journal of
Current Pharmaceutical & Clinical Research

www.ijcpcr.com

ROLE OF QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Quality assurance plays a central role in determining the safety and efficacy of medicines. Highly specific and sensitive analytical techniques hold the key to the design, development, standardization and quality control of medicinal products. They are equally important in pharmacokinetics and in drug metabolism studies, both of which are fundamental to the assessment of bioavailability and the duration of clinical response. Quality Assurance persons involves in various aspects. Quality is the primordial intention to any industry and its products manufactured. Multiple views on obtaining such quality are the current interest in the pharmaceutical industry. Acquainted with a practice that puts us in common and routine convention ensured to deliver a quality that sounds globally in terms of a spoken quality is on the dais of pharmaceutical arena. Validation is the mean of catering enormous benefits to even more than the acceptable quality level which in the global standard scale. Quality Assurance mainly Categorized into Validation Quality Assurance, Documentation Quality Assurance, Analytical Quality Assurance, In process Quality Assurance, Audit/Compliance Quality Assurance, Quality Management System Quality Assurance.

Key words: Pharmacokinetics, Metabolism, Bioavailability, Primordial intention, Validation Quality Assurance, Documentation Quality Assurance and Analytical Quality Assurance.

INTRODUCTION

Role of Quality Assurance and its Objectives

QA provides a systematic and efficient method for gathering, analyzing, and maintaining information on the quality characteristics of products, the source and nature of defects, and their immediate impact on the current operation. It permits decisions to be based on facts rather than intuition or memory and provides comparative data which is useful long after the details of the particular time or events have passed.

The objective of QA is to readily pinpoint problem areas in which management can:

a. Improve the quality, uniformity, and reliability of the total maintenance effort.

b. Improve the work environment, tools, and equipment used in the maintenance effort.

c. Eliminate unnecessary man-hour and dollar expenditures.

d. Improve training, work habits, and procedures of maintenance personnel.

e .Increase the excellence and value of reports and correspondence originated by maintenance personnel.

f. Effectively disseminate technical information.

g. Establish realistic material and equipment requirements in support of the maintenance effort

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Validation Quality Assurance

Validation is the mean of catering enormous benefits to even more than the acceptable quality level which in the global standard scale. Lending importance to validation is increasingly profound in recent years. Validation is the art of designing and practicing the designed steps alongside with the documentation. Validation and quality assurance will go hand in hand, ensuring the through quality for the products. Various Importance of Validation is for assurance of quality and time bond, Process optimization, Reduction of quality cost, Nominal mix -ups, and bottle necks, Minimal batch failures, improved efficiently and productivity, Reduction in rejections, Increased output, Fewer complaints about process related failures, Reduced testing in process and in finished goods, More rapid and reliable start-up of new equipment's, Easier scale up form development work, Easier maintenance of equipment, Improved employee awareness of processes, More rapid automation, Government regulation (Compliance with validation requirements is necessary for obtaining approval to manufacture and to introduce new products).

Documentation Quality Assurance

A written protocol should be established that specifies how qualification and validation will be conducted. The protocol should be reviewed and approved. The protocol should specify critical steps and acceptance criteria.

A report that cross-references the qualification and/or validation protocol should be prepared, summarizing the results obtained, commenting on any deviations observed, and drawing the necessary conclusions, including recommending changes necessary to correct deficiencies. Any changes to the plan as defined in the protocol should be documented with appropriate justification. After completion of a satisfactory qualification, a format release for the next step in qualification and validation should be made as a written authorization. Validation set up to establish the desired attributes. These attributes include physical as well as chemical characteristics. In the case of parenteral, these desirable attributes should include stability, absence of pyrogens, and freedom from visible particles. Acceptance specifications for the product should be established in order to attain uniformity and consistently the desired product attributes, and the specifications should be derived from testing and challenge of the system on sound statistical basis during the initial development and production phases and continuing through subsequent routine production. The process and equipment should be selected to achieve the product specification. For example; design engineers; production and quality assurance people may all be involved. The process should be defined with a great deal of specificity and each step of the process should be challenged to determine its adequacy. These aspects are important in order to assure products of uniform quality, purity and performance [2].

Analytical Quality Assurance

It deals with all Q.C Instruments and SOPS, General Test Procedure, Specifications. In order to demonstrate that a laboratory is producing data of adequate precision, accuracy and sensitivity it is necessary to assess all laboratory procedures at all stages from sampling to reporting. This is a time consuming and costly process and, for this reason, it is important to ensure that the necessary standards of performance are clearly defined and adhered to. In most laboratories, AQA will start with the examination and documentation of all aspects of laboratory management. This will include clearly identifying lines of communication and responsibility, the description and documentation of all procedures which are carried out, and the documentation of instrumental and analytical checks. Within this there should be specific control and assessment procedures designed to monitor quantitatively the accuracy and precision of specific assays. Analytical quality assurance procedures should be based on a system of traceability and feedback. Traceability, in this context, requires that all steps in a procedure can be checked, wherever possible, by reference to documented results, calibrations, standards, calculations, etc. For example, where a balance is used in a laboratory, the accuracy of measurement must be regularly checked. The weights used for this purpose should either have a certificate demonstrating that they conform to a standard, or the balance must be regularly checked against such standards by the regular use of check weights which are well documented and thus can be linked within the laboratory to the calibration standard. This principle also applies to the calibration of other equipment. Feedback is the principle that problems or omissions in the AQA system should be

brought to the attention of management. Where standards in the laboratory fall below acceptable limits, procedures should ensure that this is easily recognized and corrected. Criteria for recognition and correction of poor performance, as well as responsibilities for corrective action, must be identified. The procedures for achieving this recognition and correction must be clearly established. Statistically based assay control systems, as used in internal and external quality control programmes, should also conform to the principles of traceability and feedback to ensure that correct criteria for adequate quality are adopted, and that any problems are quickly recognised and corrected [3].

In-process Quality Assurance

It deals with in process Checks starting from dispensing to finished Product. In-process controls (IPC) are checks that are carried out before the manufacturing process is completed. The function of in-process controls is monitoring and – if necessary – adaptation of the manufacturing process in order to comply with the specifications. This may include control of equipment and environment, too. In-process materials should be tested for identity, strength, quality and purity as appropriate and approved or rejected by the Quality Control unit during the production process. Rejected in-process ,materials should be identified and controlled under a quarantine system designed to prevent their use in manufacturing .Written procedures should be established and followed that describe the In-process controls. The Objectives are In-Process Control and Quality Control. In-process control not only provides a means of controlling production, it also performs a quality assurance function. The in-process control group personnel may be assigned to production or quality control depending on the relevant company structure. In each case, autonomy in relation to the production process must be ensured. The in-process control methods that are part of the manufacturing formula are compiled and validated under the supervision of quality control. Statistical evaluation and periodic review of in-process data contributes to the general assessment of process performance and product quality.

Corporate Quality Assurance

The primary function includes assuring compliance with GLP, GCP and GMP requirements, implementation of quality systems, inspections and checks during the design and development of pharmaceutical products. International regulatory operations including compilation of dossiers for abridged ANDA - Abbreviated New Drug Application/DMF - Drug Master File/NDA - New Drug application and submissions. Torrent quality is mandated and supported by Executive Management and coordinated by an independent Corporate Quality Assurance (CQA) Department [4].

Major Functions

CQA ensures quality in Research & Development, Production, and Quality Control & Distribution of Torrent Pharmaceutical products. It assures that quality is built into Torrent products from their development in R&D Center. Also provides continued support by product design and modification of both, API & Formulations, ensuring that our R&D processes comply with the latest guidelines of GLP, GMP & GCP. Corporate Quality Assurance is also responsible for ensuring the quality of all input materials. For this, regular audits and follow up is done on Raw & Packaging Materials suppliers. Regular employees training on GLP, GMP & GCP is coordinated by CQA. Regulatory Affairs Division of CQA is responsible for registration of products in different countries. It keeps up to date with requirements of various countries and coordinates development of data for registration requirements for both, regulated and non-regulated countries.

Compliance audit Quality Assurance

An audit is 'a systematic, independent and documented verification process of objectively obtaining and evaluating audit evidence to determine whether specified criteria are met'. It maintaining the integrity of the regulatory system administered , i.e, legislation, licenses, notices, consents ensuring credible and robust regulation improving compliance with legislative requirements through public audit reporting, ensuring regulatory activity is open and transparent. Ensuring that statutory instruments are robust and are appropriately used to achieve desired environmental and conservation outcomes .Ensuring that environmental and conservation regulation is consistent and transparent. It mainly Deals with the Product Recalls [5,6].

CONCLUSION

Quality Management System Quality Assurance

It mainly deals with the Risk Management, Change Control, Deviation, Incidents and Out of Specification.

REFERENCES

1. Konam, Kishore, et al. Bioanalytical Method Development and Reaction Rate Study of Kaempferol in Albino Rats Plasma Using RP-HPLC Method. *Int. J. of Biological & Pharma. Res,* 3(2), 2012, 197-203.
2. Carleton FJ and Agalloco JP. Validation of pharmaceutical processes, sterile, Second edition, 1-16.
3. Khan Mohammed S et al. Preparation and evaluation of spray dried microparticles using chitosan and novel chitosan derivative for controlled release of an antipsychotic drug. *Int. J. of Biological & Pharma. Res,* 3(1), 2012, 113-121.
4. Britain HG. Pharmaceutical technology, 2002, 68-70.

5. Rath, Sangram Kumar et al. UV-spectrophotometric method for simultaneous Estimation of drotaverine hydrochloride and Aceclofenac in bulk and their formulation." *International Journal of Biological & Pharmaceutical Research,* 2(2), 2011, 55-59.
6. Nayak, Srikant, et al. UV-spectrophotometric method for simultaneous Estimation of paracetamol and ondancetron in bulk and their formulation. *International Journal of Biological & Pharmaceutical Research,* 2(2), 2011, 45-49.