Sudan University of Science and Technology

Collage of Graduate Studies

Deanship of Development and Quality

The Role of Organizational Structure on Validation Process Effectiveness using Benchmarking

دور الهيكل التنظيمي على فعالية عملية التحقق باستخدام المقارنة المرجعية

بحث تكميلي لنيل درجة الماجستير في إدارة الجودة الشاملة والامتياز

A Research submitted in partial fulfillment for the degree of M.Sc.
in Quality Management and Excellence

By:

Safaa Ahmed Mohammed

Supervisor:

Dr. Mustafa Hamed Elhakeem

February, 2018

بسم الله الرحمن الرحيم

Dedication

I dedicate this humble work to my dear father, my virtuous mother, my brother, sisters and all those who contributed with me to accomplishing this work.

Acknowledgement

Praise be to you. Praise be to Allah. Praise be to you. Praise be to Allah. Praise be to God. Praise be to you. Praise be to God. Glory be to you. Complete this research on the face that I hope you will accept. Thank you very much for the Sudan University of Science and Technology Management and Teachers as well as most thanks to our company for providing me with support to accomplish this work

I would like to thank Dr. Mustafa El Hakeem. who is help me as a student in the Master's program.

Abstract

Nowadays, change is an inevitable factor in the development of any organizations, and can be adapted, adopted, piloted through benchmarking in order to compete in this business environment and to improve the level of performance has been used industrial benchmarking .The study also asses benchmarking application at two Sudanese pharmaceutical companies the research is investigate the role of organizational structure on the validation process the data collection instrument used was a questionnaire which was administrated and distributed to total sample of 10 employees from two companies .The data were analyzed used statistical methods frequency distribution of the answers, percentages,alpha equation, to calculate the reliability coefficient,Median and Chi-square test for the significance of differences between the answers. The research finding supported the hypotheses that the organizational structure has a significant and positive role on process validation , validation team and documentation but there is no role on the results and for the first company the organizational structure and validation reports were fully achieved, validation process and validation documentation are considerable.

Progress finally validation team was some progress.and for second company only organizational structure fully achived and all variables are considerable Progress.

المستخلص

في الوقت الحاضر، التغيير هو عامل لا مفر منه في تطوير أي شركة، ويمكن تكييفها، واعتمادها من خلال تجريب المقارنة المرجعية من أجل المنافسة في هذه البيئة التجارية وتحسين مستوى الأداء .وعليه تم استخدام المقارنة المرجعية الصناعية . كما أن الدراسة تم تطبيقها في شركتين دوائيتين سودانيتين بحثا عن دور الهيكل التنظيمي على فعالية عملية التحقق وقد تم التأكد من صحة أداة جمع البيانات المستخدمة وذلك بادارة وتوزيع الاستبانة على عينة إجمالية من 10 موظفين من كلا الشركتين. تم تحليل البيانات باستخدام تواتر الأساليب الإحصائية' توزيع الإجابات، النسب المئوية، معادلة ألفا، لحساب معامل الموثوقية، متوسط و تشي مربع اختبار لأهمية الاختلافات بين الأجوبة. وأيدت نتائج البحث الفرضيات القائلة بأن الهيكل التنظيمي له دور كبير وإيجابي على فعالية التحقق من صحة العملية وفريق التحقق والتوثيق ولكن ليس هناك أي تأثير على النتائج وبالنسبة للشركة الأولى تم تحقيق الهيكل التنظيمي وتقارير التحقق بشكل كامل، وثائق التحقق وعملية التحقق بدرجة كبيرة من الصحة واخيراً كان بعض التقدم في فريق التحقق، اما بالنسبة للشركة الثانية الهيكل التنظيمي فقط تحقق بشكل تام وجميع المتغيرات بتقدم كبير.

Table of contents

List of Tables

List of Figures

Chapter 1

(Introduction)

1. Introduction

Organizations do have goals and objectives to achieve and could be better coordinated through a formalized procedure, the work of such organization must be divided among its members.

Some structures are necessary to make possible the effective performance of key activities and to support the effort of staff, structure provide the framework of an organization and its pattern of management. It represents a formalized framework within which management operates. It is by means of organization structure that the purpose and work of the organization can be carried out (Thomas 2015).

Organizations exist to achieve goals; these goals are broken down into tasks as the basis for jobs. Jobs are grouped into departments. Within each department, even more distinctions can be found between the jobs people perform one of these departments is validation department which the operation and activities are test protocol to demonstrate output to meets the performance standards required for the model's purpose, This is the purpose of prediction and includes the purpose of projection (qualitative correspondence with event dynamics), and their activities are monitoring all validation processes in the company such as (cleaning validation, process validation, analytical test method validation and qualification of equipment also monitoring the calibration time seclude for instruments of company, monitoring the water and HVAC (heating ventilation and air conditioning) system validation and finally monitoring the temperature and humidity of the company).

Validation defined as the confirmation which meaning comparison of requirement with evidence by examination and the provision of experimental data that the requirement for analytical requirements are fulfilled.

A consideration should be given to form a multi-functional team to plan and oversee the validation activities.

A team approach will help assure the validation processes are well thought out, the protocols are comprehensive and that the final packages are well documented and easy to follow. The team should advise "what could go wrong". The team also provides an opportunity for key functional areas to communicate early about important new and changed products and processes and can foster cooperation. After validation activities, final reports should be prepared. This report should summarize and reference all protocols and results. It should derive conclusions regarding the validation status of the process. The final report should be reviewed and approved by the validation team and appropriate management (TaisukeHojo, GHTF Chair2004).

The essence of process of identifying the highest standards of excellence for products, services, or processes, and then making the improvements necessary to reach those standards, commonly called "best practices" is benchmarking (Ross& E. 1995 p230-5).

Benchmarking has been gaining popularity, especially in the last five years. The process of benchmarking is more than just a means of gathering data on how well a company performs against others. Benchmarking can be used in a variety of industries, both services and manufacturing. It is also a method of identifying new ideas and new ways of improving processes and, therefore, being better able to meet the expectations of customers.

There are four different types of benchmarking which consist of: internal benchmarking, competitive benchmarking, functional or industry benchmarking, and process or generic benchmarking. Before deciding to benchmark, a company needs to determine what it is they want to benchmark. The type which is considering in this research is Functional or industry benchmarking which define as: performed externally against industry leaders or the best functional operations of certain companies. The benchmarking partners are usually those who share some common technological and market characteristics. They also seem to concentrate on specific functions, because there are no direct competitors involved, the benchmarking partner is more willing to contribute and share (Matters et al 1997).

1.2 Research problem:

Benchmarking between validation section in one pharmaceutical company and validation department in other company to measure the role of organization structure in the validation process in four factors (validation process, validation Team, documents and reports) to know the validation process effectiveness.

1.3 Research Objectives:

Using benchmarking when they are trying to implement a change and want to find and use world class business practices. Another reason that some executives use benchmarking is for organization to learn and see that there are different practices that can be adopted by own organization. Benchmarking can make a non-believer a believer.

1.4 Research Importance:

The importance of this research is that it deals with the role of organizational structure in the process of validation through the four factors (validation process, validation team, documentation and reports) using Benchmarking to improve performance and increase efficiency and knowledge of the obstacles that hinder this process.

1.5 Variables and model of Study:

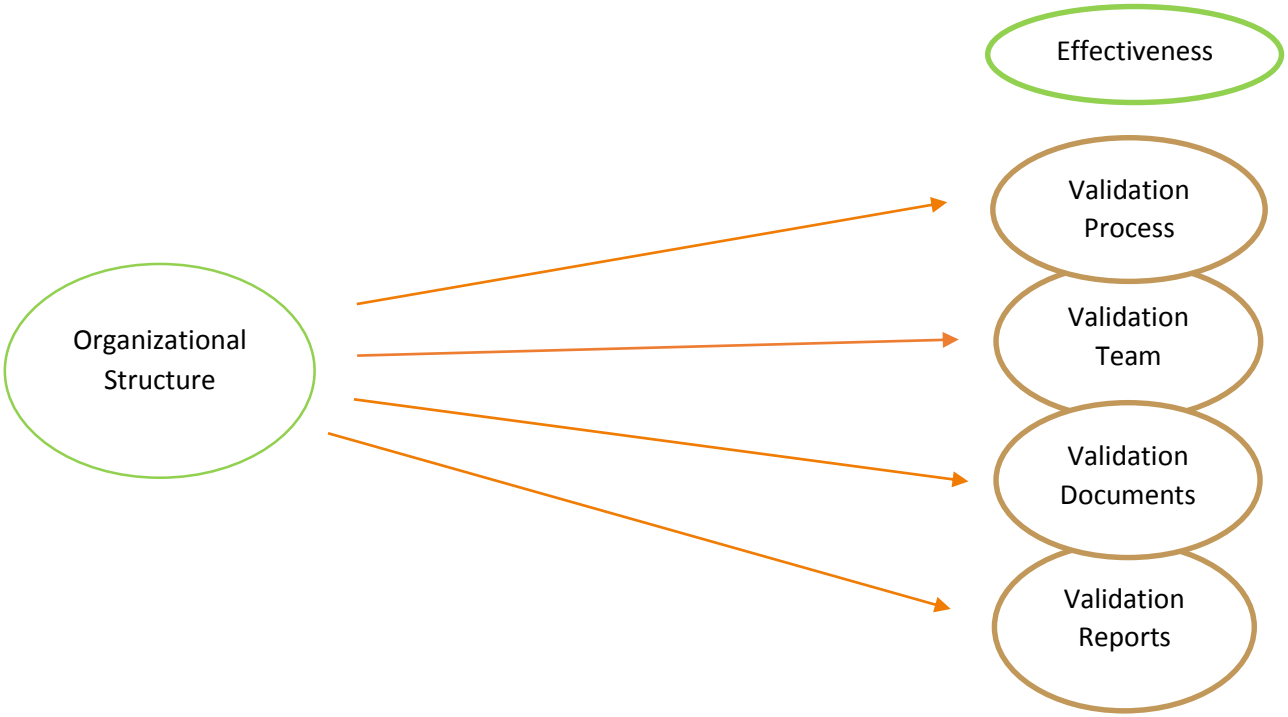


Figure (1): model of Study

1.6 Research Hypothesis:

- The relationship between organizational structure and Effectiveness of validation process.
- The relationship between organizational structure and Effectiveness of validation team.
- The relationship between organizational structure and Effectiveness of validation documents.
- The relationship between organizational structure and Effectiveness of validation reports.

1.7 Research Methodology:

Benchmarking is used by distributing questioner to companies for determining the role of organizational structure on validation process (distribution and analysis).

1.8 limit of study

Two pharmaceutical companies in Khartoum state are Considered for this study.

Chapter 2

(Literature review and Previous Studies)

2. Literature review and Previous Studies

2.1 What is an organization?

The word organization can be derived from the Greek word "organon", which means instrument or tool necessary to achieve performance (Morgan, 1997; Anderson, 1994). The original meaning was related to biology, i.e. an organ in a living being (Maturana,1978), which has evolved to denote an instrumental view of an organization as a social engineered artifact designed to accomplish one or more objectives (Strati, 2006). Today, the term organization often is defined in the following ways:

Organizations have purposes, attract participants, acquire and allocate resources to accomplish goals, use some form of structures to divide and coordinate activities, and rely on certain members to lead or manage others (Shafritz and Ott1996, p. 2).

Organization is formal structure of planned coordination, involving two or more people who share a common purpose? It's characterized by formal roles that define and shape the behavior of its members. (Robbins 2000, p. 2). Based on these two definitions organizations be a mechanism for management and coordination of the resources that perform the operative work (Mintzberg, 1979), to achieve the strategic tasks of the business (Kates and Galbraith, 2007).

2.1.1 Organizational Structures

The primary formal relationships for organization are responsibility, authority, and accountability (MontanaP and Charnov B 1993 p155-169) refers to how individual and team work within an organization are coordinated to achieve organizational goals and objectives. Structure is a valuable tool in achieving coordination, as it specifies reporting relationships (who reports to whom), delineates formal communication

channels, and describes how separate actions of individuals are linked together. Organizations can function within several different structures, each possessing distinct advantages and disadvantages. Although any structure that is not properly managed will be plagued with issues, some organizational models are better equipped for environments and tasks.

2.1.2 Major Types of Organizational Structures

Organizations large and small can achieve higher sales and other profit by properly matching their needs with the structure they use to operate. There are three main types of organizational structure: functional, divisional and matrix structure.

2.1.2.1 Functional Structure

Functional structure is set up so that each portion of the organization is grouped per its purpose. It is works very well for small businesses in which each department can rely on the talent and knowledge of its workers and support itself. However, one of the drawbacks to a functional structure is that the coordination and communication between departments can be restricted by the organizational boundaries of having the various departments working separately.

2.1.2.2 Divisional Structure

Divisional structure typically is used in larger companies that operate in a wide geographic area or that have separate smaller organizations within the umbrella group to cover different types of products or market areas. The benefit of this structure is that needs can be met more rapidly and more specifically; however, communication is inhibited because employees in different divisions are not working together.

Divisional structure is costly because of its size and scope. Small businesses can use a divisional structure on a smaller scale, having different offices in different parts of the city

2.1.2.3 Matrix

The third main type of organizational structure, called the matrix structure, is a hybrid of divisional and functional structure. Typically used in large multinational companies, the matrix structure allows for the benefits of functional and divisional structures to exist in one organization. This can create power struggles because most areas of the company will have a dual management a functional manager and a product or divisional manager working at the same level and covering some of the same managerial territory.

2.2 Validation

Is defines as establishing documented evidence which provides a high degree of assurance that specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics. According to European commission: Validation is defined as "Action providing in accordance with the principles of GMP (good manufacturing practices), that any procedure, process, equipment, material, activity or system lead to the expected results (Sharma Sumeet, Singh Gurpreet 2013). USFDA (United States Food and Drug Administration) defines validation as: "Validation is establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics.

Validation is defined as a concept that has evolved in united states in 1978, the concept of validation has expanded through the years to embrace a

wide range of activities from analytical methods used for the quality control of drug substances and drug products to computerized systems for clinical trials, labelling or process control, Validation is founded on, but not prescribed by regulatory requirements and is best viewed as an important and integral part of cGMP (current good manufacturing practices).

The word validation simply means assessment of validity or action of proving effectiveness. Validation is a team effort where it involves people from various disciplines of the plant (Nand hakumar et al 2011).

2.2.1The Regulatory History of Process Validation:

Although the emphasis on validation began in the late 1970s, the requirement has been around since at least the 1963 cGMP regulations for finished pharmaceuticals. The Kefauver-Harris Amendments to the FD&C (Federal Food, Drug and Cosmetic) Act were approved in 1962 with Section 501(a)(2)(B) as an amendment. Prior to then, cGMP and process validation was not required by law. The FDA had the burden of proving that a drug was adulterated by collecting and analyzing samples.

This was a significant regulatory burden and restricted the value of factory inspections of pharmaceutical manufacturers. It took injuries and deaths, mostly involving cross- contamination problems, to convince Congress and the FDA (Food and Drug Administration) that a revision of the law was needed.

The result was the Kefauver–Harris drug amendments, which provided the additional powerful regulatory tool that FDA required to deem a drug product adulterated if the manufacturing process was not acceptable. The

first cGMP (current good manufacturing practices) regulations, based largely on the Pharmaceutical Manufacturers Association's manufacturing control guidelines, were then published and became effective in 1963.

This change allowed FDA (Food and Drug Administration) to expect a preventative approach rather than a reactive approach to quality control. also, important in the implementation of process validation requirements because it gives the agency the authority to withhold approval of a new drug application if the "methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity."

Another requirement of the same amendments was the requirement that FDA must inspect every drug manufacturing establishment at least once every 2 years (U.S. Code, Federal Food Drug and Cosmetic Act). At first, FDA did this with great diligence, but after the worst cGMP manufacturing situations had been dealt with and violations of the law became less obvious, FDA eased up its pharmaceutical plant inspection activities and turned its resources to more important problems.

The Drug Product Quality Assurance Program of the 1960s and 1970s involved first conducting a massive sampling and testing program of finished batches of particularly important drugs in terms of clinical significance and dollar volume, then taking legal action against violate batches and inspecting the manufacturers until they were proven to comply. This approach was not entirely satisfactory because samples are not necessarily representative of all batches. Finished product testing for sterility, for example, does not assure that the lot is sterile. Several incidents refocused FDA's attention to process inspections. The

investigation of complaints of clinical failures of several products (including digoxin, digitoxin, prednisolone and prednisone) by FDA found significant content uniformity problems that were the result of poorly controlled manufacturing processes. Also, two large-volume parenteral manufacturers experienced complaints despite quality control programs and negative sterility testing. Although the cause of the microbiological contamination was never proven, food and drug administration (FDA) inspections did find deficiencies in the manufacturing process and it became evident that there was no real proof that the products were sterile. What became evident in these cases was that FDA had not looked at the process itself certainly not the entire process in its regulatory activities; it was quality control- rather than quality assurance-oriented. The compliance officials were not thinking in terms of process validation. One of the first entries into process validation was a 1974 paper presented by Ted Byers, entitled "Design for Quality" (Cherry Hill-1974).

The term validation was not used, but the paper described an increased attention to adequacy of processes to produce pharmaceuticals. Another paper by Bernard Loftus before the Parenteral Drug Association in 1978 entitled "Validation and Stability" (Loftus- 1978) discussed the legal basis for the requirement that processes be validated.

The May 1987 Guideline on General Principles of Process Validation (Rockville, MD-1987) was written for the pharmaceutical, device, and veterinary medicine industries.

It has been effective in standardizing the approach by the different parts of the agency and in communicating that approach to manufacturers in each industry.

2.2.2Validation types

2.2.2.1 Calibration

The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (for example, weight, temperature and pH), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

2.2.2.2 Cleaning validation

Documented evidence to establish that cleaning procedures are removing residues to predetermined levels of acceptability, taking into consideration factors such as batch size, dosing, toxicology and equipment size.

2.2.2.3 Commissioning

The setting up, adjustment and testing of equipment or a system to ensure that it meets all the requirements, as specified in the user requirement specification, and capacities as specified by the designer or developer. Commissioning is carried out before qualification and validation.

2.2.2.4 Computer validation

Documented evidence which provides a high degree of assurance that a computerized system analyses, controls and records data correctly and that data processing complies with predetermined specifications.

2.2.2.5 Process validation

Documented evidence which provides a high degree of assurance that a specific process will consistently result in a product that meets its predetermined specifications and quality characteristics.

2.2.2.6 Qualification

Action of proving and documenting that any premises, systems and equipment are properly installed, and/or work correctly and lead to the expected results. Qualification is often a part (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation (QA of PH-2006).

2.2.3 Validation life cycle

Validation is a continuing and evolving process. The validation process which extends from the very basic to a very broad theological and methodical investigation if how the system and processes perform. Its scope encompasses documentation revision control, training and maintenance of the system and process. Evidence of validation should be seen at the corporate level, and be reflected in the management structure.

Validation is a method for building and maintaining quality (Satyabratajena, et al 2013).

2. 3Validation Process

Establishes the flexibility and constraints in the manufacturing process controls in the attainment of desirable attributes in the drug product while preventing undesirable properties. This is an important concept, since it serves to support the underlying definition of validation, which is a systematic approach to identifying, measuring, evaluating, documenting, and reevaluating a series of critical steps in the manufacturing process that

require control to ensure a reproducible final product (European medicines agency 2012:10-11).

A successful validation program depends upon information and knowledge from product and process development. This knowledge and understanding is the basis for establishing an approach to control of the manufacturing process that results in products with the desired quality attributes. (Satyabratajena,et al 2010).

When any new manufacturing formula or method of preparation is adopted, steps should be taken to demonstrate its suitability for routine processing.

The defined process should be shown to yield a product consistent with the required quality. In this phase, the extent to which deviations from chosen parameters can influence product quality should also be evaluated. When certain processes or products have been validated during the development stage, it is not always necessary to revalidate the whole process or product if similar equipment is used or similar products have been produced, provided the final product conforms to the in-process controls and final product specification. There should be a clear distinction between in-process control and validation. In production, tests are performed each time on a batch to batch basis using specifications and methods devised during the development phase. The objective is to monitor the process continuously.

The implementation of validation work requires considerable resources such as:

• Time: generally, validation work is subject to rigorous time schedules.

• Financial: validation often requires the time of specialized personnel and expensive technology.

• Human: validation requires the collaboration of experts from various disciplines (e.g. a multidisciplinary team, comprising quality assurance, engineering, manufacturing and other disciplines, depending on the product and process to be validated).

2. 4 Validation Team

A multidisciplinary team is primarily responsible for conducting and supervising validation studies. Personnel qualified by training and experience in a relevant discipline may conduct such studies. They responsible for evaluating and certifying the acceptability of each stage in the study and for the final evaluation and certification of the process as measured against the pre-defined criteria. Members of the validation team could include representatives from or personnel with expertise in:

- Quality Assurance
- Engineering
- Manufacturing
- Others depending on company organization and product types:
- Laboratory
- Technical Services
- Research & Development
- Regulatory Affairs
- Clinical Engineering
- Purchasing and Planning

Once the validation team has been formed, the next step is to plan the approach and define the requirements. Many manufacturers develop what is referred to as a master validation plan which identifies those processes to be validated, the schedule for validations, interrelationships between

processes requiring validation and timing for revalidations. Once these have been established, and the purpose and scope for validations are clearly stated and known, protocol development can commence.

Form multi-functional team for validation, Plan the approach and define the requirements, Identify and describe the processes, specify process parameters and desired output, specify process parameters and desired output, decide on verification and/or validation, create a master validation plan, select methods and tools for validation, create validation protocols, Perform Installation qualification (IQ), Operational qualification (OQ) and Performance qualification (PQ) document results and Determine continuous process controls. (Taisuke Hojo, GHTF Chair2004).

2.4.1 Responsibilities of validation team

Creates updates and reviews/approves individual project validation plans and validation deliverables. Ensures validation compliance with the company validation master plan and project validation plan. Coordinates, implements and verify elements of validation master plan VMP. Consults on, evaluates and approves changes. Reviews and approves IQ/OQ/PQ procedures and plans. Reviews test results and makes recommendations regarding release. Assess risks and develops contingency plan (L. Nandhakumar et al 2011, 1(4)).

2. 5 Documentation

Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with good manufacturing practices (GMP) requirements. The various types of documents and media used should be fully defined in the manufacturer's Quality Management System.

Documentation may exist in a variety of forms, including paper-based, electronic or photographic media. The main objective of the system of documentation utilized must be to establish, control, monitor and record all activities which directly or indirectly role on all aspects of the quality of medicinal products. The Quality Management System should include sufficient instructional detail to facilitate a common understanding of the requirement, in addition to providing for sufficient recording of the various processes and evaluation of any observations, so that ongoing application of the requirements may be demonstrated.

There are two primary types of documentation used to manage and record good manufacturing practices (GMP) compliance:

instructions (directions, requirements) and records/reports. Appropriate good documentation practice should be applied with respect to the type of document.

Suitable controls should be implemented to ensure the accuracy, integrity, availability and legibility of documents. Instruction documents should be free from errors and available in writing. The term 'written' means recorded, or documented on media from which data may be rendered in a human readable form.

The documents should describe each unit operation, its placement in the overall process, monitoring and control points, and the component, as well as other processing material inputs and expected outputs (i.e., in-process materials and finished product). It is also useful to generate and preserve process flow diagrams of the various scales as the process design progresses to facilitate comparison and decision making about their comparability. A written protocol should be established that specifies how qualification and validation will be conducted.

2. 5.1Generation and Control of Documentation

2. 5.1.1 All types of document should be defined and adhered to. The requirements apply equally to all forms of document media types. Complex systems need to be understood, well documented, validated, and adequate controls should be in place. Many documents (instructions and/or records) may exist in hybrid forms, i.e. some elements as electronic and others as paper based. Relationships and control measures for master documents, official copies, data handling and records need to be stated for both hybrid and homogenous systems. Appropriate controls for electronic documents such as templates, forms, and master documents should be implemented. Appropriate controls should be in place to ensure the integrity of the record throughout the retention period.

2. 5.1.2 Documents should be designed, prepared, reviewed, and distributed with care. They should comply with the relevant parts of Product Specification Files, Manufacturing and Marketing Authorization dossiers, as appropriate. The reproduction of working documents from master documents, should not allow any error to be introduced through the reproduction process.

2. 5.1.3 Documents containing instructions should be approved, signed and dated by appropriate and authorized persons. Documents should have unambiguous contents and be uniquely identifiable. The effective date should be defined.

2. 5.1.4 Documents containing instructions should be laid out in an orderly fashion and be easy to check. The style and language of documents should fit with their intended use.

Standard Operating Procedures, Work Instructions and Methods should be written in an imperative mandatory style.

2.5.1.5 Documents within the Quality Management System should be regularly reviewed and kept up-to-date.

2.5.1.6 Documents should not be hand-written; although, where documents require the entry of data, sufficient space should be provided for such entries. (European Commission 2010).

2. 5.2 Good Documentation Practices

2. 5.2.1 Handwritten entries should be made in clear, legible, indelible way.

2. 5.2.2 Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable.

2. 5.2.3 Any alteration made to the entry on a document should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration, should be recorded. (European Commission 2010) Documentation associated with validation includes: standard operating procedures (SOPs), specifications validation master plan (VMP), qualification protocols and reports and validation protocols and reports.

2. 5.3 Validation master plan (VMP)

The VMP is a high-level document that establishes an umbrella validation plan for the entire project and summarizes the manufacturer's overall philosophy and approach, to be used for establishing performance adequacy. It provides information on the manufacturer's validation work programmer and defines details of and timescales for the validation work to be performed, including a statement of the responsibilities of those implementing the plan. (Quality assurance of pharmaceuticals2006).

2. 5.4 Protocol

A document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a manufacturing processor a part there offers routine use.

The protocol should be reviewed and approved also should specify critical steps and acceptance criteria. 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.

2. 6 Validation Reports

2. 6.1 Validation Reports Definition:

A document in which the records, results and evaluation of a completed validation programmer are assembled and summarized. It may also contain proposals for the improvement of processes and/or equipment. (QA of ph-2006).

In the pharmaceutical industry, it is very important that in addition to final testing and compliance of products, it is also assured that the process will consistently produce the expected results. The desired results are established in terms of specifications for outcome of the process. the result most likely will be loss of efficiency during routine Quality Control testing and a lengthy and complicated validation process as well.

these results describe in detail the methodology and results of the job analysis and the subsequent development and content validation of the written examination and structured interview. Due to the sensitive nature of the information and data discussed herein, it is strongly recommended

that this report be maintained as part of the examination files for Staff Services Analyst (General) and that its access be limited to examination staff to ensure the security and integrity of the Staff Services Analyst (General) selection process resulting from this project.

A written report should be available after completion of the validation. If found acceptable, it should be approved and authorized (signed and dated).

The report should include at least the following:

Title and objective of study. Reference to protocol. Details of material. Equipment Programs and cycles used. Details of procedures and test methods. Results (compared with acceptance criteria). Recommendations on the limit and criteria to be applied on future basis.

The report should include at least the following:

- Title and objective of study.
- Reference to protocol.
- Details of material.
- Equipment.
- Programmed and cycles used.
- Details of procedures and test methods.
- Results (compared with acceptance criteria).
- Recommendations on the limit and criteria to be applied on future basis.

2.7 Effectiveness

The word effectiveness is derived from the Latin word effectivus, meaning efficacy polish dictionary of terms adopted from foreign languages describes this word of the following terms: positive result, efficiency, efficacy and functionality.

There are various opinions regarding valuation of the organization. Mouzas (2006) emphasized two indicators to assess the performance: the efficiency and the effectiveness.

For managers, suppliers and investors these two terms might be synonymous, yet, each of these terms have their own distinct meaning. oriented companies are concerned with output, sales, quality, creation of value added, innovation, cost reduction. It measures the degree to which a business achieves its goals or the way outputs interact with the economic and social environment.

Usually effectiveness determines the policy objectives of the organization or the degree to which an organization realizes its own goals (Zheng, 2010). Meyer and Herscovitch analyzed organizational effectiveness through organizational commitment. Commitment in the workplace may take various forms, such as relationship between leader and staff, employee's identification with the organization, involvement in the decision-making process, psychological attachment felt by an individual. Shiva and Suar (2010) agree that superior performance is possible by transforming staff attitudes towards organization from lower to a higher plane of maturity, therefore human capital management should be closely bonded with the concepts of the effectiveness.

Effectiveness is an external measure of performance and indicates how well a Process fulfills the demands of various stakeholders. Simply put, it is "doing the right things." For example, in educational institutions, effectiveness is measured by teaching students what they need to know. Managers need to make sure that the services or products meet customers' expectations. When analyzing a company's processes, effectiveness takes precedence over efficiency. Effectiveness of a process is the measure of

how relevant the output is to the desired objective. A truly effective process will make customers happy by providing everything right. That is, the right results at the right place time and cost. Hence, measure process effectiveness from the customers' goal point of view.

2.7.1 The Effectiveness of validation Process:

Effectiveness is the extent to which an activity fulfils its intended purpose or function.

Effectiveness. This is a measure of the match between stated goals and their achievement. It is always possible to achieve 'easy', low-standard goals. In other words, quality in higher education cannot only be a question of achievements 'outputs' but must also involve judgements about the goals (part of 'inputs') (Fraser -1994, p. 104).

2.7.2 Implement the Effective Verification and Validation Process:

This section talks about the implementation of the V&V approach proposed to show its effectiveness. As mentioned earlier the approach is developed for a safety critical avionics application.

There is also a different school of thought for the effective approach for Verification and Validation process in which the testing for the system requirements is carried out at the system level. The testing of the software is not carried out separately on the native platform. Instead the software is tested as part of the system. This approach reduces the time required to carry out the Verification and Validation process further. This approach can be used if the critical system is reused for different applications with changes in the software and the same team carries the Verification and Validation process. In case of a new project with new test scenarios it is advisable and necessary that the entire process of software testing, system testing to cover the requirements and gain confidence about the system.

Many may contest this thought but with experience we have realized this. The tools used for the software testing were qualified and commercially available. The test set up for the embedded system testing is developed in-house as it is specific to the application. The qualification of the setup is carried out by an independent team. This team is a part of the quality team. Qualification is done by testing the features provided by the test set up. The test set-up test procedure is developed by the V&V team as it is aware of the requirements to be provided by the test set up which will help them in carrying out the tests. These test procedures are documented in the Acceptance Test Procedure document. The test procedure underwent a lot reviews before it was accepted. (Manju Nanda & Jayanthi 2013)

Wyrazów Obcych [Polish Dictionary of Foreign Terms], 1995: 269). One can also meet many production factor or set of production factors". A similar definition can be found in Słownik Języka Polskiego (Polish Language Dictionary) (1996: 484), where effectiveness is defined as between the output obtained and the inputs".

2.8 Benchmarking

continuous and systematic process of comparing products, services, processes and outcomes with other organizations or exemplars, for improving outcomes by identifying, adapting and implementing best practice approaches (Edith Cowan University, 2011). Benchmarking is different to using quality assurance (QA) models as they generally focus on minimum acceptable standards and compliance, and are often imposed by management or external inspection requirements (Henderson-Smart, et al., 2006) that may have a political agenda (Houston, 2008).

Benchmarking may provide a conceptual framework for self-evaluation (Henderson-Smart, et al., 2006).

2. 8.1 Reasons and perceived benefits of benchmarking

Benchmarking is the process by which companies look at the "best" in the industry and try to imitate their styles and processes. This helps companies to determine what they could be doing better. The decision to begin benchmarking is valuable to companies by opening many different ideas to processes, approaches, and concerns (Allan, 1997).

Increasing productivity and individual design Companies are benchmarking for a variety of reasons. The reasons can be broad, such as increasing productivity, or they can be specific, such as improving an individual design. By simply looking outside itself, a company can identify breakthroughs in thinking.

A similar process used in a different way can shed light on new opportunities to use the original process (Muschter, 1997).

2. 8.1.1 Strategic tool:

Leapfrogging competition is another reason to use benchmarking as a strategic tool. A company's competitors may be stuck in the same rut as the company deciding to benchmark. It would be possible to get a jump on competitors by using new-found strategies.

This opens an opportunity for growth that the competitors may not be aware of (http://www.utsi.com/wbp/reengineering/ benchmark.html, 2/19/97 Enhance learning).

Another reason to benchmark is overcoming disbelief and enhancing learning.

For example, selling or hearing about another company's processes and how they are working will help employees to believe that there may be a better way to compete (Brookhart, 1997).

2.8.1.2 Growth potential:

Benchmarking may cause a necessary change in the culture of an organization. After a period in the industry, an organization may become too practiced at searching inside the company for growth. The company would be better off looking outside its walls for potential areas of growth. An outward looking company tends also to be a future oriented company. This often leads to a more Enhanced organization and increased profit.

(http://www.utsi.com/wbp/ reengineering/benchmark.html, 2/19/97).

2.8.1.3 Assessment of performance tool

Benchmarking is defined as "the process of identifying and learning from best practices anywhere in the world" (Allan, 1997). By identifying the "best" practices, organizations know where they stand in relation to other companies.

The other companies can be used as evidence of problem areas, and provide possible solutions for each area. When companies benchmark, they use partners to share information with and learn from each other. Benchmarking allows organizations to understand their own administrative operations better, and marks target areas for improvement. It is an ideal way to learn from other companies who are more successful in certain areas. Additionally, benchmarking can eliminate waste and help to improve a company's market share.

(Allan, 1997; http://www.spinet.org/legeth.html, 2/19/97).

2.8.1.4 Continuous improvement tool

Benchmarking is increasing in popularity as a tool for continuous improvement. Organizations that faithfully use benchmarking strategies achieve a cost savings of 30 to 40 per cent or more. Benchmarking

establishes methods of measuring each area in terms of units of output as well as cost. In addition, benchmarking can support the process of budgeting, strategic planning, and capital planning (Lyonnais, 1997).

In the early 1980s, Ford Motor Company needed to change many aspects of its operations to cut costs due to the suffering automotive market. Management believed it could improve processes in the accounts payable department. After gathering data on Mazda's accounts payable operations, Ford analyzed and compared its own accounts payable operations. As a result, Ford reduced costs by 5percent (http://138.87.10.1/web/nacubo/ch2e.html, 2/19/97).

2.8.1.5 Vehicle to improve performance

Benchmarking also allows companies to learn new and innovative approaches to issues facing management which, in turn, provides the basis for training. Benchmarking acts as vehicle to improve performance by assisting in setting achievable goals that have already been proven successful. It overcomes disbelief that there are, by example, other ways of achieving and creating overall enhancement of an organization (Fuller, 1997).

2.8.2 Types of benchmarking:

There are four different types of benchmarking which consist of: internal benchmarking, competitive benchmarking, functional or industry benchmarking, and process or generic benchmarking. Before deciding to benchmark, a company needs to determine what it is they want to benchmark.

2.8.2.1 The first basic type of benchmarking is internal benchmarking. This is benchmarking against operations. It is one of the simplest forms since most companies have similar functions inside their business units.

internal bench marking's main objective. This enables the sharing of a multitude of information. The benefit of immediate gain comes from identifying the best internal procedures and being able to transfer them to other portions of the organization. Unless it is later used as a baseline for external benchmarking, companies implementing this type can often retain an introverted view (Matters and Evans, 1997).

2.8.2.2 Competitive benchmarking is a type used with direct competitors. Done externally, competitive bench marking's goal is to compare companies in the same markets which have competing products, services, or work processes. An example would be McDonald's versus Burger King. Under this type of strategy, it is advantageous to see what a company's related performance is only under certain conditions with direct competitors, information would be easy to reach. Particularly information in the public domain would be the most accessible. Competitors may choose to make it very difficult to obtain their priceless information (Finch and Luebbe, 1995).

2. 8.2.3 Functional or industry benchmarking is performed externally against industry leaders or the best functional operations of certain companies. The benchmarking partners are usually those who share some common technological and market characteristics. They also seem to concentrate on specific functions. Because there are no direct competitors involved, the benchmarking partner is more willing to contribute and share. A disadvantage can be the cost and scheduling of the already overwhelmed benchmarked companies (Matters and Evans, 1997).

2.8.2.4 Finally, process or generic benchmarking focuses on the best work processes. Instead of directing the benchmarking to the business practices

of a company, the similar procedures and functions are emphasized. This type can be used across dissimilar organizations.

Although it is thought to be extremely effective, it is difficult to implement. Generic benchmarking requires a broad conceptualizing of the entire process and a careful understanding of the procedures (Finch and Luebbe, 1995; Matters and Evans, 1997).

Each company should evaluate carefully its own perspective in what benchmarking is and how they wish to use this process. The company needs to determine whether their focus is on financial results or on meeting customer requirements. This is the only effective way to begin the benchmarking process.

2.8.3 The benchmarking processes

Benchmarking is a very structured process that consists of several steps to be taken. These steps are often provided for in a model. It should be noted that even though the process is very structured, it should not add complexity to a simple idea. Basically, "the structure should not get in the way of the process".

Most models of benchmarking process include the following steps, according to The Nuts and Bolts of Benchmarking (Bateman 1994), written by (Margaret Matters and Anne Evans 1997), there are five stages included in the benchmarking process which are discussed below:

2.8.3.1 Planning the exercise: this step involves identifying the strategic intent of the business or process to be benchmarked. Many times, this information can be obtained by looking at the company's mission statement which summarizes its main purposes. Then selection of the actual processes to be benchmarked must be chosen. This consists of identifying various products produced by the benchmarked company and

asking your own company if using this process will create positive results in the organization. Then the customer's expectations must be identified. Finally, the critical success factors must be determined to benchmark. These factors are links to successful business results.

2.8.3.2 Form the benchmarking team: the first step is to select overall team members. These members should be chosen from various areas of the organization. All members should cooperate and communicate with one another to get the best results out of the benchmarking process. There are three main teams comprising the overall group. The lead team is responsible for maintaining commitment to the process throughout the organization.

The preparation team is responsible for carrying out detailed analysis, and the visit team must carry out the benchmarking visit.

2.8.3.3 Collect the data: this step involves gathering information on best practice companies and their performances. Before a company identifies best practice companies, they should first identify their own processes, products, and services. This step will allow a company to fully realize the extent of improvements available. Site visits are also an important factor in collecting data because they allow for a more in-depth understanding of the processes.

2.8.3.4 Analyze data for gaps: this step involves determining how your company relates to the benchmarked company. It allows identification of performance gaps and their possible causes.

2.8.3.5 Act: this step involves determining what needs to be done to match the best practice for the process. Not only should determination of changes be made, but they also should be implemented (Matters and Evans, 1997).

Different companies have their own benchmarking methods, but no matter which method is used, the major steps involved are as follows: first, measure the performance of the best-in-class relative to critical performance variables such as cost, productivity, and quality; second, determine how the levels of performance are achieved; and third, use the information to develop and implement a plan for improvement (Omachonu and Ross, 1994).

2.9 Previous Studies:

Many previous studies have been focus on the role of benchmarking in achieving competitive advantage or continuous improvement. It is widely argued that Benchmarking is the process of understanding what is important for organization success, through deciding what to be benchmarking, understanding current performance, planning, studding others, learning from data, and using the findings. (Bester field, 2003). Most of studies emphasizes the importance of applying benchmarking. Attain y (2009) found high correlation between the benchmarking and continuous product and process improvement in the Jordanian pharmaceutical firms. Benchmarking is a term used by industry to compare business processes and performance metrics to like processes and metrics of other businesses for the improvement. compared processes or practices need not necessarily be of the same marketed product type (Camp, 1989). According to Codling (1996), benchmarking is an ongoing process of measuring and improving products, services and practices against the best that can be identified worldwide.

The use of benchmarking as a competitive tool was embraced by firms cutting across diverse industry including construction, education, aviation,

manufacturing, banking, financial services, insurance, healthcare services, and government amongst others (Luu et al., 2008; Henderson et al., 2006). Benchmarking has gained acceptance worldwide as an instrument of continuous improvement in the context of total quality management and as a means of enhancing competitiveness (Carpinetti & Melo, 2002). Au luck (2002, p. 1) proposed that benchmarking and the learning organization ideal as "institutional fairy godmothers", which offer potential to improve organizational performance in the public sector".

In this regard, benchmarking is said to have reached maturity within the UK, with over 60% of UK companies claiming some involvement.

Zairi and Ahmed (as Quoted by Auluck, 2002, p. 115) noted that benchmarking is reported to be the third most popular management technique worldwide and the fourth in the UK between 1992 and 1996. Watson (1993) stated that benchmarking has moved from being an art to a science. Geber (1990: 36) focuses on the significance of looking at best practices in his definition of benchmarking as follows: 'a process of finding the world-class examples of a product, service or operational system and then adjusting your products, services or systems to meet or beat those standards. The Working Papers of the Basel Committee on Banking Supervision contain analysis carried out by experts of the Basel Committee or its working groups. development of methodologies for validating external and internal rating systems is clearly an important issue Verification and Validation Benchmarks presented by William L. Oberkampf, Timothy G. Trucano and Sandia they said: Verification and validation are the primary means to assess the accuracy and reliability of computational simulations. Verification and validation methods and

procedures have fundamentally improved the credibility of simulations in several high-consequence fields, such as nuclear reactor safety, underground nuclear waste storage, and nuclear weapon safe Validation addresses the physics modeling accuracy of a computational simulation by comparing the computational results with experimental data. Code verification benchmarks and validation benchmarks have been constructed for several years in every field of computational simulation. (Basel Committee 2005).

Verification and Validation Benchmarks presented by William L. Oberkampf, Timothy G. Trucano and Sandia they said: Verification and validation are the primary means to assess the accuracy and reliability of computational simulations. Verification and validation methods and procedures have fundamentally improved the credibility of simulations in several high-consequence fields, such as nuclear reactor safety, underground nuclear waste storage, and nuclear weapon safe Validation addresses the physics modeling accuracy of a computational simulation by comparing the computational results with experimental data. Code verification benchmarks and validation benchmarks have been constructed for several years in every field of computational simulation.

Chapter 3

(Materials and Methods of Research)

3. Materials and methods of research

3.1 Research Materials:

This article is divided into two parts the first part is the theoretical framework, which includes the validation process and the role of the organizational structure in terms of the validation team, process validation, documents and the result as reports.

The second part in field is a benchmarking of two pharmaceutical manufacturers in Khartoum.

3.1.1The organization structure in Pharmaceutical industry:

Pharmaceutical industry is a highly innovation driven industry which throughout its history has contributed to the well-being of the humans by providing new medicines to address various diseases and have grown into one of the major sectors in the world.

refer to any industrial activity whose goal is the development, production and marketing of drugs licensed for the use as medications.

the pharmaceutical industry has several unique characteristics: highly globalized and diversified, requiring big investments and bringing a tremendous benefit not only for the public health but also in terms of economic productivity (Scherer, 2000) so the organizational structure is according to cGMP When designing a robust quality system, management has the responsibility to structure the organization and ensure that assigned authorities and responsibilities support the production, quality, and management activities needed to produce quality products.

Senior managers have the responsibility to ensure that the organization's structure is documented.

All managers have the responsibility to communicate employee roles, responsibilities, and authorities within the system and ensure that

interactions are defined and an understood. organization also has the responsibility to give the individual who is appointed to manage the quality system the authority to detect problems and implement solutions. Usually, a senior manager administers the quality system and can, thus, ensure that the organization receives prompt feedback on quality issues and this structure is described according to four major factors:

Management Responsibilities, Resources, Manufacturing Operations and Evaluation Activities

3.2 Methods of conducting research:

The researcher relied on collecting information by using the questionnaire.

3.2.1Collection of information:

10 copies were distributed to specialized staff in the validation process in both companies, questionnaires were personally delivered and responses were supported by interviews.

3.2.2The main points of the questionnaire and its way of knowing the effect of the organizational structure on the validation process:

This questionnaire was based on four axes in the knowledge of the effect of the organizational structure:

1/ Validation process.

2/ Validation team.

3/ Validation documentation.

4/ Validation result.

To know the effect of organizational structure, the questionnaire is designed in two parts. The first section includes the questions related to the employee responsible for the validation process as well as the type of organizational structure of the company. The second section includes

measuring the verification process in terms of the four axes of this process with specific options difficult to deal with to express opinion.

And the answers came as follow:

1. Not started.
2. Some progress.
3. Considerable progress.
4. Close to fully achieved/fully achieved.

3.3/ Data Analysis:

1/Manual unloading.

2/ used Microsoft and excel programs to data analysis.

3.4 Obstacles encountered by the researcher:

1/ The scarcity of references covering the study.

2/The lack of previous studies in the same field.

3/ Difficulty of data collection methods.

4/ The scarcity of references covering the field of study.

Chapter 4

(Results and Discussion)

4. Results and Discussion

4.1 Statistical methods used:

To achieve the objectives of the study and to verify hypotheses, statistical methods were used the following:

1 - charts.

2 - frequency distribution of the answers.

3 - percentages.

4 - alpha equation, to calculate the reliability coefficient.

5 - Median.

6 - Chi-square test for the significance of differences between the answers.

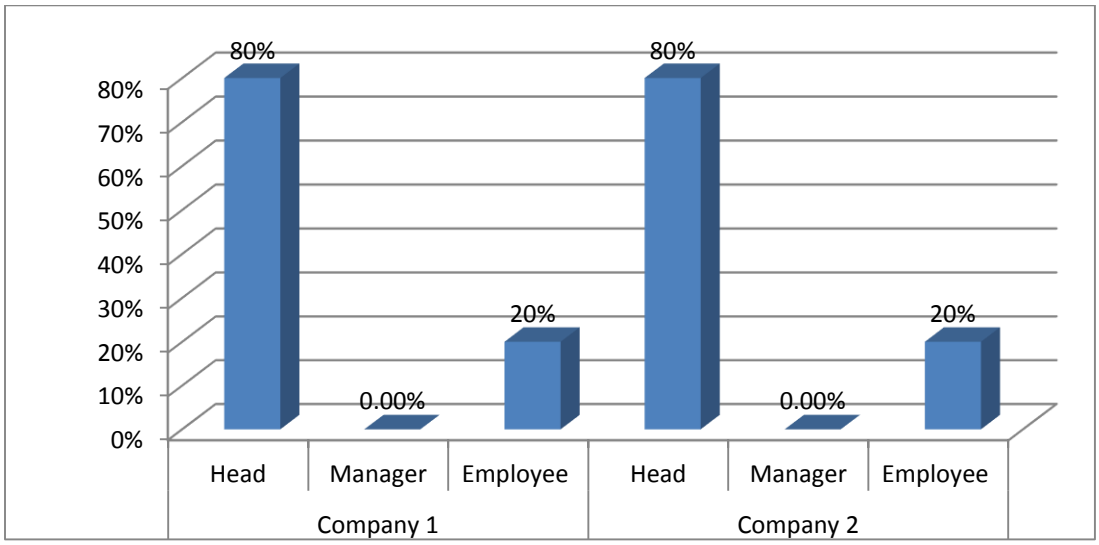
To get results as accurate as possible, has been used SPSS statistical software, which indicates a shortcut to Statistical Package for Social Sciences.

4.1.1 Descriptive of the Variables Study:

General information:

Table(1): JobTypes for two companies

Company	Job	Frequency	Percentage
Company 1	Head	4	80%
	Manager	0	0.0%
	Employee	1	20%
Company 2	Head	1	80%
	Manager	0	0.0%
	Employee	4	20%



- (Source : The Researcher)

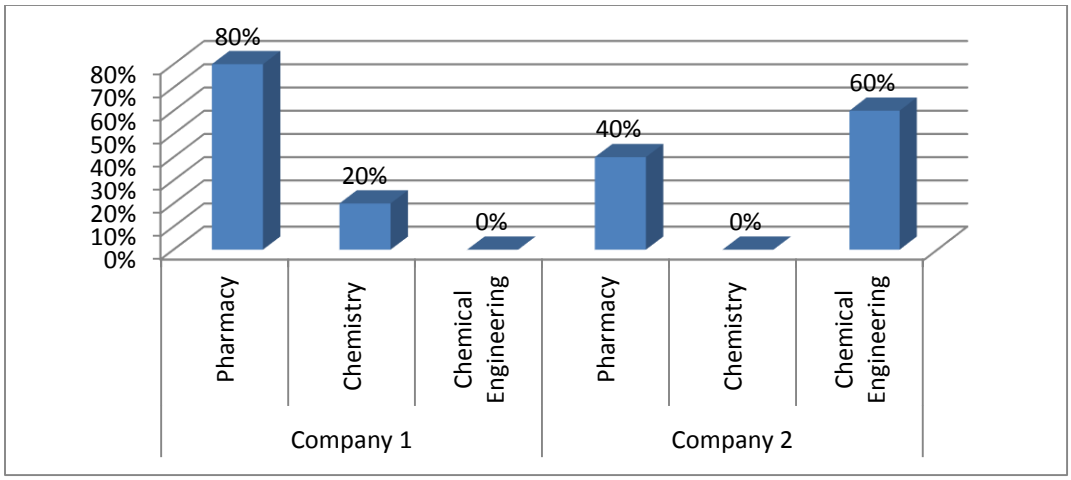
Figure(1): Job types for two companies

From table (1) and figure (1) we note that the job of most of the individuals study in the first company are head by (4) and with (80%) while the job of most of the individuals study in the second company are employee by (4) by (80%).

1- Specialization:

Table(2) : Job Describtions of two companies

Company	Specialization	Frequency	Percentage
Company 1	Pharmacy	1	80%
	Chemistry	4	20%
	Chemical Engineering	0	0%
Company 2	Pharmacy	2	40%
	Chemistry	0	0%
	Chemical Engineering	3	60%



- (Source : The Researcher)

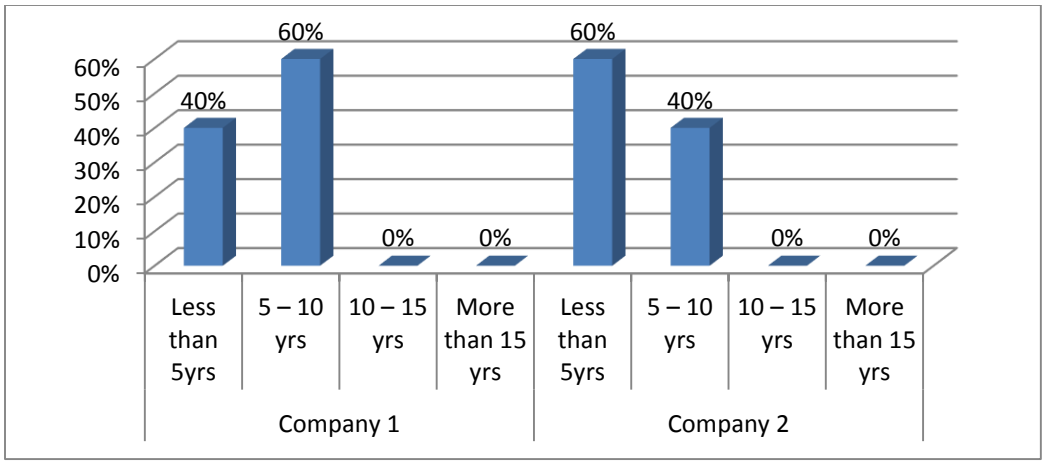
Figure(2): Job Describtions of two companies

From table (2) and figure (2) we note that the Specialization of most of the individuals study in the first company are Chemistry by (4) and with (80%) while the Specialization of most of the individuals study in the second company are Chemical Engineering by (3) by (60%).

2- Experience:

Table(3) : Experiences of two companies

Company	Experience	Frequency	Percentage
Company 1	Less than 5yrs	2	40%
	5 – 10 yrs	3	60%
	10 – 15 yrs	0	0%
	More than 15 yrs	0	0%
Company 2	Less than 5yrs	3	60%
	5 – 10 yrs	2	40%
	10 – 15 yrs	0	0%
	More than 15 yrs	0	0%



- (Source : The Researcher)

Figure(3): Experiences of two companies

Table (4): Frequency distribution of the first axis phrases Answers from table (3) and figure (3) we note that the job of most of the individuals study in the first company are head by (4) and with (80%) while the job of most of the individuals study in the second company are employee by (4) by (80%).

4.1.2 Test hypotheses:

To answer the questions of the study and verification of hypotheses will be calculated median for each of the phrases in the questionnaire and which show views of individuals the study, which was given Grade (1) as a weight for each answer " Not started ", and grade (2) as a weight for each answer " Some progress " grade (3) as a weight for each answer " Considerable progress ", grade (4) as a weight for each answer " Fully achieved " .

To know Trends answer, by calculated median. and then it will use the Chi-square test to know the significance of differences in answers.

For First company :

- **Discussion the first axis : Organizational Structure**

Table (4): Frequency distribution of the first axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	The view of organizational structure is vertical	0 0.0%	1 20%	0 0.0%	4 80%	14.2	0.003
2	The type of organizational structure is functional.	0 0.0%	1 20%	1 20%	3 60%		
3	Organization system is take GMP and WHO as standard.	0 0.0%	0 0.0%	2 40%	3 60%		
4	Validation department is work within our organization as team work	1 20%	0 0.0%	0 0.0%	4 80%		
5	Validation department placed within the structure of organization individually	5 100%	0 0.0%	0 0.0%	0 0.0%		

The value of chi-square for all phrases in the first axis (14.2), with (p-value =0.003< 0.05) , this indicates that there is significant differences at the level (5%) between answers of study individuals and in favor of Fully achieved.

- **Discussion the second axis :Validation Process**

Table (5): Frequency distribution of the second axis phrases Answers

The value of chi-square for all phrases in the second axis (4.6), with (p-value =0.204 > 0.05) , this indicates that there is no significant differences at the level (5%) between answers of study individuals.

Discussion the third axis :Validation Team

Table (6): Frequency distribution of the third axis phrases Answers:

No.	Phrases	Frequency and percentages%				Chi-value	ig
		Not started	Some progress	Considerable progress	Fully achieved		
1	all types of validation are processed	1 20%	1 20%	2 40%	1 20%	4.6	0.204
2	We define performance targets and indicators to manage the different processes	1 20%	2 40%	1 20%	1 20%		
3	have long time been used this process	0 0.0%	2 40%	1 20%	2 40%		
4	There are key elements of validation process	0 0.0%	1 20%	1 20%	3 60%		
5	There is organization' s experience with this process	0 0.0%	3 60%	1 20%	1 20%		

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	There are many people are employed in validation department	4 80%	1 20%	0 0.0%	0 0.0%	8.4	0.038
2	manager of department articipated in developing your business esign, improvement and analysis system	4 80%	1 20%	0 0.0%	0 0.0%		
3	Leader of validation team was driver for adopting this process	1 20%	0 0.0%	0 0.0%	4 80%		
4	there are especial skills involved in employs to effectively function	0 0.0%	1 20%	2 40%	2 40%		
5	we gather trainees after the end of training to find out what role was and to discuss ways of improvement in the future	3 60%	2 40%	0 0.0%	0 0.0%		

The value of chi-square for all phrases in the third axis (8.4), with (p-value =0.038 < 0.05) , this indicates that there is significant differences at the level (5%) between answers of study individuals and in favor of Some progress.

- **Discussion the fourth axis: Validation Documentation**

Table (7): Frequency distribution of the fourth axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	documents of the validation process are available	0 0.0%	0 0.0%	1 20%	4 80%	5.8	0.054
2	We have system or program for controlling validation process	0 0.0%	1 20%	0 0.0%	4 80%		
3	we use especial documents for validation process	0 0.0%	0 0.0%	1 20%	4 80%		
4	we are reviewed documents Periodically	0 0.0%	3 60%	1 20%	1 20%		
5	There is approach or model use in analyzing our business process.	0 0.0%	2 40%	2 40%	1 20%		

The value of chi-square for all phrases in the fourth axis (5.8), with (p-value =0.054 > 0.05) , this indicates that there is no significant differences at the level (5%) between answers of study individuals

- **Discussion the fifth axis: Validation Reports**

Table (8): Frequency distribution of the fifth axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	We have kind of results experienced with report.	0 0.0%	0 0.0%	1 20%	4 80%	14.5	0.001
2	We make use of results and feedback data to review	0 0.0%	0 0.0%	1 20%	4 80%		

3	Results used to determine finish product specification and critical parameters for production process.	0 0.0%	2 40%	0 0.0%	3 60%		
4	conditions which affecting production process such as heat and humidity are controlled.	0 0.0%	0 0.0%	2 40%	3 60%		
5	clean environment for healthy and safe drug is provided .	0 0.0%	0 0.0%	2 40%	3 60%		

The value of chi-square for all phrases in the fifth axis (14.5), with (p-value =0.001 < 0.05) , this indicates that there is significant differences at the level (5%) between answers of study individuals and in favor of Fully achieved.

For Second company :

- **Discussion the first axis: Organizational Structure**

Table (9): Frequency distribution of the first axis phrases Answers:

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	The view of organizational structure is vertical	0 0.0%	0 0.0%	1 20%	4 80%	15.8	0.001
2	The type of organizational structure is functional.	0 0.0%	0 0.0%	2 40%	3 60%		
3	Organization system is take GMP and WHO as standard.	0 0.0%	1 20%	0 0.0%	4 80%		
4	Validation department is work within our organization as team work	0 0.0%	0 0.0%	4 80%	1 20%		
5	Validation department placed within the structure of organization individually	3 60%	0 0.0%	0 0.0%	2 40%		

The value of chi-square for all phrases in the first axis (15.8), with (p-value =0.001< 0.05) , this indicates that there is significant differences at the level (5%) between answers of study individuals and in favor of Fully achieved.

- **Discussion the second axis :Validation Process**

Table (10): Frequency distribution of the second axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	all types of validation are processed	0 0.0%	3 60%	2 40%	0 0.0%	2.2	0.326
2	We define performance targets and indicators to manage the different processes	0 0.0%	1 20%	1 20%	3 60%		
3	have long time been used this process	0 0.0%	1 20%	3 60%	1 20%		
4	There are key elements of validation process	0 0.0%	0 0.0%	4 80%	1 20%		
5	There is organization' s experience with this process	0 0.0%	2 40%	1 20%	2 40%		

The value of chi-square for all phrases in the second axis (2.2), with (p-value =0.326 > 0.05) , this indicates that there is no significant differences at the level (5%) between answers of study individuals.

- **Discussion the third axis:" Validation Team "**

Table (11): Frequency distribution of the third axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		

1	There are many people are employed in validation department	1 20%	2 40%	0 0.0%	2 40%	4.0	0.266
2	manager of department participated in developing your business design, improvement and analysis system	1 20%	1 20%	2 40$	1 20%		
3	Leader of validation team was driver for adopting this process	0 0.0%	0 0.0%	3 60%	2 40%		
4	there are especial skills involved in employs to effectively function	0 0.0%	3 60%	1 20%	1 20%		
5	we gather trainees after the end of training to find out what role was and to discuss ways of improvement in the future	2 40%	1 20%	1 20%	1 20%		

The value of chi-square for all phrases in the third axis (4.0), with (p-value =0.266 > 0.05) , this indicates that there is no significant differences at the level (5%) between answers of study individuals.

Discussion the fourth axis: Validation Documentation

Table (12): Frequency distribution of the fourth axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	documents of the validation process are available	0 0.0%	1 20%	2 40%	2 40%	0.3	0.852

2	We have system or program for controlling validation process	0 0.0%	2 40%	2 40%	1 20%		
3	we use especial documents for validation process	0 0.0%	1 20%	3 60%	1 20%		
4	we are reviewed documents Periodically	0 0.0%	2 40%	2 40%	1 20%		
5	There is approach or model use in analyzing our business process.	0 0.0%	3 60%	0 0.0%	2 40%		

The value of chi-square for all phrases in the fourth axis (0.3), with (p-value =0.852 > 0.05) , this indicates that there is no significant differences at the level (5%) between answers of study individuals.

Discussion the fifth axis: " Validation Results "

Table (13): Frequency distribution of the fifth axis phrases Answers

No.	Phrases	Frequency and percentages%				Chi-value	sig
		Not started	Some progress	Considerable progress	Fully achieved		
1	We have kind of results experienced with report.	0 0.0%	0 0.0%	2 40%	3 60%	7.3	0.026
2	We make use of results and feedback data to review	0 0.0%	0 0.0%	3 60%	2 40%		
3	Results used to determine finish product specification and critical parameters for production process.	0 0.0%	1 20%	2 40%	2 40%		
4	conditions which affecting production process such as heat and humidity are controlled.	0 0.0%	0 0.0%	3 60%	2 40%		
5	clean environment for healthy and safe drug is provided.	0 0.0%	1 20%	2 40%	2 40%		

The value of chi-square for all phrases in the fifth axis (7.3), with (p-value =0.026< 0.05) , this indicates that there is significant differences at the level (5%) between answers of study individuals and in favor of Considerable progress.

comparison between two companies:

Table (14): comparison between two companies

	Trend of answer	
Axes	**First ompany**	**Second company**

Organizational Structure	Fully achieved	Fully achieved
Validation Process	Considerable progress	Considerable progress
Validation Team	Some progress	Considerable progress
Validation Documentation	Considerable progress	Considerable progress
Validation Reports	Fully achieved	Considerable progress

4.2 Disscution :

Role of organizational structure on validation Process :

It is noted that the organizational structure in the company (1) takes the vertical view and includes all departments (quality assurance department, quality control, production management and R&D department) under the technical management and the validation section falls under the management of quality assurance and therefore the general supervision of the processess by the quality assurance department. Thus, the responsible officer of the validation process is entrusted with several tasks related to the management of the quality assurance and its work is not exclusive to the validation and the various validation activities are carried out periodically under the supervision of quality assurance and technical management, but it does not take place on a regular basis and no plan is intended for Quality assurance.

For the company (2) we find that the organizational structure takes the vertical view but there is a comprehensive quality management which include quality assurance , quality control and validation department as a separate department includes all activities, including calibration of instruments also the management of the valdiation is keen to develop a plan at the beginning of the year for all its activities and keen to achieve them at the end of the year.

Role of organizational structure on validation Team :

The study found that the company (1) includes one empolyee within the validation department and when the validation process is done and the work as a team, While in the company 2 there are two employees with chemical engineering specialization and also the verification process is done in a team However, the employee in the company 1 proved the statistical study that he does not receive sufficient training to improve skills and does not get specialized training courses in the field compared to the

company 2 as there is overlap in the tasks assigned to him compared to employees in the company 2.

Role of organizational structure on validation Documentation :

As for the organizational structure of the documentation in both companies, we find that in the company 1, the traditional documentation process starts with vmp followed by the protocols for each validation process and finally the reports as a comprehensive standard operational procedure(SOPs) for all the activities of the vallidation department. for the company 2, the documentation system was taken from Arabic Pharmaceutical manifacturing (APM) which dependence by (FDA) we find that it is followed in its VMP system which includes the coding system and the labeling system , master protocols, process numbering system and Computerized documentation by using microsoft access This system is used in the follow up of all the instruments that need calibration processes as well as to keep the certificates in a safe manner.

Role of organizational structure on validation Report :

There is no significant difference between the two companies in the presentation of the results, where they are presented in the form of a final Report, but there is a Report of each type of Valdition using the same reference GMP and WHO, but the company (2) benefit from the outputs obtained in the work of the new annual plan.

Chapter 5

(Conclusion and Recommendations)

5. Conclusion and Recommendations

5.1 Conclusion :

1/The organizational structure is reflected in the identification of tasks and the organization of processes.

2/ Showing its role on the ability to implement the planned plans at the beginning of the year.

3/Increase training and training opportunities for staff within the department.

4/Increase knowledge opportunities and diversity of informational sources.

5/Improved documentation and data archiving methods.

6/There is no clear role on the results.

7/There is no difference in the overall vision of the organizational structure.

8/There is no difference in the number of employees within the department.

5.2 Recommendations:

The follower of this study finds that:

1/There must be a clear plan for the section and the commitment to implement it.

2/Defining special functions for the responsible officer.

3/ Increasing the training and qualification opportunities for the responsible officer and the concerned people in other departments.

4/ Development of documentation in line with the new requirements for the operation of a GMP(good manufacutring practies) and modern archiving system.

5/ Making use of the results in developing new plans for the coming years

6/Take advantage of the results of this study and try to apply them on the ground to improve the level of the Validation section.

7/ Benefit from benchmarking in the pharmaceutical industry and use it as a means to improve performance.

8/ Re-idea the gap analysis between more than one factory in Sudan to exchange experiences and experiments to develop the pharmaceutical industry in Sudan.

References

References

- **The Holy Quran**

Allan, S (1997), "Partners benchmarking, http://www. benchmarking.co.uk/bmark.htm# partners, (April 15).

American Productivity & Quality Center (APQC) (1996), Emerging Best Practices in Knowledge Management, American Productivity & Quality Center, Houston, TX

Andersen and Pettersen (1996), The Benchmarking Handbook, Chapman & Hall.

Auluck, R. (2002). Benchmarking: a tool for facilitating organizational learning. Public Administration and Development, 22(2), 109-2002.

Bateman, G. (1994), "Benchmarking management education teaching and curriculum," in Camp, R., Benchmarking: The Search for Industry Best Practices that Lead to Superior Performance, Quality Resources, White Plains, NY, p. 6. (benchmarking process).

Boxwell, R.J. Jr (1994), Benchmarking for Competitive Advantage, McGraw-Hill, New York, NY.

Besterfeild, D. H., Besterfeild, C., Besterfeild, G. H., & Besterfeild, M. (2003). Total Quality Management. (3nd ed.). Pearson, USA.

the Basel Committee on Banking Supervision. (2005). Bank for International Settlements Information, Press & Library Services CH-4002 Basel, Switzerland.

Byers, T. E. (1974) Design for quality, Manufacturing Controls Seminar, Proprietary Association, Cherry Hill, NJ, Oct. 11, (history of validation)7

Caswell, H., (1976). The validation problem. In: B. Patten (Editor), Systems Analysis and Simulation in Ecology, Vol. IV. Academic Press, New York, NY. pp. 313-325.

Csmp, R.C. (1989). Benchmarking: the search for industry best practices that lead to superior performance, Milwaukee, WI, ASQC Quality Press.

Carpinetti, L. C. R. & de Melo, A. M. (2002). What to benchmark? a systematic approach and cases. Benchmarking, An International Journal. 9(3), 244-255

Department of Pharmaceutics, Rayat Institute of Pharmacy, r, Journal of Drug Delivery & Therapeutics; 3(4), 184-188

Dr. Robert Mandle, Assay Validation Methods - Definitions and Terms Adapted from Biosciences Research Associates, Inc. www.cbrlabs.com/assay-validation.html

European Commission (2010) HEALTH AND CONSUMERS DIRECTORATE-PUBLIC Health and Risk Assessment Pharmaceuticals Brussels, SANCO/C8/AM/sl/ ares 1064587.

Fraser, M., 1994, 'Quality in higher education: an international perspective' in Green, D. (Ed.), 1994, What is Quality in Higher Education? pp. 101–111 (Buckingham, Open University press and Society for Research into Higher Education).

Finnigan, J.P. (1996), The Managers Guide to Benchmarking, Jossey-Bass, San Francisco, CA

O'Dell, C. and Grayson, J.C. (1998), ``If only we knew what we know: identification and transfer of internal best practices", Special issue on knowledge and the firm, California Management Review, March, p. 154nt

Kates, A., and Galbraith, J.R. (2007) Designing your organization: using the star model to solve 5 critical design challenges, Jossey-Bass, A Wiley Imprint.

L. Nandhakumar*, G. Dharmamoorthy, S. Rameshkumar and S. Chandrasekaran INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACY AND CHEMISTRY Available online at www.ijrpc.com IJRPC 2011, 1(4)

Loftus, B. T. (1978) Validation and stability, meeting of Parenteral Drug Association,

Luu, V., Kim, S., & Huynh, T. (2008). Improving Project Management Performance of Large Contractors using Benchmarking Approach. International Journal of Project Management, 26(7), 758-769.

Machonu, V.K. and Ross, J.R. (1994), Principles of Total Quality, St. Lucie Press, Delray Beach, FL, pp. 137-54. (benchmarking process)

Manju Nanda, Jayanthi (2013), International Journal of Software Engineering & Applications (IJSEA), Vol.4, No.2

Matters, M. and Evans, A. (1997), "The nuts and bolts of benchmarking", http:// www ozemail.com.au/~benchmark/nuts.bolts.html, (February 18).

Montana, P. and Charnov, B. Management: A Streamlined Course for Students and Business People. (Hauppauge, New York: Barron's Business Review Series, 1993), pp. 155-169.

Maturana, H.R. (1978) Biology of Language: The Epistemology of Reality, Psychology and biology of language and thought, pp. 27-63.

28/ Mintzberg, H. (1979) The Structuring of Organizations. Prentice-Hall, Engle- wood Cliffs, N.J.

Morgan, G. (1997) Images of organization. SAGE Publications Thousand Oaks, London, UK.

Mouzas S. (2006). Efficiency versus effectiveness in business networks. Journal of Business Research. Volume 59, Issues 10–11, p.p 1124–113 http://dx.doi.org/10.1016/j.jbusres.2006.09.018.

Olajide Olubayo Thomas. (2015) EFFECTS OF ORGANIZATIONAL STRUCTURE ON JOB.

Quality assurance of pharmaceuticals Volume 2, 2nd updated edition Good manufacturing practices and inspection 12/16/06.

Rayat and Bahra Campus Railmajra, Distt. Nawanshaha (2013) PROCESS VALIDATION IN PHARMACEUTICAL INDUSTRY: AN OVERVIEW Sharma Sumeet, Singh Gurpreet.

Ross, E. (1995), Total Quality Management, St. Lucie Press, Delray Beach, FL, pp. 230-5.

SATISFACTION IN THE NIGERIAN FINANCIAL SECTOR: NG-Journal of Social Development, VOL. 5, No. 1, October 2015.

Satyabratajena, Arjun G, Anil kumarravipati N V, SatishkumarD,Vinod K R, David banji (2010). Industrial Process Validation of Solid Dosage Forms–An Overview International Journal of Pharmaceutical Sciences review and research., 4(2).

Shafritz, J.M., and Ott, J.S. (1996) Classics of organization theory, 4 th ed, Harcourt Brace College Publisers, Florida, US.

Shiva M.S.A. and Suar D. (2010). Leadership, LMX, Commitment and NGO Effectiveness:

Transformational Leadership, Leader-Member Exchange, Organizational Commitment, Organizational Effectiveness and Programmed Outcomes in

Non-Governmental organizations. International Journal of Rural Management. 6(1), 2010: 117–150. DOI: 10.1177/097300521100600106.

Strati, A. (2006) Organizational artifacts and the aesthetic approach. In Artifacts and Organizations. Beyond Mere Symbolism, p. 23-39, Erlbaum.

Taisuke Hojo, GHTF Chair (2004) Quality Management Systems - Process Validation Guidance Edition 2.

U.S. Food and Drug Administration (1987). Guideline on General Principles of Process Validation. Rockville, MD: FDA, 3.

U.S. Code, Federal Food Drug and Cosmetic Act, Title 21, Section 510 (h).

Zheng W., Yang B., McLean G. (2010). Linking organizational culture, structure, strategy, and organizational effectiveness: Mediating role of knowledge management. Journal of Business Research, Volume 63, Issue 7, Pages 763–771 http://dx.doi.org/10.1016/j.jbusres.2009.06.005.

(http://138.87.10.1/web/nacubo/ch2e.html, 2/19/97).

Appendixes

بسم الله الرحمن الرحيم

كلية الدراسات العليا والبحث العلمي

جامعة السودان للعلوم والتكنولوجيا

قائمة استبيان حول:

(دراسة دور الهيكل التنظيمي على فعالية عملية التحقق)

دراسة ومقارنة مرجعية(benchmarking) في مصنعين للادوية

غرض البحث والدراسة:

لنيل درجة الماجستير

في إدارة الجودة الشاملة والتميز

إعداد الباحثة/

صفاء أحمد محمد أحمد

استبيان

(دراسة دور الهيكل التنظيمي على فعالية عملية التحقق بواسطة المقارنة المرجعية)

دراسة ومقارنة مرجعية(benchmarking) في مصنعين للادوية

هذا البحث للاغراض الاكاديمية البحتة لمعرفة دور الهيكل التنظيمي على فعالية عملية التحقق وذلك باستخدام المقارنة المرجعية **(benchmarking)** وقد تمت الدراسة في جامعة السودان للعلوم والتكنولوجيا.

كل هذه المعلومات المجمعة من هذا الاستبيان ستؤخذ بمنتهى الجدية لاجابة عن فرضيات البحث وستعامل بسرية تامة وستتم الاستفادة منها لاغراض البحث العلمي فقط وليس لغرض اخر.

نعرف قيمة وقتكم الثمين ، لكن نستميحكم عذراً ببعض الوقت للاجابة عن اسئلة هذا الاستبيان

ودمتم

الباحثة

أولا :البيانات الشخصية

الاسم (اختياري) :.....

المسمى الوظيفي :

1/رئيس قسم 2/مدير ادارة 3/موظف مسؤول

التخصص :

1/صيدلة 2/علوم كيمياء 3/هندسة كيميائية

الخبرة العملية :

1/اقل من 5سنوات ( ) 2/ من 5-10 سنوات ( )

3/ من 10-15 سنة ( ) 4/ اكثرمن 15 سنة ( )

ثانيا : الرجاء ملأ الاعمدة بوضع علامة صح اسفل واحدة من هذه الخيارات :

1. Not started
2. Some progress
3. Considerable progress
4. Close to fully achieved/fully achieved

No	The questions	1	2	3	4
1	Organizational Structure	Not started	Some progress	Considerable progress	fully achieved
a	The view of organizational structure is vertical				
b	The type of organizational structure is functional.				
c	Organization system is take GMP and WHO as standard.				
d	Validation department is work within our organization as team work				
e	Validation department placed within the structure of organization individually				
2	Validation Process:	Not started	Some progress	Considerable progress	fully achieved
a	all types of validation are processed				
b	We define performance targets and indicators to manage the different processes				
c	have long time been used this process				
d	There are key elements of validation process				
e	There is organization' s experience with this process				

3	Validation Team	Not started	Some progress	Considerable progress	fully achieved
a	There are many people are employed in validation department				
b	manager of department participated in developing your business design, improvement and analysis system				
c	Leader of validation team was driver for adopting this process				
d	there are especial skills involved in employs to effectively function				
e	we gather trainees after the end of training to find out what role was and to discuss ways of improvement in the future				
4	<u>Validation Documentation:</u>	Not started	Some progress	Considerable progress	fully achieved
a	documents of the validation process are available				
b	We have system or program for controlling validation process				
c	we use especial documents for validation process				
d	we are reviewed documents Periodically				
e	There is approach or model use in analyzing our business process.				

5	Validation reports:	Not started	Some progress	Considerable progress	fully achieved
a	We have kind of results experienced with report.				
b	We make use of results and feedback data to review				
c	Results used to determine finish product specification and critical parameters for production process.				
d	conditions which affecting production process such as heat and humidity are controlled.				
e	clean environment for healthy and safe drug is provided .				

Arbitration Committee:

Name	Position	Work Position
Abdul Muttalib Ibrahim	Assistant Professor	Quality and Excellence Center
Siddeg Ballal	Co-professor	Sudan University of Science and Technology
Amira Mohammed Ali Ahmed	Co-professor	Sudan University of Science and Technology