Exploration of the Training/Educational Background and The Roles of Regulatory Affairs Associates/Officers in selected South African Based Pharmaceutical Companies in Gauteng Province

A mini-dissertation submitted by

Collins Mukoma

In partial fulfillment of the requirements for the degree of M.Sc. in Pharmacy Administration and Policy Regulation

Supervisor:
Dr. Samuel A. Egieyeh

Co-supervisor:
Mrs. E. O. Egieyeh

School of Pharmacy
Faculty of Natural Science
University of the Western Cape
Bellville
South Africa

2021

DECLARATION

I, Collins Mukoma declare that ***"Exploration of the Training/Educational Background and The Roles of Regulatory Affairs Associates/Officers in selected South African Based Pharmaceutical Companies in Gauteng Province"***, is my work, and all the sources that I have used or cited have been acknowledged with complete references, and that I have not previously submitted this work for any other degree at any other institution.

Signed*:* 

Date: 01 March 2021

DEDICATION

To my late Grandmother Mukumela Mukoma, I will always miss you. Every milestone I reach in life is dedicated to you. Life has not been easy without you and I hope I make you proud. To my mother, Julia Mukoma, and my confidant, Choppo Lebitso I appreciate your motivation and encouragement. Finally, my young and only brother, Zwonaka Ndou, I hope I inspire you to achieve far more than I have.

ACKNOWLEDGEMENTS

I would like to sincerely thank the following people for their various and invaluable contributions to the completion of this thesis.

- **Dr. Samuel A. Egieyeh**, my supervisor for his advice and support. He has guided me through this journey, put in so much time and effort to ensure that I produce high-quality research and that I meet my deadlines.
- **Mrs. E.O. Egieyeh,** my co-supervisor, has reviewed my Thesis and advised on how it should be written professionally.
- **Mr. Feikoab Parimah,** my writing and statistical coach for all the assistance with professional writing and data analysis. I truly appreciate your selfless effort to assist with this project.
- **The Regulatory Affairs team,** who took their time and participated in this study and made it a success. I am grateful to every one of them.
- All the **Pharmaceutical Companies** in Gauteng permitted me to conduct the study in their facilities.
- My **family and friends**, for their encouragement and support. **Mr**. **Tumelo Modau, Dr. Jeffery Mukoma, and Ms. Thobile Lubisi.**

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABSTRACT

Regulatory Affairs (RA), within the pharmaceutical business, could be a profession that covers different registration parameters of a pharmaceutical product. This is a profession that was developed to protect the public by providing smart, quality, safe and efficacious pharmaceutical products. However, it is not clear if the personnel possess the fundamental education and training required to perform the roles and responsibilities in this profession. The study aimed to explore the educational training and role of RA associates/officers in pharmaceutical corporations in Gauteng, South Africa. The study was a cross-sectional survey, which utilized Google forms with both open and closed-ended questions. Using descriptive statistics, it was found that the majority of the participants (78.3%) (RA assistants, officers, and scientists) indicated that the knowledge for most of the responsibilities they carry out was acquired through informal training (i.e., learning on the job). Although various pharmaceutical companies have different titles for these personnel, it was observed that most of them perform almost the same functions (i.e., prepare submissions of license variations and renewals to strict deadlines). Furthermore, it was recorded that most RA personnel have experience of between 1-5 years (56.6 %) and that most RA personnel acquired their job through an internship (43.5%) and external vacancy (43.5%). Moreover, it was also observed that most RA personnel (43.5%) have more than one qualification (Honours Degree and MSc Degree). Although specialized training is required for RA personnel, only 30.4% of the participants were trained to provide strategic advice to senior management throughout the development of a new product. About 13.0% of the participants were trained to plan and develop product trials and interpret trial data.

CHAPTER 1

INTRODUCTION

1.1 Background

In a world of growing uncertainties, wherein increased knowledge and technological development are required to keep the continuity of business, both the employer and employee have responsibility for upgrading their skill levels (ILO, 2017). One of the features of working life today is that whatever education and training acquired at the start will certainly become redundant or obsolete during the same working lifetime (ILO, 2017). The need for continuous training to obtain new skills, knowledge, and attitudes has become important in each person's working life (Valamis, 2020). In some cases, this will necessitate a complete change from one profession to another while in others it may merely be an upgrading process (Valamis, 2020).

1.1.1 Why is the training of RA personnel important to the pharmaceutical industry?

Regulatory affairs (RA) personnel have a critical role to play in the pharmaceutical industry. They are responsible for the healthcare product's lifecycle. They also provide strategic, tactical, operational direction and support for working within current regulations to promote the development and delivery of safe and effective healthcare products to the public (Sri Harsha, 2017). The local pharmaceutical industry is currently facing great changes and challenges. Furthermore, it has also been observed that lack of skillful and capable employees has forced organizations to be proactive to sustain their workforce and business continuity (Deeksha R Pai. et al, 2016).

Therefore, RA personnel in the pharmaceutical industry need training because regulatory decisions have a direct impact on business outcomes. They need to have a comprehensive understanding of business, such as the business insight provided by extensive on-the-job training, professional development programs, or formal business training (RAPS,2017).

1.2 Purpose of the study

The purpose of the study was to explore the training and roles of RA associates/officers in pharmaceutical companies in Gauteng, South Africa. The study provides information on the

importance of appropriately training RA associates/ officers in line with their expected roles in pharmaceutical companies.

1.2.1 Aim of the study

The study aimed to explore the training and role of RA associates/officers in pharmaceutical companies in Gauteng, South Africa.

1.2.2 Objectives of the study

- To examine the pre-employment training and educational background of RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.
- To explore the roles and responsibilities of RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.
- To ascertain the in-house training provided to RA associates/officers by their respective pharmaceutical companies in Gauteng, South Africa.
- To evaluate the association between the training obtained and the roles played by RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.

CHAPTER 2

LITERATURE REVIEW

2.1 Regulatory Affairs (RA) in the Pharmaceutical Industry.

Regulatory Affairs within the pharmaceutical industry may be a profession that covers different registration parameters of the pharmaceutical product. This profession was developed to safeguard public health by providing smart, quality, pharmaceutical merchandise that is safe and effective (Sri Harsha, 2017).

It is a profession that integrates management and science to get a commercial goal within a drug development organization. This might incorporate everything regarding medicine from the earliest nonclinical studies, through clinical development into routine manufacture and promotion (Sachin & Vyawahare, 2015).

2.2 Role of Regulatory Affairs in the Pharmaceutical Industry

In the pharmaceutical business, the role of the RA department is to supply strategic and technical recommendations to different departments like analysis and development, production, quality assurance, and quality control departments. This role begins right from the earliest stages of the development of a product, creating a key contribution commercially and scientifically to the success of the development of a product.

Within the various pharmaceutical organizations, RA has numerous structures and practical reportage. However, many of them comprise elementary units that house the various specialists or experts within RA. The regulatory affairs group has conventionally resided within the analysis and development cluster of biopharmaceutical organizations, which is also known to be evolving. Most corporations have recognized the central role of the group RA such as its technical production, development, and selling (marketing) functions, and therefore, are positioning the group's reportage to a central and neutral executive.

The typical key functional units include:

• Regulatory Affairs development group was formed from regulatory technical specialists who lead the strategic control for development, production, registration and maintenance in the market. This is the team that develops the global regulatory strategies that ensure RA activities are appropriate for product development and registry results. They review the documents that need to be submitted to restrictive authorities and are usually the first port of call to contact the organization's regulators. Its members are known as regulatory liaison officers, strategists, and scientists (Hägglöf & Å Holmgren, 2013).

• The chemistry, manufacturing, and controls (CMC)/ compliance/ conformity team has a similar performance to the merchandise development team, which is concentrated on the manufacturing method development, registration, manufacturing facility, and site inspections. It assures sensible compliance that is of excellent "good manufacturing processes", which are up to date. It also assures good laboratory and clinical practices, audit compliance, and readiness for regulatory inspections of the clinical, laboratory, production facilities, and data technologies.

• The Policy and Regulatory Intelligence team is increasingly crucial to development, manufacturing, and registration strategy. This team monitors the global regulatory setting for evolving trends, participates in making policies, measures precedents, and standards to create on the market intelligence and anticipatory input to change strong, proactive regulatory methods.

• The Promotion and Advertising team works closely with the merchandise development groups and marketing groups to ensure competitive but compliant promotion and advertising communication materials. It represents the first liaison with the administrative body on promotional and advertising materials.

• The regulatory Submissions team is responsible for collecting, publishing, and dispatching the regulatory submissions to the global regulatory agencies. It is at the leading edge of the latest electronic technologies to ensure user/reviewer friendly, complete, and passable submissions. Its strategic focus and use of electronic technologies within the assembly of the dossier, from technical authoring teams to careful coordination of global needs for electronic submission, change expedient and near-simultaneous submissions to world restrictive agencies.

• The Product Labelling team is characteristically positioned within the product development regulatory groups that supply strategic direction for the development of the label content with other technical team members. The product labelling team is accountable for developing the label package insert and literature, instrumentality labels and packaging, and change the merchandise data. This team coordinates the label content reviews by the relevant technical groups for accuracy and ensures compliance to the administrative body format and timelines for submission of the label information.

2.3 Educational background and training available for Regulatory Affairs Professionals

Breaking into the global regulatory affairs industry is in many ways in contrast to following law or medicine, where the route to a prolific career may be more established or clear-cut (Amato, 2015). In contrast to these career fields, effective regulatory professionals return from a variety of backgrounds: whereby, there is no specific or one career or degree path that guarantees success in this field. Successful RA professionals generally have cross-functional training in areas like pharmacy, science, marketing, engineering, and business.

Over 88% of current regulatory professionals began working in a different industry before transitioning into regulatory affairs (RAPS, 2016). Most of those people worked initially in related industries, such as analysis and development, clinical analysis, manufacturing, pharmacology, science lab sciences, and engineering.

Most regulatory affairs employees might have undergraduate degrees in the disciplines of life science, public health, clinical science, or engineering. These degrees might also be in non-core science areas, like social science, business, or liberal arts. It is not apparent that having a specialized degree in RA may not solely cause one to be more marketable to employers. However, it could additionally improve career opportunities that in most cases would not be easy to access.

2.4 The roles and functions of Regulatory Affairs Professionals

The role of RA professionals is to act as liaisons with regulatory agencies. Preparation of organized compliance and ensuring adherence with all the applicable cGMP, good clinical practice (GCP) guidelines, and regulations. Providing experience and regulatory intelligence in translating

regulatory needs into sensible executable plans. Pharmaceutical companies use all the information that has been ascertained throughout the research, studies, and development stages to register the drug and to market it. Pharmaceutical companies must follow strict rules and guidelines to ensure the safety and effectiveness of the drug in humans throughout the drug development stages.

The success of the regulatory strategy is less dependent on the laws than on how they are understood, applied, and communicated within organizations and to outside constituents (Douglas & David, 2018). Pharmaceutical company RA professionals play an important role in guaranteeing that all pharmaceutical products accommodate the rules and regulations governing the industry. Those who are working in the pharmaceutical company as RA personnel do not solely work in the initial application phase for a new drug but they also, within the licensing and marketing stages, ensure that all products and operations meet needed effectiveness and safety standards. RA personnel combine information from the legal, business, and pharmaceutical industries to determine if laws are being followed and form the link between the pharmaceutical company and regulatory authorities like the Food and Drugs Agency (FDA) and the European Union (Douglas & David, 2018).

In this era of ever-changing regulations and legislation, it is the responsibility of the RA professional to keep up to date with these changes in all the regions in which the organization distributes its product. They advise on scientific and legal limitations and needs, especially on the scientific data generated by the research and development unit (World Health Organization, 2003). They are responsible for submitting registration documents to regulatory agencies and carry out all subsequent negotiations necessary to maintain the marketing authorization of the product in question. The work of a regulatory professional is diversified and dynamic. The profession affords a novel perspective of assorted aspects of the commercialization of diverse products (i.e., medicines, medical devices, cosmetics, and nutritional). The foregoing roles and responsibilities highlighted the fundamental knowledge required to participate within the processes and procedures for product regulation. The current study explored the training and roles of RA associates/officers in pharmaceutical companies in Gauteng, South Africa. The study underscores the importance of appropriate pre-employment and in-service training for RA associates/ officers in line with their expected roles in pharmaceutical companies

CHAPTER 3

METHODOLOGY

3.1 Study design

This was a cross-sectional survey, using electronic Google forms/questionnaires, to collect data from study participants. In a cross-sectional study, all factors (exposure, outcome, and confounders) are measured simultaneously from a population, or a representative subset, at a specific point in time. The main outcome measure obtained from a cross-sectional study is prevalence (Hennekens CH, 1987).

3.2 Pilot testing

A pilot test was conducted using five pharmacist assistants from a pharmaceutical company before the actual study. A pilot test aimed to determine the clarity, validity, ambiguity, relevance of the questions and to determine the amount of time required to complete the questionnaire. The questionnaire was modified based on, the result obtained from the pilot test, was to ensure that the data collected would achieve the objectives of the study.

3.3 Bias

Response bias was avoided by making sure that participation was voluntary, questionnaires were anonymous and self-administered. The pilot study was conducted with pharmacist assistants, who were not part of the study population to reduce bias.

3.4 Study setting

The study was conducted in 19 selected pharmaceutical companies in the Gauteng Province of South Africa. The province was chosen since it has more pharmaceutical companies than other provinces in South Africa (Gauteng Business, 2019/20).

3.5 Study population

The study population (n = 23) was composed of RA associates (who help medical and pharmaceutical companies navigate regulatory approval processes so that products conform to all

local, state, and federal regulations), RA assistants (are often employed by pharmaceutical or medical devices companies, and assist in obtaining government approval for drugs, medical devices, veterinary products, cosmetics, and foods), and RA officers (ensure that products such as cosmetics, pharmaceuticals, and veterinary medicines meet legislative requirements by studying scientific, legal documents and ensuring compliance with regulations), from 19 selected pharmaceutical companies in Gauteng, South Africa.

3.6 Data collection instrument

A structured electronic Google form questionnaire was used for data collection (Appendix xxx). The questionnaire was only available in English as it is one of the mediums of instruction in South Africa. The questionnaire comprised of closed-ended questions rated using the Likert scale.

3.7 Data analysis

All data were entered into a Microsoft Office Excel™ spreadsheet and cross-checked by a second person for accuracy and correctness. Thereafter, the data was exported into SPSS for further analysis. After data cleaning, descriptive statistics were employed to summarise the data, making use of frequency, mean, mode, median, standard deviation where applicable. Correlation analysis was used to measure the alignment of training and roles.

3.8 Ethical Considerations

Ethical considerations were put in place to ensure that the study would not have any negative impact on the participants. All participants were informed that participation was voluntary and that they had the right to withdraw from the study at any stage. All respondents were provided with a consent form before participation to indicate that they agree to participate in the study. Confidentiality was ensured by not linking inputs to individuals but by a study identification. Ethical approval to conduct the study was obtained from the University of the Western Cape Humanities and Social Science Research Ethics Committee (HS 20/1/10).

CHAPTER 4

RESULTS

4.1 Introduction

This study set out to examine the pre-employment training and educational background of RA associates, assistants, and officers and to evaluate/re-evaluate the association between the training obtained and the roles played by RA associates, assistants, and officers in pharmaceutical companies. Here the results of the analysis of the completed data collection instrument are provided.

4.2 Demographic data of the participants

Table 1 shows that of the 23 participants, 86.4% were females. Most of the participants were between the age of 26-35 years (78.3%), with several of them being black (78.3%). It was also observed that most companies refer to RA personnel with different job titles (39.1%). Most of the participants had worked for less than 2 companies (69.6%), wherein several of them had between 1-5 years (56.6 %) experience in RA Department. Furthermore, most RA personnel acquired their job through an internship (43.5%) and external vacancy (43.5%), and about (43.5%) of the participants have postgraduate degrees (Honours and MSc Degree).

4.3 Roles and responsibilities that participants were formally or informally trained on

In **Table 2**, it was observed that most of the RA personnel were mostly trained on the job for the responsibilities and roles that they perform (which is informal training). Furthermore, out of the 23 Participants, 21 (91.3%) of them were informally trained to prepare submissions of license variations and renewals to strict deadlines. Regarding keeping up to date with national and international legislation, guidelines, and customer practices, 78.3% of participants acquired their skills or training on the job (informally).

Table 1. Demographic characteristics of respondents

Variable	Frequency	%
Sex:		
Male	4	(17.3)
Female	19	(82.6)
Age:		
18-25	2	(8.6)
26-35	18	(78.2)
36-45	3	(13.0)
Race:		
Black	18	(78.3)
White	2	(8.7)
Indian	3	(13.0)
Type of pharmaceutical company:		
Small	9	(47.4)
Big	10	(52.6)
Job title		
Regulatory Affairs Associates	6	(26.1)
Regulatory Affairs Officers	4	(17.4)
Regulatory Affairs Assistances	4	(17.4)
Other	9	(39.1)
How many pharmaceutical companies have you worked for in this position?		
Less than 2	16	(69.6)
More than 2	7	(30.4)
Years of experience in this position?		
1-5 Years	13	(56.6)
6-10 Years	7	(30.4)
10-15 Years	2	(8.7)
more than 15 Years	1	(4.3)
How did you get into Pharmaceutical Regulatory Affairs?		
Through internship	10	(43.5)
Internal vacancy	3	(13)
External vacancy application	10	(43.5)
What is your current educational qualification?		
Matric	1	(4.3)
Higher Certificate	2	(8.7)
Diploma	3	(13.0)
Bachelor's degree	7	(30.4)
Other	10	(43.5)
What formal or informal training have you received for/related to Regulatory Affairs?		
formal	8	(36.4)
informal	9	(40.9)
both	5	(22.7)
Did your previous education prepare you for your current roles and responsibility?		
No	12	(52.2)
Yes	11	(47.8)

- Note: small Company (Also known as biotech companies, derive their products from the extraction or manipulation of living organisms) and Big Company (Also known as Pharma companies, create medicines from chemicals and

synthetic processes; Formal training (Training that is delivered in a systematic intentional way). Informal training (Training that is unstructured, often unintended, and it occurs outside of a conventional learning setting)

More than half of the participants (78.3%) were also informally trained to monitor and set timelines for license variations and renewal approvals as well as write clear, accessible product labels and patient information leaflets. The roles in which a higher proportion of the participants reported that they received formal training included the following: planning and developing product trials and interpret trial data (87%); providing strategic advice to senior management throughout the development of a new product (69.6%); undertaking and managing regulatory inspections (65%); developing and writing clear arguments and explanations for new product licensees and license renewals; liaising with, and making presentations to, regulatory authorities; negotiating with regulatory authorities for marketing authorization. Conclusively, informal training was the type of training received for most of the roles and responsibilities. The formal training did not prepare the RA for the current roles and responsibilities.

Table 2. Roles and responsibilities that participants were either formally or informally trained on.

Roles and responsibilities	Formal training	(%)	Informal training	(%)
• Keep up to date with national and international legislation, guidelines, and customer practices	5	(21.7)	18	(78.3)
• Collect, collate, and evaluate scientific data from a range of sources	9	(39.1)	14	(60.9)
• Develop and write clear arguments and explanations for new product licensees and license renewals	12	(52.2)	11	(47.8)
• Prepare submissions of license variations and renewals to strict deadlines	2	(8.7)	21	(91.3)
• Monitor and set timelines for license variations and renewal approvals	8	(21.7)	18	(78.3)
• Write clear, accessible product labels and patient information leaflets	5	(21.7)	18	(78.3)
• Plan and develop product trials and interpret trial data	20	87.0)	3	(13.0)
• Advise scientists and manufacturers on regulatory requirements	7	(30.4)	16	(69.6)
• Provide strategic advice to senior management throughout the development of a new product	16	(69.6)	7	(30.4)
• Undertake and manage regulatory inspections	15	(65.2)	8	(34.8)
• Review company practices and provide advice on changes to systems	10	(43.5)	13	(56.5)
• Liaise with, and make presentations to, regulatory authorities	12	(52.2)	11	(47.8)
• Negotiate with regulatory authorities for marketing authorization	12	(52.2)	11	(47.8)
• Take part in the development of marketing concepts and approve packaging and advertising before a product's release.	9	(39.1)	14	(60.9)

4.4 Roles and responsibilities participants are currently performing

The result of the study (Table 3) shows that over 60% of the participants still perform six out of the 14 stated roles. Many of the participants (91.3% and 87% respectively) are keeping up to date with national and international legislation, guidelines, and customer practices as well as preparing

submissions of license variations and renewals to strict deadlines on the job. Overall, the results showed that the RA is still performing most of the stated roles and responsibilities.

Table 3. Roles and responsibilities participants are currently performing.

Roles and responsibilities	No	(%)	Yes	(%)
• Keep up to date with national and international legislation, guidelines, and customer practices	2	(8.7)	21	(91.3)
• Collect, collate, and evaluate scientific data from a range of sources	5	(21.7)	18	(78.3)
• Develop and write clear arguments and explanations for new product licensees and license renewals	9	(39.1)	14	(60.9)
• Prepare submissions of license variations and renewals to strict deadlines	3	(13.0)	20	(87.0)
• Monitor and set timelines for license variations and renewal approvals	6	(26.1)	17	(73.9)
• Write clear, accessible product labels and patient information leaflets	10	(43.5)	13	(56.5)
• Plan and develop product trials and interpret trial data	20	(87.0)	3	(13.0)
• Advise scientists and manufacturers on regulatory requirements	7	(30.4)	16	(69.6)
• Provide strategic advice to senior management throughout the development of a new product	14	(60.9)	9	(39.1)
• Undertake and manage regulatory inspections	18	(78.3)	5	(21.7)
• Review company practices and provide advice on changes to systems	11	(47.8)	12	(52.2)
• Liaise with, and make presentations to, regulatory authorities	10	(43.5)	13	(56.5)
• Negotiate with regulatory authorities for marketing authorization	10	(43.5)	13	(56.5)
• Take part in the development of marketing concepts and approve packaging and advertising before a product's release.	12	(52.2)	11	(47.8)

Correlation of roles and responsibilities of participants with the training

To visualize the types of training associated with the roles and responsibilities outlined, we combined Table 2 and Table 3 into a graph (Figure 1). The bar chart shows over 60% of the participants reported informal training related to seven roles and responsibilities of RA. A higher proportion of the participants reported acquisition of formal training for the following roles and responsibilities: Plan and develop product trials and interpret trial data; Provide strategic advice to senior management throughout the development of a new product; Undertake and manage regulatory inspections. A plot of the percentage of participants that are currently performing the outlined roles and responsibilities and the type of education received (formal or informal) is shown in Figure 2.

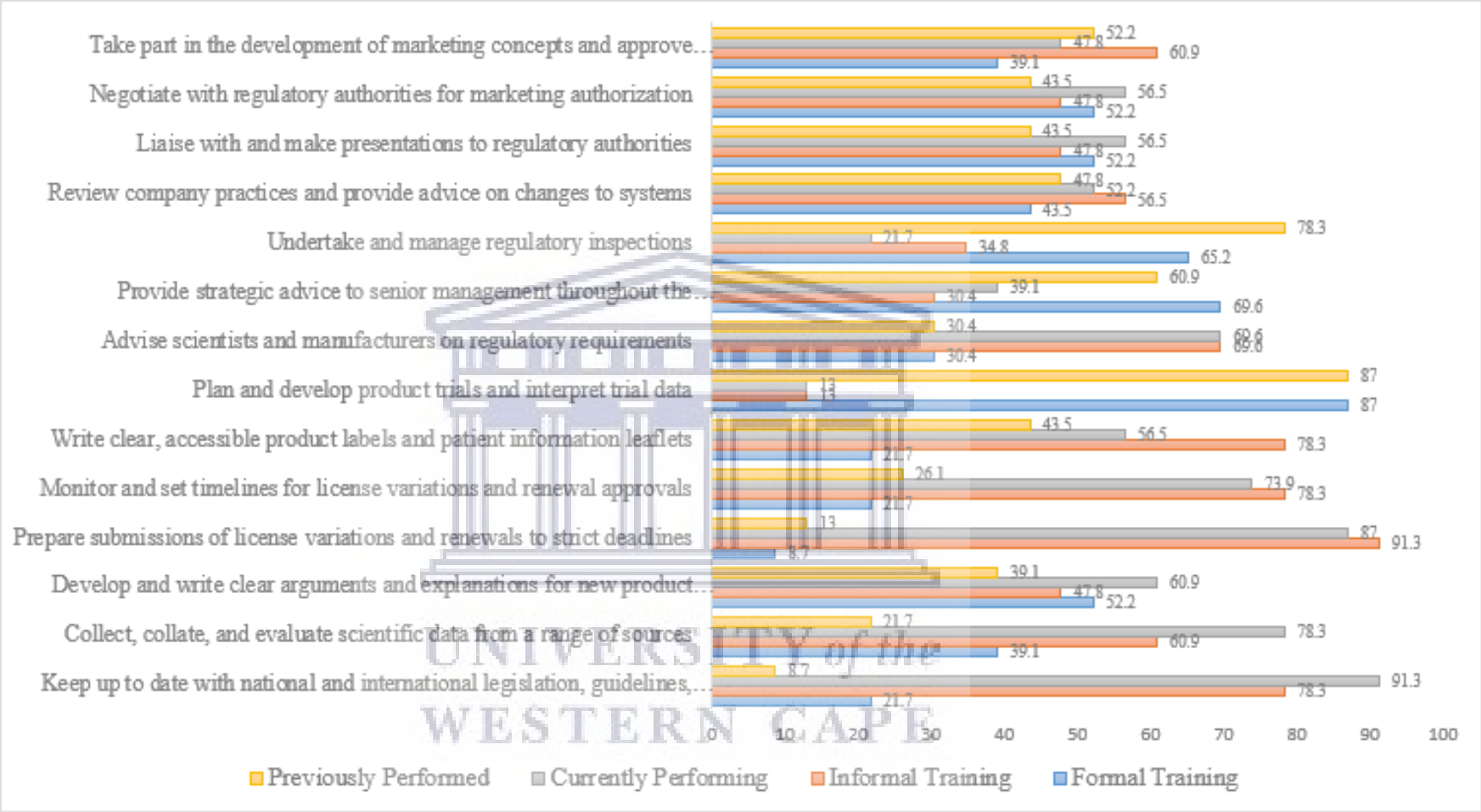


Figure 1. A bar chart showing the types of training associated with the roles and responsibilities of Regulatory Associates (RA).

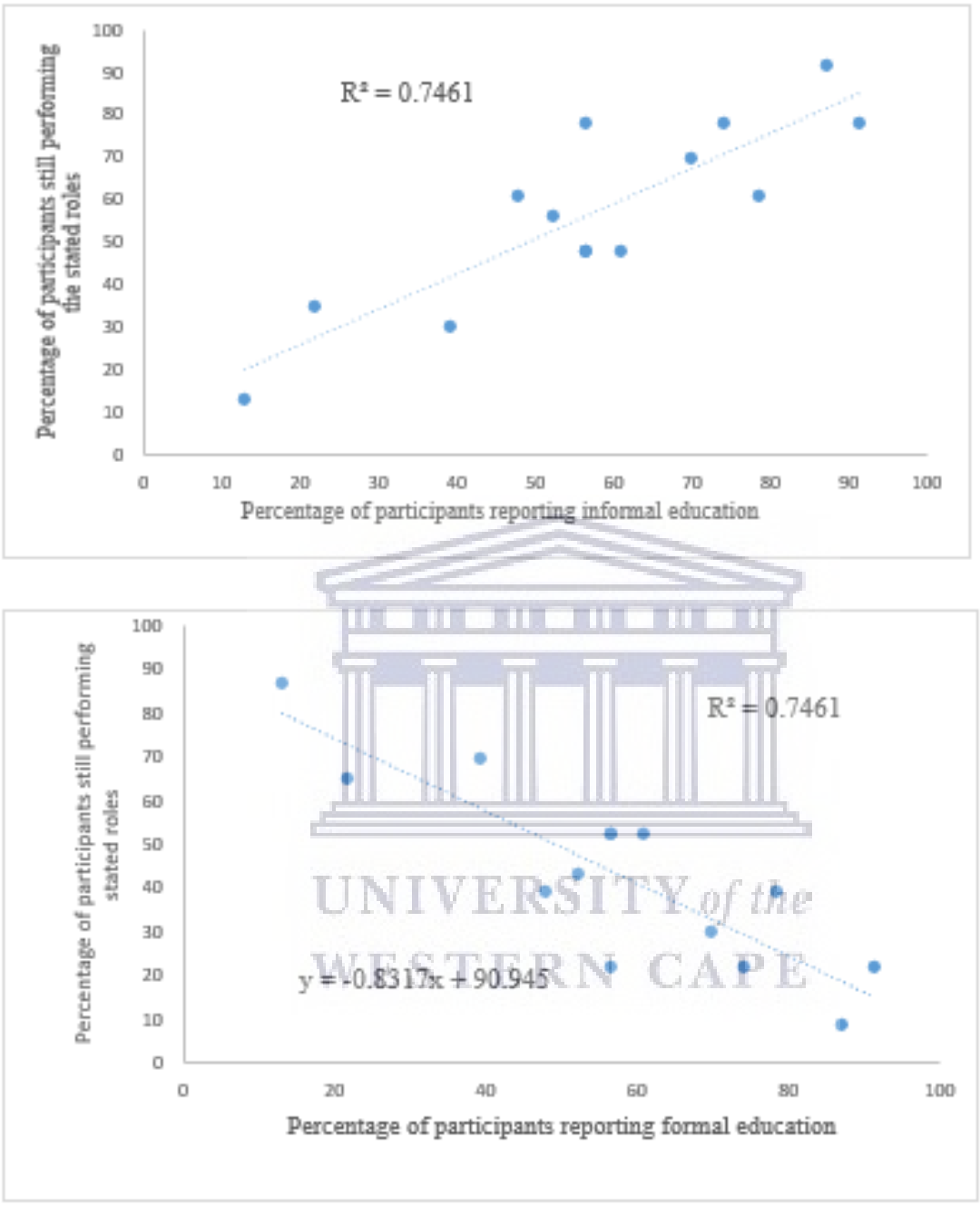


Figure 2. A bar chart showing A plot of the percentage of participants that are currently performing the outlined roles and responsibilities and the type of education received (informal [top graph] and formal [bottom graph]).

The results showed a positive correlation (regression coefficient, R2 = 0.746) between the percentage of participants that are currently performing the outlined roles and responsibilities and the type of training (in this case, informal) received for the roles. Conversely, formal training showed a negative correlation to currently performed roles and responsibilities. Overall, the results suggest that there was a negative correlation between formal training and current roles and responsibilities, which further shows that the formal training might not prepare the RA for their intended responsibilities.

CHAPTER 5

DISCUSSION

5.1 Introduction

The purpose of the study was to explore the training and roles of RA associates/officers in pharmaceutical companies. The study sought to provide information on the importance of appropriate training of the RA associates/ officers about their expected roles in the pharmaceutical companies. This study set out to achieve the following objectives:

• To examine the pre-employment training and educational background of RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.

• To explore the roles and responsibilities of RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.

• To evaluate the association between the training obtained and the roles played by RA associates/ officers in selected pharmaceutical companies in Gauteng, South Africa.

5.2 Pre-employment training and educational background of RA associates/ officers

The findings from the study showed that most RA personnel have experience of between 1-5 years (56.6 %) and that most RA personnel acquired their job through an internship (43.5%) and external vacancy (43.5%). Furthermore, it was also observed that most RA personnel have more than one qualification (Honours Degree and MSc Degree) (43.5%). From the findings of the study, it can be deduced that there is no specific training nor the specific level of qualification or entry level for one to become a Pharmaceutical RA professional. This is because, unlike other career fields such as Law (LLB) or Medicine (MBCHB), RA professionals come from several backgrounds. There is no one degree or career trajectory that promises success in this field. Successful professionals typically have cross-functional training in areas such as science, pharmacy, engineering, marketing, and business.

RA is a relatively new field in our country (South Africa) that has seen very rapid growth in the last few years (Ajay, S. and Bhatt, A, 2010). Availability of personnel appropriately trained to the specific requirements of the role they will perform in the RA department is critical for capacity

expansion. Our study attempts to understand the specific areas of knowledge and skills that are important for the role of a RA officers/associates. The survey was conducted amongst RA personnel from industry pharmacy who had less than a year to more than ten years of RA experience.

5.3 The roles and responsibilities of RA associates/ officers

The key role of RA professionals is broader than the registration of merchandise. Their role begins right from the development of a product to formulation, marketing, and post-marketing strategies. Moreover, they also need to keep up to date with national and international legislation, guidelines, and customer practices.

This, furthermore, broadens their scope by also being part of collecting, collating, and evaluating scientific data from a range of sources, which includes developing and writing clear arguments and explanations for new product licenses and license renewals. Wherein, they prepare submissions of license variations and renewals to strict deadlines and monitor timelines for license variations and renewal approvals.

The responsibilities of RA associates/officers, further include writing clear, accessible product labels and patient information leaflets, and being involved in planning and developing product trials, and interpreting trial data. In which they also advise scientists and manufacturers on regulatory requirements and provide strategic advice to senior management throughout the development of a new product.

Roles vary from company to company and industry to industry, but with the right skills and experience, most regulatory professionals have the chance to climb up the hierarchical ladder to the director level. Large companies may have multiple departments that focus on different aspects of regulatory affairs, whereas smaller companies might have just had a small team with broad responsibilities. Regulatory affairs offer a wide range of diverse positions and career pathways. Furthermore, one can work on anything from labelling to process management.

5.4 Association between the training obtained and the roles played by RA associates/officers.

The results suggest that there was a negative correlation between formal training and current roles and responsibilities, which further shows that the formal training might not prepare the RA for their intended responsibilities.

Training and skills development comprises a broad range of activities and arrangements, including, formal and informal training, job-rotation, traditional classroom courses, internal vs external training, cooperation with e.g. competence mapping, training plans or development plans, introductory training for new personnel, mentoring, and the use of new organisation or technologies in training, such as E-learning. One other important issue is the question of the cost/benefits of training and how to measure and evaluate the outcome of training activities.

The importance of training is stressed by a growing gap between existing competencies and skills and those competencies and skills that are required to meet future challenges and ensure a successful modernisation of official statistics. A framework of skills/capabilities begins with a gap analysis and a description of how to close the gap. Lack of resources is a major barrier.

To stay updated competencies of employees, need to be assessed and trained regularly. This is sometimes referred to as competence management, other times as development plans. The key issue is that the management regularly assesses the skills and knowledge of the employees in a systematic way and follow-up on this.

5.5 Possible effect of lack of training in a working environment

Regularly when formal preparation is examined, the numerous advantages of training receive some conversational attention. While the abundance of advantages makes training worth putting resources into, comprehend the results of not carrying out the training into the organization's plan. Failure to carry out training in the organization implies dismissing all areas of the organization. Training is elementary in running an effective organization. By not training the personnel could influence their usefulness, wellbeing, and the general prosperity of the organization (Courtney Osborn, 2018).

Incapacitated Performance and Lower Retention Rates

Incapacitated performance is one of the adverse results of failure to train staff. Personnel who have not been prepared may run into major issues with proficiently delivering excellent work. The absence of adequate information and preparation could prompt a lower level of execution. Personnel who are all around prepared with the abilities important to play out their work and fulfill record-breaking constraints, may put out top-notch work and emphatically affect the association. In addition, the absence of training can prompt more disappointment, sat around, and miserable workers. Having personnel who feel like they are not creating and are getting disappointed with their work, regularly prompts those workers to leave an organization and influencing rates worker degrees of consistency.

Lack of Knowledge of Industry Trends and Policies

In our quickly evolving society, remaining at the bleeding edge of the business as far as information is significant. An organization that is an innovator in its industry can drop in its rankings just because of a lack of training. By failing to train the staff on patterns and approaches inside the business, the whole organization could pass up key progressions and advancements inside the business. Moreover, not preparing the workers on new approaches, orders, prerequisites, and practices as they emerge, and can even run into legitimate issues with the association, which, thus, can be very exorbitant (Joshua Sophy, 2017).

5.6 The importance/Benefits of Training and development in the workplace

Training and development improve the sufficiency of an organisation's staff inside a team through enlightening activities. This enhances the knowledge and abilities of personnel through information and instructive activities on the most capable strategy to improve their current tasks, (Terrique Alie, 2020).

Helps personnel with keeping awake with the most recent with the latest business designs:

For present-day organisations to thrive, they need to ceaselessly make and find approaches to remain mindful of the predictable changes. Subsequently, getting ready is key for delegates and heads, especially when you are endeavoring to remain mindful of industry changes and rules.

Having the information and keeping alert to date with the business patterns will help the relationship with staying before the competitors.

Grows work satisfaction and certainty:

Training and improvement give various benefits to the organization. Right when the staff see that their supervisor is helping them with improving their knowledge and authority, they feel convinced subsequently growing their work satisfaction, productivity, and resolve.

Improving and keeping up personnel's abilities and information:

There is reliably a consistent space for self-awareness and improvement. Informative classes fill in as a lift for personnel to augment their capacities just as offer associations to help a huge level of ability.

Gives an upper hand:

In the public eye today, adventures, patterns, advancement, and business conditions are persistently creating. For organizations to stay before their resistance, they need to recognize the meaning of planning and progression. With an incredible training and improvement program set up, personnel will change viably to the business changes as needs be giving organization an advantage.

CHAPTER 6

CONCLUSIONS, RECOMMENDATIONS, AND LIMITATIONS

6.1 Conclusions and Recommendations

Many regulatory affairs personnel were trained informally (learning on the job) to perform their roles. Even though various pharmaceutical companies have different titles for these personnel, the survey shows that most of them perform almost the same responsibilities. Key recommendations based on the study include that there should be a common understanding of the training, responsibilities, experience, and qualifications for anyone who wishes to enter or be part of Regulatory Affairs in the pharmaceutical industry. Curriculum change in Pharmacy School to include the modules that will prepare pharmacists for these roles. Post-employment training and on-the-job training to advance the skills of RA associates.

6.2 Limitations of the study

The study sample size was small due to the unavailability of some of the RA associates, officers, and scientists. This was due to COVID-19 retrenchment and lockdown regulations which led to the shutting down of some of the pharmaceutical companies. Also, some of the few targeted participants working from home, in which some inferential statistics could not be performed since there were not enough participants.

REFERENCES

Ajay, S. and Bhatt, A, (2010) 'Training needs of clinical research associates', Perspectives in Clinical Research, 1(4), pp. 134–138. doi: 10.4103/2229-3485.71771.

Amato F. Stephen, (2015 & 2016) Regulatory Affairs for Biomaterials and Medical Devices. A volume in Woodhead Publishing Series in Biomaterials. Book. Scope of Practice & Compensation Report for the Regulatory Profession

Douglas J Pisano and David S. Mantus, (2008) 'Textbook of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics'.2nd edition.

G.Sai Hanuja, B.Sai Kumari, M.V.Nagabhushanam, D.Nagarjuna Reddy, Brahmaiah Bonthagarala, (2016) Regulatory Requirements for Registration of Generic Drugs in "BRICS" Countries, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6, November-December, 20-40.

Guide to good storage practices for pharmaceuticals., (2003) WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh Report. Geneva, World Health Organization.

Hennekens CH, Buring JE. (1987) Epidemiology in Medicine, Lippincott Williams & Wilkins.

https://www.raps.org/news-articles/news-articles/2017/3/why-regulatory-professionals-need-business-training

https://www.valamis.com/hub/continuous-learning/2020

https://smallbusiness.chron.com/effects-lack-employee-training-42687.html

https://smallbiztrends.com/2017/09/workplace-safety-training-statistics.html

I Hägglöf, Å Holmgren, in Drug Discovery and Development (Second Edition), 2013

International regulatory affairs updates, (2005). available at http, //www.iraup.com/about.php OECD/ILO (2017), Better Use of Skills in the Workplace: Why It Matters for Productivity and Local Jobs, OECD Publishing, Paris.

S.M.Shakeel, Shaik Salman Basha, M.V.Nagabhushanam, D.Nagarjuna Reddy, Brahmaiah Bonthagarala, (2015). Comparision of Regulatory Requirements for Generic Drugs Dossier Submission in the United States and Canada, International Journal of Pharmaceutical Science and Health Care, ISSN 2249 – 5738, Issue 6, Vol. 6, November-December 2016, 1-19
Sachin C Iskar, Dr. Ns Vyawahare, "Drug Regulatory Affairs", 3rd edition

Sharmila Reddy V, Monica N.V.N., Anusha S, Evangeline L, Nagabhushanam M.V., Nagarjunareddy D, Brahmaiah B, (2017) Regulatory Requirements of Similar Biologics for

Marketing Authorization in India, ISSN: 2321 – 6794, DOI: https://doi.org/10.22270/ijdra.v5i1.193, International Journal of Drug Regulatory Affairs; 5(1), 20-24.

Terrique Alie, (2020) The Benefits Of Incorporating Training and Skills Development In The Workplace

Y. Sri Harsha, (2017) Role of Regulatory Affairs in a Pharmaceutical Industry, IJPRBS,; Volume 6(2): 170-177.

APPENDICES

APPENDIX A: Letter of permission

UNIVERSITY of the WESTERN CAPE

School of PHARMACY
FACULTY OF NATURAL SCIENCES
Private Bag X17 Bellville 7535
Telephone +27 21 9593388
Fax +27 21 9593407

UNIVERSITY OF THE WESTERN CAPE

HUMANITIES AND SOCIAL SCIENCE RESEARCH

LETTER OF PERMISSON TO CONDUCT A STUDY AT YOUR INSTITUTION

Dear Sir/Madam

My name is **Collins Mukoma** and I am currently studying towards a Masters in Regulatory Science at The University of Western Cape (UWC). As part of the qualification I am required to conduct a research. The topic of the research is **"Exploration of the Training/educational background and The Roles of Regulatory Affairs Associates/ Officers in selected South African based Pharmaceutical Companies in Gauteng Province"**.

The purpose of the study is to explore the training and role of Regulatory Affairs associates/officers in pharmaceutical companies in Gauteng, South Africa. The study could help recommend ways of improving and unifying the training of Regulatory Affairs (RA) Associates/ Officers in line with expected roles in the pharmaceutical company.
I therefore kindlily ask for permission to conduct the above-mentioned study at your institution. The request of conduct of this study will be accompanied with the ethical approval granted by The University of Western Cape (UWC), Humanities and Social Science Research Ethics Committee (HSSREC)
I trust that you will find the above-mentioned request in order. Please do not hesitate to contact myself and my supervisor on the following contacts details:

Contacts Details:

Researcher: Mr Collins Mukoma
mpfunzo@yahoo.com or mpfunzo14@gmail.com
083 623 0044
Pharmacist (B.Pharm)
Sunninghill
2157
Gauteng

Supervisor: Dr Samuel A. Egieyeh
segieyeh@uwc.ac.za
0219593388 or 0843477250
B. Pharm, M.Pharm, PGDiploma (Drug Development), PhD (Bioinformatics)
School of Pharmacy,
University of the Western Cape
Bellville
7535
Cape Town

APPENDIX B: Informed consent & questionnaire

UNIVERSITY of the
WESTERN CAPE

School of PHARMACY

FACULTY OF NATURAL SCIENCES
Private Bag X17 Bellville 7535
Telephone +27 21 9593388
Fax +27 21 9593407

UNIVERSITY OF THE WESTERN CAPE

HUMANITIES AND SOCIAL SCIENCE RESEARCH

INFORMED CONSENT

Dear Participant

My name is **Collins Mukoma** and I am currently studying towards a Masters in Regulatory Science at The University of Western Cape (UWC). As part of the qualification I am required to conduct a research. The topic of the research is **"Exploration of the Training/educational background and The Roles of Regulatory Affairs Associates/ Officers in selected South African based Pharmaceutical Companies in Gauteng Province"**.

The purpose of the study is to explore the training and role of Regulatory Affairs associates/officers in pharmaceutical companies in Gauteng, South Africa. The study could help recommend ways of improving and unifying the training of Regulatory Affairs (RA) Associates/ Officers in line with expected roles in the pharmaceutical company.
As a valued Regulatory Affairs personnel, you have been selected to participate in this research. Please note that participation is voluntary. Information will also be treated as confidential and therefore should you wish to withdraw at any stage of the study, you are allowed to do so without any hesitation. Permission to conduct a survey has already been sought with the relevant authorities at your institution and in accordance to its policies and processes.

Should you wish to participate in this voluntary study, please consent on the below declaration:

I.....(full names of participant) hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating in the research project.

I understand that I am at liberty to withdraw from the project at any time, should I so desire.

I consent / do not consent to this interview being recorded (if applicable).

SIGNATURE OF PARTICIPANT DATE

.....

A place of quality,
a place to grow, from hope
to action through knowledge

Study Questionnaires

Please answer all the questionnaires.

1. Participants demographics a. Age

- ◯ 18-25
- ◯ 26-35
- ◯ 36-45
- ◯ 46-55
- ◯ Above 55

b. Race

- ◯ Black
- ◯ White
- ◯ Indian
- ◯ Coloured
- ◯ Other

c. Gender

- ◯ Female
- ◯ Male

2. Which pharmaceutical company do you work for?

Your answer

3. What is your Job title?

- ◯ Regulatory Affairs Associates
- ◯ Regulatory Affairs Officers
- ◯ Regulatory Affairs Assistants
- ◯ Other:

4. How many pharmaceutical companies have you worked for in this position?

- ◯ Less than 2
- ◯ More than 2

5. Years of experience in this position?

- ◯ Less than a year
- ◯ 1 – 5 years
- ◯ 6 – 10 years
- ◯ 10 – 15 years
- ◯ More than 15 years

6. How did you get into Pharmaceutical Regulatory Affairs?

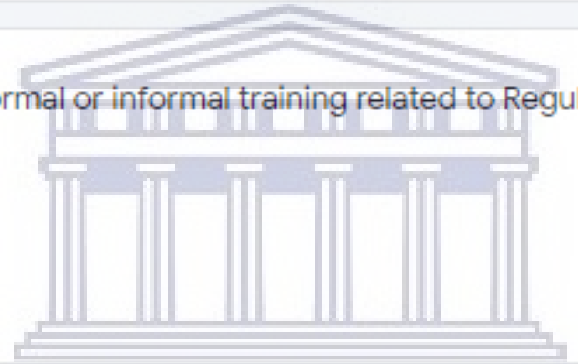
- ◯ Through learnership/internship
- ◯ Internal Vacancy application
- ◯ External Vacancy application
- ◯ Other: _____

7. What is your current educational qualification?

- ◯ Matric
- ◯ Higher Certificate
- ◯ Diploma
- ◯ Bachelor Degree
- ◯ Other: _____

8. Did you receive formal or informal training related to Regulatory Affairs? *

- ◯ Yes
- ◯ No



9. Did your previous education prepare you for your current roles and responsibility?

- ◯ Yes
- ◯ No

10. Which of the following roles and responsibilities were covered in any formal or informal training that you had?

- [ ] Keep up to date with national and international legislation, guidelines and customer practices
- [ ] Collect, collate and evaluate scientific data from a range of sources
- [ ] Develop and write clear arguments and explanations for new product licences and licence renewals
- [ ] Prepare submissions of licence variations and renewals to strict deadlines
- [ ] Monitor and set timelines for licence variations and renewal approvals
- [ ] Write clear, accessible product labels and patient information leaflets
- [ ] Plan and develop product trials and interpret trial data
- [ ] Advise scientists and manufacturers on regulatory requirements
- [ ] Provide strategic advice to senior management throughout the development of a new product
- [ ] Undertake and manage regulatory inspections
- [ ] Review company practices and provide advice on changes to systems
- [ ] Liaise with, and make presentations to, regulatory authorities
- [ ] Negotiate with regulatory authorities for marketing authorisation
- [ ] Take part in the development of marketing concepts and approve packaging and advertising before a product's release.

11. Which of the following roles and responsibilities do you perform now in your current position?

- [ ] Keep up to date with national and international legislation, guidelines and customer practices
- [ ] Collect, collate and evaluate scientific data from a range of sources
- [ ] Develop and write clear arguments and explanations for new product licences and licence renewals
- [ ] Prepare submissions of licence variations and renewals to strict deadlines
- [ ] Monitor and set timelines for licence variations and renewal approvals
- [ ] Write clear, accessible product labels and patient information leaflets
- [ ] Plan and develop product trials and interpret trial data
- [ ] Advise scientists and manufacturers on regulatory requirements
- [ ] Provide strategic advice to senior management throughout the development of a new product
- [ ] Undertake and manage regulatory inspections
- [ ] Review company practices and provide advice on changes to systems
- [ ] Liaise with, and make presentations to, regulatory authorities
- [ ] Negotiate with regulatory authorities for marketing authorisation
- [ ] Take part in the development of marketing concepts and approve packaging and advertising before a product's release.

APPENDIX C: permission to conduct the study

UNIVERSITY of the WESTERN CAPE

School of PHARMACY

FACULTY OF NATURAL SCIENCES
Private Bag X17 Bellville 7535
Telephone +27 21 9593388
Fax +27 21 9593407

UNIVERSITY OF THE WESTERN CAPE

HUMANITIES AND SOCIAL SCIENCE RESEARCH

Dear Sir/Madam

RE: Permission to conduct a study at your Pharmaceutical Company Site.

I am a part-time post-graduate student at the University of the Western Cape. As part of the requirements for my masters' degree qualification, I have to conduct a research project. The title of my study **is "Exploration of the Training/educational background and The Roles of Regulatory Affairs Associates/ Officers in selected South African based Pharmaceutical Companies in Gauteng Province".**

I therefore kindly request your permission to conduct the study on the above-mentioned research title.

The study will commence once ethical approval has been granted by the University of the Western Cape **Humanities and Social Sciences Research Ethics Committee (HSSREC):** Attached please find a copy of the protocol for your information.

I trust that you will find the above in order. Please feel free to contact me or my supervisors, should you require any additional information.

Sincerely,

Mr Collins Mukoma (Student)

Signature:

Date: 18-03-2020

Email: mpfunzo@yahoo.com

Dr Samuel A. Egieyeh (Supervisor)

Signature

Date: 18-03-2020

Email: segieyeh@uwc.ac.za

Humanities and Social Sciences Research Ethics Committee (HSSREC):
University of the Western Cape, Research Office
Robert Sobukwe Rd
New Arts Building
C-Block, Top Floor, Room 28
Bellville Western Cape
SOUTH AFRICA
Tel: (+27) 21 959 4111
Email: research-ethics@uwc.ac.za