

VITAL ROLE OF QUALITY ASSURANCE AS A BACKBONE IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The overview on the vital role of a Quality Assurance department in a pharmaceutical industry and how it is related to other departments as an important factor is well discussed in each subsection. It also explains on how Quality Assurance can increase the revenue of the industry and it also explains on the work flow from the raw material till the finished product and the role of Quality Assurance in each flow. It gives a clear picture on how the Quality Assurance is manage and gives ideas on how to enhance the flow. The role of Quality Assurance in regulatory affairs and also business development is explained.

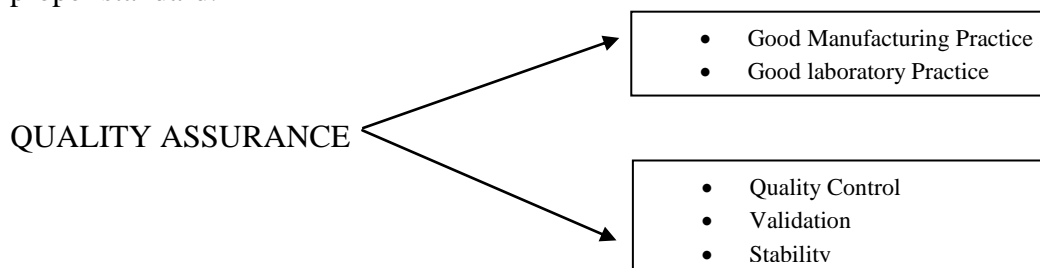
KEYWORDS: Quality Assurance, Good Manufacturing Practice, Good Laboratory Practice, Quality control, Quality.

DEFINITION

- Quality is defined as the totality of features and characteristic of a medicinal product and its ability to satisfy the stated and the implied needs.^[1]
- Quality assurance QA is defined as the sum total of the organized arrangement made with the object of ensuring that the medicinal products are of the quality required for their intended use.^[1]
- 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 Control the part of GMP which is concerned with sampling, specifications and testing.^[2]

1. OVERVIEW OF QUALITY ASSURANCE

Quality assurance is a very crucial aspect in every field of industry; it can be in the field of engineering, pharmaceutical products, food and beverage products and etc.^[1] Name any field and quality is a must in it, the reason why QA is mentioned as a vital aspect is due to the fact that every products that are produce needs to meet a certain criteria of quality which will be safe and efficacy for the consumers.^[1] A product that is not safe to be used will not be given authentication or approval to be marketed to the public. Looking at the scope that we are about to discuss is the field of pharmaceutical industry, as we know pharmaceutical industry produces medications, that is consume on a daily basis in our life by humans and even animals.^[2] As medications are something that is crucial and it's a need in our lives, thus the quality of the product should be in a very high standard to ensure that the product does not cause harm.^[2] As we all know medications are something that is used for disease or any illness in our body. Thus due to the reason, that the medication could also be harmful to the body, if the quality is not kept up to the requirements. Good Manufacturing Practice and Good Laboratory Practice is a very important aspect of QA, every methods and steps that is implemented should follow the GMP and GLP guidelines.^[3] GMP ensures that the product is manufactured according to the standard to avoid any product related problem or any manufacturing related problem. In order for the production in a pharmaceutical industry to continue they have to obtain approval from the authorities and the particular authorities are keener on the GMP procedures that are used.^[3] GLP is an important aspect for personnel's that are related to the lab works and analysis. Every methods and SOP should follow the GLP guidelines.^[4] This also includes in the documentations that is done also should follow the proper standard.



- Quality assurance is a process that is done for validating and to ensure that the products that are released are safe and meets the requirements in every aspects, from the raw material till the product leaves the industry as a packed and finished product.^[5]
- Quality assurance should be independent of any financial stress. Financial stress here is meant that, the management should avoid causing financial stress to the particular

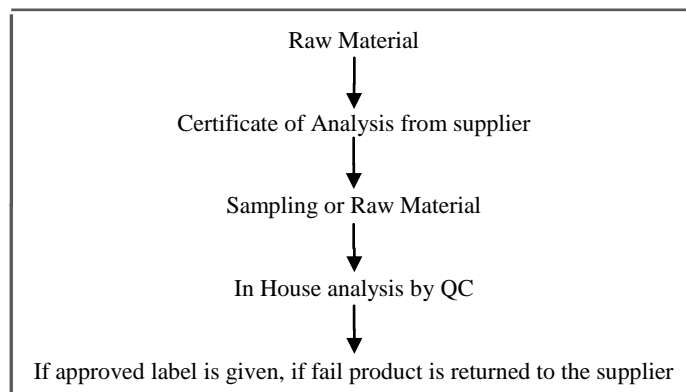
department as this could lead to a great impact on the quality of the product. As the quality of the product declines it could cause a major impact on the profit of the industry. Thus QA department should always be free from financial stress and should have sufficient manpower to ensure that the products 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.

- As mentioned above that QA is a vital department in any industry or field, as we are aware that every industry has policies and procedures as guideline to be followed. Thus they have to ensure that the guidelines and specifications are followed in each products that is produced from industry, any deviation could cause a product damage or product without a proper standard could lead and cause to product recall or batch productions is stopped abruptly.^[5] Each product that are produced and release should have the final authorities to give approval.

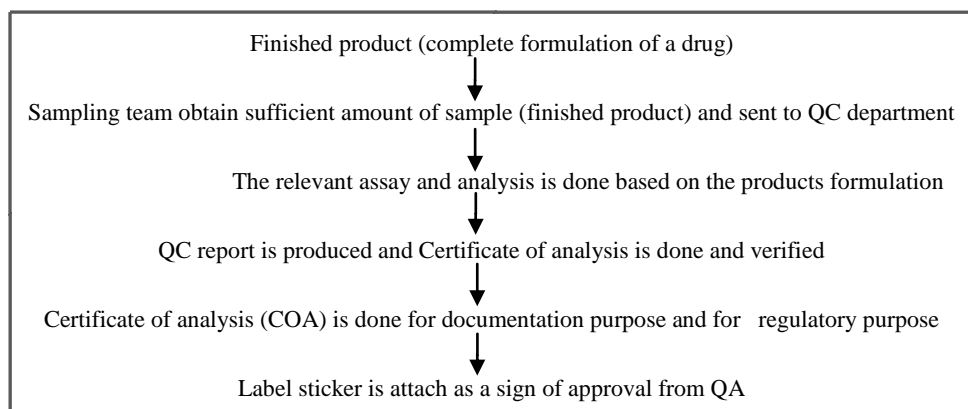
2. DRUG PRODUCT QUALITY

The quality of a drug does not only means here on the finished product, the quality of the product starts from the raw material to the final day when the product leaves the industry, and the quality of the product is also monitored till the expiry of the product in the market.^[6] The responsibility of the quality assurance does not only stop when the product leaves the industry but it is maintained also as the Product is in the market. The product quality is measured as follows; the methods and process are all repeated for each batch, as the batch is released from the industry.^[6]

2.1) Raw material, as we know it is the most important aspect of a drug formulation. The QA plays a role here by ensuring the product that is obtained from the vendor has gone through the analysis that is required and make sure the product meets the regulatory requirement in the specification of the raw material. The industry will obtain the Certificate of Analysis (COA) from the supplier, once the COA is obtained then it is checked by QA to ensure it is up to the standard.^[7] Then the sampling team will also obtain sufficient amount of the raw material to do a in house analysis. The in house analysis is done to ensure that the content and the results obtain in the COA from the supplier is genuine.

**Figure: 2.1**

2.2) Manufacturing of medication, as the medications are manufactured it has to follow with the standard SOP to ensure the product meet the quality requirement.^[7] As each process of manufacturing is over and it goes to the next level of manufacturing it is monitored by the relevant staff to ensure that the product is up to the specifications that are required, this steps are repeated till the final stage of the drug. As the drug is completed then the sampling team will obtain the sample to be produced to the QC department, so further analysis is done on the finished product. The analysis is done based on the British Pharmacopeia or the United States Pharmacopeia all aspect of the analysis and assays is done to ensure that the product is safe and efficacy for the product to be released to the market for public use.^[7]

**Figure 2.2**

2.3) Packaging of the finished product is a crucial step in a pharmaceutical industry, packaging can be further divided into, secondary packaging and tertiary packaging. The packaging substances are obtained from external suppliers. As the packaging materials have arrived then the sampling team will obtain few packaging materials to be sent to the quality control department, then the role of QC here is to check the quality of the packaging materials to ensure it meets the required standard of finished product.^[7] The color, the writings, the leaflet for patient and all necessary aspects on the secondary and the tertiary

packaging is well inspected to ensure there are no damages and it meets the Requirement in the aspect of quality. In the perspective of primary packaging that is done through the packaging machine it will be inspected by the QC personnel for every 15mins of packaging. This is done randomly to avoid any defect to the packaging. In case of any packaging problem the process will be stopped immediately and will be evaluated back according to the SOP to rectify the problem.

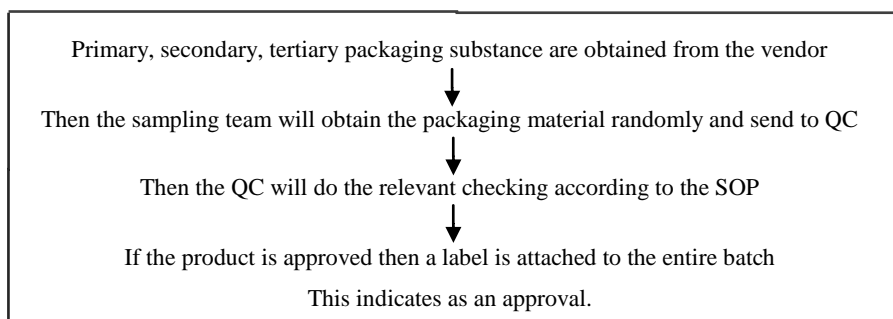


Figure 2.3

3) VALIDATION AND TECHNICAL SUPPORT IN QUALITY ASSURANCE

Validation as how it is mention in the heading it would give us a rough idea, as we all know validation it means of validating something. In pharmaceutical industry validation plays a very vital role under 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.^[8] 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.^[8] 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 1st analyst and the 2nd 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.

3.1) 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 then 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 entire QC team is called up for a briefing on the new method and ways to obtain the results for further clarification demonstration is also conducted.^[9]

3.2) Process Validation

- Process validation is normally based on the general production team and the business improvement team where they will work together in enhancing the process of production to obtain the standard results with a more efficient process. The process is also validated and before the new process is implemented, they should obtain NPCB approval on the new process.^[10] 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 done regularly on a particular 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 a better safety and quality of the drug. Trial and errors and pilot studies are always done repeatedly on a new method before it could be sent to NPCB for approval, these shows that quality and customers requirement are the main concern and priority in a pharmaceutical industry.^[10] Quality of a medication should never be compromise as it could lead to many other effects which could even be fatal to patient, thus 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.

4. STABILITY IN QUALITY ASSURANCE

Stability is a team that supports the quality assurance team by checking on the stability of the products that have been manufactured by the particular industry. Before the drug is released to the market the drug is ensured with a good stability.^[11] The most interesting part of the stability team is that they even do the stability testing on drugs that has been released to the market. This works in a very different concept where the retention team will support the stability team. Each drug that has been released to the market is stored by the retention team for the stability studies to be conducted.^[11] The stability study of the product that has been marketed is done on a 3months basis.

Example drug A is released to the market on 10/07/2017 then this particular batch of product is kept in sufficient amount by the retention team.^[12] So the stability team will conduct a stability test on the Drug A after 3months in the market, 6months,9months, 12 months and this continue till the expiry date of the drug A in the market. The stability studies of drug A is done on every 3months basis till the expiry date of the product.^[12] If in between of the stability study period of drug A it was found that the Drug stability has a problem then the product will be recalled from the market. Example after 6moths drug A in the market and when tested for stability studies it does not produce a standard result then Drug A will be recalled from the market. This can also be said as Post Marketing Surveillance by the pharmaceutical industry.

Any problem on the drug stability before it is released to the market or even after it is released to the market that particular product must be recalled, if the batch has not been marketed then it should be inhibited.^[13]

5. QUALITY ASSURANCE IN REGULATORY AFFAIRS OF A PHARMACEUTICAL INDUSTRY

A regulatory affair as it is mentioned on the heading the first thing that strikes us on the word regulatory is regulation and laws. In this section we are about to discuss on 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 give a better profit to the industry. Regulatory affairs particularly deal with the regulatory aspect of a medication and pharmaceutical industry thus in the regulation aspect also QA documentation is needed in order to obtain clearance on any related regulatory issues.^[14] 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. Dossiers is a very important aspect in a regulatory affairs department, this dossiers are generally used to register the manufactured products in other countries.^[14] This dossier should contain details about every aspect of the drugs; the major aspect in a drug dossier is the Quality assurance details and the Certificate of Analysis (COA). The dossier prepared is sent to the specific countries authorities for registration of the drug in that particular country. It will nearly take 2 years for a drug to be registered in a different country in a export basis. Every detail of analysis and assay that is 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.^[15]

- **2 TYPES OF DOSSIERS**

- Common Technical Dossier (CTD)
- Asean Common Technical Dossier (ACTD)

The CTD is used for registration of drugs in countries that are not included as Asean, this is the general format that is used. In CTD QA documentation plays a very important 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.^[16] 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 Asean 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 Asean countries.^[16] 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 how Quality Assurance contribute to the drugs that are about to be registered in other countries and how it contribute to the revenue of the particular pharmaceutical industry.^[17] 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.^[17]

6. QUALITY ASSURANCE IN BUSINESS DEVELOPMENT

As how it is mentioned and clearly explained in all sections that quality assurance has a vital role to be played in a pharmaceutical industry. Business development here meant by a

department that works on developing the long term business plan for the particular pharmaceutical industry. They plan in ways to look forth and sustaining the industries profit, they normally work by bring in a new medications from other countries so they could be a sole distributor in the country which gives them profit also.^[18] They plan in ways to penetrate the market in the public through various ways, they will have to compete with the other industries by thinking in different and various ways that could make them to outshine the others. They also concentrate on clinical trials and Research and Development to encourage on the new findings of drugs to be the patent of the drug.^[18] They invite new drugs from overseas which they could see it as a potential profit gaining drug, then the business development team will work on getting the drug to be registered in their country. Normally on this cases there will be an agreement on the royalties and the terms of payment for certain years. Once the drug is approved to be sale then the business development team will proceed to market the drug in various ways. Business development team will also venture into other sectors of business which could bring revenue to the organization without solely depending on the pharmaceutical products.^[18] The role that quality assurance plays or to be said as contributing to the business development team is by producing the data on the quality of the drugs that has been manufactured as a factor to promote the industry. The quality of the drug reflects on the pharmaceutical industry.^[19]

Objective of Business Development

- 6.1) to bring in new products to the industry to be the sole distributor this could contribute to the profit of the industry.
- 6.2) Keeping tract on drug patents and to increase the generic production
- 6.3) Generate more profit and revenue for the industry
- 6.4) to encourage on Research and Development that could lead to new drug discoveries
- 6.5) Enhancing the existing drug for a better quality.

The business development team also works In a way to enhance the mutual understanding and benefits with other Pharmaceutical industries, they join venture in developing the business.^[19] As it has mention quality plays a very important role, thus in order for the other industries to have a good relationship or trust on us they would first look into the quality of the products that have been produced by the industries.

7. CONCLUSION

As a conclusion on the entire discussion it clearly shows that quality assurance is somehow related to all the departments in a pharmaceutical industry, and it plays an important role in each department to enhance the process of that particular department. As how the title mentions that the quality assurance plays a vital role and it is said as the backbone of a pharmaceutical industry. Quality Assurance they emphasize on customers satisfaction and also based on the guidelines which have been set up by the authorities. As the thalidomide incident which took place long ago it shows a clearly failure in the quality assurance and the clinical trial phase which lead to such a big disaster which caused teratogenicity (Phocomelia).^[20] The drug was first invented for morning sickness problem in the pregnant women's. Due to lack of proper analysis and quality check it has caused a black history, thus this also clearly proves that the quality assurance has a very important role in production of medication.^[20] Quality assurance is not only implemented or emphasized in pharmaceutical industry whereas it is emphasized on every production industry which is related to every field. As it was said that QA works based on customers satisfaction, customer is the main source which gives profit and revenue to any industry. If the product does not have qualities then it will be a big failure to the industry.^[20] QA has its role in every part of an industry which is inter-related, QA can form many branches of department "under their Umbrella" to increase the efficacy and the standard of the quality by every means and methods.

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