THE EFFECT OF QUALITY ASSURANCE ON WORKERS' SAFETY IN LABORATOIRE PHARMACEUTIQUE DU RWANDA

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DECLARATION A

"This dissertation is my original work and has not been presented for a Degree or any other academic award in any University or Institution of Learning".

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Name and Signature of Candidate

8, October 2010

Date

DECLARATION B

"I/We confirm that the work reported in this dissertation was carried out by the candidate under my/our supervision".

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11/10/10

Date

APPROVAL SHEET

This dissertation entitled "The effect of quality assurance on workers' safety in Pharmaceutical Laboratory of Rwanda" prepared and submitted by NTAGARA NGABO Donatien in partial fulfillment of the requirements for the degree of Master of Arts in Project Planning and Management has been examined and approved by the panel on oral examination with a grade of PASSED.

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DEDICATION

To my lovely wife KAGABO Monique,

To my children NGABO Kevin, KEZA Karen, KALIZA Kate, KARABO Karla,

To my parents NGABO Theoneste and MUKAREMERA Marie,

To my brothers and sisters for their valuable advice and financial support during the course of the study,

To Eng. Kambanda Rucweli Hormisdas,

I dedicate this research study.

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ABSTRACT

This report is a result of an academic research entitled "The effect of quality assurance on workers' safety in *Laboratoire Pharmaceutique du Rwanda* (LABOPHAR). The objectives of this study were: to assess working condition of personnel in the factory, to find out the degree of awareness on good manufacturing procedures and safety by workers; and to establish the relationship between quality assurance and workers' safety.

The study used cross-sectional research design. The study population was 20 workers, directly involved in manufacture of drugs. One validated structured questionnaire was used to collect data. Simple percentages, frequency counts were used to analyze the data.

Results showed lack of working conditions due to non conformity to appropriate and standardized personal protective equipments (85% of respondents). As for quality of heating, ventilation and air conditioning, 100% of respondents confirmed poor ventilation through directional flow and regulation of indoor air. Findings showed lack of regular and continuing training in good manufacturing procedures (85% of respondents). Fifty percent affirm working every time in fixed posture. Findings revealed a significant positive relationship between Quality of Assurance and Workers' Safety ($r=0.673$). From findings, it was recommended to provide workers with sufficient and certified protective equipments; to provide the factory with a ventilation system and regulation of temperature; to carryout regular trainings on safety and good manufacturing procedures.

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ACRONYMS

LABOPHAR: Laboratoire Pharmaceutique du Rwanda.

WHO: World Health Organization

SOP: Standard Operating Procedures

HVAC: Heating Ventilation and Air Conditioning

GMP: Good Manufacturing Procedures

PPE: Personal Protective Equipments

ILO: International Labor Organization

OSHA: Organization for Safety Health Administration

RQ: Relevant questions

TQ: Total number of questions

CHAPTER ONE

PROBLEM AND ITS SCOPE

Background of the study

Oakland (1993) defines quality assurance as a philosophy and a process in which all the functions and activities of an institution are treated equally, planned, controlled and implemented for in a systematic and scientific manner.

According to him quality assurance is a way of broadly preventing quality problems through planned and systematic activities (including documentation). These include the establishment of a good quality management system and the assessment of its adequacy, audit of the operation of the system and the review of the system itself.

Quality assurance is also defined as a set of activities that an organization undertakes to ensure that a product or service will satisfy given requirements for quality, in other words, that standards are specified and reached consistently for a product or service Oakland (1993).

Its goal is the anticipation and avoidance of faults or mistakes. Basically, it involves setting attainable standards for a process, organizing work so that they are achieved, documenting the procedures required, communicating them to all concerned, and monitoring and reviewing the attainment of standards.

The levels of skills and expertise of staff, the amount of resources available, weak or strong leadership, efficiency of its administrative

systems are factors that determine the product quality. Quality assurance practices adopted by any product or service providers should include elements of Total Quality Management namely Staff Development, Strategic Planning, Work Process, Team Work, Prioritize Customers and performance evaluation.

Lawrence and Bernett (2000) define safety as a state of being safe, the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable.

According to them safety can take the form of being protected from the event or from exposure to something that causes health or economical losses. It can include protection of people or of possessions. Safety can be limited in relation to some guarantee or a standard of insurance to the quality and unharmful function of an object or organization. It is used in order to ensure that the object or organization will do only what it is meant to do.

Employees have a right to good working conditions but most of them do not know their rights and this is one of the main reasons why safety/occupational injuries and illnesses have continued to occur. The most important factor in the welfare of the employee is the safety of the employee and his family. It can also be argued that this is the most important single factor in the success of the company. Those who are sick and are away cost the company money, those who are partly sick are inefficient and those who are injured in the course of their work are an

additional expense to the company. Once workers are injured, the production of the industry falls due to loss of "work time".

According to the Commission of the European countries (1994), about 0.008 million people die each year from accidents at their work places out of a total of 120 million workers. About 10 million workers are victims of occupational diseases each year. In the US alone, an estimated 10 million work related injuries and 0.43 million new work related illnesses occur each year. International Labor Office estimates, 120 million accidents occur annually at the places of work world wide. Of these, 0.21 million are fatal accidents, meaning every day more than 0.0005 million men or women go for work and never return (Kliesch, 1992).

According to the International Labor Organization (ILO), fatal work accidents remain a key indicator of poor working conditions and environment. The number of accidents is compared to the number of active workers exposed to the risk responsible for the fatalities. On making this comparison, the average fatal accident rate using ILO estimates is in the range 6-7 per 100000 workers. This rate continues to grow in many developing countries (ILO, 1992)

In Japan and Sweden, there has been a 70% reduction of fatal accidents, 62% in Finland and 65% in the Federal Republic of Germany during 2 decades. The annual decline in fatal accidents in industrialized countries ranges from 2.1% in Belgium, 6.9% in Japan and 3.1% in Finland (National board: 1988). However the trends in the developing countries have not yet shown similar changes. Countries such as Brazil, Colombia and Mexico, which account for half of the working population in Latin

America, the annual incidence of occupational fatalities is in the range of 14027 deaths per 100000 workers, Malaysia reports 29.9/100000 workers, Thailand 32.3/100000, the Republic of Korea 29.6/100000 (ILO, 1992).

A study done by International Finance Corporation, a World Bank group showed that safety hazards for workers in pharmaceutical facilities are similar to those of other industrial facilities. In addition, occupational and safety issues that may be specifically associated with drug manufacturing which may include physical hazards, biological hazards and exposure to chemicals including gases and vapors(Harrison, Tom, et al.,1999).

In the developing countries, occupational injury and illness rates are higher than in the US, an average of 0.009 million workers sustain disabling injury and 137 die from work related diseases (Levy, 1988)

In *Laboratoire Pharmaceutique du Rwanda* (LABOPHAR), reports from workers revealed that there are worried about their safety. They were complaining about physical consequences resulting from the nature of their work. Such consequences are back pain, breath trouble, irritations, working in uncomfortable conditions.

Statement of the problem

In LABOPHAR like many other pharmaceutical industries, workers are exposed to many safety hazards. Good manufacturing practices (GMP) and standard operating procedures (SOP) were put up internationally as tentative solution to the safety hazards in industries.

Despite of the existence of these measures situation at LABOPHAR is different. Employees complain about their uncomfortable working conditions. The reasons as to why things are happening in that way are not known. It is therefore against such a background that the researcher carried out the study to establish the possible causes of these anomalies in order to generate information that will help cover the information gap.

Purpose of the study

The purpose of this study was to determine the magnitude of quality assurance at LABOPHAR and its effect on safety of workers with an aim of generating information which will be used by LABOPHAR management to improve quality and helps prevent safety hazards so that the health and safety of the workers is safe guarded.

Specific objectives

- To assess how working conditions affect workers' safety in LABOPHAR;
- To examine the degree of awareness of GMP and safety by workers of LABOPHAR;
- To establish the relationship between quality assurance and workers' safety in LABOPHAR.

Research questions

- How do working conditions affect workers safety in LABOPHAR?
- What is the degree of awareness by the workers on GMP and safety at LABOPHAR?
- What is the relationship between quality assurance and workers' safety in LABOPHAR?

Scope of the study

This study covered the LABOPHAR. Geographically, LABOPHAR is located in Huye District, Southern Province of Rwanda at 130 km (80.7 miles), from the capital Kigali heading the Republic of Burundi.

This study dealt with quality assurance and its effect on the safety of workers who are directly involved in the process of production in the factory.

Significance of the study

The problem of safety still continues to frequently occur in the factory and yet there is no study carried out in LABOPHAR to determine why the problem continues to occur and why the available safety unit in the factory has failed to address the problem. If the situation persists, this may lead to absenteeism or death from work. The problem of safety affects both the employee in such a way that he/she won't be earning and the employer in such a way that productivity of the factory goes down due reduced performance.

The study will help generate information that will be of help to management so as to improve the safety of workers in order to prevent and control the injuries and illnesses.

Also, this study is of great importance to industrial firms since it discusses quality assurance as a way forward to sustainable development from the point of view of the responses that were obtained from the field.

Scholars interested in quality assurance and safety will also find this study useful for consultation since it is the first of its kind in Rwanda. This study will be beneficial to other researchers by providing necessary knowledge and information to be used as a basis for further research about safety in industry projects.

Operational definitions of key terms

Directional airflow: According to the World Health Organization (WHO), directional airflow is a rectified airflow over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (WHO, 2007).

Heating ventilation and air-conditioning (HVAC): the main purposes of a Heating, Ventilation, and Air-Conditioning system are to help maintain good indoor air quality through adequate ventilation with filtration and provide thermal comfort (WHO, 2007).

Personal protective equipments: means safety materials, devices and clothing whose purpose is to protect from injury or illness (WHO, 2002).

Personnel awareness: Is the fact that an operator, because of knowledge, training and experience, is qualified to perform safely and properly a specified job (Researcher, 2010).

Quality assurance: is broadly the preventing of quality problems through planned and systematic activities (including documentation). These will include the establishment of a good quality management system and the assessment of its adequacy, the audit of the operation of the system, and the review of the system itself (Pryor, White and Toombs, 1998).

Safety: The Occupational Safety and Health Administration (OSHA) defines safety as an area of industrial Safety and public health that deals with the protection of workers' health, through control of the work environment to reduce or eliminate hazards. Industrial accidents and unsafe working conditions can result in temporary or permanent injury, illness, or even death. They also take a toll in reduced efficiency and loss of productivity (OSHA, 2009).

Standard operating procedure (SOP): An authorized written procedure, giving instructions for performing operations (WHO, 2007).

Validation: The documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results (WHO, 2007).

CHAPTER TWO

REVIEW OF RELATED LITERATURE

Introduction

In this chapter the researcher reviewed the literature related to quality assurance and workers' safety. The review was conceptualized under the objectives of the study and focused mainly on quality of equipments and personnel skills and their relationship on safety of workers.

Concepts, ideas, opinions from authors/ Experts

Concept of quality assurance

The WHO defines Quality Assurance as a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use. Quality assurance therefore incorporates GMP and other factors such as product design and development (WHO, 2003).

To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of quality assurance incorporating GMP and quality control. It should be fully documented and its effectiveness monitored. All parts of the quality assurance system should be adequately staffed with competent personnel, and should have suitable and sufficient premises, equipment, and facilities.

According to the WHO (2007), GMP is that part of quality assurance, which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP aims primarily at diminishing the risks inherent in any pharmaceutical production. Such risks are essentially of two types: cross-contamination (in particular of unexpected contaminants) and mix-ups (confusion) caused by, for example, false labels being put on containers.

Under the GMP all necessary resources are provided, including:

(i) appropriately qualified and trained personnel;
(ii) adequate premises, suitable equipment and services;
(iii) appropriate materials, containers and labels;
(iv)approved procedures and instructions;
(v) adequate personnel, laboratories and equipment for in-process controls;

As for Oakland (1993), quality assurance is broadly the preventing of quality problems through planned and systematic activities (including documentation). These will include the establishment of a good quality management system and the assessment of its adequacy, the audit of the operation of the system, and the review of the system itself.

Paying keen interest to ensuring that the organization quality assurance procedures can always lead to some positive consequences which include: (1) Organizational advantages which are related to a larger and rigorous operative process management; (2) Commercial benefits expectations which are directly linked to an enterprise's image improvement and (3)

Operative benefits expectations which in some cases have been overvalued.

In order to have an in depth understanding of the concept of quality assurance, one must first of all understand what quality is. Deming (1986) was one of the first authors to talk about meeting or exceeding customers' expectations and requirements that are determined or modified through continuous communication between customers, front-line associates, and management.

Quality can also be defined as the extent to which processes, products, services, and relationships are free from defects, constraints, and items which do not add value for the customer. Quality is fitness for use, a conformance to requirements, not goodness (Pryor, White and Toombs, 1998).

Using Pryor's definition, organizations can implement a variety of quality initiatives such as Strategic quality management and Total quality management as well as various organizational development initiatives relating to teams, empowerment, and other concepts that have the potential of improving all aspects of the operations of the organization. However, in order to ensure long-term survival and success, major change or improvement initiatives should be implemented in conjunction with the use of various management models such as the Strategic management, the 5P's Model and so forth.

For an organization to become successful in quality assurance, it must comply with the 5P's model, that is: principles, purposes, people, processes, performance. Of the 5Ps developed by Pryor et al. (1998), the

research retained principles, people, and processes as factors that may play a major role in quality assurance.

Principles

These are the guiding philosophies, assumptions, or attitudes about how the organization should operate and conduct business. They are the integrity base, ethics, and core values to which employees are expected to make a commitment when they are hired. These core values are the foundation for the way decisions are made and employees behave (Pryor, et al., 1998)

Processes

Processes are the organizational structures, systems, and procedures that are used to make the products or perform the services that the organization provides, as well as the infrastructure and rules that support these systems and procedures. Performance appraisal methods, communication patterns, and production systems are examples of processes. Processes are generally defined by the people doing the job and are often not well documented; because it is difficult to manage and improve (or even replicate) undocumented processes. Therefore, managers should ensure that all processes are documented by checklists, process maps, or process flowcharts. Chandler (1962) states that streamlined processes that are well documented and principles that are well communicated can drive behavior that is necessary to achieve performance excellence. From the above statement, it is clear that organizations that respect and follow processes in a well documented way

are more likely to satisfy with quality assurance requirements. (Pryor et al., 1998)

People

According to Pryor et al. (1998), to perform work that is conformed to principles and processes in order to achieve organization's purpose, organization needs people (individuals and teams). They are the active components through which work results are accomplished. The arguments provided above show that people are central element in the success of quality assurance implementation.

Concept of safety

On the other hand safety is define as a state of being safe, the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable. This can take the form of being protected from the event or from exposure to something that causes health or economical losses (Lawrence and Bernett, 2000).

It can include protection of people or of possessions. Safety can be limited in relation to some guarantee or a standard of insurance to the quality and unharmful function of an object or organization. It is used in order to ensure that the object or organization will do only what it is meant to do.

According to Garg (2008), Industrial Safety is an area of safety engineering and public health that deals with the

protection of workers' health, through control of the work environment to reduce or eliminate hazards. Industrial accidents and unsafe working conditions can result in temporary or permanent injury, illness, or even death. They also take a toll in reduced efficiency and loss of productivity.

Conceptual framework

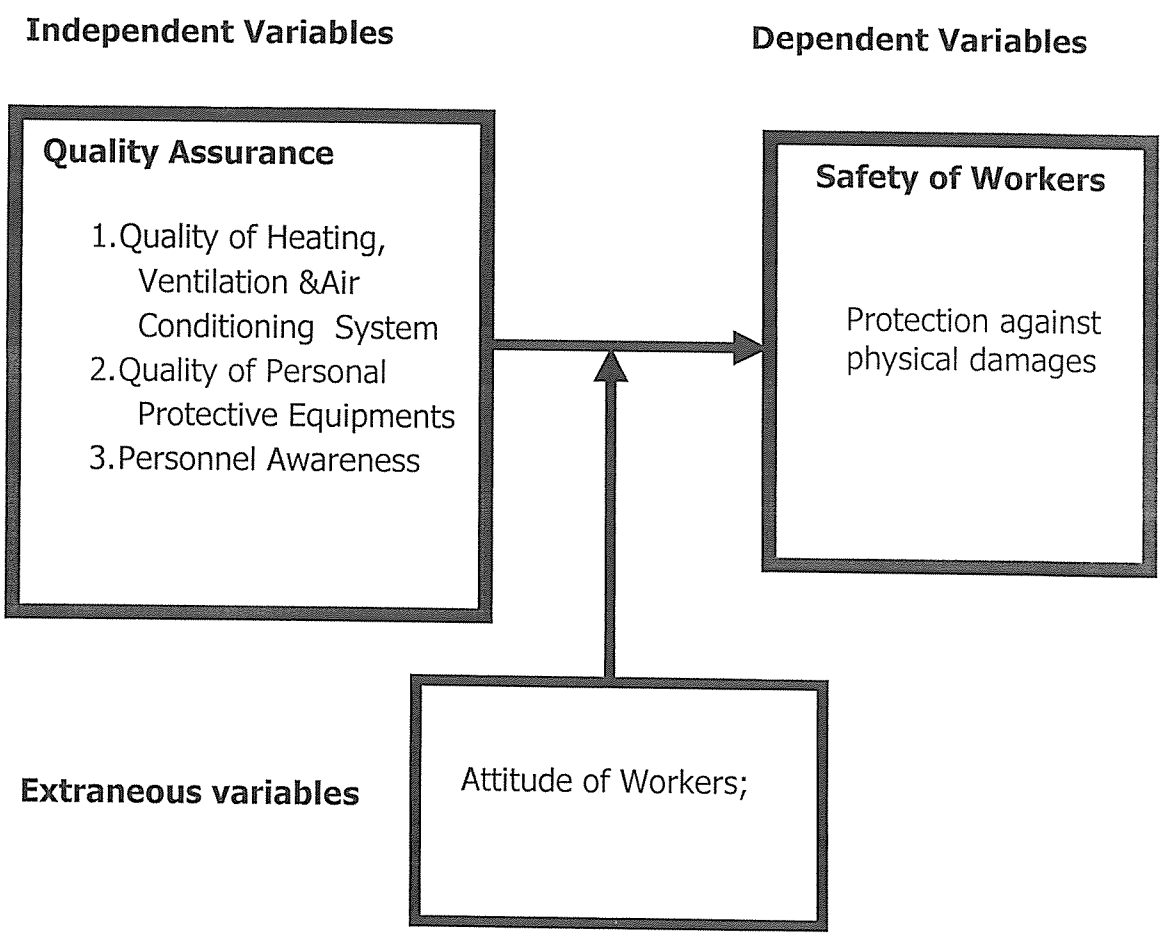

Fig: 1

As far as research topic is concerned, "Quality Assurance" make up the independent or explanatory variable. According to Amin (2005), the independent variable or the predictor variable is the one that influences the dependent variable which, in this respect, is "Workers' Safety". This variable can also be influenced by some extraneous variables such as attitude of workers, changing technology over time.

Related studies

Standards of quality assurance

Good Manufacturing Procedures (GMP) establishes and determines international standards in order to guarantee quality assurance in pharmaceutical industries. They are three major fundamentals.

Heating Ventilation and Air Conditioning as a Safety Measure

The main purposes of a Heating, Ventilation, and Air-Conditioning (HVAC) system are to help maintain good indoor air quality through adequate ventilation with filtration and provide thermal comfort (Harriman, Brundrett, and Kittler, 2010).

The premium condition for a pharmaceutical factory is to encompass in its premises a Heating, ventilation and air-conditioning Systems (HVAC System). This system plays an important role in ensuring the manufacture

of quality pharmaceutical products. A well designed HVAC system will also provide comfortable conditions for operators.

HVAC system plays important role in product protection, personnel protection and environmental. This is because HVAC system design influences architectural layouts with regard to items such as *airlock* positions, doorways and lobbies. The architectural components have an effect on room pressure differential cascades and cross-contamination control. The prevention of contamination and cross-contamination is an essential design consideration of the HVAC system. In view to these critical aspects, the design of the HVAC system should be considered at the concept design stage of a pharmaceutical manufacturing plant.

The advantage of HVAC is that directional airflow within production or packing areas help in preventing contamination. However, airflows should be planned in conjunction with operator locations, to minimize contamination of the product by the operator and also to protect the operator from dust inhalation. Moreover, it is important to note that most of the system design principles for facilities manufacturing solid dosage forms also apply to other facilities such as those manufacturing liquids, creams and ointments.

According to the Standards for the Establishment of Pharmaceutical Factories, the Article 57 of the Pharmaceutical Affairs Act state that for antibiotics (including capsules, tablets, liquids, ointments, etc.), the various types of facilities described in the rules governing each dosage form shall be installed. In processing and packaging areas, air purification and sterilization equipment, and equipment for the regulation of

temperature and humidity, shall be installed in accordance with actual needs. As stated above, equipment for the regulation of temperature and humidity air purification are parts of HVAC System.

Jeebhay and Mbuli (2007) in their study highlight the use of HVAC system in the aim of protecting workers, and more attention needs to be paid to the work environment. This is true since HVAC system isolates dust and conditiones air, while manipulating hazardous products such as chloramphenical. This feature helps preventing workers from diseases like breathing trouble, lung cancer. Meredeth (1978) further stresses that for controlling exposures on hazardous pharmaceutical chemical products for long-term solution to overexposure is to improve the ventilation (HVAC System).

From the same source, it has been proved that management of many plants rather use other protective means like: face masks, goggles in order to cut short term cost and they only think about HVAC when an incident has occurred.

Personal Protective Equipments as safety measures (PPE)

OSHA (2003) define PPE as tools designed to protect employees from serious workplace injuries or illnesses resulting from contact with chemical, radiological, physical, electrical, mechanical, or other workplace hazards.

Otherwise, employees are more often exposed to harmful substances which can have adverse effects upon their lives. Dealing with chemical

substances such as erythromycin, penicillin, tetracycline, streptomycin and clindanycin requires specific PPE certified standards as follows:

(i) Certified protective overalls and gloves;
(ii) Certified face masks;
(iii) Certified goggles.

The provision of personal protective equipment (PPE) such as gloves, face masks, goggles, etc., is very necessary and important in the prevention of direct contact with hazards. According to Methan and Davis (2000) one of the roles of PPE in work place safety, it avoids allergic reactions vitamin deficiency, fungal infections, toxic effects mostly through the skin and respiratory system due to the exposure to chemical products.

Taking the example of certified goggles, OSHA standards require that employers provide workers with suitable eye protection. To be effective, the eyewear must be of the appropriate type for the hazard encountered and properly fitted. For example, the BLS survey showed that a big number of the injuries to workers wearing eye protection resulted from objects or chemicals going around or under the protector. Eye protective devices should allow for air to circulate between the eye and the lens (Occupational Safety & Health Administration, 2009).

In this respect, OSHA requires that all PPE should be of safe design and construction, and should be maintained in a clean and reliable fashion. Employers should take the fit and comfort of PPE into consideration when

selecting appropriate items for their workplace. PPE that fits well and is comfortable to wear will encourage employee use of PPE.

Most protective devices are available in multiple sizes and care should be taken to select the proper size for each employee. If several different types of PPE are worn together, make sure they are compatible.

If PPE does not fit properly, it can make the difference between being safely covered or dangerously exposed. It may not provide the level of protection desired and may discourage employee use. After analysis of these, it can be concluded that a good PPE should meet or be equivalent to recognized standards.

However, other disorders due to unfavorable working conditions have been observed in some pharmaceutical industries, as musculo-skeletal disorders (low back pain, cervical spine and upper extremities disorders) are associated with a number of certain jobs and tasks, such as static work postures, frequent bending etc. Such hazards can be prevented through job designing (ergonomics), job placement, training and education (Gunnar et al, 2000).

Employee's awareness and safety measures

The ability for personnel to perform adequately a task with respect to an established procedure is an important factor in pharmaceutical production. Every operation is performed in accordance with pre-established procedures. Failure to do so may lead the operator to hazard exposure.

According to the World Health organization (2007), all personnel in pharmaceutical plant should be aware of the principles of GMP that affect them. The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture and control of pharmaceutical products rely upon people. For this reason, there must be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly defined and understood by the persons concerned and recorded as written descriptions.

The ability to do this requires from the personnel initial and continuing training, including hygiene instructions, relevant to their needs. Regarding with theory and practices of GMP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness periodically assessed.

Levy (1988) argues that personal skills development is very essential because it is the workers who are familiar with their jobs and therefore if fully equipped with knowledge through trainings probably from prior experience, they can identify hazards. This is known as the empowerment approach which involves workers in the education program.

On the other hand, communication from top management is also important. Managers should tell workers about the harmful nature of the substances they are working with and why they must use the controls of protective equipments provided. A study carried out by Donagi and

Avraham (1998) reveals that workers are either not informed of the hazards of the substances they work with or the information provided to them is technical and poorly understood. Furthermore, the health and safety training provided for workers is inadequate in that it does not provide them with the necessary skills to monitor employers' compliance with health and safety measures.

Employers usually use the issue of trade secrets as an excuse for not providing information. They only divulge such information if trade unions apply pressure and when crises develop. Trade unions argue that the right to know, the right to refuse dangerous work, and the right to appropriate health and safety training are some of the basic tenets of any health and safety program at the workplace.

For this reason, there must be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly defined and understood by the persons concerned and recorded as written descriptions. The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any one individual should not be so extensive so as to present any risk to quality.

Employee's awareness implies also the mastery of established standard procedures. One of established standards is the ISO 9001.

Brenner et al. (2004) assert that routine auditing and corrective action procedures required by ISO 9001 to address management system failures encourage root-cause analysis that can identify problematic work practices that might otherwise precipitate not only quality failures but occupational

health and safety concerns. ISO 9001 can improve worker safety through the identification and elimination of potentially hazardous practices, development of a formal corrective action process and institutionalization of routine audits and management reviews.

The GMP also stipulates that a pharmaceutical production process without a standardized operating procedures leads not also to contamination of product but also to contamination personnel.

Workers' safety at work place

Accidents not only affect workers loosing their livelihood but also employers in terms of compensation to be paid to the workers. Accidents are a significant cause of dispute between workers and management. With the coming in of new set up of industries e.g., steel production, engineering, fertilizers, chemicals and petro-chemicals, oil refining etc., and increasing use of machine power, industrial complexities in terms of process of production have increased. This has given rise to hazards and risks. Safety measures are to be adopted against such risks and hazards. The Factories Act, 1948 has laid down certain measures for the safety of workers employed in the factories. (Factories Act, 1948)

Workers safety guards against chemical products.

OSHA's safety requires that protective clothing should be used in conjunction with other protective methods. For example, engineering or administrative controls to limit chemical contact with personnel should always be considered as an alternative measure for preventing chemical exposure.

According to Bark et al. (2006), when workers are dealing with hazardous chemical substances as a first step they should follow some basic principles of prevention. These principles consist of four control levels or principles of operational control. Each principle has an increasing level of control. They are listed here by priority. This means that workers should first apply the first priority and if not possible then apply the second priority and so on. Here the basic principles :(i) Elimination of the hazard; (ii) Enclosure / isolation of the hazard;(iii) Ventilation of the area where the hazard is, and; (iv) Use personal protection equipment (PPE).

Prevalence of safety hazards

Pharmaceutical industries like all other factories expose workers to numerous occupational health hazards. These hazards affect the general wellbeing of the workers and hence the productivity of the factory. (Amre et al.,1999).

A study done by Harry N. Phoolchund indicated that workers in developing countries face as many, if not more, work-related health problems as their counterparts in industrialized nations. This study concentrated on occupational safety hazards in pharmaceutical industry. In the Third World countries, factory workers have a high level of work related accidents and are also exposed to the high toxicity than their counterparts in the developed nations.

Industrial hygiene surveys carried out in the United States in seven beet pharmaceutical plants to evaluate workers exposures to chemical contaminants used or generated in the process of manufacture indicated

that employees where highly exposed to chemical dust, gas, fumes (Mann, 1989).

CHAPTER THREE: METHODOLOGY

Research design

The researcher used cross-sectional design in conducting the study. This was used because it is used in collecting and analyzing data on annual basis. Besides, the method allows a deep insight to analyze the changes that have occurred over a given period of time, and in this case, the time scope of the study which covered the years 2007 to 2009. The cross-sectional design was used because it is concerned with describing the characteristics of an event, community or region, providing data on population or item being studied by only describing the who, what, when and where of a situation at a given time (Amin, 2005).

Study Population

The study population was selected from LABOPHAR, a pharmaceutical industry in Rwanda. The respondents were workers from the manufacturing unit because they are involved directly in the manufacturing of drugs.

Table 1: Study Population

Particulars	Male	Female	Total
Employees/workers	15	5	20

Table 1 shows that a total of 20 respondents formed the study population. This was actually the established population who are directly involved in the process of making drugs while implementing the good manufacturing practice (GMP) so as to ensure quality of the products and safety of the workers.

Sample Size

Since the number in the study population was manageable, the researcher chose to take all the members in the study population to represent the sample size. All respondents were concerned and affected by quality assurance at the same level, irrespective of gender, age and years spent at work. The sample size of 20 respondents included 15 males and 5 females. According to Amin (2005), from smaller population say N=100 or less, there is little point in sampling; survey the whole population. In this study the researcher used a census.

Research instruments

To collect data quantitative data the researcher used a questionnaire. The questionnaire was used as a main instrument in collection of data all along this research. By the same token, an observational checklist was used.

Validity and reliability of research Instruments

The researcher made sure that at least the instrument used was valid and reliable. In achieving this, validity and reliability tests were done.
To establish the reliability of the questionnaire, the researcher used the method of expert judgment. To affect this after constructing the

questionnaire, the researcher contacted the supervisor and two other experts, to ensure the reliability and validity of the research instrument. After the consultations, the researcher made the necessary adjustment, to ensure that the questionnaire was made to the advice of the experts. This made the questionnaire more clearly, relevant, specific and logically arranged. In additional to that a pre-test was conducted in order to test and improve on the reliability of the questionnaire. To improve the validity of the data collection instrument, the number of relevant questions were divided by the total number of questions, and the outcome was above optimal.

V= RQ/TQ= 28/32 =0.857

Where by, V= Validity

RQ= Relevant questions

TQ= Total number of questions

The above expression, indicates that, the number of questions on the questionnaire, were above the required 0.7 scores. Hence, the instrument used was valid.

Data gathering procedures

An introductory letter was obtained from Kampala International University requesting for permission to undertake this research in LABOPHAR. The researcher introduced himself to the targeted samples. The researcher then prepared questionnaire and pretested it before administering.

From 3rd July, 2010 the researcher spent 50 days to collect data in LABOPHAR.

Lastly the questionnaires were collected and data were entered in SPSS, frequencies were highlighted, and percentages were computed. The Pearson correlation coefficient was used to measure how the independent variable (Quality Assurance) influences the dependent variable (Workers Safety).

Ethical Consideration

There was a need for the researcher to use professional and ethical standards to plan, collect and process data. The researcher ensured that he was objective and used objective methods in data collection.

The researcher made sure that he uses only those techniques for which he was qualified by education, training and experience. Whenever in doubt, the researcher sought clarification from the research community especially the immediate supervisor and research colleagues.

The researcher also ensured that data was interpreted according to general methodological standard and made sure that elements that were irrelevant to data interpretation were excluded from the report.

The researcher ensured that he reports accurately what he found out in the study, properly explaining the methods used and reasons for doing.

Limitations of the study

A major barrier to this study was lack of sufficient secondary data. Limited literature on quality assurance on workers' safety in the University library

and other libraries around made the study to be only restricted to use a few literature materials the researcher managed to access.

Language barrier caused a problem where some of the respondents could not express them selves well and some times misunderstood the questions so the researcher had to help the respondents to interpret the questions.

CHAPTER FOUR

PRESENTATION, ANALYSIS AND INTERPRETATION OF DATA

This chapter deals with the presentation, analysis, interpretation and discussion of findings. It shows the results of the study collected from the field using questionnaires as the primary source of data in an effort to establish the extent at which the quality assurance affect the safety of workers at LABOBHAR. The findings are based on the information that was obtained from workers in the factory, and the key informants. The results and interpretations of the findings are presented by tables,.

Discussion and presentation of the findings were guided by the following objectives:

- To assess how working conditions affect workers' safety in LABOPHAR.
- To find out the degree of awareness of GMP and safety by workers of LABOPHAR.
- To establish the relationship between quality assurance and workers' safety.

Respondent identification

Table 2. Education Level

	Frequency	Percent	Valid Percent
Primary	18	90	90.0
Secondary	2	10	10.0
Total	**20**	**100**	**100.0**

According to table above, the majority of the personnel (90%) have not completed the secondary school. The education level of the workers had an influence on the occurrence of occupational hazards. Some of the respondents had not studied beyond post secondary implying they did not have basic training about the job. This is in agreement with Levy (1988), that poor occupational situation at work places is partly due to inadequate training of workers. Therefore proper training of workers leads to good occupational situation at a work place.

Table 3. Year spent at work

		Frequency	Percent	Valid Percent
	1-5 years	1	5	5
	6-10 years	3	15	15
	11-15 years	14	70	70
	16-20 years	2	10	10
	Total	20	100.0	100.0

The table 3 shows that the majority of Labophar personnel, (80%) have more than 10 years experience in the organization. Hence, they are supposed to be aware of the principles of GMP that affect them and they are supposed also to have received initial and continuing training, including hygiene instructions, relevant to their needs (WHO, 2007).

Assessment of working conditions of personnel in the factory

Table 4. Quality of HVAC System in the factory (n=20)

Description.		**Frequency**	**Percentage.**
Is the factory of Labophar ventilated?	Yes	08	40
	No	12	60
	Total	**20**	**100**
Is it ventilated through a direction airflow system	Yes	0	0
	No	20	100
	Total	**20**	**100**
Is the temperature in the factory regulated	**Yes**	20	100
	No	0	0

As we can see in the Table above, on the question asked to 20 respondents whether the factory is ventilated, 12 workers (60%), confirmed that the factory is not adequately ventilated and 8 workers (40%) assert the contrary. The figures showed that they may not have the same knowledge or understanding on quality of Heating-Ventilation and Air-Conditioning System. How ever when they were asked whether the factory is ventilated through a directional airflow system, the whole personnel (100 %) working in the factory affirmed that there is no a controlling system for directional air flow. According to World Health Organization requirements, (WHO,2007) this constitute an obstacle to the safety of workers because the merit of HVAC is that directional airflow within production or packing areas help in preventing not only contamination of products but also prevents the worker against dust inhalation. This is confirmed by the study conducted by Jeebhay and Mbuli (2007) as they stressed on the use of HVAC system in the aim of protecting workers while manipulating hazardous products.

This is also supported by Meredeth (1978), when she suggests that for controlling exposures on hazardous pharmaceutical chemical products, the best long-term solution to overexposure employees is to improve the HVAC System.

To the question asked to workers on the regulation of the temperature in factory, 100% of employees responded by "no". This is in contradiction with the Article 57 of the Pharmaceutical Affairs Act stating in processing and packaging areas, air purification and sterilization equipment, and equipment for the regulation of temperature and humidity, shall be installed in accordance with actual needs.

The observation check list revealed that workers some time had the habit of removing face masks. This was due to increase of temperature at certain time of the day.

Table 5. Availability of Personnel Protective Equipments (n=20).

Description		**Frequency**	**Percentage.**
Are PPE (Personal Protective Equipments) availed by Labophar to workers?	**Yes**	20	100
	No	0	0
	Total	20	100
Does Labophar provide goggles to workers?	Yes	0	0
	No	20	100
	Total	**20**	**100**
Does Labophar provide gloves to workers?			
	Yes	20	100
	No	0	0
	Total	20	100
Does Labophar	**Yes**	20	100

provide face masks to workers?	**No**	0	0
	Total	**20**	**100**
Does Labophar provide overalls to workers?	Yes	20	100
	No	0	0
	Total	**20**	**100**
Are they provided at adequate amounts all time?	Yes	5	25
	No	15	75
	Total	**20**	**100**
Do you think it is necessary to put on PPE during your work?	Yes	20	100
	No	0	0
	Total	**20**	**100**
If yes, do you put your PPE on all the time you are at work?	Yes	8	40
	No	12	60
	Total	**20**	**100**

In your opinion, what can be the reason of not putting the PPE during the work?	Uncomfortable	17	85
	Under/over size	3	15
	Total	**20**	**100**

Based on the table above, respondents were further asked whether there are personal protective equipments (PPE's) availed to workers in the factory, all the respondents 100% (20/20) said that PPEs are available in the factory. However, primary data reveled that workers in factory use only gloves and face masks as confirmed by 100 % of workers. However, the GMP states that workers handling hazardous products are required to put: (i) Certified protective clothing and gloves; (ii) Certified face masks; (iii) Certified goggles. This is backed-up by Levy (1988) confirming that provision of personal protective equipment (PPE) such as gloves, face masks, goggles etc, is very necessary and important in the prevention of direct contact with hazards (Levy, 1988).

The observation checklist also reveled that the PPE used by workers are not marked by a "certified" Label.

To the question whether PPE are provided in adequate amount all the time, 75% of workers confirmed that there are not sufficient PPE in the factory and workers do not put PPE all the time. This was confirmed by 60% (12/20) of workers. Respondents were also

asked to give their opinion on the reason why workers do not put PPE all the time, 85% (17/20) of them asserted that PPE provided to workers are uncomfortable while 15% (3/20) said PPE are under or oversized.

The observation above encountered concerns expressed by Meredeth (1978), where she suggests that for controlling exposures on hazardous in pharmaceutical, the best long-term solution to overexposure is to improve the ventilation (HVAC System) and in short term, he suggests the use of a certified PPE.

The degree of awareness on good manufacturing procedure and safety by workers of LABOPHAR.

The researcher was also interested in knowing how employees are aware of procedures guiding the GMP and Safety.

Table 6. Awareness of workers on GMP and safety

Description		**Frequency**	**Percentage.**
Are you aware that work in the pharmaceutical industry is associated with hazards?	Yes	20	100
	No	0	0
	Total	**20**	**100**
If yes, are you informed of any potentially harmful health effects of the	Yes	4	20
	No	16	80

hazardous product you handle?			
	Total	**20**	**100**
Does the management provide to workers a regular safety training programs?	Yes	4	20
	No	16	80
	Total	**20**	**100**
Do you report to your superiors any accidents/illnesses that occur at your work place?	Yes	16	80
	No	4	20
	Total	**20**	**100**
What is the response when an accident is reported to your superior?	Investigation is carried out and Corrective measures are taken.	18	90
	No action	2	10
	Total	**20**	**100**

Do you receive initial and continuing training, including the GMP instructions by?	Every time.	0	0
	Some time.	3	15
	Not at all.	17	85
	Total	**20**	**100**
Do you have standardized operating procedures that aim to identify and eliminate hazardous practices in LABOPHAR?	Yes	5	25
	No	15	75
	Total	**20**	**100**
When processing or packaging products, workers are in static work posture, or frequent bending	Every time	10	50
	Some time.	10	50
	Not at all.	0	0
	Total	**20**	**100**

From the above table, it was reveled that employees in LABOPHAR are conscious that working in pharmaceutical plant is associated with hazards. This was confirmed by 100% of workers. However, to the question whether they are informed on potential harmful effects of products that they usually handle, 80% of them said no whereas only 20% said yes. This is contrary to Glanville's recommendation stipulating that managers should tell workers about the harmful nature of the substances they are working with and why they must use the controls of protective equipments.

The results from the table above is also in accordance with the study carried out by Alexander and Aladjam (1998) which reveled that workers are not informed of the hazards of the substances they work with or the information provided to them is technical and poorly understood. As for the question on whether management provides to workers a regular safety training programs, the answer from respondents showed that 80% do no recieve regular training provided to employees. Regular training in pharmaceutical industry is mandatory.

Respondent where also asked whether they report to their superior any accidents or illness that occur at workplace, 80% (16/20) responded by yes. As for the way with which management react to that, the majority of respondent 80% (16/20) agreed that management carry out investigation and take corrective measures.

The subsequent question was concerned about initial and continuing training including hygiene instructions beneficial to workers. Respondents answered "not at all" to the majority of 85%. Reason of this

question was to asses whether workers have basic knowledge on GMP instructions.

Respondent were also asked whether there exists standardized procedures that aim to identify and eliminate hazardous practice in LABOPHAR, 75% (15/20) responded affirmatively. This is not in line with ISO 9001 since it helps preventing workers from hazards. Brenner, et al. (2004) adds that organizations adopting ISO 9001 lead to improvement of safety.

The researcher also asked respondents about position of workers when processing or packaging products. This reveled that 50 % of employees are either in standing or uncomfortable position every time and other 50% are in standing or uncomfortable position sometime. This means that 100% of workers in Labophar are exposed to muscular-skeletal disorders such as low back pain, cervical spine and upper extremities since. However, 50% of them are highly exposed since they stay every time in standing position. This is backed up by assertion that low back pain is the commonest occupational health disorder (Gunnar et al, 2000). According to them, occupational factors that are associated with an increased risk of low back pain are static work postures, frequent bending. The observational checklist also showed that when employees are processing or packaging products there are not sufficient and adequate chairs for every employee in the factory.

The relationship between quality assurance and workers' safety

Data from Likert scales were reduced to the nominal level by combining all "agree" and "disagree" responses into two categories of "agreed" and "disagreed". By the same token, correlation analysis was used to examine the relationship between quality assurance and workers safety in Labophar. The relationship between Quality Assurance and the Workers' Safety was determined using spearman's correlation coefficient as shown in the correlation matrix below

Table7. Factors determining workers safety in Labophar analyzed using Correlation analysis

		Quality of HVAC	Quality of Personal Protective	Personnel Awareness
Safety of Workers	Correlation Coefficient	0.661	0.699	0.661
	Sig. (2-tailed)	0.001	0.001	0.001
	N		20	20

**. Correlation is significant at the 0.01 level (2-tailed).

The table 4.4 indicates that there was a significant positive relationship between Quality of Assurance and the Workers' Safety (r=0.673, Sig. = 0.001). This implies that Quality of HVAC System enhanced the Safety of Workers. The table further indicates that there were significant positive relationship between Quality of HVAC System and the Safety of Workers

(r=0.661, Sig. =0.001). This implies that Quality of HVAC System plays a positive role in Safety of Workers. The table indicates also that there were significant positive relationship between Quality of Personal Protective Equipments and the Safety of Workers (r=0.699, Sig. =0.001). This implies the quality of Personal Protective Equipments has a positive effect on workers' safety. The table, also indicates that there were significant relationship between personnel awareness and workers' safety (r=0.661, Sig. =0.001). This implies that the personnel awareness on GPM and safety has a positive effect on safety of workers.

CHAPTER FIVE

FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

This chapter focused on brief discussion of the main findings. Moreover, the researcher reported what he could say about the research study, the answers to the research questions, as well as the conclusions drawn. The related recommendations were also presented in this chapter.

Under here, discussions are made based on the objectives of the study.

In this study, the researcher carried out an inquiry about the effect of quality assurance on workers' safety. Three questions arose by the researcher's undertaking: the question of knowing the working conditions of personnel in the factory, the degree of awareness on good manufacturing procedure and the safety by workers as well as whether there is any correlation between quality assurance and workers' safety.

FINDINGS

Assessment of the working conditions of personnel in the factory

Regarding working conditions, the researcher focused on quality of HVAC System as well as the availability of PPE. The findings from the research have reveled that Heating, Ventilation & Air Condition System (HVAC) is not adequate in Labophar, since the air does not flow through an appropriate system. This was confirmed by the large majority of workers (100%).The absence of HVAC System in pharmaceutical plant leads workers to exposure from dusts. This affirmation is supported by research carried out by Jeebhay and Mbuli (2007). The use of HVAC System is

priority over other protective means. Meredeth (1978) also stressed the use of HVAC in the protecting workers. She suggested that for controlling exposures on hazardous pharmaceutical chemical products such as tetracycline, erythromycin, penicillin, etc., the best long-term solution to overexposure is to improve the HVAC System. Adding to this, the temperature in the factory is not regulated. Thus, linking this to the fact that workers do not put PPE all the time, as it was confirmed by 60% of employees, the fact that workers are exposed to dusts inhalation is irrefutable.

As for Personal Protective Equipments, the majority of the factory workers mentioned the use of PPE as the method of protection. This however conformed to Levy's (1988) recommendations that the use of PPE is so important and necessary to prevent direct contact with most hazards. However, the literature review reveled that, when there is lack of HVAC System in pharmaceutical plant, the use of certified PPE is mandatory. This includes (i) certified protective goggles, (ii) certified gloves, (iii) certified, and (iv) certified overalls. Contrary to what was observed from data analysis, 100 % of workers do not wear neither goggles nor overalls. They only relay on face masks and gloves as it was confirmed by 100 % of employees. However, it should be noted that these were not available in all the factory sections and were not in adequate amounts, 75% of employees confirmed that. Also, employees confirmed that the PPE availed to them were not put all the time due to their uncomfortable features. This was confirmed by 85% of workers in the factory.

According to Meredeth, the use of PPE per se is not enough protection. It only constitutes a short term solution; hence it can be complemented by use of certain special equipment to handle hazardous substances and also to follow safe operating procedures. The recommendations of Meredeth, on the use of safe operating procedures are backed-up by requirements from ISO 9001, stipulating that ISO 9001 can improve worker safety through the identification and elimination of potentially hazardous practices, development of a formal corrective action process and institutionalization of routine audits and management reviews. Nevertheless, data interpretation reveled to the researcher that LABOPHAR factory, does not use standardized procedures aiming to identify and eliminate hazardous practices. This was confirmed by 75% of employees working in Labophar.

Awareness on good manufacturing procedure and safety by workers of LABOPHAR.

In an attempt to know whether employees in factory were aware that working in the pharmaceutical industry is associated with hazards, 100% (20/20) confirmed this. However, to the question whether employees are informed on any potentially harmful heath effects of the hazardous products they handle, 80 % of them asserted not to be informed. The controversy is due to the fact that management does not inform workers on probable hazards they are exposed to. This phenomenon therefore calls for Levy's advocacy for education that aims at changing workers' behavior which could lead to the practice of safety measures while at work. (Levy, 1988)

It was also observed that first aid kits were not present in all the factory sections. It should be appreciated that first aid minimizes the consequences of accidents as a tertiary preventive measure. Therefore first aid kits are important in the work places which are prone to accidents. So if first aid facilities are absent in the factory and an accident occurs, no immediate treatment is given and the problem is aggravated further and may become complicated.

The signs of no-entry were absent in majority of the sections. This was contrary to the WHO guidelines which stipulate that there should be symbols and no-entry signs displayed conspicuously in appropriate places. These help remind workers more especially those who do not work in that particular section and visitors to be cautious all the time. Absence of these signs could have led to hazardous occurrences in one way or another.

The results showed also lack of use of standardized operating procedures (SOP), as confirmed by 75% of employees. SOPs and rules of procedures should be written down and displayed in work stations for easy memorization and quick reference. There is need for display such as proper and consistent use of PPE; following proper procedures etc. the absence of SOP display could have been one of the reasons for the occurrence of hazards. This is supported by Brenner, Fairris, and Ruser (2004), when they observed that adopting ISO 9001 can lead to improvements in occupational health and safety in a variety of ways. In the process of formally documenting procedures for example managers

can identify and eliminate hazardous practices and add safety precautions. This logic of things is also supported by the 5P's Model where it is stipulated that it is difficult to manage and improve (or even replicate) undocumented processes.

Musculo-skeletal disorders are also one of hazards from which employees in Labophar may be exposed to, since 50% of workers in Labophar are every time on static work posture or frequent bending position when processing or packaging products. The remaining 50% of workers asserted that they are sometime either in static work posture or in frequent bending position. From these figures, it is shown that 100% of workers are most likely to develop musculo-skeletal disorders such as low back pain, cervical spine and upper extremities disorders.

CONCLUSIONS

Bearing in mind the foregoing discussion, a number of conclusions were drawn.

Factory work is associated with a number of hazards. Most of these occupational hazards are preventable but not much has been done to change the course of occurrence of these hazards.

1. All the workers knew it is important to put on PPE during work but they did not put them on all the time because it was uncomfortable to them hence inefficient protection of the workers against safety hazards.

2. Lack of ventilation and Regulation of air exposes workers to possible inhalation of dusts, hence inefficient protection of workers against safety hazards.

3. Workers are partially or fully operating in a static work posture or frequent bending position. This leads workers to probable musculo-skeletal disorders.

4. There are not appropriate standards operating procedures to identify and eliminate hazardous practices, hence add safety precautions.

5. The Education level of the workers had a very big bearing on the occurrence of hazards in the factory.

6. Workers are not educated on the safety measures in the factory. This therefore means workers are not helped to change their behaviors to practice safe occupational behaviors.

7. Fully equipped first aid kits are not provided in the factory sections. Therefore by the time a worker is taken to the hospital after an accident, the problem will have aggravated.

8. There is a correlation between quality assurance and safety of workers.

RECOMMENDATIONS

- In very short term, the factory management should supply sufficient PPE to the workers, ensure that they are fitting and consistently used by the workers. PPE should comply with International Standards.
- The factory management should also ensure that fully equipped first aid kits are strategically placed in all the factory sections. They should also train individuals on first aid skills.
- The conditions of the work stations should be improved, that is; reduce as maximum as possible contact with chemical dusts by improving the ventilation system and regulation of temperature.
- Management should introduce routine auditing and corrective action procedures required international recognized standards that can identify problematic work practices that might otherwise precipitate not only quality failures but occupational health and safety concerns.
- The management should also carry out regular education of workers on safety matters so as to ensure that some of the common accidents that are caused due lack of knowledge are avoided in the factory.
- Ergonomic issues affecting workers in Labophar should be deeply revised.

The research process is based on the fact that no research answers all questions. In this regard, further research undertakings are irrefutably needed. Since findings from this research showed that the safety of workers in Labophar is affected by the quality assurance, the following topics seem to be relevant to future studies:

1. Workers' attitudes as determinant factor of hazards reduction in Industries: A Case of Labophar.
2. Which quality assurance measures should pharmaceutical projects put in place to insure workers' safety of greater productivity and efficiency? A case of Labophar.
3. Management style as determinant factors of hazards reduction in Industries: A case of Labophar.

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APPENDICES

APPENDIX I: TRANSMITAL LETTER

KAMPALA
INTERNATIONAL UNIVERSITY

P.O.BOX 20000
KAMPALA- UGANDA.
TEL:-041-266813

OFFICE OF THE DEPUTY DIRECTOR
SCHOOL OF POSTGRADUATE STUDIES AND RESEARCH

June 21, 2010

RECU
Le 05/07/2010

The Director General
Rwanda Pharmaceutical Laboratory Project

Dear Sir/Madam,

RE: INTRODUCTION FOR NTAGARA NGABO DONATIEN

This is to inform you that the above named is our registered student (MPP/20013/82/DF) in the School of Postgraduate Studies pursuing a Master of Arts in Project Planning and Management.

He is interested in carrying out research in your organization entitled **"The Effect of Quality Assurance on workers' Safety: A case of Rwanda Pharmaceutical Laboratory Project"**.

Any assistance rendered to him regarding research will be highly appreciated.

Yours faithfully,

KAMPALA INTERNATIONAL UNIVERSITY
SCHOOL OF POST GRADUATE STUDIES
P.O. BOX 20000 KAMPALA

Tunde Yara PhD
DEPUTY DIRECTOR-SCHOOL OF POSTGRADUATE STUDIES AND RESEARCH

Permission granted to
NTAGARA NGABO DONATIEN

LABORATOIRE PHARMACEUTIQUE
LABOPHAR
B.P. 340 BUTARE
DU RWANDA

by [illegible]
General Director
LABOPHAR

APPENDIX II:

A QUESTIONNAIRE TO BE ADDRESSED TO WORKERS IN FACTORY OF LABOPHAR

Kampala International University

School of Postgraduate Studies

P.O. Box 20000 Kampala

Republic of Uganda

Jully 3, 2010

Dear Sir/Madam

Re: Introductory letter

The purpose of this questionnaire is to find out information regarding Quality Assurance and Workers' Safety in LABOPHAR. All information provided here in will be treated strictly confidential and purely for academic exercise only leading to the award of Masters Degree in Project Planning and Management.

This is to seek your help by asking you to please fill in the questionnaire pertaining to the research topic. The Study is purely an academic exercise and the responses given will be treated with confidentiality.

Yours sincerely

NTAGARA NGABO Donatien

I. Respondent identification

I.1. Education level

1. Primary
2. Secondary
3. University

I.2. Work experience

1. 1-5 years
2. 6-10 years
3. 11-15 years
4. 16-20 years
5. 21-25 years

II. Assessment of working conditions of personnel in the factory

A. Quality Assurance (Independent Variables)

II.A.1. Quality of HVAC System

II.A.1 Is the factory ventilated adequate?

1. yes
2. No

II.A.1.1 If yes, is ventilated trough a directional airflow system?

1. Yes
2. No

II.A.2 Is the temperature regulated?

1. Yes
2. No

II.B. Quality of Personal Protective Equipments

II.B.1. Are PPE's (Personal Protective Equipments) availed by the factory?

1.Yes

2.No

II.B.2. If yes, are they supplied in adequate amounts at all times?

1.Yes

2.No

II.B.3 Does the Labophar provides the following Personal Protective Equipments (PPE) in the Factory?

		Yes	no
II.B.4.1	Goggles.		
II.B.4.2	Face masks.		
II.B.4.3	Overalls.		
II.B.4.4	Gloves		

II.B.4. Do you think it is necessary to put on PPE during your work?

1.Yes

2.No

II.B.4.1. If yes, do you put your PPE on all the time you are at work?

1.Yes

2.No

II.B.4.2 In your opinion, what can be the reason of not putting the PPE during the work?

1.uncomfortable

2.under/over size

III. The degree of awareness of GMP and safety by workers of LABOPHAR

III.1. Are you aware that work in the pharmaceutical industry is associated with hazards?

1.Yes.

2.No.

III.1.1 If yes, are you informed of any potentially harmful health effects of the hazardous product you handle?

1.Yes.

2. No.

III.2. Does the management provides a regular safety training programs?

1.Yes.

2. No.

III.3. Do you report to your superiors any accidents/illnesses that occur at your work place?

1.Every time.

2.Some time.

3.Not at all.

III.4. What is the response when an accident is reported to your superior or the ?

1. An investigation is carried out and corrective measures are taken
2. No action.

III.5. Do you receive initial and continuing training, including GMP instructions as?

1.Every time.

2.Sometime.

3.Not at all.

III.6. Do you have standardized procedures that aim to identify and eliminate hazardous practices in LABOPHAR?

1.yes.

2.No.

III.7 When processing or packaging products, workers are in static work posture, or frequent bending position?

1. Not at all.
2. Some time.
3. Every time

IV. To establish the relationship between quality assurance and workers' safety

		SCORE				
		Strongly Agree	Agree	Not sure	Disagree	Disagree
	I. Quality assurance	5	4	3	2	1
	A. Quality of HVAC System					
.A.1	The Labophar's factory is adequately ventilated and facilitate the working condition					
.A.2	The temperature of Labophar's factory is regulated and facilitate the working condition					

	B. Quality of Personal Protective Equipments	5	4	3	2	1
.B.1	In order to facilitate working conditions, Labophar provides to workers a certified compound of PPEs(goggles, face masks, clothing and gloves)					
	C. Personal awareness	5	4	3	2	1
.C.1	Labophar's management provides a regular safety training programs to workers in the factory					
.C.2	There are standardized that aim to identify and eliminate hazardous practices in LABOPHAR?					

. Workers' safety		5	4	3	2	1
.II.1.	In your opinion, do you think that the work conditions in LABOPHAR manufactory are favorable to protect employees against physical damages?					

APPENDIX III: OBSERVATIONAL CHECKLIST

1. Are there signs of "no entry to non staff" notices and danger signs visible?

1 = yes ☐ 2 = No ☐

2. Are PPEs available?

1 = yes ☐ 2 = No ☐

3. Are they adequate?

1 = yes ☐ 2 = No ☐

4. Is there a fully equipped first aid kit?

1 = yes ☐ 2 = No ☐

5. Do workers wear face masks all the time?

1= yes ☐ 2 = No ☐

6. Do workers wear goggles all the time?

1 = yes ☐ 2 = No ☐

7. Do workers wear gloves all the time?

1 = yes ☐ 2 = No ☐

8. Do workers wear overalls all the time?

1 = yes ☐ 2 = No ☐

9. Is there any label marked "CERTIFIED" on Personnel Protective Equipments in the factory?

1= Yes ☐ 2= No ☐

10. Is the ventilation adequate in workplace?

1 = yes ☐ 2 = No ☐

11. Is the temperature regulated?

1 = yes ☐ 2 = No ☐

12. When workers are processing or packaging products do they use chairs that fit with the position where settings of machines are located?

1 = yes ☐ 2 = No ☐

13. When you are processing or packaging products are there sufficient and adequate chairs for every employees in the factory?

1 = yes ☐ 2 = No ☐

APPENDIX V: CURRICULUM

Personal profile

- **Name:** Ntagara Ngabo
- **Second name:** Donatien
- **Date and Birth Place:** 1968, RD Congo
- **Parents:** Ngabo Theoneste and Mukaremera Marie
- **Marital status:** Married
- **Nationality:** Rwandan
- **Telephone number:** +250 788525680
- **E-mail:** ngabodonat@yahoo.co.uk

Educational Background

Academic

- 2009-2010: Kampala International University (Master of arts Project Planning and Management)
- 2003 - 2006: National University of Rwanda (NUR) (Bachelors' degree in Public Administration)
- 1988-1994: I.S.P.T RD Congo Kinshasa (Bachelors Degree in Engineering: Electro mechanic)
- 1982 - 1988: Secondary studies at I.T.I Goma RDC (Mechanic)
- 1975 - 1981: Primary studies at E.P Karisimbi (RDC)

Professional

- 2 weeks in Pharmaceutical Manufacturing Processes in Barcelone, Spain
- 3 days in « DgMarket » soft ware at RPPA/Rwanda
- 3 days in "Safety in Rwanda Industries" by MIFOTRA/Rwanda
- 2 weeks in Public procurement at RIAM
- 2 weeks in « International Procurement And Contrat Negociation » at Wold Bank
- 3 intensive day training in Project management at Kampala International University
- 3 intensive day training in Entrepreneurship at Kampala International University
- 5 days training in Proposal writing, fundraising and mobilization at Kampala International University
- 1 intensive days training in Project Planning and Management at Makerere University
- 1 intensive days training in Monitoring and Management at Makerere University.
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Work Experience

- 01/October/2001-Currently: Technical Director in LABOPHAR

Dissertation and Thesis

- Dissertation in Public Administration «**Problematique de l'Affectation de budget alloue aux entites locales Affe, case studies of Gisagara District** »

Computer knowledge

- Microsoft Word
- Microsoft Excel
- Power point
- software / DgMarket

Languages spoken

- French : Excellent
- English : Very Good
- Kinyarwanda : Very Good
- Swahili : Very Good