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Role Of Quality Control In Pharmaceutical Company.

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ABSTRACT

The pharmaceutical quality management system is a concept of management function that design and implement the "Quality policy". The pharmaceutical manufacturing industries all over the world have just begun to apply the United States Food and Drug Administration (USFDA) guidelines in the 21st century. The study tries to identify the quality metrics based on Quality Indicators for a pharmaceutical industry and to investigate the utilization of quality KPIs. Methodology: The work experience from a successfully working pharmaceutical organization related to Research and and Development (R&D) of pharmaceutical products are discussed here. Important areas were identified and analysed based on the data collected from the deviation reports of selected organization and other resources. The R&D centre uses a software system for Quality management system including, Deviation management, Change management, Laboratory investigation, Incident management and Corrective Action and Preventive Action (CAPA).

Keyword: Quality, pharmaceutical company,world health organization,good manufacturing practices,food and drug administration,quality risk management

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INTRODUCTION

In pharmaceutical quality control test and laboratory servers one of the most important role in pharmaceutical manufacturing and control. A important portion of the CGMP act related to the quality control laboratory and sample testing. Same concept put in bulk drug [1].

The quality in the pharmaceutical company has become a very important subject.

A literature review was regulate on the quality in the pharmaceutical company, recognize publications that basis on ideal matter, methodological matter, or the application of different implementation andrules were applied in the pharmaceutical companies. The essence of these sources was inspected and a number of articles were recognized .

The composition survey has two purpose deeply seen with the quality instructions and rules related tothe pharmaceutical companies and the institution such practices and rules to make a secure remains to use.

Method

There are some procedure of evaluate the production of quality control. A quality control graph is a that draw whether testing products or processes are assembly their calculatedconception and, if not, the level by which they differ from those conceiving. When each graphassay a particular assign of the product, it is known a multivariategraph. When a chart measures difference in some product impute, it is known a multivariate graph [2].

A search was construct of the following databases: WHO, FDA, ICH, EU to load their resembling instruction. Apply the Google search engine; also a number of papers and articles were load.

Two testing themes could be recognize in the articles knowing in this literature review.

They are involved

Guidelines of the pharmaceutical quality.

General practices recently applied in the pharmaceutical company.

The widely essencial guidelines that are generally applicable in the pharmaceutical company are:

WHO guidelines

WHO has issued a manual on the GMP in specific, characterize: Quality assurance of pharmaceuticals, a collection of instruction and connected materials, capacity good manufacturing practices and evaluation [3].

Annexes guidelines of WHO

Annex 1:- Radiopharmaceutical products.

Annex 2:- Good manufacturing practices for pharmaceutical products: main principles.

Annex 3:- Model Certificate of GMP.

Annex4:- Sterile pharmaceutical products.

Annex 5:- Guidance on GMP inspection.

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Annex 6:- Pre-approval inspection.

Annex 7:- Quality system requirements for national GMP inspectorates.

GMP Guidelines :-GMPs are enforced in the United States by the U.S. Food and Drug Administration (FDA),. The regulations use the phrase "current good manufacturing practices" (CGMP) to describe these guidelines. Courts may theoretically hold that a product is adulterated even if there is no specific regulatory requirement that was violated as long as the process was not performed according to industry standards However, since June 2007, a different set of CGMP requirements have applied to all manufacturers of dietary supplements, with additional supporting guidance issued in 2010. Additionally, in the U.S., medical device manufacturers must follow what are called "quality system regulations" which are deliberately harmonized with ISO requirements, not necessarily CGMPs [4].

The World Health society (WHO) description of GMP is use by pharmaceutical regulators and the pharmaceutical industry in over 100 countries worldwide, mainly in the increasing world The European Union's GMP (EU-GMP) enforces parallel supplies to WHO GMP, as does the FDA's adaptation in the US. parallel GMPs are used in other countries, with Australia, Canada, Japan, Saudi Arabia, Singapore, Philippines], Vietnam and others having highly developed/sophisticated GMP requirements. In the United Kingdom, the Medicines Act (1968) covers most aspects of GMP in what is commonly referred to as "The Orange Guide," which is named so because of the color of its cover; it is officially known as Rules and Guidance for Pharmaceutical Manufacturers and Distributors.

CGMP Inspection :-Regulatory agencies (including the FDA in the U.S. and regulatory agencies in many European nations) are authorized to conduct unannounced inspections, though some are scheduled. FDA routine domestic inspections are usually unannounced, but must be conducted according to of the Food, Drug and Cosmetic Act , which requires that they are performed at a "reasonable time". Courts have held that any time the firm is open for business is a reasonable time for an inspection [5].

Other goods practices :-Other good-practice systems, along the same lines as GMP, exist:

- Good agricultural practice (GAP), for farming and ranching
- Good clinical practice (GCP), for hospitals and clinicians conducting clinical studies on new drugs in humans
- Good distribution practice (GDP) deals with the guidelines for the proper distribution of medicinal products for human use.
- Good laboratory practice (GLP), for laboratories conducting non-clinical studies (toxicology and pharmacology studies in animals)
- Good pharmacovigilance practice (GVP), for the safety of produced drugs
- Good regulatory practice (GRP), for the management of regulatory commitments, procedures and documentation [6].

Figure 1(GMP).

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GLP(good laboratory practice) in quality :-

Quality manage Laboratory Area & equipment should stumble upon the general &certain situation for Quality Control sector individual in part 3. Lab equipment should not be usually continue involving high opportunity district to prevent casual angry-pollution.

The workers property, and apparatus in the lab should be suitable to the responsibilitiescompulsory by the character and the level of the developed operations. The utilize of exteriorlabs, in consistency with the valuescomplete in section 7, dealevaluation, can be received for exactingcause, but this should be confirmed in the Quality Control report [7].

Figure 2(GLP).

FDA Guidelines

Pharmaceutical manufacturers have now begun to appreciate and pertain the FDA's cGMPs for the 21st Century: A danger-Based advance; the proposal outlines direct, close to and forever phase that FDA trust will obtain two existence to be execute. On the industrialsurface, FDA states three idea that will conduct the reviewprocedure: advances in dangerorganizationskill, advances in quality organizationskill and advances in pharmaceutical skill and developedknowledge (Larson 2004). The mainlysignificantprocedure are rules of nationalinstruction

.

The regulations contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such a drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it claims to possess.

The FDA has completed that current quality systems mutually with manufacturing processes and product information, can switch various types of changes to conveniences, apparatus and processes without the should for narrow compliance [8].

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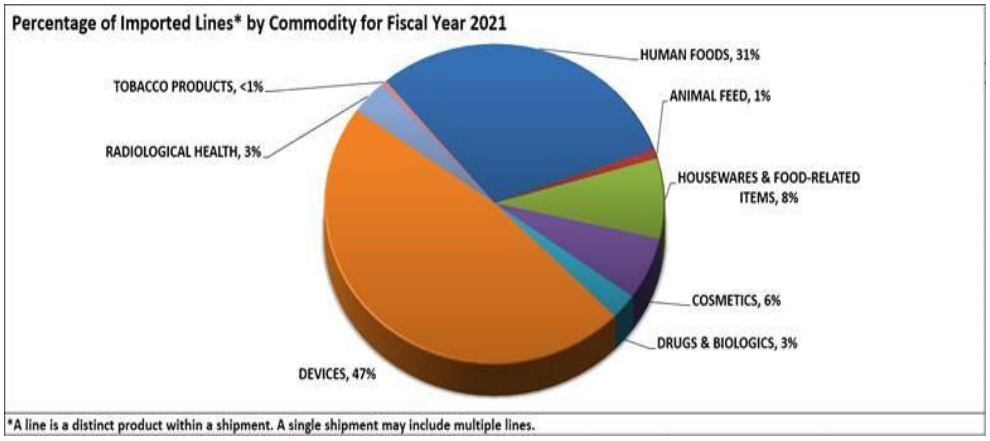

Figure 3(FDA).Regulated product

ICH Guidelines: The International Conference on Harmonization of technical supplies for listing of pharmaceuticals for person apply (ICH) is a individual mission that gathers the administrative authorities of Europe, Japan and the United States and specialist from the pharmaceutical company in the three dissimilarregion; to converse scientific and technical aspects of manufactured goodslist [9]**.**

The ICH topics are divided into four categories and ICH topic codes are assigned according to these categories

Q : Quality Guidelines
S : Safety Guidelines
E : Efficacy Guidelines
M : Multidisciplinary Guidelines

ICH procedure are not binding for anybody per se but the power of the ICH procedure lies in the assurance for realization by ICH narrow Members using suitable national/regional apparatus.

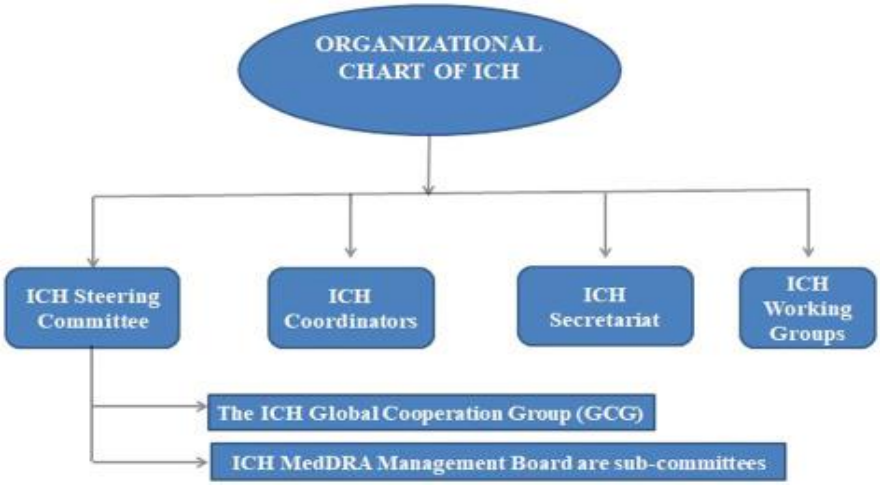

Figure 4(ICH).

Total quality management:-Total quality management (TQM) is a concept rather than a technique. It is a philosophy that stresses a systematic, integrated, and consistent perspective that would involve everyone and everything in the organization. (Isaac et al 2004) TQM is a management philosophy that builds a customer driven, learning organization that s devoted to total customer satisfaction through continuous improvement in the effectiveness and efficiency of the organization and its corresponding

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processes (Corrigan 1995). TQM is widely known for improving quality and other performances such as productivity, profit, market share, and competitive edge of organizations of various types (Sun 2000) (Isaac et al 2004) [10].

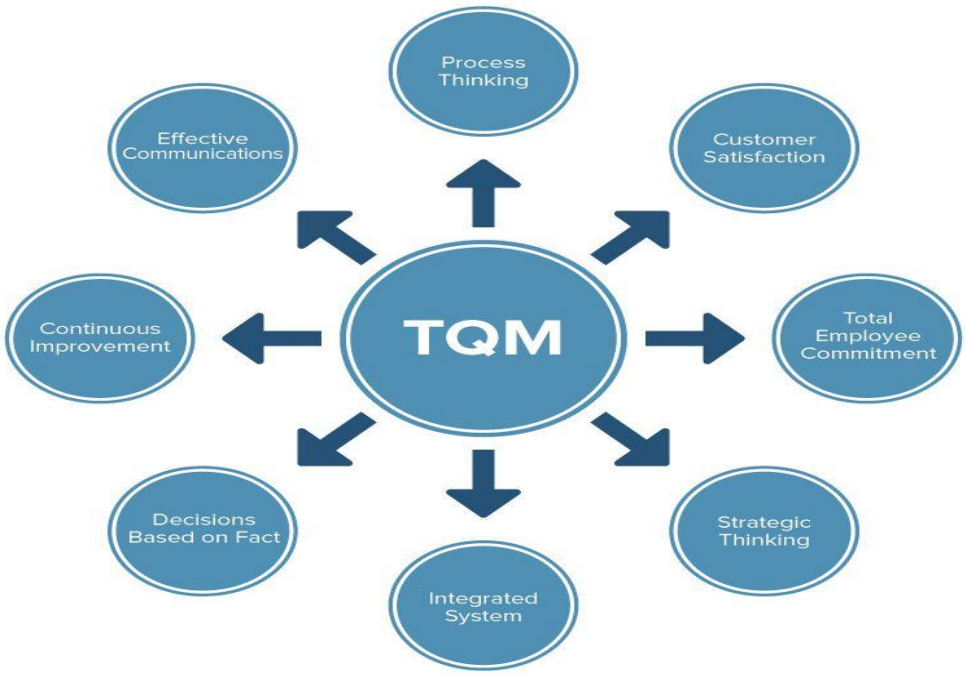

Figure 5

Quality risk management:-

every products and all processes have an naturalingredient of danger.

In an association that is intending to pertain an efficient quality dangerorganizationadvance, a apparentmeaning of what is careful ''danger'' should be approved upon since of the too various stakeholders in the pharmaceutical company and their matchingvariouswelfare.

The FDA has noticed that it requirements to reorder its events and processes to combine the work out of dangerorganization programs (RMP) inside the charity and contained by the company it regulates. so, the FDA has in progress publishing place papers and rule on what it expects to notice in an RMP.

Risk Management Plans should be used to identify risk. (Griffith 2004) Quality Risk Management is defined as a method for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product through the product lifecycle where decisions can occur at any point in the process (ICH Q9 2003) [11].

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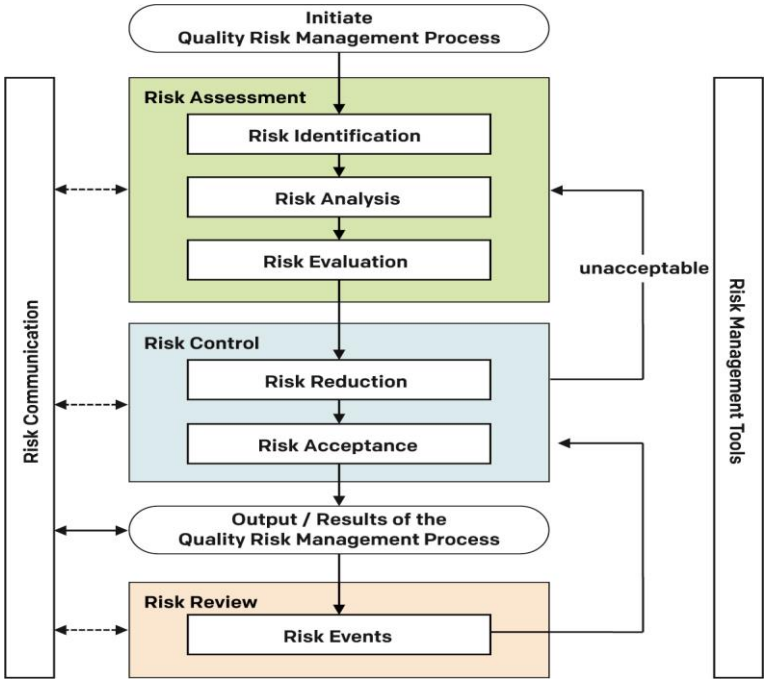

Figure 6(risk management).

Quality by design:-ICH Q8 defines design space from the concept that quality cannot be tested into product but has to be built in by design (ICH Q8 2003). Based on the ICH Q8; which concerns pharmaceutical development with targeting designing quality into the ingredients, formulation and manufacturing process to deliver the intended performance of the product. Design space is presented by the applicant and is subject to regulatory assessment and approval (ICH Q8 2003) [12].

Corrective action and preventive actions:-The organization should focus on correcting and preventing problems. Preventing problems is generally cheaper than fixing them after they occur. The organization should also start thinking about problems as opportunities to improve (EPA 2009).

In general, CAPA experts recommend that root-cause investigations follow a four-step process (Bartholomew 2006):

Identify the problem.
- Evaluate its magnitude, which includes assessing risk.
- Investigate and assign responsibility.
- Analyze and document the root cause of the problem.

Six Sigma:- Harry and Schroeder term Six Sigma as "a business procedure that enables company to increase proceedssignificantly by shake-up operations, improving quality, and eliminating defects or mistakes in nothing a corporation does…." It can aid an associationdecrease defects and developproductivity using several essential tenets (Harry and Schroeder 2000; Johnson and Swisher 2003; Pande, Neuman, and Cavanagh 2000; Williams 2003). (Goeke & Offodile 2005) Six Sigma Projects are based on DMAIC model [13]**.**

Design for Six Sigma (DFSS) is an Engineering design process, business process management method related to traditional Six Sigma**. It is used in many industries, like finance, marketing, basic engineering, process industries, waste management, and electronics. It is based on the use of statistical tools like linear regression and enables empirical research similar to that performed in other fields, such as social science. While the tools and order used in Six Sigma require a process to be in place and functioning, DFSS has the objective of determining the needs of customers and the business**, and driving those needs into the product solution so created [14]**.**

Process capability analysis :- Process capability is the comparison of the "Voice of the Customer" (VOC) with the "Voice of the Process" (VOP). VOC, which is built on customer requirements, is defined by the

specification limits of the process, which are fixed, while VOP is defined by control limits, which are based on performance data and vary over time (Tarpley 2004). Metrics such as capability index namely Cp & Cpk were developed several years ago to calculate this comparison between control and specification limits (Tarpley 2004) [15].

The capability index a ratio that compares process spread to tolerance spread and results in a single number. It is a management tool which is used to compare process performance. (Ruth II 2005).

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