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Role of Quality Assurance Department in Pharmaceutical Industries: A Review

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ABSTRACT

The overview of the Quality Assurance Department in Pharmaceutical Industry is well discussed. It explains the vital role and the objectives of Quality Assurance Department. It also explains on how Quality Assurance can increase the revenue of the industry and how it is related to the other department as an important factor. This review gives the information about the role of Higher management and Importance of Quality Assurance in Pharmaceutical industry. It gives clear idea on how Quality Assurance Department works. The role of the Quality Assurance in Validation, Regulatory Affairs, and also in Business Development is explained.

Keywords: Quality Assurance, Regulatory Affairs, Objective, Importance, GMP.

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INTRODUCTION

Quality may be a broad construct and concern for each item or article of use- it's going to be house-hold item, household appliance, and aid merchandise, machinery purchased from the market, cars for private or industrial use, foods and food merchandise or medicines for animal and human consumption. Nobody needs compromise in quality of any item they use so Quality assurance is that the method or the tip of the method of vouching for the integrity of a product to satisfy the quality for its supposed use. Quality assurance is Associate in Nursing obligation mechanically obligatory on the manufacturer of any product to make sure that it meets the requirements of the user within the measures supposed for use- quality, safety, efficacy, responsibility, strength and or sturdiness etc. For the end-user, the benchmark of quality is perfection- they can't enable but 100%[1].

There is a growing awareness that an improvement in the quality of pharmaceutical products and services is a vital factor in the battle to maintain sales and remain commercially viable in the fast-growing and changing market. In many markets, quality competition is at least as important as price competition and this trend is bound to continue. With the prospects of more stringent product liability legislation and the threat of heavy financial penalties for products and services which fail to meet safety, good manufacturing compliance (GMP) or functional requirements, profitable trading will depend on sound Quality Assurance best practices. Material resources are becoming scarce and most expensive, and it is therefore economically desirable to minimize losses on scrap products by more effective quality control[2].

Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) is a very important part of Quality Assurance (QA), every method and steps should follow the GMP and GLP guidelines. GMP ensures that the product is manufactured according to the standard to avoid any product or any manufacturing related problems[3]. In pharmaceutical industries for production they have to obtain approval from the authorities and the particular authorities are keener on the GMP procedures that are used. GLP is an important parameter for personnel's that are related to the lab work and analysis. Every method and SOP must follow the GLP guidelines. Quality assurance includes the following[4].

- Good Manufacturing Practice
- Good Laboratory Practice
- Quality Control
- Validation

- Stability

Standard operative Procedures (SOP's) are designed by knowledgeable personnel and authorities, and routinely applied by every pharmaceutical industrial outfit into their own templates-ensures a GMP guidelines. The strict control of those rules of GMP guiding about the manufacture of pharmaceutical products, and the laboratory follow-up of the producing processes from begin to end, is termed Quality Control (QC). So, in broad terms, the elimination of error to its minimum through internal quality control ends up in a top quality Assurance (QA) or certification of the products as safe, good, and suited its intended use. QC involves the sampling and testing of starting materials, intermediate, bulk and finished products, plus packaging materials to ensure safety and compliance with regulatory standards[1]. Quality Assurance, gives simply, an assurance that the pharmaceutical product has been manufactured according to GMP guidelines, and that it contains all necessary ingredients in right proportions, and is pure, safe, packaged in the appropriate containers and labelled correctly. Quality control plus GMP equals Quality assurance. (QC + GMP = QA)[1]. Quality Assurance (QA) plays an important role in the manufacture of products and services in pharmacy and biotechnology, as part of GMPs (Good Manufacturing Practices)[6].

DEFINITION

- **Quality** - Quality may be a rather more sophisticated term than it seems. Each quality professional defines quality may be a somewhat totally different approach. There are a range of views which will be taken in shaping quality (e.g. customer's perspective, specification-based perspective). A contemporary definition of quality derives from Juran's "fitness for supposed use." This definition essentially says that quality is "meeting or extraordinary customer or client expectations"[7].

- **Quality Assurance** - is a large concept that focuses on the entire quality system including suppliers and ultimate consumers of the product or service. It includes all activities designed to produce products and services of appropriate quality. According to ASQ, QA includes all those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given needs[7].

- **Quality Control** - Quality control focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects. According to ASQ, QC includes the operational techniques and the activities which sustain a quality of product or service that will satisfy given needs; also the use of such techniques and activities[7].

- **Quality management** - is the sum of functions that involved in the determination and achievement of quality (includes quality assurance and quality control)[7].

- **Good Manufacturing Practice** - GMP is part of QA which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use[2].

QUALITY ASSURANCE

Principle

"Quality assurance" is an broad concept covering all matters that individually or together influence the standard of a product. It is the totality of the arrangements created with the aim of guaranteeing that pharmaceutical product are of the standard needed for his or her supposed use and safe. Quality assurance thus incorporates GMP, GLP and different factors, including those outside the scope of this guide such as product design and development[8].

Quality assurance is a process that is done for validating and to conform that the products that are manufactured are safe and meets the regulatory authority requirements in every aspects, from the raw material to packed finish product[5].

Quality assurance could be a smart follow within the manufacture of pharmaceutical product, because it is that the method of vouching for integrity of product to satisfy the quality for the intended use. It is a bond that ensures manufacturers meet the needs of end-user needs in terms of safety, quality, efficacy, strength, reliability and durability. Quality is a benchmark of perfection for the end-user[9].

Quality assurance must be independent of any financial stress. Financial stress here means that, the management should avoid causing financial stress to the particular department as this could lead to a great impact on the quality of the product. Poor quality of the product could cause a major impact on the profit of the industry. Hence QA department must be free from financial stress and should have sufficient manpower to ensure that the products validations are done according to schedule. As delay from the QA department could delay in the product release to the market which could also cause a major impact on the revenue of the industry[5].

The system of quality assurance applicable to the manufacture of pharmaceutical product ought to guarantee that:

(a) All pharmaceutical products are designed and developed in a such way that it takes account of the requirements of GMP and other associated codes such as those of good laboratory practice (GLP) and good clinical practice (GCP);

(b) Production and control operations are specified in a written format and GMP requirements are adopted;

(c) Managerial responsibilities are clearly specified in the job descriptions;

(d) Arrangements are created for the manufacture, supply and use of the right starting and packaging materials;

(e) All needed controls on starting materials, intermediate product, and finished product and alternative in-process controls, calibrations, and validations are carried out;

(f) The finished product is correctly processed and checked, by using the defined procedures;

(g) Not any pharmaceutical product are sold-out or supplied before the approved persons have certified that every production batch has been created and controlled in accordance with the necessities of the marketing authorization and also the different rules relevant to the assembly, control and release of pharmaceutical products;

(h) Necessary arrangements are created exist to confirm, as far as possible, that the pharmaceutical product are keep by the manufacturer, distributed, and later handled so quality is maintained throughout their shelf-life;

(i) There is a procedure for quality audit and/or self-inspection that regularly appraises the effectiveness and applicability of the quality assurance system;

(j) Deviations are reported, investigated and recorded

(k) There is a system for reporting and approving changes that may have an effect on quality of product;

(l) Regular evaluations for checking the standard of pharmaceutical product ought to be conducted with the target of confirming the consistency of the method and guaranteeing the continual improvement [8].

The manufacturer should consider responsibility for the quality standard of the pharmaceutical product to confirm that they are fit for his or her meant use, befits the wants of the promoting authorization and don't place patients in danger because of inadequate safety, quality or efficacy. The attainment of this quality objective is that the responsibility of senior management and needs the participation and commitment of workers in many various departments and in the least levels at intervals the company, the company's suppliers, and the distributors. To achieve the standard objective dependably there should be a comprehensively designed and properly enforced system of quality assurance incorporating GMP and Quality control. It ought to be absolutely documented and its effectiveness monitored. All elements of the standard assurance system ought to be adequately staffed with competent personnel, and will have appropriate and sufficient premises, equipment, and facilities[8].

Objectives of Quality Assurance

Quality assurance has a number of objectives that include the following:

a) To protect the user of the product from accidental defect in its design, manufacture, storage, or usage instructions.

b) To offer a guarantee that the person who is administering medicine is confident that every unit will achieve the desired effect[2].

c) Making sure of complete compliance with applicable industry regulations, statutes, laws, and guidelines.

d) Protecting the product and manufacturer against penalties, negative publicity, loss of credibility, fiscal losses, etc.[6].

AN OVERVIEW OF THE QUALITY ASSURANCE DEPARTMENT IN PHARMACEUTICAL INDUSTRY

In the pharmaceutical industry, the key units or department that are under regulatory consideration are Production, Quality control/Quality assurance, Ware house and Engineering/Utilities. The responsibility of the QA department is to look over on function of production, Analytical laboratory, Warehouse, Utilities, and the Environment (Hygiene) to assure that good manufacturing practices, good laboratory practices and good storage practice are in place[1].

The quality of a product does not occur by accident. People throughout an organization do not always follow instructions, rules, or perform their role correctly. It is the responsibility of quality management to deal with such type of situation and ensure that all members of the industrial team are aware of their quality responsibilities and do their work accordingly. Quality must be designed into products – discipline, attitude and inventiveness must be encouraged to create easy to make and easy to use fool proof products. Quality must then be planned into manufacture – methods must be devised so that the easiest way to do the job is the right one; so that, where appropriate, worker interest is created; and elsewhere complete control is built into the process. Finally, quality must be built into the product – the people concerned with the cutting, fitting and assembling must be well trained and enthusiastically led to achieve "right first time" production. This is the simple overall formula, but it is by no means simple to put into practice[2].

Senior Management must be clearly able to developing and implementing an effective Quality Policy to make quality assurance an effective part of business. The implementation of such a policy involves everyone in the organization. It must be clearly recognized that every employee (from board to shop floor) is responsible for ensuring that GMP and good quality practices are achieved[2].

The Quality Executive

The role of Quality executive in trade is these days extremely specialised. The post isn't one which will usually be used as a "stepping stone" during a promotional ladder. The explanation is fairly obvious; an individual during a Quality executive role will gain quality and short term action by effecting value reductions and in creating favourable selections, etc., just for the corporate to own to pay later. There area unit smart reasons on why there area unit dangers in creating short term assessments on achievements during this sphere. Its employment that's basically concerned in long run consequences and as a consequence it's not forever a very in style job[10].

The idea that the work of quality organizations was merely that of "inspecting out" defective work that had already been made was widespread within the past, particularly in management circles. It's faithful say, particularly over the last decade, that there has been significant technical advance within the nature of the work of quality specialists. These have taken them an extended method far away from the previous plan of review pure and easy. Today's stress within the work of quality specialist is towards the hindrance of defect altogether. The trendy read is that "no inspection is good inspection". So as to attain this goal, a high degree of expertise is needed in these new techniques that involve significant study and practical experiences resulting in qualification as quality practitioners[10].

Quality cannot however be achieved solely by the Quality Executive, it depends on everybody being actively concerned. the standard Executive's contribution is basically one in every of coordinative the efforts of others to confirm the action of quality by communication data on the numerous aspects touching quality to any or all involved and exercise management over quality observance throughout the organization. It should be the task/goal of all managers to confirm that the standard perform of their own departments is consummated. This places an important responsibility on all senior managers[11].

The Responsibility of Senior Management

To achieve the specified quality standard means that management organization and management thinking should be structured thus on make sure that quality and reliability figure suitably in company coming up with. It's essential for any manager not solely to own an honest appreciation of the basics of quality and responsibility, however conjointly absolutely perceive his/ her own responsibility for the management and accomplishment of quality and responsibility. Only by having this data will he/she verify the proper levels of resources that should be deployed. To

determine the quality and reliability requirements of customers or the intended market place;

a) To control the design and manufacture of goods to meet these requirements;

b) To provide the customers with adequate confidence those goods when received and put into operation will conform to their specifications/requirements[11].

In some industries, it may well be that these are infrequent judgements taken for a long-running production line. In different industries, every project could have totally different needs. The resources one has to deploy will vary greatly and be dependent on the importance of its operate. All managers have to be compelled to be ready to speak and act during a knowledgeable means concerning the problems that have an effect on product quality, and conjointly perceive the factors that verify the state of product quality. This implies that they ought to regard quality as an equal factor with value and delivery in running their business[11].

Managers should remember that the standard of their product could be a important think about the continued fight and profit of their company. Not solely ought to they be concerned with manufacturing product at the correct value and at the correct time, however they ought to additionally make sure that they're promoting the correct product which it will totally meet the customer's and regulatory compliance necessities. Marketing, Design, Production and Services Managers ought to all remember of their responsibilities for GMP/quality best practices as a significant a part of their commitment to make sure the continued potency, profit and name of their company . Lip service isn't enough; in today's economic atmosphere there square measure positive industrial advantages in adapting a full of life quality policy, however this may solely happen once knowledgeable and totally trained managers have adequately planned and enforced that policy. Managers become knowledgeable and competent through expertise, however they need to be trained at some stage, or stages, within the essentially vital problems[10].

Quality in today's world is one in all these basic problems. The initial seeds of the importance of quality assurance to higher management ought to be seeded once a manager is receiving his management education, and later change courses ought to be provided to match necessities of quickly ever-changing technology and restrictive compliance requirements. Finally, senior management has the last word responsibility to make sure a good quality assurance system is in place to realize the product quality and reliability[10].

COMPETITION IN THE MARKET PLACE

Price Competition:

At a time once material resources are getting scarcer and costlier and labor prices still increase, all waste represents a burden on the commercial economy and results in higher product prices. By reducing the number of defective product and also the failure rate of factory-made things, precious resources square measure preserved and production prices decreased[11].

Quality Competition:

In an increasing range of markets, quality competition is a minimum of as necessary as price battle. The success of Japanese and German business, each operative with a powerful currency rate of exchange, is obvious to all or any. Products with a name for quality and reliability sell in giant quantities throughout the world, typically overcoming the domestic competition in spite of their higher costs. This success, which is shared by only too few industries round the world, has been achieved terribly for the most part by the priority given to quality assurance[11].

PRODUCT AND SAFETY LIABILITY

Pharmaceutical manufacturing industries are presently changing into alert to the entire implications of strict product liability; although for some time those businesses dealing to the USA are in danger of great penalties for inadequate or defective product. The introduction of latest product liability legislation throughout the developed world is presently at hand. This might have a profound impact on trade, and each one businesses would like to continue profitable dealing have to be compelled to place confidence in to the appliance of safety- destined procedures that is in a position to attenuate product liability risks[11].

Quality assurance, already renowned as an important management tool, has presently been usually accepted among the United States as a result of the first implies that of implementing effective product liability prevention programs. Now is the time for the pharmaceutical trade to imitate, for corporations that ignore the hazards will certainly be in goodish financial peril[11].

QUALITY ASSURANCE IN BUSINESS DEVELOPMENT

As we all know that quality assurance features a very important role within the pharmaceutical industry. Business development is supposed for developing the future business plan for the actual pharmaceutical industry. They arrange in such ways in which they increase the industries profit and that they ordinarily work by introducing a brand new medication from alternative countries in order that they may be associate solely distributor within the country which supplies them profit also. They arrange in ways that to penetrate the market within the public in numerous ways that, they'll have to be compelled to compete with the opposite industries by thinking completely different and distinctive ways in which may create them different from others[12]. They also specialize in clinical trials and analysis and Development to encourage on the new findings of medication to be the patent of the drug. They additionally invite new medicine from another country that they take into account features a potential profit gaining drug, then the business development team can work on obtaining the drug to be registered in their country. Ordinarily in these cases, there will be associate agreement on the royalties and also the terms of payment certainly years[13].

Once the drug is approved to be sale then the business development team can proceed to plug the drug in numerous ways in which. Business development team additionally works in different sectors of business that might facilitate in revenue to the corporate while not solely depending on the pharmaceutical products. The role of Quality Assurance in Business Development is to provide knowledge and or record on the standard of the medicine or products that has been made by that specific organization. The standard of the drug reflects on the pharmaceutical trade[13].

Objective of Business Development

a) To bring in new pharmaceutical product to the trade to be the only distributor this might contribute to the profit of the trade.

b) Keeping tract on drug patents and to increase the generic production.

c) Generate additional profit and revenue for the trade.

d) To encourage on analysis and Development that might cause new drug discoveries.

e) Enhancing the prevailing drug for a stronger quality.

The business development team additionally works in a way to enhance the mutual affection and advantages with different Pharmaceutical industries, they be part of venture in developing the business. Because it has mention quality plays a really vital role, therefore so as for the opposite industries to own an honest relationship or trust on United States they would initial check up on the standard of the products that are created by the industries[12].

QUALITY ASSURANCE IN VALIDATION AND TECHNICAL SUPPORT

In pharmaceutical industry validation plays a really very important role beneath the QA department. This team here will validate each methods and each process that is carried out in the QA department to ensure that it gives results according to the standard that is set, moreover this team also work on various angle in enhancing each methods to give more quality in the results that is obtain. The reason it is mention here as technical support also is due to the fact that this team supports the other for example validation team supports the QC team and also supports the stability team. But all of this comes under one major department which is known as Quality Assurance. Each assay method and the SOP are validated on a regular basis to ensure that the procedures that are used to carry out by the QC to obtain results are all effective[12]. As per normal when the 1st analyst does the assays and if they have a problem in obtaining the results then the 2nd analyst will do a check back on the same drug with the same method if yet the results obtained is not as per the required standard then the case will be pass over to the validation team to test back the method that is approved, as when the validation does the analysis and obtain a standard results then the first analyst and the second analyst is called up for a small briefing on the errors that they have made which cause a wrong results. This is how it is co related as technical support team[14].

Method Validation:

The SOPs that are established is further studied and tested to enhance the efficacy and to obtain results more accurate for each assay. New methods are also tried as trial and error to check on the results obtain, if the results obtain is more accurate than the current method then amendments will be done. [9] But amendments can only done after obtaining approval from the NATIONAL PHARMACY CONTROL BURAE (NPCB) once the approval is obtained then the method is changed to the new method. Then the whole QC team is termed up for a meeting on the new methodology and ways that to get the results for more clarification demonstration is additionally conducted [15].

Process Validation:

Process validation is often based on the final production team and also the business improvement team wherever they will work along with each other in enhancing the method of production to get the standard results with a more efficient process. The process is also validated and before the new process is implemented, they should obtain approval on the new process. Once the new process procedure has obtained the approval then the entire production staffs is called up for a briefing on the new method that is approved. The process validation team will also validate the ongoing process method to ensure that the methods used can obtain the standard results as per the requirement. The process validation is completed frequently on a specific time line basis. As we could conclude that a validation team is a team that supports the other teams as well they work in various ways to ensure that the results that are obtained is more accurate to the standard that is required, they also come up with various analysis technique on drugs just to enhance the current method to a better method for much better safety and quality of the drug. Trial and errors and pilot studies are continuously done repeatedly on a replacement methodology before it may well be sent for approval, these shows that quality and customers requirement are the main concern and priority in a pharmaceutical industry. Quality of a medicine ought to never be compromise because it may lead to several different effects that may even be fatal to patient, so to avoid such tragedies to take place the quality of a medication should be always be tested to ensure it has a good quality that is safe for patients, as public is the main source of business to the industry [12].

QUALITY ASSURANCE IN REGULATORY AFFAIRS OF A PHARMACEUTICAL INDUSTRY

A regulatory affair because it is mentioned on the heading the primary factor that strikes us on the word regulatory is regulation and laws. In this section we discuss about how does quality assurance is related to the regulatory affairs department and how they work hand in hand for the betterment of the particular pharmaceutical industry to offer much better profit to the industry. Regulatory affairs mainly deals with the regulatory aspect of a pharmaceutical products and pharmaceutical industry hence in the regulation aspect also QA documentation is very important in order to obtain clearance on any related regulatory issues. The overview on the job scope in the regulatory affairs is working close with the authorities to ensure product is registered according to the regulation guideline[16]. Dossiers is a very important aspect in a regulatory affairs department, this dossiers are generally used to register the manufactured products in other countries. This dossier must include details concerning each side of the drugs; the major important aspect in a drug dossier is the Quality assurance details and the Certificate of Analysis (COA). The prepared dossier is sent to the specific countries authorities for registration of the drug in that particular country. It will nearly take two years for a drug to be registered in a different country in an export basis. Each and every details of analysis and assays that are done in the QA department is given in the form as report to be attached in the drug dossier before it is sent for registration [17].

Two Types of Dossiers

a) Common Technical Dossier (CTD)

b) Asian Common Technical Dossier (ACTD)

The CTD is used for registration of drugs in countries that are not included as Asian, this is the general format that is used. In CTD QA documentation plays a really necessary role, due to the fact that every authorities are more concern on the drug quality, thus when the drug has a good quality then it has high chances of getting the drug to be registered in the particular country. These directly bring a big amount of revenue to the industry. ACTD is a common format of drug dossier which is used to register the drug in Asian countries, looking at this format of dossier also the QA documentation is an important aspect that is required, if the drug has a very good quality then it has high chances of the drug to be registered in Asian countries[12]. In addition to this, by having drugs registered in various countries makes the company to gain a good benefit and also gain good profit. This clearly shows that however Quality Assurance contribute to the medication that are about to be registered in alternative

countries and the way it contribute to the revenue of the particular pharmaceutical industry. If the drug is registered in a particular country and if any amendments to be done on the drug, then the authorities of the country should be informed about the changes and we have to obtain the approval from the country. This has clearly explained the co-relation between the regulatory affairs and the quality assurance[12].

REFRENCES

1. Gabriel Akwaj, B.Pharm, MPSN, Regulation and Research. PHAMATEX INDUSTRIES LTD, Lagos, Nigeria. An Overview of Quality Assurance Department in Pharmaceutical Industry. https://www.academia.edu/8865972/An_Overview_of_Quality_Assurance_Department_in_the_Pharmaceutical_Industry
2. Dr. Shabir GA, Higher Management Role and Importance of Quality Assurance in the Pharmaceutical Industry. September 30, 2013.
3. Banker G. S., Siepmann J., & Rhodes, C. (Eds.). Modern pharmaceutics. CRC Press; 2002.
4. Guideline, I. H. T. Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients. Q7A, Current Step, 2000: 4.
5. Cardinal, L. B. Technological innovation in the pharmaceutical industry: The use of organizational control in managing research and development. Organization science, 2001; 12(1):19-36.
6. What is the Role of Quality Assurance in the Pharmaceutical Industry. Oct 4, 2016. Available from www.cafepharm.com/cpwire/Article .
7. Sower, Victor E. Essential of Quality with cases and experiential exercises. New York; John Wiley and Sons; 2011.
8. Quality Assurance of Pharmaceutics: a compendium of guide lines and related materials. Volume 2. GMP and Inspection. 2nd ed. WHO Press; 2007.
9. The Role of Quality Assurance in the Pharmaceutical Industry. Available from http://www.rscal.com/role-quality-assurance-pharmaceutical-industry/
10. International Conference on Harmonization (ICH), Food and Drug Administration (FDA), Guidance for Industry, Q10: Pharmaceutical Quality Systems, April 2009.
11. Medicines and Healthcare Products Regulatory Agency (MHRA): Rules and Guidance for Pharmaceutical manufacturers and Distributors. Pharmaceutical press, London; 2007.
12. Cruz L, Cruz F, Ashwinder Singh: Vital role of Quality Assurance as a Backbone in Pharmaceutical Industry. International Journal of Advances in Pharmaceutics 2015; 4:104-110.
13. Smith, M. C. Principles of pharmaceutical marketing. Routledge 2014.
14. Huber, L. Validation of analytical methods. Validation and Qualification in the Analytical Laboratories. Interpharm Press; 1998; 107.
15. Agalloco, J. P., Carleton, F. J. (Eds.). Validation of pharmaceutical processes. CRC Press; 2007.
16. Cockburn, I. M. The changing structure of the pharmaceutical industry. Health Affairs 2004; 23(1):10-22.
17. Carpenter, D. P. The political economy of FDA drug review: processing, politics, and lessons for policy. Health Affairs 2004; 23(1):52-63.