AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

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DECLARATION

I, the undersigned, Leila Dockrat, declare that this research is my own work. It is being submitted in partial fulfilment of the requirements for the degree in Master of Science in Pharmacy Administration and Policy Regulation, to the University of the Western Cape, in partnership with Hibernia College, Ireland. It has not been submitted before for any degree or examination in or any other university, and that all sources I have used or quoted have been indicated and acknowledged by references.

Signed at Johannesburg on this the 3rd day of September, 2017

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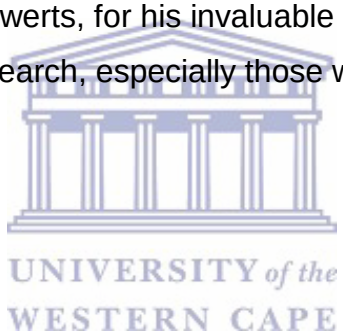

ABSTRACT

The pharmaceutical manufacturing sector operates within a highly regulated environment, with companies accountable to South African statutory bodies. The responsible pharmacist (RP) is responsible for their company's adherence to the legislation requirements. Whilst the Pharmacy and the Medicines Acts outline the RP's, there is no mandatory training requirement prior to registration as an RP, nor thereafter. This study investigated the role and competencies required of newly registered RPs in meeting their professional responsibilities in the pharmaceutical manufacturing sector.

An online survey questionnaire elicited responses from RPs (n=102) about views and perceptions pertaining to their role and responsibilities. In addition, semi-structured interviews were conducted with statutory (n=3) and non-statutory representatives (n=5). Survey findings indicated that the majority (89,5%) of RPs felt competent and that they possessed the necessary skills and training. Almost two-thirds of respondents (63,2%) were experienced RPs who shared some reservations, that RPs may be excluded from far-reaching decisions with potential consequences for the company and patients. They added that RP performance monitoring was not regular, which may indicate that some companies view the RP as an appointment of convenience. The majority of respondents (89,5 %) were in favour of the development of training guidelines.

Findings from the semi-structured interviews indicated that RPs were not fully aware of their scope of duties and the implications thereof. The interviewees were also concerned that some companies, by not giving the RP role the level of importance and authority it required, were practicing tokenism. Further, that not all RPs had the necessary in-depth knowledge of the applicable laws, regulations, guidelines and codes.

A competency framework for newly appointed RPs is needed to streamline their roles and responsibilities in the pharmaceutical manufacturing sector.

Keywords

Responsible Pharmacist, pharmaceutical manufacturing sector, competency framework

LIST OF ABBREVIATIONS

API	Active Pharmaceutical Ingredient
CoA	Certificate of Analysis
DoH	Department of Health
GDP	Good Distribution Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
GVP	Good pharmaco-Vigilance Practices
GWP	Good Warehouse Practices
GxP	Broad term for the quality standards of Good Practices in pharmaceutical industry including GDP, GLP, GMP, GPP, GVP, GWP
MCA	Marketing Code Authority
MCC	Medicines Control Council
MRA	Medicines Regulatory Authority
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
QPV	Qualified Person for Pharmacovigilance
RP	Responsible Pharmacist
PHC	Primary Health Care/Primary Healthcare
PSSA	Pharmaceutical Society of South Africa
PV	Pharmacovigilance
SAHPRA	South African Health Products Regulatory Authority
SAPC	South African Pharmacy Council

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CHAPTER 1

INTRODUCTION

In this chapter, the background for the investigation is introduced, providing the broader context, the importance of the pharmaceutical market to the African continent. Thereafter, the specific context is introduced, the South African pharmaceutical manufacturing industry and the importance of the role of the Responsible Pharmacist in this industry. The rationale for this study is then discussed. The research question is expressed, and the research problem described, followed by the objectives of this study and the structure of this report.

1.1 THE AFRICAN PHARMACY INDUSTRY CONTEXT

The African pharmaceutical market is the fastest growing in the world, said African Development Bank Chief Economist (Sanchez, 2013). Based on projections over the next five years, it is estimated to grow between 6 and 11 % (Sanchez, 2013; Rosenkrantz, 2015; Adão, 2015).

The South African pharmaceutical market is a high-potential growth driver within the healthcare sector and is anticipated to grow an average of 6 % a year (Oxford Business Group, 2015; Adão, 2015). The pharmaceutical manufacturing sector is an important growth driver for the South African economy, and considerable opportunities exist as the government moves to partner with this sector amongst others, as the Department of Health prepares for the roll out of universal health coverage through the National Health Insurance (NHI) scheme. However, beyond its economic importance, the pharmaceutical manufacturing sector is crucial to achieving long term healthcare targets for South Africa, which is also aligned to the global health goals, namely goal 3 of the United Nations

Sustainable Development Goals, (WHO, 2016), and the Responsible Pharmacists (RPs) in the pharmaceutical manufacturing sector, are crucial for the successful production of quality medicines for the country.

The pharmaceutical manufacturing sector operates within a highly regulated environment, with pharmaceutical companies accountable to statutory councils such as the South African Pharmacy Council (SAPC) and the Medicines Control Council (MCC). At the center of the expectations for such professional accountability is the Responsible Pharmacist (RP), a role of considerable responsibility and accountability.

RPs from all pharmacy sectors are required to register with and are accountable to, the SAPC for compliance to the Pharmacy Act 53 of 1974 (the Pharmacy Act). For the RP in the pharmaceutical manufacturing sector, there is an additional Act with which to comply, namely, the Medicines and Related Substances Act 101 of 1965, as amended (the Medicines Act). The RP is accountable to the Medicines Control Council (MCC) for compliance to the Medicines Act; the RP is responsible for ensuring that the company he/she represents, acts according to the requirements of the manufacturing license issued by the MCC and the guidelines on Good Manufacturing Practices.

All companies wishing to operate as manufacturers, importers or exporters, distributors or wholesalers of medicines are required to be licensed in terms of the provisions of the Medicines Act.

The RP in the pharmaceutical manufacturing sector is the person responsible for the manufacturer's compliance with the license conditions and thus, when compared to RPs in the other pharmaceutical sectors (such as retail, community, hospital and Institutions), has additional responsibilities, which are linked to the conditions of the manufacturing license.

The SAPC (GPP guideline, section 2.1) and the MCC (SA GMP guide Annex 16, current version, 5) stipulate that the RP shall have appropriate qualifications and experience in the services and must be appropriately qualified because it is a legislative requirement, and it gives effect to the purpose of the legislation, which is, to ensure that the

manufacturing industry produces pharmaceutical products that meet all requirements in terms of their quality, safety and efficacy.

Whilst it is the MCC that issues the manufacturing license, it is the SAPC's responsibility among others, to ensure registration of the professionals, the pharmacists, and the pharmaceutical operating sites. The SAPC registers the pharmacist and the company/entity as a pharmacy, as well as the pharmacist as the RP for that company/entity.

The requirement for registration as an RP is the same for all sectors of pharmacy, that is, that the applicant pharmacist completed the year of internship and the year of community service. Although the pharmacy registered in the pharmaceutical manufacturing sector has additional requirements, namely, the conditions of the manufacturing license, the SAPC does not have additional requirements for registration of the RP for that sector. The same requirements apply to the RP in the pharmaceutical sector as, for example, to the RP in the retail sector. It is left to the pharmaceutical company to select the best candidate for the RP role.

Where a company proposes a candidate who meets only the minimum requirements, that is, the candidate has complied by completing their internship and community service, the SAPC would not deny registration of that pharmacist as RP for that company. It would be possible for pharmacists who lack experience in the pharmaceutical manufacturing sector, to be registered as RP in that sector.

The key question is: Does such a pharmacist – that is, an RP in the manufacturing sector – with two years of experience following their B Pharm degree, meet the criteria: "appropriate qualifications and experience in the services rendered by such pharmacy"?

Anecdotal evidence from informal discussions with RPs in the industry suggests that there are RPs in the manufacturing sector who may have insufficient experience in this particular sector, to fulfil their responsibilities in terms of the manufacturing license and their ability to fulfill their role as RPs.

Whilst the Pharmacy and the Medicines Acts outline the duties of the RP, there is no mandatory training requirement prior to registration as an RP, nor thereafter. Continuous

professional development (CPD) is the professional responsibility of all pharmacists including the RP, however, there are no RP-specific CPD requirements or an RP-competency framework outlining training requirements to strengthen competencies required for the RP in the pharmaceutical manufacturing sector.

The Oxford dictionary defines competence, as the ability to do something well, or, having a high level of professional or technical skill to perform a particular job or task ('Competence', 2017). Competency is a widely used term and may have various meanings. Broadly stated, it is a combination of practical and theoretical knowledge, cognitive skills and attributes, and includes more personal aspects of superior performers, such as the traits and values of the person, all of which contribute to enhanced performance. The knowledge, skills and attributes are specific to the context in which the term is used, therefore, for the pharmaceutical manufacturing sector, competency of the RP would refer to the knowledge base, skills and attributes necessary to perform the RP role successfully.

Currently, there is no formalized competency framework specific to the RP role in the pharmaceutical manufacturing industry. A local case study identified the roles and competencies of South African public health-sector pharmacists practicing as sub-structure and sub-district pharmacists (Bradley, 2013). However, a competency framework for pharmacists in the manufacturing sector is yet to be documented for South Africa. Such a framework would offer a structured approach to listing the necessary components of competencies for the pharmaceutical manufacturing sector, as elicited from experienced pharmacists in that sector.

1.2 PURPOSE OF THIS STUDY

The main purpose of this study was to identify a potential competency framework for RPs in the South African pharmaceutical manufacturing sector.

This study aimed to investigate how RPs feel about their level of experience and authority in relation to the responsibilities of being the RP. In addition, it explored RPs views, perceptions and attitudes about the training requirements for RPs in the South African

pharmaceutical manufacturing sector. In this regard, inquiry was made into their current training in the manufacturing sector and how this impacted on their role as the RP. The proposed hypothesis tested was:

> Does the current SAPC minimum registration requirement (i.e. B Pharm, and experience from internship and community service), adequately support the RPs for their role and responsibilities in the pharmaceutical manufacturing sector?

1.3 RESEARCH OBJECTIVES

The objectives of the study are to:

- Explore RPs views, perceptions and attitudes about their role in the pharmaceutical manufacturing sector
- Determine whether RPs considered themselves adequately equipped for their role and responsibilities at the time of registration, and
- Examine whether RPs acquired the necessary training to fulfil their self-identified CPD requirements.

1.4 IMPORTANCE OF THE STUDY

The pharmaceutical manufacturing sector is complex as there are numerous aspects to it, each requiring in-depth knowledge and skill, which takes several years to master. There are usually several different departments within the company which perform some aspect of pharmaceutical activity which could have an impact on the medicine in terms of quality, safety and efficacy; these include production, quality control, quality assurance, regulatory affairs, pharmacovigilance, procurement, logistics, warehousing and distribution, marketing and sales.

Bearing in mind the imperative for the release of only safe and compliant medicines, effective control systems within the manufacturing process are extremely important. Companies with adequate controls for the various GMP operations would require the RP to maintain and improve on the systems. Companies where controls are inadequate

would require that the RP identify the inadequacies, and implement strategies to correct and improve them.

The appointment of RPs who are not appropriately qualified may increase the risk of non-compliance by the license holder, with the requirements of the Medicines and Pharmacy Acts and the conditions of the manufacturing license. Non-compliance in turn, could have numerous consequences. For example, it could result in the production of sub-standard product. If such a product is not identified as sub-standard before its release, this would result in sub-standard product being released to the market. Such a product may be recalled if identified timeously, which may produce negative consequences for the company, or it may be used, which may produce negative consequences for the patient and the company. The experienced RP who has the required level of authority within the company, would be in a better position to ensure that the company complies with all requirements and in this way, that only compliant products are released to market.

CHAPTER 2

LITERATURE REVIEW

This chapter presents the investigation of literature regarding the competencies required for the Responsible Pharmacist in the manufacturing sector. The framework for the role is reviewed, namely, legislative requirements, such as applicable Acts, regulations, guidelines and codes. Thereafter, literature regarding generic competencies identified at the international level for various sectors of pharmacy, is discussed. Local literature is then reviewed with a focus on a local study which investigated the competencies required for select pharmacists in the primary healthcare sector. The chapter also covers similar roles in other countries, such as that of the Qualified Person in the European Union. Since the current RP role evolved from the previous Managing Director (MD) role, this MD role is also reviewed for clearer understanding of the current challenges for the RP today.

2.1 INTRODUCTION

In the community pharmacy sector and the hospital sector, the Pharmacy Act and the Good Pharmacy Practice guidelines are a good start to understanding one's duties and responsibilities as a Responsible Pharmacist (RP). However, the pharmaceutical industry is more complex and appears to have less guidance for the RP. From anecdotal evidence, gathered through informal discussions with numerous RPs in the pharmaceutical manufacturing sector, there are several RPs who, at the time of their registration as the RP, did not feel sufficiently equipped for the duties that accompanied the role. They met the legal requirements, i.e. they held a B Pharm degree, had completed their internship and community service, thus, they had at least two years-experience post their graduation. However, a few years' experience was considered insufficient to fully understand and appreciate their duties and responsibilities in the pharmaceutical manufacturing sector, which extended beyond their experience.

Compliance with legislative requirements is a team effort, as the expertise for the different aspects in manufacturing lies with several different pharmacists. Therefore, the RP may have to delegate several aspects of their duties to other pharmacists. For their role, RPs are required to understand all applicable laws and have a working knowledge of all GxP (Good Practices applicable to the pharmaceutical manufacturing plant, including the standards required in manufacturing, distribution, the laboratory, warehouse and distribution), especially the SA GMP guideline, Annex 16. It is notable that the law allows for registration of RPs without any requirement on the training of these essential aspects, either before registration or in a stepwise or modular fashion, in the years after registration. Other than the volumes of law and the GMP guideline, it seemed there was little else from the statutory bodies, the professional body, the SAPC nor the regulatory authority, the MCC.

Other resources for training on the role of the RP would be to attend courses or workshops held by trainers to the pharmaceutical manufacturing industry, and well as the Professional Society of South Africa, the PSSA. Trainers may be found through the SAPC website or through advertising specific to the the pharmaceutical manufacturing industry. The PSSA is an independent association for pharmacists and allied professionals in the healthcare industry. SAAPI, the South African Association of Pharmacists in Industry, is the sector of the PSSA that represents pharmacists and allied professionals in the pharmaceutical manufacturing sector. Other sectors of the PSSA include hospitals and institutions, academia, and community pharmacy. SAAPI runs introductory workshops on several topics pertinent to the pharmaceutical manufacturing industry, including the topic covering responsibilities and duties of the RP. It should be noted that the PSSA cannot set mandatory training modules for pharmacists as they are a voluntary association.

Newly registered RPs are expected to do self-training on all necessary aspects of the business in order to fulfil their role. Based on views expressed in informal discussions with RPs, it appears that RPs are not necessarily senior managers, hence, RPs often have limited authority in the company to challenge structures or situations that impact on their role. In this regard, RPs may be placed in a situation where they are the “scapegoats” being responsible for overall compliance but not having the necessary authority to

implement the requisite structures or processes to address areas of risk. It is necessary to investigate whether these views are widespread among RPs in the pharmaceutical manufacturing sector.

2.2 THE RP'S ROLE IN THE SOUTH AFRICAN LEGISLATION

In South Africa, the RP is defined in terms of the Pharmacy Act, No. 53 of 1974. In summary, the RP is responsible to the South African Pharmacy Council (SAPC) for complying with all provisions of the Act and any other legislation applicable to the services, which pertain to the practice of pharmacy, and legislation applicable to the pharmacy that is under his or her personal supervision. The Medicines and Related Substances Act (referred to as the Medicines Act), No. 101 of 1965, does not directly mention the RP. The RP duties are detailed in the SA GMP guidelines. In summary the Medicines Act covers the labelling of medicines, records and registers, the sale of medicines to registered and approved customers, registration of medicines with the Medicines Control Council, (MCC), adherence to standards, reporting of adverse events and technical errors, and advertising of medicines and control of scheduled substances.

Both the SAPC (GPP guideline, section 2.1) and the MCC (SA GMP guideline, Annex 16) stipulate that the RP shall have "appropriate" qualifications and experience in the services rendered by such pharmacy. However, there are no definitions for what may be considered as "appropriate".

2.3 SHORTAGE OF PHARMACISTS

There is a shortage of pharmacists, as there is a shortage of professionals in South Africa. Several studies have been done in this regard. It seems that South Africa is not the only country experiencing a shortage in pharmacists, but that the shortage is global (Chemaly, 2011). Locally, the SAPC's report on Pharmacy Human Resources for Health (SAPC, 2011) paints a similar picture.

The shortage of pharmacists in South Africa may be one of the reasons that the SAPC has not stipulated sector-specific registration requirements. This means that a newly qualified generalist pharmacist has several options to operate within and may register to work in any of the pharmacy sectors. As a result, such an approach could result in RPs working in several sectors, but it may also lead to the registration as RP of insufficiently experienced pharmacists to fulfil the desired RP role that is required within a particular sector.

There appears to be little coverage of the RP's role in the pharmaceutical manufacturing sector. An article of interest, a legal opinion, gives a viewpoint on the RP role from the legal perspective, including legal cases where the legislation was challenged (Doms, 2008). The SAPC, (Mokoena, 2013) offered a general outline of the legal basis for the role and the general duties as they applied to the RP in community/retail pharmacies, with little reference to that of the pharmaceutical manufacturing sector. Another presentation given more recently, unveiled the changing role of the RP since its evolution from the Managing Director (Hoffmann, 2017).

2.4 COMPETENCIES FOR PHARMACISTS AT THE INTERNATIONAL LEVEL

The International Pharmaceutical Federation (FIP in French, IFP in English), the World Health Organisation (WHO) and the United Nations Educational, Scientific and Cultural Organization within the UN (UNESCO) have established a global pharmacy education taskforce for analysis and policy planning of the global pharmacy workforce (IFP Global Pharmacy Workforce Report, 2012). Below is a table from their report, showing the competency clusters for different domains of pharmacy.

Table 1. Domains and illustrative competencies from the Global Competency Framework version 1 for pharmaceutical services (IFP Global Pharmacy Workforce Report, 2012)**:**

Scientific Knowledge

Pharmaceutical Public Health	Pharmaceutical Care
Health promotion: Medicines information and advice	Patient consultation and diagnosis; Assessment of medicines, Compounding medicines; Dispensing medicines; Monitor medicines
Population focus	**Patient focus**
System focus **Organisation and management** Budget and reimbursement; HR management; Improvement of service; Procurement; Supply chain and management; Workplace management	**Practice focus** **Professional/Personal** Communication skills; CPD; Legal and regulatory practice; Professional and ethical practice; QA and research in the workplace; Self-management
Management Knowledge	

Hence, much preparatory work has been done at the global level regarding the competency framework for pharmaceutical services, with no elaboration directed to the pharmaceutical manufacturing sector.

2.5 COMPETENCY FRAMEWORK FOR LOCAL PHARMACISTS PRACTICING IN THE PRIMARY HEALTHCARE SETTING

In a local case study (Bradley, 2013), the competencies of sub-structure and sub-district pharmacists in the primary healthcare setting were identified as follows:

Table 2. Competencies of sub-structure and sub-district pharmacists:

Professional pharmacy practice	**Personal, interpersonal, cognitive**
Legal and regulatory aspects of pharmacy practice Clinical aspects of pharmacy practice Technical aspects of pharmacy practice Public service legislation and practice **Health system/Public Health** Health systems and organisation Health programmes Public health **Management** Planning and organising Financial management and budgeting Human resource management Physical resource management Project management Information management Monitoring and Evaluation **Leadership** Strategic leadership and vision Change management Service deployment and innovation	**Personal** Self-development Adaptability Assertiveness Time management Professionalism **Interpersonal** Relationship building Networking Negotiation Teamwork Cultural competency **Cognitive** Problem solving Prioritising Decision making Communication skills (oral and written)

The clusters, *Professional pharmacy practice* and *Health system/Public health*, refer to the public health services sector (Bradley, 2013) and would not be applicable to the pharmaceutical manufacturing sector. However, competency which clusters appear to be generic, could be applied to pharmacists practicing in other sectors too. Pharmacists in the manufacturing sector share several general professional competencies with those in the public health-sector, but the different roles and responsibilities flowing from the requirements of the manufacturing license, requires a more specific competency framework for this sector, which is yet to be documented for South Africa.

2.6 THE QUALIFIED PERSON IN EUROPE

The Qualified Person (QP) in the European Union is well established (since 1975) in the EU member states and the European Economic Area. No batch of medicinal product may be released in the EU without prior certification by the QP. The QP is typically a pharmacist, but may be a chemist or biologist or someone with another permitted academic qualification, who has several years of experience in the pharmaceutical manufacturing environment, and has passed official examinations attesting to this knowledge. There are several EU directives concerning the QP (Directive 2003/94/EC; Directive 91/412/EEC; Directive 2001/20/EC; Directive 2001/82/EC; Directive 2001/83/EC) which cover, amongst others, GMP, GCP, Community codes, manufacture, certification. This certification process for the QP is outlined in the legislation, with mandatory Continuous Professional Development. The local SA GMP guide Annex 16 regarding the RP, is based on the EU GMP guide Annex 16, regarding the certification by a QP and batch release.

There are several guidance documents available for both the QP in community pharmacy as well as the QP in the pharmaceutical industry, from the Competent Authority or the professional body of the member state. Several other countries base their local requirements on the QP as outlined in the EU legislation. The concept of the QP is well established in Europe and there is ample support in terms of guidance documents in both the community and pharmaceutical manufacturing sectors. In addition, Israel (Fragman, 2016) and Malta (Pisani, 2009) have also specified the role of the QP.

A starting point for the professional and regulatory authorities in South Africa would be to develop local versions of such documents, to support RPs in the local pharmaceutical manufacturing sector.

It is interesting that even in countries, such as those in the EU, that seem more advanced in terms of their legislation and support for the RP/QP role, there may also be times when there is confusion amongst the pharmacists regarding their roles. A survey conducted in the UK, which aimed to explore the views of pharmacists about the impact of new regulations of the RP (Vora, 2012), is such an example. Government consultation started in October 2007 and from the professional body, in May 2009. While the results showed

that almost half (48 %) of respondents were negative about the new role, engagement from the consultations was positively received among the pharmacists. Support from the professional body can make a significant impact on newly registered RPs and their perceptions of their professional role.

2.7 THE PHARMACIST IN THE US: The US appears not to have a QP/RP-type role for the pharmaceutical manufacturing sector. In community /retail pharmacy, there is registration of the "Pharmacist in Charge", which seems very similar to the RP role in the community sector in South Africa. The Joint Committee on Administrative Rules, Administrative Code, provides details for the registration of the Pharmacist-In-Charge. It therefore appears that the US has a similar role to the RP in the Community pharmacy sector, namely, the Pharmacist-in-charge. However, a similar role for the RP in the pharmaceutical manufacturing sector could not be found. Looking at the US Federal Drug Authority (FDA) website, the FDA holds the quality control unit responsible for quality related decisions such as batch certification and release. The FDA may, if there are significant GMP concerns, take regulatory or legal action or enter into consent of permanent injunction with the company. In consent decrees, the FDA may name the Head of the quality unit and other senior executives at the company, in the decree itself. If it is found that the GMP issues are not addressed adequately, the FDA may seek additional legal measures against the named individuals. It seems that the responsibilities of the role of RP/QP lie inherently within the company's executive management.

2.8 THE MANAGING DIRECTOR ROLE VERSUS THE RP ROLE

The RP role in the pharmaceutical manufacturing sector in South Africa had evolved from that of the Managing Director (MD). In a local study, the researcher examined the statutory requirement restricting the MD position in a pharmaceutical company to pharmacists (Goodall, 1986). This restriction (Section 22 of the Pharmacy Act, prior to 2003) was the subject of longstanding debate before its final removal by the Amendment Act of 1997, enacted in 2003. Although legislation was amended, amongst others, to

remove the restriction of the MD role to only pharmacists, it is important to revisit some of the findings of that study, as it may have bearing on this study regarding the RP role.

In the study (Goodall, 1986), objections to the restriction of Section 22 included the following:

> The MD is often an appointment of convenience, a figurehead vested with the responsibility for the company but without requisite authority to carry out his duties; the MD does not in fact, manage the business; as many pharmaceuticals are often multifaceted businesses; the MD, a pharmacist, is not always the best person to lead the company, that pharmacists lack adequate training in business methods and management.

In the study, viable alternatives were sought to the MD position restriction including the recommendation of a Pharmaceutical Director. This proposal was intended to retain the spirit of the law, that pharmacists remain in a position of authority over the pharmaceutical aspects of the business, but remove the business management and fiduciary responsibilities required of the MD. The proposed pharmaceutical director position, was still expected to retain a high level of authority, that of a company director.

The amendments to the legislation of 1997, enacted in 2003, have left the RP with the broad responsibilities and accountabilities for all pharmaceutical aspects of the business, without defining the appropriate experience required, nor prescribing the necessary authority level of the position. Companies as businesses do not always choose the most experienced candidate for the RP role, and RPs are often not senior members of the management team of the company. There is anecdotal evidence from views expressed in informal settings during discussions with RPs in the industry, that some companies still see the RP as an appointment of convenience, a figurehead or token, behavior which is detrimental to both the token RP as well as other pharmacists and managers in the company (Wright and Taylor, 1998). The role is often added and secondary to another, such as the Quality Assurance manager or Regulatory Affairs manager role. In this way, the RP role still bears many challenges of the now defunct, MD role.

2.9 DISCUSSION

The RP's role in the pharmaceutical manufacturing sector in South Africa has evolved from that of the Managing Director. Prior to 2003, only pharmacists were allowed to own pharmacies (retail sectors) and the pharmacist responsible to the SAPC was the Managing Director. Legislation then changed, the Pharmacy Act was amended in 1997, enacted in 2003; the restriction on pharmacy ownership was removed and pharmacies were allowed to be owned by persons/entities other than pharmacists. The Managing Director became the Responsible Pharmacist, a new role which retained the principle idea that this was the pharmacist accountable for compliance to the legislation, but without the business aspects such as fiduciary duties of a company director, and direct responsibility for the management of the business. Licensing of pharmacies was introduced and a RP had to be appointed to be the natural person accountable to the SAPC and MCC for compliance to the Acts. The role of the RP in the community pharmacy sector appears to be better established with guidance documents and clear responsibilities and duties in the codes of practice, Good Pharmacy Practice (SAPC, 2010) and Codes of Conduct (SAPC, 2008). However, this does not appear to be the case for other sectors, such as the pharmaceutical manufacturing sector, a fairly new role which is only in existence since 2003.

The role of the RP is similar to that of the QP in Europe, but the scope is broader. In the EU, the QP role is well-established, with training requirements and mandatory CPD, and the focus is batch certification and release (EU Guidelines, 2003). There are codes and guidance documents in place too which may be used as a starting point for local documents with the same aim.

In the US, the Pharmacist-in-charge appears to share a similar role to that of the RP in the community pharmacy sector, but not so for the RP in the pharmaceutical manufacturing sector. Instead, the FDA appears to have legislative powers to ensure that the executive heads of the company carry the ultimate role and responsibilities of the RP as understood locally.

2.10 CONCLUSION: Under the constraints of work pressure and the RP's role in the pharmaceutical manufacturing sector, investigating the training needs is required to support and assist the RPs to fulfil their duties and responsibilities adequately. It is necessary to examine whether RPs in the pharmaceutical manufacturing sector understand their role with its inherent expectations, and to identify the gaps that need imminent attention.

The next chapter focuses on the research design, the methods employed to investigate the perceptions of RPs and their counterparts about the RP role, and the competencies required for the pharmaceutical manufacturing sector. Significant features of the research design with regards to the technique for sample selection, data gathering, and data analysis are reviewed.

CHAPTER 3

METHODOLOGY

3.1 INTRODUCTION

This research aims to investigate the role and competencies which are required for the Responsible Pharmacist (RP) in the pharmaceutical manufacturing sector. It explores the RPs role from the perspective of practicing RPs, and from the perspective of the statutory councils and other experienced RPs in the sector. This chapter provides a synopsis of the research design, and the significant features with regard to the technique for sample selection, data gathering, and data analysis.

3.2 RESEARCH DESIGN

A mixed method approach, i.e. both quantitative and qualitative forms was employed in this study. An advantage of this approach is that the researcher is able to obtain objective and subjective data for the subject of inquiry, across the independent quantitative and qualitative arms of the study (Teddlie and Yu, 2007)

The quantitative phase of the study employed a survey questionnaire (Phase 1); the qualitative phase employed semi-structured interviews (Phase 2). The two phases were conducted independently of each other.

The design for each phase is presented separately.

3.3 QUANTITATIVE RESEARCH – PHASE 1: SURVEY QUESTIONNAIRE

Survey research was chosen as the preferred method for this study. The advantages of surveys are that the research data are based on real world observations, provides breath of coverage of many people which makes it generalizable, and that a large amount of data can be produced in a relatively short time, at low cost. The disadvantages, however, include neglected significance of data, data produced that may lack detail and the difficulty in securing a high response rate to the survey (Kelley, Clark, Brown & Sitzia, 2003).

The program, SurveyMonkey® (SurveyMonkey.com, 2016), was chosen to allow RPs easy access to an electronic survey by clicking on a link serviced by the SurveyMonkey® website hosting the survey, through emails sent by the same program.

3.3.1 Study population

A sample is a portion of the population which has been selected to be an unbiased representation of the larger population, and is a less expensive way of gathering information on the larger population (Suresh, Thomas and Suresh, 2011). Sampling procedures may take the form of probability sampling or non-probability sampling. Following the quantitative form of research design for the Phase 1 survey questionnaire, this study employed probability sampling, where all RPs from the target audience, namely, the pharmaceutical manufacturing sector, had an equal opportunity of participating in the survey.

Probability Sampling:

Simple random sampling: where each person in the given population, has an equal chance or probability of being selected, is seen as the most common form of sampling (Teddlie and Yu, 2007).

Following the quantitative form of research design employed for Phase 1 of this report, the sampling technique will be based on probability theory. According to Thompson (1999), the use of probability theory for quantitative design which includes the use of

questionnaires or surveys, is known for its two central features, that is, the researcher has access to all members of the population and every member has an equal chance of being selected (all members have a chance of being selected, they cannot have “no chance” of being sampled). One consequence and a benefit of probability sampling is that it allows the researcher to minimize sampling error.

3.3.2 Sampling strategy

The total population for this study consists of all RPs whose names appeared in the SAPC register (2016) for the pharmaceutical manufacturing sector, at the time of the study. Access to the SAPC list of RP email addresses was requested in September 2016 and provided on 7 December 2016. The list consisted of email addresses of all RPs for the pharmaceutical manufacturing sector. The list represented the complete study population which is the focus of this study. The survey was distributed to all RPs for the manufacturing pharmaceutical sector, registered with the SAPC, that is, all RPs had an equal opportunity of receiving the survey and thus an equal opportunity of being part of the sample. The sample became all RPs who responded to the survey request.

The purpose of the questionnaire was to investigate the RPs views, perspectives and attitudes about their role, whether they felt adequately prepared for the role at the time of their registration as RP and later, whether they considered themselves to have acquired the necessary training to fulfil their self-identified CPD requirements.

The questionnaire was drawn up consisting of 22 questions with multiple choice answers. (Appendix 1). The questionnaire was developed in November 2016, on an online-based survey tool, namely, the SurveyMonkey® program.

An email introduction was also developed online. The introduction to the survey included a brief background on the aims of the study and an explanation on the anonymous, consensual nature for participation (Appendix 2). The email addresses of all RPs on the SAPC register were loaded into the program which automatically forwarded individual electronic invitations to the RPs. The email consisted of the introduction to the survey

together with a web link to the survey. Those RPs who clicked on the web link, were assumed to have agreed to participate as stated in the introductory email.

The email invitations were sent out, on 13 December 2016, to all listed RPs as per the SAPC register of December 2016. Since most employees in pharmaceutical companies take their annual leave during the period, 15 December to 15 January, reminder emails were deemed necessary. Therefore, two follow up "reminder" emails were sent out in January 2017. The survey was closed on 2 February 2017.

On 13 February 2017, a follow-up inquiry was directed to the same audience, that is, the complete list of RPs for the pharmaceutical manufacturing sector as obtained from the SAPC, qualifying their response to one question only. This inquiry was deemed necessary to obtain clarity on the responses obtained for question 16 from the first survey.

Question 16 stated*: Are there times when you feel you have been excluded from far-reaching important decisions, which may have impacted your role as RP?*

The follow-up question read: *If you answered "Yes" to the previous question (question 16), please provide the broad category of the situation; please select whichever are applicable".*

The following options were given:

The situation could have potentially affected the manufacturing license
The situation involved advertising and promotional activities
The situation created an ethical dilemma
The situation involved batch release and certification
The situation involved regulatory compliance
Other (please specify)

This follow-up inquiry (Appendix 3) ran for two weeks only, with no "reminder" email.

3.3.3. Data Analysis

As part of its program, SurveyMonkey® provides data collection and basic data analysis. The data were analysed and sorted at face value i.e. no statistical analysis was employed.

The form of measure of most answers followed the Likert scale. The scale was developed to measure attitudes with a series of up to five alternative responses. Responses to each question were noted numerically and expressed as a percentage. The resultant data represents trends in the opinions of the study sample.

A 2-page questionnaire was drawn up consisting of 22 questions with multiple choice answers. (Appendix 1). The questionnaire was developed on an online-based survey tool, namely, the SurveyMonkey® program. An email was also developed online to introduce the survey. It included a brief background on the aims of the study and an explanation on the anonymous, consensual nature for participation (Appendix 2). The email addresses of the sample group were loaded into this SurveyMonkey® program which sent out individual electronic invitations to the chosen RPs. The email consisted of the introduction to the survey together with a web link to the survey. Those RPs who clicked on the web link, were assumed to have agreed to participate, as mentioned in the email introduction.

3.4 QUALITATIVE RESEARCH – PHASE 2: SEMI-STRUCTURED INTERVIEWS

3.4.1. Study population

Qualitative research offers an in-depth exploration of a subject's experience and understanding of the world. The researcher begins with a general, preconceived concept and proceeds to explore other individuals' experiences and understandings of the concept (Willig, 2001). Phase 2 of this study aimed to explore the role of the RP from different perspectives. Interviewees were chosen from the statutory bodies, the South African Pharmacy Council (SAPC) and the Medicines Control Council (MCC), as well as from non-statutory individuals who were all experienced RPs in the pharmaceutical manufacturing industry. This section of the chapter discusses the recruitment of participants, data collection, data analysis and ethical considerations.

Qualitative research lends itself to understanding participants' experience of specific phenomena to gain "deeper understanding of social phenomena and their dynamics" (Attride-Stirling, 2001). From this approach, knowledge and meaning about the world are

assumed to be situated in subjective realities which are shaped by various factors (Yardley, 2000).

In this study, data were collected through semi-structure interviews, using a digital recorder, namely, the Dictaphone®. The use of semi-structured interviews aimed to provide rich and detailed views and perceptions from the sample, about the role and competencies which are deemed necessary for RPs in the pharmaceutical manufacturing sector.

3.4.2. Sampling strategy

Using the process of snowball sampling, interviews were requested with the statutory bodies at a central level. Snowball sampling is a qualitative sampling strategy recommended when the researcher is interested in a connected network of people (Neuman, 2000). The use of this method provides access to a sample otherwise unknown to the researcher, but either directly or indirectly linked to each other (Neuman, 2000). For this research, the sampling came to a halt when there were no more participants available for the interviews, or none willing to participate in the study. An outline of the snowball sampling technique employed for this study, is included in Appendix 4.

Since the sample consisted of two categories of participants, Phase 2 of this study was conducted in two sub-phases, Phase 2A and 2B. Participants from the statutory bodies formed Phase 2A of the data collection process. Three participants were recruited into this phase, namely, one representative from the SAPC and two representatives from the secretariat of the MCC, namely, the Medicines Regulatory Authority (hereafter, referred to as the MCC). Participants from non-statutory bodies formed Phase 2B of the data collection process. Five participants were recruited into this phase, namely, one representative from the PSSA, three representatives from different training companies which offer RPs' training in the manufacturing sector, and one representative from the Marketing Code Authority. Overall, a total of eight participants were interviewed for Phase 2. This small sample size was used to capture rich, detailed data as opposed to broad, generalizable findings (Bryman, 2012).

Selection criteria: The selection criteria for the semi-structured interviews were that the participants be pharmacists who are registered with the SAPC, employed by either the statutory or non-statutory bodies and had worked directly with RPs from the pharmaceutical manufacturing industry. The purpose for considering participants from each of the sectors was to obtain a detailed and holistic view about their firsthand experiences with RPs in the pharmaceutical manufacturing sector.

Invitation letters were emailed to pharmacists employed in the SAPC, MCC, PSSA, RP training companies and the Marketing Code Authority, since November 2016 to January 2017. In the case of the MCC and SAPC, authorization was required to conduct interviews with representatives from these bodies, and these were obtained prior to the interviews. A list of possible semi-structured interview questions, together with a consent form were compiled (see Appendix 5). Interviews were conducted between November 2016 and February 2017. An introduction on the research topic was sent to participants beforehand together with the list of prepared questions and the consent form. In all cases, written consent was obtained before the interviews commenced. The list of questions was used as a guide or to prompt participants in relevant areas to ensure that sufficient data could be collected. All interviews were conducted at a mutually convenient time in a venue chosen by the participants, in most cases, at their place of employment. The interviews lasted approximately an hour each.

3.4.3 Data Analysis

The data were analysed using the following approach of thematic analysis, where each step forms a vital part of the overall analysis (Braun and Clarke, 2006). The researcher transcribed the data from the digital recorder and reread the transcripts to become familiar with the data. The transcripts were checked for manual identification of common themes and information of significance. The themes were assigned codes and frequently occurring themes were organized into trends. All transcripts were rechecked to ensure accuracy of the process, and to ensure that themes and significant information had not been overlooked.

Interview extracts were then identified to illustrate important points or themes. The extracts were then integrated in the dissertation to address the research question.

3.5 ETHICAL CONSIDERATIONS

Phase 1 – Survey questionnaire

All RPs invited to participate in the survey via an introductory email, were informed of the voluntary nature of the study. The survey was completed online, and was anonymous. Participation was completely voluntary, with the respondent permitted to exit the survey at any time, or to answer only those questions which they selected to. No identifiable information was requested nor provided.

Phase 2 – Semi-structured interviews

Participation in the interviews was completely voluntary. This was conveyed verbally during the telephonic requests for interviews as well as in the introductory emails (Appendix 5) sent ahead of the interviews, and again at the start of each interview, prior to the signing of the consent form. The email clearly described the right of the participants to withdraw from the study at any stage, that is, before, during or after the interview, without the need for an explanation and any repercussions. Consent forms were provided with the introductory email and were signed prior to all interviews, after a brief overview of the study had been provided, including the aims and process of the study.

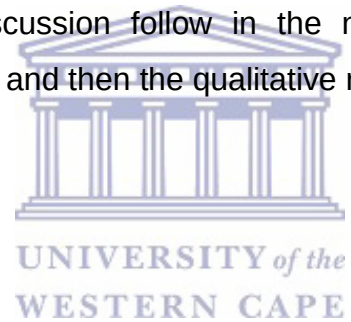
As provided in the request for an interview, the privacy of data and confidentiality of participants was re-emphasized. All identifiable information was removed and the recordings were password protected. The participants were assigned a number to ensure anonymity in the transcripts and research reports. Their identities were coded and are known only to the researcher and the supervisor. Access to the audio recordings was restricted to the researcher and the supervisor. These recordings will be preserved for a five-year period. The research is not focused on the participants' personal history, but

rather on their perceptions and views of the competencies required for the role of the RP in the pharmaceutical manufacturing sector.

Ethics approval to conduct the study was obtained from the University of the Western Cape, Senate Research Committee, Number BM/16/7/10.

3.6 Conclusions

This chapter provided an overview of the methodology used in this research study. This included the selection of methods for the two phases of the study, the sampling strategy regarding selection, sample size and sampling procedures. Finally, the data collection methods and data analysis procedures to be used for interpretation of the data, were covered. The results and discussion follow in the next chapter, starting with the quantitative research (phase 1) and then the qualitative research (phase 2).



CHAPTER 4

RESULTS AND DISCUSSION

4.1 INTRODUCTION

In this chapter, the results and discussion of the quantitative and qualitative phases of this research are presented. The quantitative phase of the study employed a survey questionnaire (Phase 1); the qualitative phase employed semi-structured interviews (Phase 2). The two phases ran concurrently and were conducted independently of each other from November 2016 to February 2017.

Phase 1, the survey questionnaire, was carried out in two parts. The first survey consisted of 22 questions (Phase 1A). The second survey consisted of one question (Phase 1B); it was sent to further explore the response received for question 16 from the first survey. Question 16 referred to "*Exclusion from far-reaching decisions which impact the RP role".*

Phase 2, the semi-structured interviews, were conducted in two parts. The first part consisted of interviews with participants from statutory bodies, namely, the MCC and the SAPC (Phase 2A). The second part consisted of interviews with participants from non-statutory bodies and individuals involved in the training of RPs for the pharmaceutical manufacturing sector (Phase 2B). Thus this research will dissect the factors of the RP role that represent the necessary competencies required for successful performance in the role.

The results for Phases 1 (consisting of parts 1A, and 1B) and Phase 2 (consisting of parts 2A and 2B are discussed below.

4.2 RESULTS FOR PHASE 1A OF SURVEY QUESTIONNAIRE

Sample size:

In December 2016, the SAPC register for RPs in the pharmaceutical manufacturing sector, consisted of a total of 268 pharmacists. For this study 268 survey invitations were sent out electronically via email, using the SurveyMonkey® program. Seventeen emails "bounced" i.e. these email addresses were invalid and only 102 responses were received. The sample size was thus 102 RPs. From a total of 268 RPs registered with the SAPC for the manufacturing sector, this sample size represented a response rate of 38,06 % to the survey.

Although 102 participants responded to Question 1, only 87 answered more questions i.e. the response rate for questions 2 to 22 was 32,46 % (87 responded and 15 did not). Of the 87 respondents, not all respondents answered all questions. The results tabulated below specify the number of responses that were analysed for each question in the survey.

4.2.1 Pharmacy sector confirmation question

In this study 102 respondents answered this question.

Answer choices	**Responses**	
	%	N
Retail Pharmacy	0,98	1
Hospital/Clinic Pharmacy	0,00	0
Manufacturer, including Importer/ Exporter	97,06	99
Wholesaler	1,96	2
Total respondents		102
Non-respondents		0

The scope of this study was limited to the pharmaceutical manufacturing sector. The register for only RPs in the pharmaceutical manufacturing sector, was requested and

obtained from the SAPC. Since 3 respondents were from other sectors, it is possible that the register still reflected RPs who have since resigned or moved to other pharmaceutical sectors.

4.2.2 Confirmation of RP registration in current position

In this study 87 respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Yes	91,95	80
No	2,30	2
Used to be	5,75	5
Total respondents		**87**
Non- respondents		**15**

Had the SAPC register been completely accurate, none of the respondents would have selected “No”. The discrepancy may have arisen because of the possibility that the register of the SAPC does not capture all resignations immediately. Given that all emails were registered as being those of RPs in the manufacturing sector, it may be assumed that all 102 respondents were once registered as RPs with the SAPC and that the three choices in the survey did not provide for an alternative plausible scenario for the 2 respondents (2,30 %) who subsequently replied in the negative (“No”).

4.2.3 Number of years as the RP

In this study 87 respondents answered this question and 15 did not.

Answer choices	Responses	
	%	N
Less than 3 years	25,29	22
3-5 years	26,44	23
More than 5 years	48,28	42
Total respondents		**87**
Non-respondents		**15**

The groups “Less than 3 years” and “3-5 years” are considered to be newly registered RPs, and the group, “More than 5 years”, is considered to be the more experienced RPs.

Without prior knowledge of the demographics for all registered RPs (total of 268), it is difficult to comment on the significance of this result. If the percentage of all RPs with more than 5 years’ experience, was indeed approximately half, then the result (48 %) for this sample would be representative of the population being tested. Alternatively, if the majority of respondents were among the more experienced RPs that responded, it could imply that the younger/less experienced RPs had refrained from responding to the survey.

4.2.4 Age range of the respondents

In this study 87 respondents answered this question and 15 did not.

Answer choices	Responses	
	%	N
Under 30	2,30	2
31-40 years	31,30	27
41-50 years	27,59	24
Over 50 %	39,08	34
Total respondents		**87**
Non-respondents		**15**

When considering the previous question regarding years of experience, with this question on age ranges, it would appear that the survey was completed by the older pharmacists and perhaps, older RPs. Only 2 respondents were under 30 years, compared to 85 respondents who were 31 years and older. Alternately, two thirds (66,67 %) of respondents were in the range, 40 years and over. For a more accurate comment, one would need to know the age of all RPs for the manufacturing sector.

4.2.5 Degree/qualification held:

In this study 84 respondents answered this question and 18 did not.

Answer choices	**Responses**	
	%	N
B. Pharm.	83.33	70
Dip. Pharm.	5,95	5
M. Pharm.	10,71	9
Other (specify)	17,64	18
Total respondents		**84**
Non-respondents		**18**

In this study 18 respondents provided further information on other degrees obtained, in addition to their B. Pharm degree, e.g. PhD, BSc (Industrial pharmacy), MSc (Industrial Pharmaceutics), MBA (5), LLB, etc. In total, it appears that 10,71 % of respondents had attained Masters' level qualifications.

4.2.6 Years of experience at time of registration as RP:

In this study 87 respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N

Approx. 2 years	20,69	18
2-5 years	16,09	14
More than 5 years	63,22	55
Total respondents		**87**
Non-respondents		**15**

The majority, approximately two thirds (63,22 %) of the respondents had more than 5 years of experience at the time of their registration as RPs, i.e. they exceeded the minimum years of experience required for registration, which is internship and 1 year of community service. This result reinforces the finding that the survey was completed by the more experienced RPs.

4.2.7 Experience in other sectors:

In this study 86 of respondents answered this question and 16 did not.

Answer choices	**Responses**	
	%	N
Yes	90,70	78
No	9,30	8
Total respondents		**86**
Non-respondents		**16**

For those who had answered positively, by indicating “Yes”, the next question provides more detail.

4.2.8 Experience in which other sectors of pharmacy:

In this study 75 of respondents answered this question and 27 did not.

Answer choices	Responses	
	%	N
Retail pharmacy	48,00	36
Hospital/clinic	36,00	27
Wholesaler	16,00	12
Total respondents		**75**
Other (specify)		26
Non-respondents		**27**

It is interesting to note that pharmacists engage across sectors and from their experiences, are likely to occupy leadership positions such as that of the RP. Had the converse been true, that 70 % (90) respondents had replied negatively ("No"), that they do not have experience in other sectors, one may surmise that it is difficult to move across sectors and occupy a RP position, a leadership position. Twenty-six respondents further commented on other sectors of pharmacy which were not listed as options in the survey, namely, training, consulting and academia, indicating that many respondents had experience in several other sectors of pharmacy. One could speculate that their varied experience may have added to their ability to undertake the responsibility of the role of the RP.

4.2.9 Awareness of RP courses/workshops

In this study 86 of respondents answered this question and 16 did not.

Answer choices	Responses	
	%	N
Yes	72,09	62
No	27,91	24
Total respondents		**86**
If Yes, please specify		40
Non-respondents		**16**

Ideally, one would expect all (100 %) of the respondents would be aware of RP workshops or courses. That over a quarter (27,91 %) of respondents were not aware of any RP courses/workshops, shows that there is still a need for better dissemination of the information regarding such courses. The 40 respondents which specified courses, listed mostly those courses which are well-known or offered by established providers to the pharmaceutical manufacturing sector. Quad Pharma and SAAPI were found to be cited most often.

4.2.10 Training for RP role prior to registration

In this study 85 of respondents answered this question and 17 did not.

Answer choices	Responses	
	%	N
Yes	22,35	19
No	77,65	66
Total respondents		**85**
Other, please specify		11
Non-respondents		**17**

Ideally, the candidate RPs should have received some training and mentoring on the RP role in the pharmaceutical manufacturing sector, prior to their registration as the RP. That this was the case for just over a fifth (22,35 %) of RPs, shows that there was room for improvement in terms of support for the candidate RP.

4.2.11 Training for RP role after registration as RP

In this study 87 of respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Yes	44,83 %	39
No	55,17 %	48
Total respondents		**87**
If Yes, please specify		28
Non-respondents		**15**

Ideally, all RPs should attend training specific to their role. That over half (55,17 %) of respondents have not as yet attended such RP-specific training, may indicate a lack of awareness of such focused training courses. However, other factors may also be the reason, such as, budget constraints or a preference of some RPs for self-initiated training rather than group/formal classroom or workshop-style training.

4.2.12 Additional training, excluding RP courses noted from previous question:

In this study 86 of respondents answered this question and 16 did not.

Answer choices	Responses	
	%	N
No formal training	15,12	13
On-the-job training	81,40	70
Self-training	73,26	63
Total respondents		**86**
Other (please specify)		14
Non-respondents		**16**

Respondents could select more than one answer; therefore, it is difficult to comment on the result for the 15,12 % of respondents who indicated that they were not privy to formal training. More appropriate phrasing of the choices may have allowed for conclusions to be drawn. Those who provided further information ("Other") listed training on several aspects of the RP role in manufacturing e.g. training courses covering QA, QC, the marketing code, regulatory affairs, GMP, GCP, auditing, etc., which is a positive response.

4.2.13 Undertaking of formal management/leadership training

In this study 87 of respondents answered this question and 15 did not.

Answer choices	Responses	
	%	N
Yes	58,62	51
No	41,38	36
Total respondents		**87**
Other (Specify)		28
Non-respondents		**15**

It is important to note that 41,36 % of respondents indicated that they had not received any type of formal leadership training. With reference to the positive responses noted from respondents who had received training or had attended courses, these results show an overlap with the previous question (4.2.12 regarding “Additional Training”). The intention of this question was to further qualify their positive responses (“Yes”). Given this response, it appears that this was unclear, that the question was not well worded. Hence, further comments cannot be made on the “Other” responses. However, as responses for sections 4.2.12 and 4.2.13 were very similar, this could serve as validation of self-initiated training required for the RP role.

4.2.14 Level of seniority in the company

In this study 87 of respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Junior	20,89	18
Senior	63,22	55
Executive	16,09	14
Total respondents		**87**
Non-respondents		**15**

In an ideal situation, one would expect that an RP occupies a senior or executive level position in the manufacturing company. Almost two thirds (63,22 %) of respondents indicated that they report directly to the company’s Chief Executive Officer/Head, and that 16,09 % occupy a head/leadership position. Only one-fifth (20,69 %) of the respondents stated that they have junior level positions, without a direct reporting line to the head of the company. It should be borne in mind that the possibility exists that a significant number of junior level-RPs did not participate in this survey, therefore the findings may not be reflective of a representative sample of RPs from the pharmaceutical manufacturing sector, and therefore cannot be conclusive.

4.2.15 Seniority level provides necessary required authority of RP

In this study 87 of respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Yes	63,22	55
No	22,99	20
Unsure/Maybe	13,79	12
Total respondents		**87**
Non-respondents		**15**

Considering the responses obtained to the previous question (4.2.14), it may be assumed that RPs with senior and executive levels of seniority, would most likely have responded positively to this question. It is noteworthy that more than a third (36,78 %) of respondents felt that their level of seniority did not provide them with sufficient authority to perform their duties as RP. The question therefore arises: What meaningful contribution does the RP actually make when occupying a senior position in a pharmaceutical manufacturing company?

4.2.16 Exclusion from far-reaching decisions which impact the RP role

In this study 86 of respondents answered this question and 16 did not.

Answer choices	**Responses**	
	%	N
Yes	43,02	37
No	44,19	38
Unsure/Maybe	12,79	11
Total respondents		**86**
Non-respondents		**16**

Considering responses to the previous question (4.2.16), where the majority (63,22 %) of respondents indicated that their level of seniority provided the required authority for the RP role, it is interesting to note that less than half, only 44,19 % and not 63,22 %, of respondents felt that they were included from far reaching decisions. Based on this discrepancy in responses, it would seem that even those RPs in senior level positions, felt that they were excluded from decisions that impacted their role as RP.

4.2.17 Possessing necessary skills, training for RP role at time of registration

In this study 87 of respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Yes	60,92	53
No	32,18	28
Unsure/Maybe	6,90	6
Total respondents		**87**
Non-respondents		**15**

This question elicited the RPs' perceptions about their competence at the time of registration. The majority of RPs (60,92 %) felt that they had the necessary skills, training and experience as newly registered RPs. If one considers the previous question, *4.2.6, (Years of experience at time of registration as RP*), where a high percentage, almost two thirds (63,22 %) of respondents had more than 5 years of experience at the time of their registration as RP, the result obtained for this question is not unexpected. With over 5 years of experience, it is understandable that the majority of respondents felt that they had the necessary competencies for the role of RP.

4.2.18 Acquiring skills and training post-registration for the RP role in the pharmaceutical manufacturing sector

In this study 87 of respondents answered this question and 15 did not.

Answer choices	**Responses**	
	%	N
Strongly agree	44,83	39
Agree	48,28	42
Neither agree nor disagree	5,75	5
Disagree	1,15	1
Strongly disagree	0	0
Total respondents		**87**
Non-respondents		**15**

Only one (1,15 %) respondent felt that he/she had not as yet acquired the necessary skills for the role as RP, with 5 (5,75 %) respondents being unsure. The overwhelming majority (81 i.e. 93,10 %) felt confident that they had acquired the skills necessary for the RP role in the pharmaceutical manufacturing sector.

4.2.19 Acceptance/helpfulness of guidelines for the RP role in the pharmaceutical manufacturing sector if developed by MCC/SAPC/PSSA

In this study 86 of respondents answered this question and 16 did not.

Answer choices	**Responses**	
	%	N
Strongly agree	52,33	45
Agree	37,21	32
Neither agree nor disagree	3,49	3
Disagree	5,81	5
Strongly disagree	1,16	1
Total respondents		**86**
Non-respondents		**16**

The overwhelming majority of respondents (89,53 %) were in favour of guidelines being introduced for the RP regarding their training. With the pharmaceutical manufacturing industry in South Africa being recognized as one of the fastest growing in the world, the quest for guidelines from the respondents denotes that a formalized framework is needed to elucidate RP's roles and responsibilities, competencies, and ongoing training in their role, to meet the population's health needs.

4.2.20 Acceptance/helpfulness of mandatory training modules as CPD, specific to the RP role in the manufacturing sector, if developed by MCC/SAPC/PSSA

In this study 86 of respondents answered this question and 16 did not.

Answer choices	**Responses**	
	%	N
Strongly agree	50,00 %	45
Agree	32,56 %	32
Neither agree nor disagree	6,98 %	3
Disagree	9,30 %	5
Strongly disagree	1,16 %	1
Total respondents		**86**
Non-respondents		**16**

When one considers the previous question (4.2.19) together with this one (4.2.20), it is clear that the overwhelming majority of respondents i.e. 77 (89,53 %) reiterated their support for structured and formalized training, whether it is translated in the form of mandatory CPD or not.

4.2.21 Regular evaluation of performance of RP role

In this study 87 of respondents answered this question and 15 did not.

Answer choices	Responses	
	%	N
Strongly agree	18,39	16
Agree	27,59	24
Neither agree nor disagree	28,74	25
Disagree	22,99	20
Strongly disagree	2,30	2
Total respondents		**87**
Non-respondents		**15**

These results show a wide variety of opinions. Over a quarter (28,74 %) of respondents were unsure, which may indicate that the question was not clear enough. Considering the significance of the RP role to the pharmaceutical manufacturing company, ideally, all RPs should have ongoing assessments on their performance in the role of RP. However, less than half (46,51 %) of the respondents were in agreement (either “strongly agreed” or “agreed”) with the statement, but a quarter of respondents (25,29 %) have line managers who may not be assessing their performance as RPs.

4.2.22 Suggestions for further training requirements

In this study 87 of respondents answered this question and 15 did not.

Answer choices	Responses	
	%	N
Yes	32,18	28
No	67,82	59
Total respondents		**87**
Non-respondents		**15**

In this study, almost a third (32,18 %) of the respondents provided further comment on training which showed a high level of engagement with this topic. Suggestions varied with some common themes such as business/commercial training, leadership/management training, post graduate qualification and specialization. A number of respondents provided detailed suggestions for further training. A full report on their suggestions appears in Appendix 6.

4.3 RESULTS FOR PHASE 1B: SECOND/FOLLOW-UP SURVEY QUESTIONNAIRE

On reviewing the results of the survey, a decision was made to focus on question 16, "*Exclusion from far-reaching decisions which impact the RP role",* by way of a second survey to obtain further clarity on the RP role in the pharmaceutical manufacturing sector. Question 16 was repeated in an email invitation, with a link to one new question, an opportunity to select possible reasons for feeling excluded in decision-making. The email invitation was sent to the same target group, i.e. all 268 RPs in the pharmaceutical manufacturing sector, as per the current SAPC register. The email called on all RPs who had responded positively ("Yes") to question 16 in the first survey, inviting them to respond to only one question posed in the second survey. The results of the second survey are given below.

4.3.1 Exclusion from far-reaching decisions which impact the RP role

In this study 50 respondents answered this question

Answer choices	**Responses**	
	%	N
Yes	68,00	34
No	26,00	13
Unsure/Maybe	6,00	3
Total respondents		**50**
Non-respondents		**0**

In the first survey (see 4.2.16), 37 respondents had answered positively ("Yes"), while 11 had selected "Unsure/Maybe". The second survey was sent out to reach these 48 respondents, to obtain clarity on the reasons for their response (being excluded from far-reaching decisions). That the second survey received 50 responses shows that the second survey had reached the target respondents.

4.3.2 Situations from which the RP felt excluded in decision-making

In this study 33 respondents answered this question and 18 did not.

Answer choices	**Responses**	
	%	N
The situation could have potentially affected the manufacturing license	48,48 %	16
The situation involved advertising and promotional activities	48,48 %	16
The situation created an ethical dilemma	45,45 %	15
The situation involved batch release and certification	24,24 %	8
The situation involved regulatory compliance	57,58 %	19
Other (please specify)	12,12 %	4
Total respondents		**33**
Non-respondents		**18**

The above results demonstrate a wide spectrum of risks which RPs face, with each category representing serious consequences for the RP, the company, and the patients they serve. Of main concern for most of the respondents (57,58 %) was the category, "decisions which affected regulatory compliance". In addition, almost half of the RPs

attested that decisions would have negatively affected the manufacturing license (48,48 %), advertising and promotional activities (48,48 %) and issues of ethics (45,45 %). Such concerns are key to the pharmaceutical manufacturing sector and therefore need attention.

4.4 DISCUSSION ON RESULTS FOR PHASE 1: SURVEY QUESTIONNAIRE

4.4.1 Sample size: Response rates to surveys are known to be low, approximately 30 % (Nulty, 2008). A total of 102 RPs responded to the survey, from a total of 268 RPs in the pharmaceutical manufacturing sector, arriving at 38,06 %. Therefore, this study met its target sample size.

4.4.2 Age, experience and seniority level of respondents: Two thirds (66,67%) of respondents were in the range 40 years and over and approximately two thirds of respondents (63,22 %) had more than 5 years of experience at the time of their registration. These results appear to indicate that the majority of RPs did have experience prior to being registered as RPs in the pharmaceutical manufacturing sector. It could also indicate that the survey was completed by the older RPs and that a smaller number of the younger, more inexperienced RPs did not respond to the survey.

Approximately two thirds of respondents felt that their level of seniority provided sufficient authority for their role as RP. This result is contrary to the hypothesis for this study, that the majority of RPs are not sufficiently experienced and do not feel they have sufficient authority for their role as the RP.

A limitation of this study is that it calls on the RP to rate themselves in terms of their perceptions of their own level of competence, a subjective assessment. Had another arm been added to this study, which included non-RPs and their impressions of the competence of the same RPs (the focus of this study), the results may have revealed more robust data. It is possible that incompetent RPs do rate themselves as competent. The phenomenon of being unaware or ignorant of one's own incompetence, has been studied across various fields and is not unusual (Dunning, Johnson et al, 2003). It is therefore, not conclusive evidence that RPs rated themselves as competent.

4.4.3 Exclusion from far-reaching decisions which may have impacted the RP role: for the fifty RPs who responded to this second survey, it is significant that only a quarter (26 %) of respondents indicated that they have been included in far-reaching decisions which impacted their role. Therefore, approximately three quarters (74 %), either felt that they had been excluded, or that they were unsure whether they had been excluded. The responses to the situations in which RPs felt they may have been excluded from, demonstrate a wide spectrum of risks associated with their role as RPs in the pharmaceutical manufacturing sector. Not only do the identified risks cover a wide spectrum, each individual risk may carry serious consequences for the RP, the company, the patient, and for the pharmacy profession.

The next section provides the results and discussion for the qualitative research

4.5 QUALITATIVE RESEARCH RESULTS

The following results represent a thematic analysis of the responses obtained from the interviewees for the semi-structured interviews. The results are divided into responses from the statutory bodies (Phase 2A), and non-statutory bodies (Phase 2B). The statutory bodies referred to representatives from the SAPC (n=1) and the secretariat of the MCC (n=2). Individuals from the non-statutory bodies consisted of experienced RPs in the industry who interact with RPs, such as trainers to the pharmaceutical manufacturing sector (n=3), a representative from the Marketing Code Authority (n=1), and from the professional body, the PSSA (n=1).

The statutory bodies were chosen to determine their expectations and perceptions of the RP role in the pharmaceutical manufacturing sector, from their unique perspective. A brief overview of the key bodies selected for interviews, is provided in Appendix 7.

Criteria for the non-statutory bodies were as follows: all candidates had to be RPs, have over 10 years of experience in the pharmaceutical manufacturing industry, have direct involvement with other RPs, especially newly registered RPs. The trainers to the

pharmaceutical manufacturing sector were considered ideal candidates for interviews as they met all criteria and dealt directly with the majority of newly registered RPs. Trainers from three different companies were selected for the interviews to determine reliability of findings from different target groups within the study. The Marketing Code Authority (MCA) regulates the marketing and advertising of medicines with reference to the Marketing Code. In terms thereof, a company's internal procedure for the approval of advertising material should have sufficient checks and balances to ensure a robust process. Advertising should always be fair, accurate, balanced, ethical, and meet all necessary legal requirements as well as the industry standard, as set out in the Marketing Code. The MCA mediates disputes between pharmaceutical companies regarding advertising practices alleged to be in breach of the Marketing Code. A breach of the Marketing Code exposes both the RP and the company to serious risk, including criminal conviction. It is for this reason that a representative from the MCA, who met the before-mentioned criteria (experienced RP in the pharmaceutical manufacturing sector), was also interviewed and included for this qualitative phase of the research.

A proposed list of questions as provided to the statutory bodies, is attached in Appendix 5; the additional list of questions for the interviewees from non-statutory bodies, is attached in Appendix 8.

4.6 RESULTS FOR PHASE 2A OF SEMI-STRUCTURED INTERVIEWS WITH STATUTORY BODIES

The responses to interview questions are summarized below. Responses to questions 1 and 2 are combined hereafter.

4.6.1 Confirmation of the basis for the RP role and responsibilities: Pharmacy Act, No. 53 of 1974 and the Medicines Act, No. 101 of 1965, Good Pharmacy Practice guidelines and Codes of Conduct; Services for which a pharmacist may levy a fee; Good Manufacturing Practice; Good Wholesale Practice (draft for comment).

4.6.2 Inquiry regarding guidelines specific to the role of the RP in the pharmaceutical manufacturing sector

Both the MCC and SAPC representatives agreed with the listed basic requirements. The SAPC representative did not refer to other Acts, guidelines or codes. The MCC representatives referred to other requirements such as, knowledge of contracts and the Marketing Code. All interviewees emphasized the importance of in-depth knowledge of the legislation, the guidelines, and the codes. All confirmed that there are no specific guidelines for RPs.

4.6.3 Support for applicant RP for the pharmaceutical manufacturing sector e.g. guidelines/code of practice?

The statutory bodies responded that there were no draft guidelines in process. The MCC representative explained the MCC's role as regulator of the medicine in terms of quality, safety and efficacy, to safeguard public health. Accordingly, support to the RP does not fall within its mandate. The MCC inspects the manufacturer as a pharmacy registered for manufacturing activities including importing and exporting. The MCC deals with the entity (the company) which holds the license. The RP does not get the license; the license is issued to the company. The RP is employed by the company as the person responsible for ensuring compliance with the conditions of the license. The SAPC is the custodian of the profession; it looks at the professional roles and responsibilities of the pharmacist, the person, and not at manufacturing GMP issues which are central to MCC inspections. Since MCC is not responsible for the professional, they may review and give input on any guidance for RPs if their advice is sought, but they will not initiate or drive such an initiative.

The application for registration as RP is made online through the SAPC website. Guidance for the professional duties and responsibilities of the RP are given in the Medicines Act, the Pharmacy Act, the SAPC's ethical rules and Good Pharmacy Practice. Further guidance is provided in the MCC's SA Guide to GMP, especially chapter 2 (personnel) and Annex 16 thereof (Organisation and Personnel).

The requirements for registration as RP are that the B Pharm graduate has completed both internship and community service. If these requirements are met, the application

primarily fulfils an administrative requirement rather than a basis for assessment of the candidates' suitability for the RP position. The SAPC does not assess the RP-candidates' experience; the application is dealt with more as a recording than an assessment for suitability. The assumption of the SAPC is that the company, which has chosen the best candidate and undertakes to provide necessary training where required, has made the assessment.

The SAPC registers the RP, which is a prerequisite for the application to the MCC for the manufacturing license for the manufacturing company, which is registered as a pharmacy with the SAPC. Hence, the MCC does not assess RPs' applications. The MCC assesses the license application of the manufacturing company. Information regarding the experience and seniority level of the RP forms part of the application. At this point, the RP is already registered as such. The MCC does not request the SAPC to reconsider the registration of a RP. The true test of the RP's suitability and competence would be determined during inspection. The MCC grants the manufacturing license to the company, the manufacturing pharmacy. This license places several obligations on the RP nominated therein.

The SAPC considers its current approach to be very supportive of the RP. There are several lines of communication between the SAPC and RPs, namely direct access to a SAPC representative dedicated to the province, various levels of engagement for all pharmacy sectors e.g. forums for pharmaceutical services, industry groups and associations, and meetings with RPs. However, the SAPC is willing to address valid issues should these be identified within their mandate.

4.6.4 Continuous Professional Development: possibility of it becoming mandatory for the RP in the pharmaceutical manufacturing sector

The SAPC representative confirmed that there is draft legislation under review which is expected to come into law in the near future, possibly within a year, which will make the recording of CPD a mandatory professional requirement.

4.6.5 CPD training specifically designed around the new RP in the pharmaceutical industry

The SAPC did not consider it their role to dictate/ prescribe or recommend the type of training for any sector of pharmacy. Since Continuous Professional Development was required of all professionals, it is the responsibility of the RPs to assess their own training needs and the *recording* of such appropriate training, was the mandatory aspect. There was no plan to develop any recommended list of training requirements for any of the pharmacy sectors.

4.6.6 Seniority and authority of the RP in the pharmaceutical manufacturing sector; plans to assist the RP in developing leadership capability

The SAPC representative confirmed that the law does not require that the RP position be that of a manager, rather, that it is for the company registering that RP to choose the best candidate in terms of experience, competence and qualification, and then to ensure that the RP is supported with all necessary and appropriate training including ongoing training, and given sufficient authority to execute their duties as RP. It is a GMP requirement that the company define the necessary knowledge, skills, and attributes necessary for their employees to perform their GMP tasks with competence. Hence, the possibility that companies may be registering inexperienced RPs is not considered that problematic in light of the shortage of skilled professionals, including pharmacists. For this reason, the SAPC do not foresee amending their minimum requirements for RP registration as this may result in more pharmacies not having an RP, which would lead to an untenable situation. Furthermore, the SAPC considers the current requirement (B Pharm graduate who has completed the internship and community service) to be sufficient preparation for the role of RP, irrespective of the sector, with the understanding that the person nominated by the company, was the best candidate and ongoing training would be provided as required.

The SAPC considers itself to be supportive of the RP, with information regarding further training currently available on its website. There are no specific plans for the SAPC to

develop RP leadership capability, as this is not its mandate. If a trainer in the industry wanted the SAPC to review and accredit a leadership training program for pharmacists, the SAPC would assess it, but it would not initiate such a project.

The MCC representative agreed that the RP role in the manufacturing sector, requires considerable experience over several aspects which affected GMP and the company's license. The MCC representative agreed that the ideal position for the RP was at the executive level, that is, reporting directly to the head of the company, or being the head of the company. Such seniority would provide the requisite authority to ensure execution of the RP duties. The MCC is aware that there are inexperienced RPs who lack sufficient authority within their companies to perform their duties adequately and to fulfil their responsibilities. Such RPs are a risk to the company, to patients, and the public whom the MCC have a legislative duty to protect. As the regulator of the medicine, the MCC noted that where the RP reported directly to the head of the company, that such companies had fewer critical issues and represented a lower risk in terms of patient safety. The MCC inspectors have been in situations where they had questioned the company organogram in terms of the authority level of the RP, and made recommendations for SUCH improvements. In addition, MCC inspections have revealed that there are RPs who lacked sufficient experience, and in such cases, made recommendations for improvement to the company in that regard.

As the regulator, the MCC is not the appropriate body responsible for training of RPs. In general, the MCC would gladly review any initiative in this regard if requested to.

4.6.7 Consequences for the RP who has been found guilty of failure to fulfil their responsibilities/ major misconduct

The SAPC representative emphasized that although they are enjoined to uphold and safeguard the rights of the public, and to foster acceptable standards of pharmaceutical practice, they are not punitive in their approach. SAPC consists of several committees, such as, committees for disciplinary enquiries and preliminary investigations. The RP

would receive fair assessment and support, as the emphasis was to uphold the standards, encourage good practice, and uphold the reputation of the profession.

The MCC, as the regulator, viewed the situation from the perspective of the medicine which is for public use, and not from the perspective of the professional, the pharmacist. It should be noted that an infringement would be borne jointly by the head of the company and the RP. In addition, the Department of Health held all directors of the company responsible for compliance to the requirements of the Medicines Act. All directors of the company are required to confirm this in writing as part of their trading license with the Department of Health. The MCC also stated that gross misconduct could result in the company losing their manufacturing license. A few examples of gross misconduct were discussed such as, failure to implement corrective actions within a mutually agreed timeframe following an MCC-inspection; promotion of medicines beyond the scope of the registered package insert; promotion of schedule 2 to 5 medicines to the general public; failure to implement timeous safety restrictions despite MCC-follow up requests; and, manufacture of product beyond the scope of the manufacturing license (e.g. manufacture of a solid dosage form in a facility licensed only for liquid dosage forms).

Suspension or loss of the manufacturing license would be disastrous for any company, affecting all its products. Since it is the MCC that may revoke the license, it is the MCC that “gives teeth” to the RP role. In this way, the MCC is in a position to send an industry-wide message to company heads, regarding the importance of GMP, licensing obligations and the RP role.

Regarding the current training of RPs for such repercussions, the SA GMP guide and the Acts and their regulations give ample guidance on the scope and depth of the RP duties and responsibilities and failure to comply would jeopardize the license.

4.6.8 Accreditation of courses/workshops in the industry which train on the responsibilities of the RP

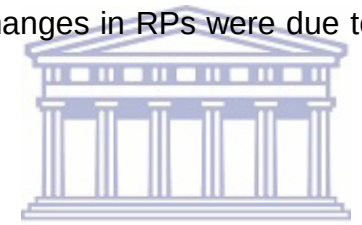
The SAPC representative is responsible for accrediting all providers of pharmacy education which includes post graduate training via short courses or workshops. SAPC-

accredited service providers in the industry, including those training on the RP's role and responsibilities, are listed on the SAPC website's Educational section. However, not all workshops/courses available in the industry have been submitted to the SAPC for assessment and accreditation.

Trainers to the pharmaceutical manufacturing sector may consult the MCC's secretariat for advice on course content. However, as the regulator, the MCC does not directly develop training courses for the industry, as this would be a conflict of interest.

4.6.9. Turnover of RPs in the pharmaceutical manufacturing sector

With regard to the turnover of RPs in the pharmaceutical manufacturing sector, both the SAPC and MCC stated that changes in RPs were due to several factors and no further comment was available.



4.6.10 Consequences for RPs where they have been found negligent?

By law, the RP runs the risk of losing his/her registration as a professional. In extreme cases, the SAPC may remove the guilty RP from the roll of pharmacists, that is, not only can they not work as a pharmacist for the company involved, but they may not work as a pharmacist in the country for any company/pharmacy. Where the act of non-compliance involves GMP and licensing, the MCC may revoke the company's license, affecting all products of that company.

The SAPC representative reiterated that it did not consider its role to include policing the profession, but rather as a supportive role, preserving and maintaining professional standards. The MCC also saw its role as supportive to the RP, with the emphasis on safeguarding the public. Thus, support may mean the timeous implementation of corrective measures such as, the recall of affected batches of sub-standard product.

4.6.11 Preparation of RPs for management of proposed local pharmaceutical industry in SA

The SAPC representative's general comment was that the whole process, from assessment and accreditation of the B Pharm curriculum, the educational institution, selection of students for B Pharm, registration of tutors and their interns, as well as assessment and regulation of the pharmacies and all personnel handling medicines, served to prepare the pharmacist for very responsible roles. The intention is also to give the B Pharm student a broad-based education, ensuring a generalist graduate who, with a sufficiently broad knowledge base could provide a very wide variety of pharmaceutical services. Thereafter, it is for the company to ensure that they select suitable candidates for the role of RP according to the company's needs. The company is also responsible for ongoing training of the RP and other pharmacists.

This concludes the results for the interviews with the representatives from the MCC secretariat and the SAPC.

The following section provides the results for the interviews with other key players in the industry, namely, the trainers, the professional body and the Marketing Code Authority representative. For this audience a separate set of questions were developed, the details of which are set out in Appendix 7. Interviewees were provided with the questions developed for the statutory bodies, should they wish to comment on them, as well as their specific list of questions. This additional list of questions was developed to explore the RP role from the perspective of the industry, the pharmaceutical manufacturing sector, striving to meet the requirements and implement the legislation, guidelines and codes of the statutory bodies.

The results are presented as a summary, representative of all interviewees from non-statutory bodies, namely, trainers to the pharmaceutical manufacturing sector (n=3), a representative from the Marketing Code Authority (n=1), and from the professional body, the PSSA (n=1).

4.7 RESULTS FOR PHASE 2B OF SEMI-STRUCTURED INTERVIEWS WITH NON-STATUTORY BODIES

4.7.1 Confirmation of the basis for the RP role and responsibilities: Pharmacy Act, No. 53 of 1974 and the Medicines Act, No. 101 of 1965, Good Pharmacy Practice guidelines and Codes of Conduct; Services for which a pharmacist may levy a fee; Good manufacturing Practice; Good Wholesale Practice (draft for comment).

All interviewees agreed that the listed requirements were correct. In addition, all interviewees referred to other requirements as important references as well, such as, the Consumer Protection Act No. 68 of 2008; Counterfeit Goods Act No. 37 of 1937; Protection of Personal Information Act No. 4 of 2013; the Marketing Code; Administrative law and contracts. All interviewees emphasized the importance of in-depth knowledge of the legislation, the guidelines, and the codes and confirmed that there is no specific guideline for RPs.

4.7.2: Key competencies considered to be essential for the RP role

The interviewees each named several competencies which they considered essential for the RP role. All suggestions were collated and used to draw up a proposed competency framework, grouping competencies under themes. The framework proposed by Bradley (2013), regarding the competencies of sub-structure and sub-district pharmacists in the primary healthcare setting, was used as a starting point. This study is mentioned in more detail in chapter 2, section 2.5. A proposed competency framework for RPs in the pharmaceutical manufacturing sector, based on the input from all interviewees, is presented in Chapter 5, section 5.2.

4.7.3: Courses which cover training on the essential competencies for the RP role

The following trainers who provided training courses/workshops specific to the RP role, were mentioned during interviews: Joy Berry-Baker at QuadPharma, Leneri du Toit and

Esthi Beukes for SAAPI, Salima Mahomed and Salma Ismail for Twins Foundation, and MRA regulatory consultants.

4.7.4: Ideal training program for a newly registered RP with limited experience in the pharmaceutical manufacturing sector

All interviewees mentioned the competencies listed in question 2. In addition, the following deserve special mention: all interviewees agreed (i) that experience in the industry, across various departments, was essential for success, as in-depth knowledge of the relevant legal requirements would enhance the RP's ability to defend his/her position, both internally with other managers or management, as well as externally with the MCC or SAPC during inspections; (ii) that mentoring of the candidate RP in the role of deputy RP, prior to accepting the role of RP is essential; (iii) on the importance of hands-on knowledge of batch review and certification; hands-on knowledge (preferably via a workshop with numerous real life examples) of the marketing code and certification process as well as high level understanding of the complaints process where there is a potential breach; and (iv) the importance of self-management and development, taking the initiative, self-empowerment and upholding the image of the profession.

4.7.5: Role of the MCC, SAPC and PSSA/SAAPI regarding the support for the newly registered RP

All interviewees were of the opinion that the current situation was not ideal and more could be done. The expectations can be summarized as follows, as they relate to the role that bodies such as the MCC, SAPC and PSSA/SAAPI, could play in supporting the new RP:

Interviewees' comments regarding the MCC's role: most interviewees felt that the MCC's role was not key in this regard, that they could be called on for advice but that as the regulator, they were not directly responsible for support of the RP.

Interviewees' comments regarding the SAPC's role: most interviewees felt that the SAPC could do more to support the RP and their suggestions included:

- provision of a declaration document attached to the RP application which outlined the RP roles and responsibilities with suggested training
- development of a mandatory training course to be run over an extended period e.g. several modules over 3 months, after which the attendee would receive accreditation
- developing a post graduate qualification specifically for the pharmacist in industry, the pharmaceutical manufacturing sector
- developing a list of training programs to guide the selection of CPD for the RP in industry

PSSA/SAAPI: most interviewees felt that the professional body, especially the sector for the pharmacists in industry, should be the key entity driving development of courses which should obtain accreditation from the SAPC.

Employers: most interviewees felt that, although there were many companies that were supportive of the RPs training needs, there were also significant numbers of RPs who were not being supported by their employers. In these cases, the RPs were seen as a burden and an expense, and even as a token. For such situations, it is important to bear in mind that the legislation requires the employer to ensure that the pharmacy has sufficient staff, with appropriate qualifications and training to carry out their duties, and that ongoing GMP training is a pre-requisite for GMP compliance. The employer has an obligation to choose a competent candidate, give the RP sufficient authority i.e. direct report to the head of the company, and support the RP's training.

4.7.6: Role of academia in preparing the pharmacy student for the role of RP

The responses to this question fell in both camps, i.e. yes, academia could play a role, and, no, it was not the responsibility of academia to prepare or educate pharmacy students regarding the RP role in the pharmaceutical manufacturing sector. On the one hand, it was acknowledged that academia trained the student on theoretical aspects, which needed practical application and experience in the manufacturing sector, before the RP role could be understood. On the other hand, it was suggested that academia include more awareness of the RP role, as it brings together so many aspects of the theoretical training on research and development, clinical operations, etc., and that this awareness could be done in the final year of study. Academia was also considered to be key in developing a post graduate specialized qualification specific to the manufacturing sector.

Following these responses, the researcher attempted to contact a few universities regarding lectures on the RP role in industry. One university did respond, confirming that the RP role was discussed with second year students in lectures on Good Pharmacy Practice and again in fourth year, the students received lectures on regulatory affairs which also introduced the RP role. Due to time constraints, no other information was obtained from any other university regarding lectures that cover the RP topic.

4.8 DISCUSSION ON RESULTS FOR PHASE 2, SEMI-STRUCTURED INTERVIEWS

Interviews provided rich data on the topic in addition to responses to questions developed prior to the meetings.

The following discussion points covered during the interviews were considered pertinent to this topic:

Initiatives of SAAPI, a sector of the PSSA: The Professional Society of South Africa, the PSSA is an independent association for pharmacists and allied professionals in the healthcare industry. SAAPI, the South African Association of Pharmacists in Industry, is the sector of the PSSA which represents pharmacists and allied professionals in the pharmaceutical manufacturing sector. Other sectors include hospitals and institutions, academia, and retail/community pharmacy.

The representative of SAAPI mentioned a number of projects which they are investigating for future rollout to the pharmacists in industry. Internally at SAAPI, they have identified various issues to be addressed, a few of which have already started. Some of these are to:

- offer training at different levels to cater for pharmacists with differing levels of experience, from basics for juniors to more advanced information for the more experienced pharmacists.
- offer business skills for the pharmacist, with a focus on topics such as management and leadership, finance, forecasting and budgeting, computer skills, as well as "soft" skills, e.g. time management.
- encourage enrollment and participation from more of the younger pharmacists
- broaden its focus, from mainly regulatory topics, to include topics such as distribution and quality assurance
- build better relationships between the different sectors in pharmacy, and
- grow the profession.

It was also mentioned that SAAPI was working at improving their dissemination of information, as much of the work they do is not widely known. Some support for the RP was already available and perhaps it was necessary for more active marketing of courses on offer.

Recalls: During one of the interviews with a trainer to the industry, the interviewee raised the topic of recalls, that it was their personal impression that there has been an increase in the number of recalls in recent years. This may be attributed to the RPs' inexperience regarding batch certification and release, leading to a higher risk of error. Recalls may occur for several reason, and this was one of the reasons too. Following this interview, the researcher contacted both the MCC as well as an independent bulk mailing company, Medpages, for information on recalls. Due to time constraints, information from the MCC is still pending and information from Medpages is very limited.

Medpages was able to provide information as follows: annual figures for recall letters for the period, 2002 to 2010. Thereafter, one figure for the total period, 2011 to date, May 2017, with approximate annual figures for the same period.

An employee of Medpages provided information regarding recalls, with the company's permission. The information provided is tabulated below. Information for the competitor company, Promail, was also available, as it was common practice for companies to request quotes from both bulk mailing companies. In this way, one could calculate the total number of recall letters for the period.

Promail ceased business in approximately 2009-2010. Medimail had changed ownership in 2011 and again a few years later. The different systems on which the data were stored, made it difficult to access specific annual figures at short notice, hence the estimates. The approximate figures provided, courtesy of Medpages, appear below.

Table 3. Recalls/DHCP letters by Bulk mailers:

Table 3.1: Medimail and Medpages 2002-2010:

Year	Medimail (+ Promail)	Total
2002	2 (+1)	3
2003	3 (+1)	4
2004	3 (+1)	4
2005	4 (+1)	5
2006	5 (+1)	6
2007	7 (+2)	9
2008	24	24*
2009	8 (+2)	10
2010	9	9

Table 3.2: Combined figures for Infixion, New Media and Medpages

Year	Combined figures for Infixion, New Media and Medpages
2011-May 2017	209
Estimates for the period: 2011 – May 2017	
2011	±10
2012	±15
2013	±20
2014	±30
2015	±40
2016	±60
2017 (5 months)	±30

*In that year, several companies sent out similar letters for a common active ingredient.

Consequences for the company and others where the RP has insufficient experience:

The following list represents a summary of the risks that a company may face when the RP has insufficient experience, as discussed by interviewees:

- Consequences for the final user, the patient: Poor decision making skills and lack of assertiveness and/or experience, may lead to over-cautious approach on the one hand, or a risk of releasing non-compliant product to the market. An over-cautious approach may lead to delayed batch releases which results in stock shortages. The non-compliant product on the market may lead to recalls or increased adverse events. Stock shortages cause interruptions in patient medication. Consequences for the patient are numerous, from therapeutic switches where prescribed medicines are not in stock, to adverse events from use of non-compliant medicine.
- Consequences for the company: the manufacturing company is a complex web of systems, with numerous departments. The RP also performs a coordinating role between different departments. Where the RP has insufficient experience, he/she may unconsciously or consciously rely on decisions of non-pharmacists. Such

decisions could be made with a business-focus instead of a pharmaceutical, scientific focus. In the long run, many such decisions place the company's license at risk.

- Consequences for interpersonal relationships: where the RPs are not considered competent by their peers, decisions may be made in their absence or without due consultation. Such an RP may lose credibility amongst peers in the company. A situation of tokenism may result, where the RP holds the title only in name, but does not perform the duties, and relies on others to do so. Such situations create disharmony and are risky for the company (Wright and Taylor, 1998, p.1). Non-RP pharmacists in that company may have to take on more responsibility beyond their own roles and job descriptions.

4.9 CONCLUSIONS

This chapter provided an overview of the results for the quantitative and qualitative research methods used in this study. This included the criteria for selection of candidates for the qualitative phase. Finally, the data collection methods and data analysis procedures used for interpretation of the data, were covered.

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

This study was undertaken to investigate the views, perceptions and attitudes of RPs in the pharmaceutical manufacturing sector pertaining to their training as RPs in this sector. The study endeavoured to analyse the influence that RPs' training and experience have had on their role as RPs. The ultimate objective of this study, was to assess whether the RP in the pharmaceutical manufacturing sector, has adequate training at the time of their registration as the RP in the pharmaceutical manufacturing sector and in the years immediately thereafter, up to five years later. The study also aimed to identity areas in RP training, support and development that could be improved upon.

The key focus area of this research was to determine the RPs role from the perspective of the RPs themselves, as well as from the perspective of the statutory councils, the SAPC (n=1) and the MCC (n=2), and from the perspective of non-statutory bodies such as trainers to the pharmaceutical manufacturing industry (n=3), the professional association (PSSA) (n=1) and the Marketing Code Authority (n=1). Results from the study indicated that there is a need for increased support for the RPs.

5.1 INTERPRETATION OF RESULTS FOR QUANTITATIVE RESEARCH – SURVEY QUESTIONNAIRE

Given that, two-thirds of respondents (66,67 %) to the survey were over 40 years old, that just under two thirds (60,92 %) had indicated that they possessed the necessary skills and training for their role at the time of registration, and that approximately half the respondents (48 %) had been in the role of the RP for over 5 years, it may be inferred that the majority felt competent in their role as the RP, that the majority of respondents

were experienced pharmacists, and possibly experienced RPs. However, despite these positive results, some responses point to what may be problematic practices in the industry. In response to the question - whether RPs felt there were times when they had been excluded from far-reaching decisions which impacted their role – just less than half (43,02 %) responded positively ("Yes"), approximately the same percentage (44,19 %) responded negatively ("No") with a few (12,79 %) who were not sure ("Unsure/maybe"). Options regarding exclusion from far-reaching decisions, included: situations that involved the manufacturing license, promotional activities, ethical dilemmas, batch release and certification, and regulatory compliance. In addition, there was an option to provide other situations. It is significant that, of the thirty-three RPs who responded to this question, all selected more than one category. These categories demonstrate a wide spectrum of risks that RPs face, with each category representing serious consequences for the RP, the company, and the patients they serve.

An area of concern was whether line managers evaluate the RPs' performance and the frequencies at which such evaluations are conducted. Ideally, all RPs should be evaluated regularly on their role, given the importance of the RP role in retaining the manufacturing license, the companies' license to operate, yet, less than half the respondents (46,51 %) agreed that this was the case, that they were regularly evaluated on their performance as RPs. This result may indicate that a significant number of companies do not place sufficient emphasis on regular and continuous monitoring to ensure that the RP's performance is optimal. One may speculate that the company is sufficiently satisfied that they have a registered RP, and are not overly concerned with the competency level or ongoing performance of that RP.

Training is another area of concern. Over a quarter of the respondents (27,91 %) were not aware of RP-specific courses. Over half (55,17 %) of the RPs had not attended RP-specific courses. Training of all pharmacists in the pharmaceutical manufacturing sector, including the RP, is a GMP requirement. Companies are expected to define the necessary knowledge, skills, and attributes necessary for their employees to perform their GMP tasks with competence and to provide the necessary training to enable RPs to attain the required level of competence. The overwhelming majority of respondents (89,54 %) were in favour of the development of guidelines endorsed by the MCC/SAPC/PSSA, to assist

the RP in their role. The option of mandatory training modules specific to the RP role received substantial support by respondents (82,56 %), which demonstrates that consideration must be given to the development of RP-specific training, that has been developed in partnership with the MCC and SAPC.

5.2 INTERPRETATION OF RESULTS FOR QUALITATIVE RESEARCH – SEMI-STRUCTURED INTERVIEWS

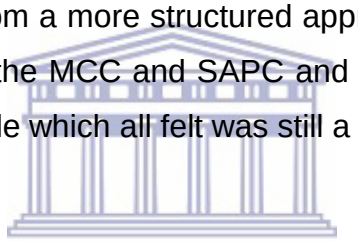
All representatives of the trainers to the pharmaceutical industry as well as the MCC and the MCA representatives were in agreement that there are registered RPs who are not aware of their duties and responsibilities and are often not fully aware of the implications of their lack of knowledge. The interviewees were also concerned that some companies, by not giving the RP role the level of importance and authority it required, were practicing tokenism (Wright and Taylor, 1998), and employed RPs purely to fulfil the administrative legal requirement to obtain a manufacturing license. This is especially risky where the RP is not very experienced, does not occupy a senior position and lacks assertiveness.

The MCC representative suggested that closer collaboration between the MCC and the SAPC could facilitate the registration of more RPs who were appropriately experienced for the pharmaceutical activities of companies. The MCC could, in such a scenario, be part of proactive assessments of RP applications, prior to the SAPC registration. The MCC representative was concerned that, in addition to there being RPs who are not sufficiently experienced for their role, there are also RPs who, although having several years of industry experience, lacked essential RP experience and this impacted negatively on their competence.

The MCC representative noted that RPs are not always aware of the scope of their duties and responsibilities. For example, although it was fairly common knowledge that batch certification and release were key duties, there were many RPs who were not sufficiently knowledgeable on other key aspects, such as regulatory compliance, marketing and advertising, pharmacovigilance, and other GMP areas such as warehousing, distribution and logistics. It was also noted that not all RPs had the necessary in-depth knowledge of

the applicable laws, regulations, guidelines and codes. Continuous learning and application of the law was essential and key to demonstrating the competence of the RP in practice.

During interviews with the trainers to the industry, another concern which was raised, was that RPs are not always aware of their “blind spots” and some are unwilling to admit their lack of knowledge. This could be due to several factors including ignorance. The opinion was also expressed that mentoring of the new RPs was one possible way of enhancing their skill and competence levels. All trainers interviewed agreed that it was necessary for new RPs to have extensive training which covered essential aspects of their duties in a modular fashion, including training in a workshop environment. It was unanimously agreed that although the training they offered attempted to cover as much as possible, that RPs would benefit more from a more structured approach, a training that had been developed in consultation with the MCC and SAPC and endorsed by them. This would also give credibility to the RP role which all felt was still a way away from where it should be.



Although Continuous Professional Development (CPD) is a pharmacist’s professional responsibility, there are no RP-specific CPD requirements or an RP-competency framework outlining training requirements to strengthen competencies required for the RP role in the pharmaceutical manufacturing sector. Therefore, it is possible that the RP may participate in the CPD program fully, yet still not receive training that is specific to their responsibilities as RP in the pharmaceutical manufacturing sector and sufficient to cover all necessary aspects of their role, having regard to the expectations of the SAPC and MCC. For this reason, it is necessary that there be guidance from the SAPC and MCC, on RP-specific CPD. This will ensure that, over time, the newly registered RP is assured of attaining the prerequisite skills to fulfil their duties.

Based on the input from all interviews, a proposal for a competency framework was developed. The basis for the framework was taken from the framework proposed by Bradley (2013), regarding the competencies of sub-structure and sub-district pharmacists in the primary healthcare setting, discussed earlier in section 2.5. Several competencies mentioned during interviews, were specific to the RP in the pharmaceutical manufacturing

sector, hence the basic table from the local study (Bradley, 2013) was adapted to reflect this difference. The table below could function as a starting point for the development of a training program, consisting of several modules specific to the RP role.

Table 4. Proposed competency framework for the RP in the pharmaceutical manufacturing sector

PROFESSIONAL PHARMACY PRACTICE	
Legal aspects – in depth knowledge of - Medicines and Related Substances Control Act Act 101 of 1965, as amended - Pharmacy Act, Act 53 of 1974 Others: - Consumer Protection Act 68 of 2008 - Counterfeit Goods Act 37 of 1937 - Protection of Personal Information Act 4 of 2013 General: - Administrative law - Contracts Licensing obligations: obligations to ensure that the company acts in accordance with the requirements of its license; regulation 19 to the Medicines Act sets out provisions of the license, including Site Master File, compliance with GMP Regulatory aspects of pharmacy practice - Understand principles of registration of new products, maintenance of registered products, change control between master documents, production documents and dossiers - MCC Guidelines for regulatory affairs - WHO and ICH principles and African harmonization initiatives - Understand MCC structure, committees, secretariat functions, processes - Understand delegation of MCC liaison	**Technical aspects of pharmacy practice – Manufacturing and GMP** - Manufacturing operations; specialized knowledge where necessary e.g. sterile products - Logistics, Procurement, Warehousing and Distribution - Quality Control, qualifications, validations - Quality Assurance system; - Batch review, certification, release, Annual Product reviews - Auditing; Complaints, Recalls, Returns - GMP guidelines: SA GMP guide (currently at version 5), PIC/S, WHO. - Related guidelines: GPP, GWP, GDP, GLP, GCP - Training on GMP - Risk assessment and management
	Marketing and Sales

Regulatory Affairs - Registration of medicines – requirements for approval and maintenance of registered product - Registration dossiers; technical/quality aspects, clinical aspects, inspectorate aspects - Good Documentation Practices; documentation management - MCC Dossier Guidelines re Quality, Clinical, Inspectorate, other - Labelling: change control - Information systems - MCC liaison	- Certification on the Marketing Code - Knowledge of advertising/promotional approval processes - Understanding clinical trial publications used as references - Delegation of approval to Marketing Code Compliance Officer - Training of reps and others
Pharmacovigilance - Pre-registration Clinical operations - Post-registration adverse event reporting - Recalls and DHCP letters	**Management** - Planning and organizing - Financial management and budgeting - Human resource management - Project management - Information management - Monitoring and evaluation
Leadership - Strategic leadership and vision - Change management	
Personal, Interpersonal, Cognitive	
Personal - Self-development - Adaptability - Assertiveness - Time management - Professionalism	**Cognitive** - Problem solving - Prioritising - Decision making - Communication skills (oral and written) - Understanding delegation
Interpersonal - Relationship building - Networking - Negotiation - Teamwork - Cultural competency	

5.3 LIMITATIONS OF THE STUDY AND SUGGESTIONS FOR FURTHER RESEARCH

A few of the limitations and shortcomings of the study were, timing of the survey - most pharmaceutical manufacturing companies had an annual shutdown period or encouraged annual leave, during the period, 15 December to 15 January, thereby delaying the data collection process. Securing interviews and the authorization for the interviews, was also time-consuming, further delaying appointment time. Not all requests for interviews were accepted. Assistance from successful interviews resulted in recommendations for other interviews.

The response rate for the survey questionnaire was only 38,06 %. Although it was adequate, the majority of respondents were experienced RP, hence there is possible bias in favour of experienced RPs. Other limitations of this study were ambiguous questions, and the limited investigation into risk exposure, as only one question addressed this aspect.

Based on the results from the survey questionnaire (quantitative method) and the semi-structured interviews (qualitative method), this mixed method approach identified a possible discrepancy between the RPs' self-assessment and that of their counterparts' regarding the assessment of their competence.

The survey questionnaire addressed only the RPs in question, requesting their opinion on their own level of competency in their role. As pointed out in the qualitative phase of the survey, not all RPs are aware of their own shortcomings as RPs and may consider themselves competent where they are not. An alternative approach may have been to send a questionnaire to other managers within the same organization, who dealt with the RP, to give their opinion on the RP's level of competence. That result could have been compared to the RPs' self-assessment to see whether there were significant gaps in the perceptions of the two groups. Despite these limitations, significant data were collected which have provided valuable insights into the research question.

The mixed methods approach also helped to identify detailed aspects of RPs' competencies, which were not identified from the survey questionnaire alone, hence this approach is valuable for identifying training needs. The snowballing technique used for selection of interviewees, added to the study's rigor. This approach led to interviewees not previously considered and/or known to the researcher. Without this approach, fewer interviews would have been finalized.

5.4 SUMMARY AND CONCLUSION

Currently, the SAPC treats all applications for the RP role in the same way, irrespective of the sector in which they are employed. No additional requirements are imposed on the pharmacist applying for the role of RP in the pharmaceutical manufacturing sector. The RP in this sector is the person responsible for the manufacturer's compliance with the license conditions and thus, when compared to RPs in the other pharmaceutical sectors (such as retail, community, hospital and institutions), has additional responsibilities. These additional responsibilities flow from the conditions of the manufacturing license. Results from this study show that the RP in the pharmaceutical manufacturing sector requires additional support in terms of training on the various aspects of their role.

In spite of the limitations and shortcomings of this study, valuable insights were gathered into the RPs' perceptions of their role, as well as the perceptions of other key players interacting with the RP. Future studies could include other sectors of pharmacy, a greater number of interviews from all key bodies, with the interviews conducted after training on interview technique.

The proposed hypothesis tested was:

> Does the current SAPC minimum registration requirement (i.e. B Pharm, and experience from internship and community service), adequately support the RPs for their role and responsibilities in the pharmaceutical manufacturing sector?

Currently, the newly registered RP is left to devise their own program of CPD, without a formal competency framework for their role. Results from the quantitative phase of the

study, the survey questionnaire, point to the majority of RPs considering themselves to have the necessary competencies for their roles. Results from the qualitative phase of this study, the semi-structured interviews, show that from the perspective of the MCC, trainers in the industry, and the marketing code authority, the current RPs are not all sufficiently equipped for successful discharge of their duties. There is thus a need to develop more structured MCC/SAPC-endorsed training, which is specific to the RP in the pharmaceutical manufacturing sector, to ensure that RPs have the necessary competencies to cover the full scope of the duties. It is in the interest of the public at large that the RP is competent in their role to ensure delivery of medicines that are safe, efficacious and of good quality.

The qualitative phase of the study also identified a few grey areas regarding the roles and expectations of the SAPC and the MCC and whom each one saw as being responsible for the training of the RP. Since the SAPC is responsible for the training of all pharmacists, it is necessary for the SAPC to initiate the investigation into a competency framework for RPs in the pharmaceutical manufacturing sector. This can be jointly done with the MCC, with input from other key players such as the trainers to the industry, all pharmacists and experienced RPs in the pharmaceutical manufacturing sector.

It is proposed that a RP-specific modular training program be developed which could form part of the CPD for the RP. Initially, such CPD could be voluntary, while the program is tested, with the objective to making the training of the newly registered RP mandatory over a period of, for example, the first 2-3 years. On completion of all required modules, the RP would obtain a certificate of recognition.

There are several guidance documents available in the EU for the QP in the pharmaceutical manufacturing industry, developed by the Competent Authority or the professional body of the member state. The professional and regulatory authorities in South Africa could use these as a starting point to develop local versions of such documents, to support RPs in the local pharmaceutical manufacturing sector.

It is a GMP requirement that companies provide ongoing training of their employees. This includes all necessary and adequate training for all pharmacists they employ including the RP. Once developed, the RP-specific training could become the standard for the

pharmaceutical manufacturing sector, raising the current unmeasured, yet diverse, levels of RP competence, to a uniform minimum standard that meets both SAPC and MCC expectations. This would enhance the competency levels of the profession and ultimately contribute towards improved safety of patients.

To quote one of the RP respondents who had provided additional comment at the end of the survey:

> "…*RPs must realize that they are also responsible for the "ethics" of the business [issues which can bring a pharmacy into disrepute] which includes aspects far wider than just compliance with the Pharmacy or Medicines Control Act…"*

RPs must view themselves, not simply as legal compliance officers fulfilling a role to advance the financial interests of the company, but also as responsible for upholding sound ethical standards, being the "conscience" for the company.

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APPENDICES

APPENDIX 1: Survey questionnaire (initial) – 22 questions

RP SURVEY QUESTIONNAIRE:

No.	QUESTION	OPTIONS
1.	Please select the sector of pharmacy in which you practice:	1. Retail Pharmacy 2. Hospital/Clinic Pharmacy 3. Manufacturer (including Importer/Exporter) 4. Wholesaler
2.	Are you the Responsible Pharmacist (RP) at your place of work?	1. Yes 2. No 3. Used to be
3.	How long have you been the RP in the pharmaceutical manufacturing sector?	1. <3 years 2. 3-5 Years 3. >5 years
4.	Please select your age range:	1. <30 years 2. 31 - 40 Years 3. >51 years
5.	What degree/qualification do you hold?	1. B Pharm

		2. Dip. Pharm 3. M Pharm 4. Other (please specify): *(free text box)*
6.	At the time that you registered as RP, how many years of experience did you have in the pharmaceutical manufacturing sector?	1. Approx. 2 years 2. 2-5 years 3.>5 years
7.	Did you have experience in other sectors of pharmacy?	1. Yes 2. No
8.	If you have responded "YES" to the previous question, in what other sector did you have experience?	1. Retail Pharmacy 2. Hospital/Clinic Pharmacy 3. Wholesaler 4. Other Please specify: *(free text box)*
9.	Are you aware of any course or workshop that covers the roles and responsibilities of the RP for the pharmaceutical manufacturing sector?	1. Yes 2. No 3. If YES please specify: *(free text box)*
10.	Prior to registering as a RP, did you attend any course or workshop to supplement your roles and responsibilities as the RP for the pharmaceutical manufacturing sector?	1. Yes 2. No 3. Other Please specify: *(free text box)*
11.	After registering as a RP, have you since attended any course or workshop that covered the roles and responsibilities of the RP?	1. Yes 2. No

		3. If YES, please state the name of the course or workshop *(free text box)*
12.	Excluding workshops/courses mentioned in questions 9-11, what other training did you attend/undergo for your role, either prior to or immediately after registering as RP?	1. No formal training 2. On-the-job training including company SOPs 3. Self-training including review of Pharmacy Act No 53/1975 and Medicines Act No. 101/1965 4. Other (please specify): (*free text box)*
13.	Have you had formal management/leadership training?	1. Yes 2. No 3. If YES, please specify: (*free text box)*
14.	What is your level of seniority in the company?	1. Junior, I report to a senior manager who reports to the Person who is overall in charge of the business e.g. Owner/CEO 2. Senior, I report to the Person who is overall in charge of the business e.g. Owner/CEO 3. Executive, I am the Person who is overall in charge of the business e.g. Owner/CEO/General Manager
15.	Do you feel that your level of seniority in the company provides the required authority to enable you to exercise your role and responsibilities as the RP of the company?	1. Yes 2. No

		3. Unsure/Maybe
16.	Are there times when you feel you have been excluded from far-reaching important decisions, which may have impacted on your role as RP?	1. Yes 2. No 3. Unsure/Maybe
17.	Do you feel you had the necessary skills, qualifications, training and experience for the role of RP at the time of your registration as the RP?	1. Yes 2. No 3. Unsure/Maybe
18.	Since registering as RP, do you feel you have acquired the necessary skills, qualifications, training and experience for the role of RP? Alternately, do you feel that your experience over the years in the pharmaceutical manufacturing sector contributes to your function as an RP?	1. Strongly agree 2. Agree 3. Neither agree nor disagree 4. Disagree 5. Strongly disagree
19.	If the MCC/SAPC/PSSA developed a set of guidelines for the RP role for the pharmaceutical manufacturing sector, would this be helpful to you?	1. Strongly agree 2. Agree 3. Neither agree nor disagree 4. Disagree 5. Strongly disagree
20.	If the MCC/SAPC/PSSA developed a set of mandatory training modules for the RP role for the pharmaceutical manufacturing sector, as an annual requirement for Continuous Professional Development (CPD), would this be helpful to you?	1. Strongly agree 2. Agree 3. Neither agree nor disagree 4. Disagree 5. Strongly disagree
21.	Do you agree/disagree with this statement: You are regularly evaluated on your performance as the RP i.e. the RP role forms part of your ongoing performance assessment.	1. Strongly agree 2. Agree 3. Neither agree nor disagree 4. Disagree 5. Strongly disagree
22.	Do you have further comments/suggestions for training requirements that would optimize the RP's role at a senior level in the pharmaceutical manufacturing sector?	Optional: (*free text box*)

APPENDIX 2: Introductory email invitation to survey

Dear Responsible Pharmacist (RP)

I am a pharmacy master's student at UWC.

I work in the pharmaceutical manufacturing sector and have observed an aspect regarding roles and responsibilities of the Responsible Pharmacist that I would like to research in order to change and possibly improve workplace conditions for RPs in this sector.

As part of my Master's degree, I am conducting research entitled:

AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

The objective of the study is to explore the views, perceptions and attitudes of RPs about their role in the pharmaceutical manufacturing sector. Inquiry will be made into whether RPs consider themselves to be adequately equipped for their role and responsibilities at the time of registration and thereafter, whether they consider themselves to have acquired the necessary training to fulfil their CPD requirements. Part of the broader aim of this research is to identify ways in which the RP could be better supported in the CPD training context.

Your contribution to this study is extremely important and its success depends on the number of participants who complete the questionnaire as accurately as possible. Please assist me in submitting a truthful reflection of RPs in the pharmaceutical manufacturing industry. Participation is entirely voluntary and anonymous; you are not required to disclose any identifiable information and you can withdraw at any time. All data collected will be kept confidential. By completing the survey, you indicate that you voluntarily participate in this research.

The survey will take approximately 10 minutes to complete. Please click on the link below or paste it in your browser:

researchlink

Fullwebdaddressforsurvey

Dissemination: The research will be written up as a Master's dissertation and may be followed up with a journal article. In this process the confidentiality of all participants will be maintained as the survey is anonymous. The research report, as well as any publication emanating from the research can be made available to you upon completion of the review process. If you are interested you are welcome to contact me regarding these documents.

Thank you in advance for helping me with this important research project. If you have any queries and would like to discuss them, please contact me:

Leila Dockrat

RPSurveyLD@gmail.com Cell: 082 xxx xxxx

APPENDIX 3: Survey questionnaire (follow-up) – 1 question

Email invitation with repetition of question 16 from initial survey, as link to second survey:

Dear RP

Sincere thanks for responding to my recent survey regarding your role and responsibilities as the RP in the pharmaceutical manufacturing sector. Your responses are most valuable to my study.

I would like to expand on Question 16 (included below). I therefore, have one more question which will take only a minute of your time.

Participation is entirely voluntary and anonymous.

Should you wish to see the original survey or have further questions in this regard, please contact me at: rpsurveyld@gmail.com or, cellphone: 082 xxx xxxx

Thank you sincerely for your assistance with this study.

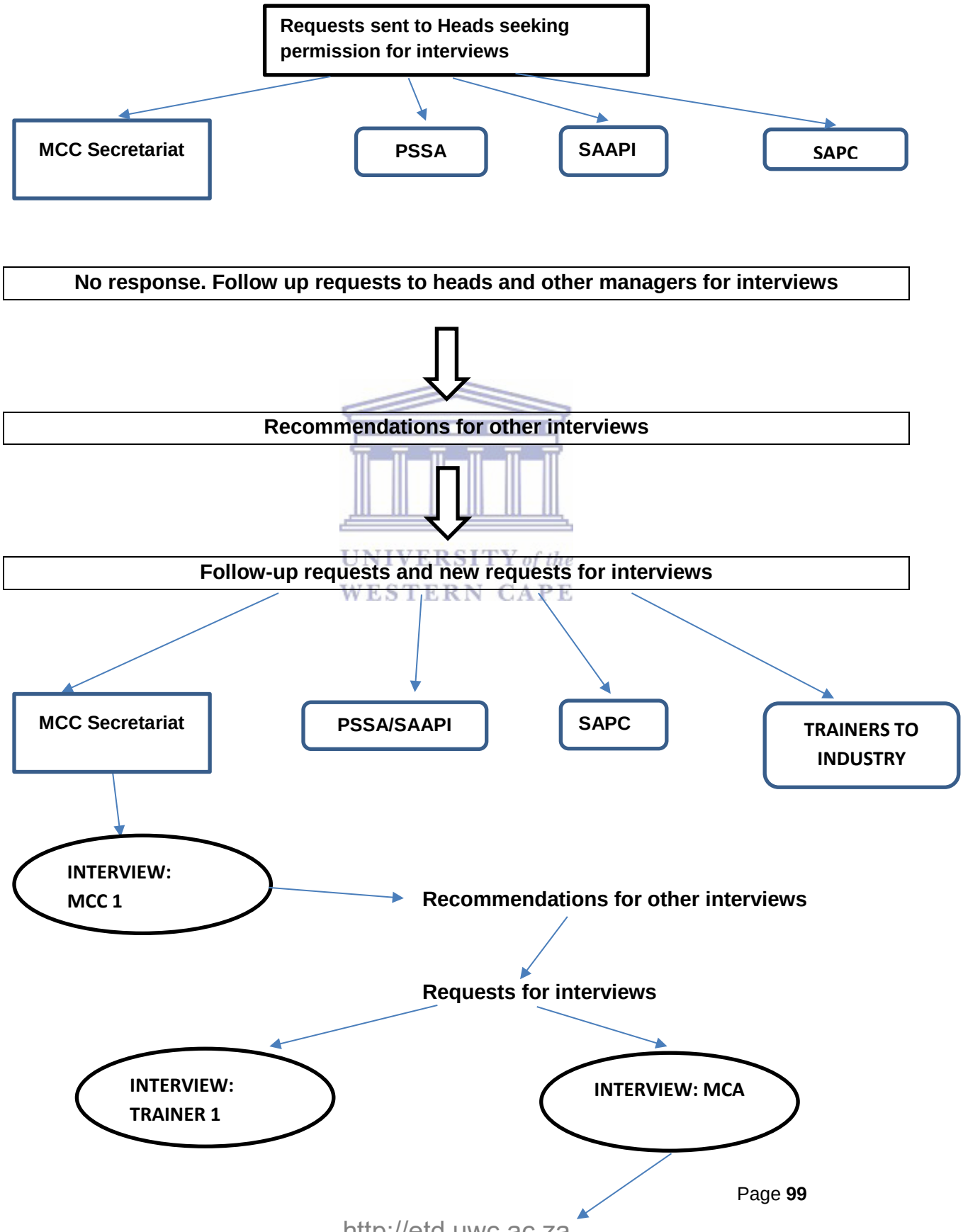
Leila Dockrat

No.	QUESTION	OPTIONS
1.	Are there times when you feel you have been excluded from far-reaching important decisions, which may have impacted on your role as RP?	1. Yes 2. No 3. Unsure/Maybe

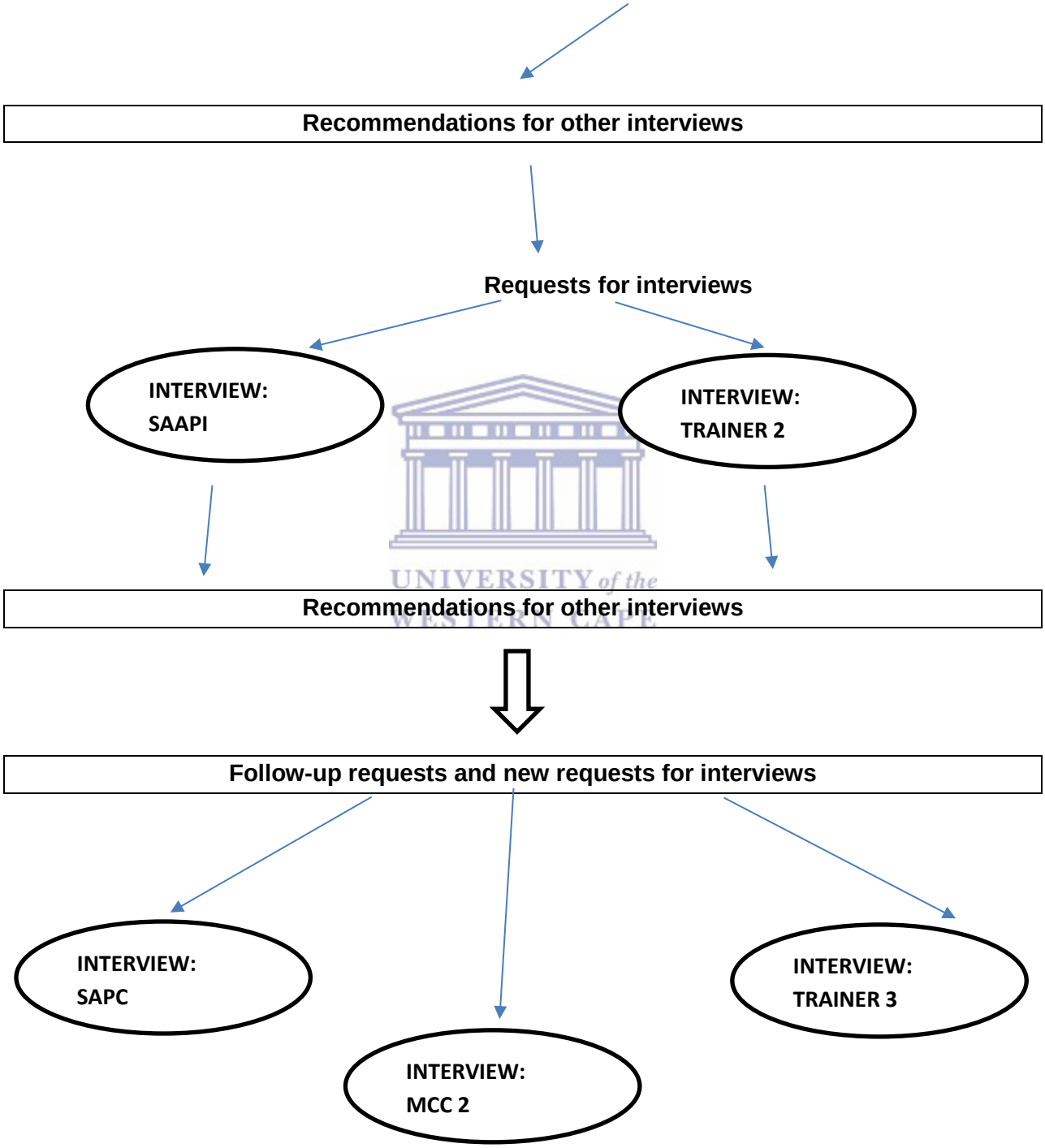
Selection of any of the 3 options above, served as a link to the survey, with only one question:

No.	QUESTION	OPTIONS
1.	If you answered YES to the previous question, please select the broad category of the situation; please select whichever are applicable:	1. The situation could have potentially affected the manufacturing license
		2. The situation involved advertising and promotional activities
		3. The situation created an ethical dilemma
		4. The situation involved batch release and certification
		5. The situation involved regulatory compliance
		6. Other (please specify): (*free text box)*

APPENDIX 4: Snowball sampling for interviews for qualitative study



(Appendix 4: Snowball sampling continued)



APPENDIX 5: Email request for interview with questions for semi-structured interview – statutory bodies

Dear Representative of the MCC/SAPC

I am a pharmacy master's student at UWC.
I work in the pharmaceutical manufacturing sector and have observed an aspect regarding roles and responsibilities of the Responsible Pharmacist that I would like to research in order to change and possibly improve workplace conditions for RPs in this sector.

As part of my Master's degree, I am conducting research entitled:
AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

The objective of the study is to explore the views, perceptions and attitudes of Responsible Pharmacists (RPs) about their role in the pharmaceutical manufacturing sector. Inquiry will be made into whether RPs consider themselves to be adequately equipped for their role and responsibilities at the time of registration and thereafter, whether they consider themselves to have acquired the necessary training to fulfil their CPD requirements. Part of the broader aim of this research is to identify ways in which the RP could be better supported in the CPD training context.

You are invited to participate in an interview to explore your views of the current process for registration of RPs, the CPD requirements, ongoing training requirements for RPs. In addition, I hope to discuss your future vision for these aspects, whether there are plans to devise guidelines and standards and mandatory annual CPD for RPs in the pharmaceutical manufacturing sector.
The interview will take approximately 45-60 minutes and be audio-taped, and transcribed verbatim. Common themes will be identified, coded and analysed.

Voluntary participation: Participation is entirely voluntary, there is no obligation to answer questions that cause discomfort and you are free to end the interview or withdraw from the study at any time without undue consequences.

Confidentiality: All information gained from the interview will be kept strictly confidential. Interviews are to be recorded with your permission (informed consent). The audio files and transcripts will be password protected and labeled with pseudonyms to protect your identity. As the researcher I am the only individual who will have direct access to this material.

Dissemination: The research will be written up as a Master's dissertation and may be followed up with a journal article. In this process the confidentiality of all participants will be maintained. The research report, as well as any publication emanating from the research can be made available to you upon completion of the review process. If you are interested you are welcome to contact me regarding these documents.

Thank you in advance for helping me with this important research project. If you have any queries and would like to discuss them, please contact me:
Leila Dockrat
RPSurveyLD@gmail.com 082 xxx xxxx

CONSENT TO PARTICIPATE IN RESEARCH

Dear representative of the MCC/SAPC

Title of Study: AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

Researcher: Leila Dockrat

Please read this form carefully and feel free to ask any questions you may have before deciding whether or not to participate in this study.

This research aims to explore the views, perceptions and attitudes of Responsible Pharmacists (RPs) about their role in the pharmaceutical manufacturing sector. Inquiry will be made through an anonymous questionnaire, into whether RPs consider themselves to be adequately equipped for their role and responsibilities at the time of registration and thereafter, whether they consider themselves to have acquired the necessary training to fulfil their CPD requirements. Part of the broader aim of this research is to identify ways in which the RP could be better supported in the CPD training context.

You are invited to participate in an interview to explore your views of the current process for registration of RPs, the CPD requirements, ongoing training requirements for RPs. In addition, I hope to discuss your future vision for these aspects, whether there are plans to devise guidelines and standards and mandatory annual CPD for RPs in the pharmaceutical manufacturing sector.

Participation entails an interview of approximately 60 minutes which will be audio-taped (with your permission), and transcribed verbatim for the purposes of analysis.

Benefits to Participants: the study will contribute to the body of knowledge regarding the competencies and authority levels of RPs in the pharmaceutical manufacturing sector, and their CPD in this regard. Interviewees' contributions may potentially influence the aforementioned key focus areas of this study.

Potential Risks to Participants: the interviews will present minimal risk and discomfort to participants in terms of their wellbeing, no more so than would be ordinarily encountered in daily life. Participants are free to decline to answer certain questions if they so wish.

Confidentiality: All information provided in the interview will be kept strictly confidential. The audio files and transcripts will be password protected and labeled with pseudonyms to protect your identity, and will only be directly accessible by the researcher.

Voluntary Participation: Participation is entirely voluntary and no person will be advantaged or disadvantaged in any way for choosing to participate or not to participate in this study. You are under no obligation to answer questions that cause discomfort and you are free to end the interview or withdraw from the study at any time.

Dissemination of Results: Insights gained from you and other participants will be used in writing a dissertation, which will be available to read after the examination process. Findings may also be published in academic journals. Though direct quotes from you may be used, your identity will be protected through the use of a pseudonym and no other identifying information will be included.

Contacts and Questions: If you have any further questions or concerns please feel free to contact me:

Leila Dockrat

RPSurveyLD@gmail.com 082 xxx xxxx

Statement of Consent

Your signature below indicates that you have read and understood the information provided above, have had an opportunity to ask questions, and agree to participate in this research

Participant's Signature	**Place**	**Date**
Participant's Unique Identifier:		
Researcher's Signature	**Place**	**Date**

SECTION A: RESEARCH PROJECT PROPOSAL

Project title: AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

PHASE 2: PROPOSED MCC AND SAPC SEMI-STRUCTURED INTERVIEW QUESTIONS

ATTACHMENT 2.3: PROPOSED QUESTIONS FOR SEMI-STRUCTURED INTERVIEWS

The following questions are a guide for a semi-structured interview with one representative each of the SAPC and the MCC (two separate interviews)

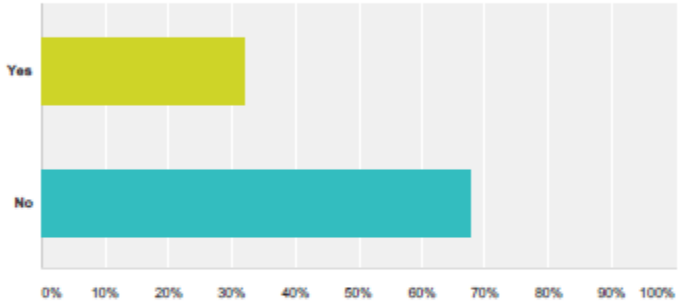
No.	QUESTION	Comments/Notes
1.	The following form the basis for the RP role and responsibilities: Legislation: The licencing of pharmacies is controlled via the Pharmacy Act, No 53/1974 and the Medicines Act, No. 101/1965 Good Pharmacy Practice and Codes of Conduct Services for which a pharmacist may levy a fee Good Manufacturing Practice Good Wholesale Practice (draft for comment) Are there other guidelines/codes applicable to RPs in the pharmaceutical manufacturing sector?	Legislation and Codes of Conduct - applicable to all sectors. GPP guidelines are applicable to Retail Pharmacists GMP guidelines are applicable to pharmacists in pharmaceutical manufacturing The question is raised to ensure that there is agreement on the basic references, that all relevant codes and guidelines have been taken into account
2	Other than the references in question 1, are there any guidelines specific to the role of the RP in the pharmaceutical manufacturer?	
3	When a pharmacist applies for registration as the RP in the pharmaceutical manufacturing sector, is there any support provided to assist that RP in their role, e.g. code of practice for the RP in the pharmaceutical industry? If not, are there such guidelines/codes in draft? If yes, when are these expected to be released for comment?	It is likely that the SAPC and MCC have identified a gap in the training of the RP in the pharmaceutical manufacturing sector and are working on appropriate codes and guidelines.
4	Currently, CPD is voluntary for professionals, including pharmacists. What are your views about CPD becoming mandatory for the RP in the pharmaceutical manufacturing sector?	
5	Are there plans to include CPD training specifically	

	designed around the new RP in the pharmaceutical industry?	
6	In the pharmaceutical manufacturing sector, the RP is not always in a senior position reporting directly to the head of the company. Would you agree that, in order for the RPs to effectively execute their responsibilities, they should have necessary authority within the company structure. In light of this, are there plans to assist the RP in developing leadership capability?	
7	Scenario: Where a RP has been found guilty of failure to fulfil their responsibilities /major misconduct e.g. evidence of off-label marketing of a medicine, that RP is at risk of losing his/her license. What is your feeling about such a situation? In your view is the current training for a RP prepared him/her for such repercussions?	
8	There are a few courses/workshops in the industry which train on the responsibilities of the RP. Are any of these courses /workshops endorsed /recommended by the SAPC or the MCC? Was the SAPC or MCC involved in developing the course material? If the answers to these questions are negative, does the SAPC or MCC have plans to develop courses for RPs in the pharmaceutical manufacturing industry in the future?	
9	Can you comment on the turnover of RPs in the pharmaceutical manufacturing sector?	This question may lead to the shortage of pharmacist, which leads to registration of inexperienced RPs
10	Can you comment on the consequences for the RP where they have been found negligent?	How strict is the SAPC when things go wrong? Is there an investigation into the training of that RP
11	The government is looking at opportunities to establish a local pharmaceutical industry in SA. How equipped are pharmacy training schools or CPD programmes able to prepare RPs to undertake the management of this?	

APPENDIX 6: RP responses to Question 22 – further detailed suggestions on training

Q22 Do you have further comments/suggestions for training requirements that would optimize the RP's role at a senior level in the pharmaceutical manufacturing sector?

Answered: 87 Skipped: 15



Answer Choices	Responses	
Yes	32.18%	28
No	67.82%	59
Total		87

#	If YES, please add your comments here:	Date
1	I think that at the initial stage of becoming a RP, if the person does not have a lot of experience, an initial training course is advantageous. However at the end of the day the RP needs to know the Medicine's Act, the Pharmacy Act and the requirements of GMP. There is also no substitute for experience and on the job learning. Theory versus putting things into Practice are not one and the same.	2/7/2017 8:44 AM

2	The now defunct "Managing Director" legal requirement ensured that 'MD"s were generally held in higher esteem by non-professionals in the management of pharmacy companies (even though some of the manufacturing industry regarded them as mere "covers"). The change in ownership of pharmacies to allow lay people has aggravated the problems that RPs have today. I am aware of a number of RPs who have been bullied and/or sidelined by non-professionals who are corporately placed in some authority position over the RP e.g. Store managers in operations like Clicks etc who decide on pharmacist expected output often limiting proper patient consultation time severely, forcing a "standard of care" on pharmacists which the pharmacist may not agree with e.g.excessive antibiotic use, inappropriate vaccination schedules, "pushing " certain types of medicines etc. Even RPs in the manufacturing industry are sometimes "bullied" e.g. negative marketing information being withheld from them, pressured to release suspect stock, pressured to forgo badly needed equipment and services etc. RPs must realize that they are also responsible for the "ethics" of the business [issues which can bring a pharmacy into disrepute] which includes aspects far wider than just compliance with the Pharmacy or Medicine Control Act e.g. complying with human relations requirements, the Company Act, fraud, dishonest dealings, payment of tax to SARS, etc. If you have not already done so, a good place to get much more information in this regard is to consult with Gary Black of the WP PSSA. Again, if you have not done so, see Robert Ian Goodall's MBA(Wits) dissertation titled "Legal Aspects Of Management Of Pharmaceutical Manufacturing Facilities" 1986. At that stage 35% of the "MD" respondents (the research was also questionnaire -based " admitted to not being in charge of the company and a further 12% felt that they did not have 100% control. However the rest felt that they did have control. Question 21 requires a perspective - MCC audits as well as SAPC audits does test the level of competency of the RP. I have been consulted a number of times where RPs were slated by the MCC inspectors as being incompetent. Question 20 - A pre-determined annual CPD curriculum may inhibit RPs to think for themselves. It must be carefully constructed taking all the various considerations in to consideration. Not all pharmacists agree on scientific issues which may include on how GMP and QA issues should be interpreted and applied . It is a question of whose science will prevail. On issues of ethics and responsibility definitely and no grey areas should be applied.	2/6/2017 11:46 AM
3	Qualified Person Training Modules from NSF-DBA can be adapted for RP training in SA. This was initially envisaged to occur via UKZN Extended Learning Programme but never materialised.	2/6/2017 9:25 AM
4	A university certificate course will be much appreciated	2/6/2017 8:27 AM
5	Definitely Guidelines on the Roles & Responsibilities to give clear guidance to the industry	1/27/2017 12:37 PM
6	MCC to present training sessions throughout the year	1/27/2017 12:26 PM
7	Some training in Finance and Marketing will help the RP to be a worthy contributor to the company whilst enhancing his/her ability to discharge their duties as an RP	1/27/2017 10:46 AM
8	RP's need training on the legal aspects of their roles and also other Acts to which they may be held accountable. RP's need to be part of the exco team in companies RP's need to be empowered with knowledge so that they may make informed decisions confidently	1/16/2017 9:18 PM
9	Quality management training Basic technical training on manufacturing techniques In addition to the training requirements, the prerequisite for an RP position should be knowledge and experience in the respective field of practice.	1/16/2017 8:49 PM
10	I would welcome an online training course with certification	1/16/2017 3:33 PM
11	Train business owners (non-pharmacists) on the importance of the RP.	1/16/2017 11:29 AM
12	Formal training for RPs is strongly recommended, especially in the case of junior RPs who have not had many years of experience in the pharmaceutical industry.	1/16/2017 9:23 AM

13	New guidelines because one tends to think you know all. Refresher by sector and years of experience to avoid discussion on issues that are relevant to new RP's. RP's should not be registered if they have less than 5 years experience in the sector and as well as more than 3 years experience in Quality related roles.	1/16/2017 8:58 AM
14	The RP's are overruled, disrespected, excluded from meetings etc. by non-pharmacist owners, they do not appreciated or want to understand the responsibilities as per the Acts. All goes about making money, quality & compliance is in their eyes the responsibility of the pharmacists. The "attitude" of non-pharmacist managers i.e. marketing, MD, GM & CEO etc. as well as owners is the issue not the pharmacists "lack of training", this problem was far less before the act changed when pharmacist had to be the owners, managing directors of pharmacies (prior 2003). Where have you seen that attorneys or charted accountant practices are owned by non-registered attorneys or chartered accountants where a "pharmacist" owns their practice and only needs their qualified persons to "make" money?	1/16/2017 8:41 AM
15	Senior management should be trained or at least be aware of the legal and other responsibilities of RP.	1/16/2017 8:18 AM
16	Stop changing the rules all the time and use commonsense	1/16/2017 7:03 AM
17	Set a Minimum Industry/Manufacturing/Import-Export Experience of at least 5 Years	1/16/2017 12:14 AM

18	Pharmacists should only be able to register as an RP within their sector after a minimum of 5 years in middle management roles reporting to the existing RP in their chosen sector (retail/manufacturing/clinical etc.). We have too many very inexperienced RP's, appointed by companies wanting to be compliant but not wanting to pay industry related salaries for experienced pharmacists. These RP's are often making fundamentally high risk decisions, often bullied by top management, without experience or knowledge to handle the same Although I have had experience on the production floor, in regulatory & QA, I have been in the role of RP (previous managing director) for the past 17 years and have mostly taught myself through mistakes, rather than learning from a mentor.	1/6/2017 5:27 PM
19	GMs or CEOs in the pharma industry should also have a more comprehensive insight into the roles and responsibilities of the RP.	12/26/2016 8:41 PM
20	To me there are two problems. It is the training firstly. As there are now few manufacturers in SA it is very difficult to obtain hands on training which is essential to understand as me concepts. The other problem is the seniority in the business. RP's have become token employees due to the legal requirement but my experience in business has been that the commercial side of the company is not interested in the RP	12/22/2016 6:53 AM
21	The definition of RP is not broken down to the specific sector of the industry that you may find yourself in. It will help to have more guidance on the expectations from MCC in this regard. Training should also be sector specific.	12/21/2016 2:28 PM
22	negotiation techniques legal training in laws such as labour laws and company finance laws and regulations financial management training marketing and sales basic understanding courses	12/20/2016 8:26 PM

23	I think it is essential that RP's be adequately trained/mentored to fulfill the massive responsibility of the RP and its ever changing responsibilities. It needs to be considered also that a RP requires time/resource to train initially, to keep up with new requirements (and thus relevant trainings) to stay abreast and to be able to fulfill the role effectively to protect their organisation and themselves (in their personal capacity). In addition, it would help if it could be a Pharmacy Council regulation/legal requirement for the RP to sit on a company's Exco so that they have 'power' to be involved in decision making. The biggest challenge for most RP's is that they have multiple hats and are spread thin....they just can't get to everything. They're often the Head of Quality and/or Regulatory and thus have many operational duties in additional to their RP role, resulting in them not being able to have oevrsight of all RP duties and responsibilities throughout the company. Lastly, they're often over ruled by the GM/CEO or 'outvoted' at Exco level which leaves them exposed.....	12/20/2016 3:22 PM
24	The RP role should be with quality department and not regulatory or other departments of the company. The RP role should be more aligned with QP for EU. There should be a separate forum for all the RPs' in the pharma industry. Currently, it is my opinion that RP role is lost in SA Pharma industry where registration of a product is more valued than quality compliance.	12/19/2016 4:59 PM
25	Presently, our B.Pharm degree courses are mainly focussed on teaching about RETAIL. There must be more emphasis on the other fields of pharmacy. Here are my suggestions: 1. Update the present B.Pharm degree (4 years) to include an option to specialise further in the following fields (extra 1 year): - Production Pharmacist - RP of Pharmaceutical/complementary medicine manufacturing facility - Hospital Pharmacy: including radiology & oncology & sterile - any other areas where pharmacists are required, e.g. medical aid, on-line pharmacies, etc. 2. Both GMP (including those of other countries, e.g. PIC/S, FDA, WHO, EU, CANADA, AUSTRALIA) and GPP should be taught. At the moment the emphasis is on GPP. 3. Include a basic course on complementary medicines.	12/17/2016 9:09 AM
26	Having been fortunate enough to work with RPs (QPs) across the globe, the disparity between an RP here and in the US/Anzac/EU is concerning. RPs should have a stringent training course that qualifies them, renewable every three years after a verbal and/or oral board exam. RPs in industry merely are seen as 'Pharmacists', just like any dispensing lacky at a Clicks. There is no understanding or respect for RPs in industry, even though we play an integral role. Most CEOs sees RPs as an irritation and waste of money. The function of an RP should be professionalised in SA, with a greater emphasis on legal training as well. I'm happy to chat to you further on the topic if you wish	12/16/2016 6:37 AM
27	Industry should develop programs for prospective RPs. From my experience training courses don't offer much benefit.	12/15/2016 12:28 PM
28	Leadership training is essential	12/14/2016 4:54 AM

APPENDIX 7: A brief overview of the key bodies selected for interviews

MEDICINES CONTROL COUNCIL (MCC):

A statutory body, established by the Medicines and Related Substance Act 101 of 1965. Extract, as taken from the website (www.mccza.com):

The Medicines Control Council applies standards laid down by the Medicines and Related Substances Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines are controlled through the determination of schedules for various medicines and substances.

The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration. Many of these evaluators are from various academic institutions, mainly medical and pharmacy schools.

The office of the Registrar provides administrative and technical support to Council and its activities. The Registrar is also an executive secretary to Council. The Registrar's office is a Chief Directorate/Cluster, Food Control, Pharmaceutical Trade & Product Regulation, within the Department of Health. There are four Directorates, which are largely responsible for co-ordination and execution of various activities. The cluster is, therefore, secretariat to the Council.

SOUTH AFRICAN PHARMACY COUNCIL (SAPC):

A statutory body established in terms of the Pharmacy Act 53 of 1974. Extract as taken from the website (www.pharmcouncil.co.za):

South African Pharmacy Council (SAPC) is the regulator established in terms of the Pharmacy Act, 1974 (Act 53 of 1974) to regulate pharmacists, pharmacy support personnel and pharmacy premises in South Africa. Our mandate is to protect, promote and maintain the health, safety and wellbeing of patients and the public ensuring quality pharmaceutical service for all South Africans.

SOUTHERN AFRICAN PHARMACEUTICAL REGULATORY AFFAIRS ASSOCIATION (SAPRAA):

An extract from their website (www.sapraa.org.za). The objectives of SAPRAA shall be the following:

- To promote professionalism amongst regulatory personnel in Southern Africa.
- To communicate with the Regulatory Authorities and the Pharmaceutical Industry (in South Africa and neighbouring countries) on matters affecting the regulation of medicines.
- To establish and maintain contact with registration personnel in the general field of pharmaceutical, veterinary and agricultural matters, medical devices and any other areas concerned.
- To arrange informative meetings with speakers who will be leaders in their area to promote the development of professionalism in the regulatory field.

PHARMACEUTICAL SOCIETY OF SOUTH AFRICA (PSSA):

An association for pharmacists established since 1946 from an amalgamation of the various provincial associations, the first having been formed in 1885. Extract as from the website (www.pssa.org.za):

Vision: To be the undisputed leader and guardian of the pharmacy profession.

Mission: To support and promote the profession of pharmacy in improving medication use and advancing patient care.

Objectives:

- To promote the professional, educational and economic interests of the members of the Society and of the pharmaceutical profession;
- To encourage professional integrity and improve standards of professional conduct of
- To promote and maintain the image of the pharmacy;
- To uphold and assist in the promotion and maintenance of the health of the people of South Africa through the provision of a safe dependable pharmaceutical service and
- In recognising the diversity of the population of South Africa, to promote the representation of all sectors of the South African community in its membership.

SOUTH AFRICAN ASSOCIATION OF PHARMACISTS IN INDUSTRY (SAAPI)

SAAPI is a sector within the PSSA. Extract as from their website (www.saapi.org.za):

SAAPI is an association of pharmacists and allied professionals who practice in the healthcare industry

SAAPI is not restricted to pharmacists only, but welcomes the participation of our non-pharmacist colleagues who share our vision

MISSION: “To maintain and promote professional standards, responsibilities and interests of pharmacists in industry in order to play an active role in ensuring the quality, safety and efficacy of manufactured medicines, as well as in the health care delivery system in SA.”

VISION: We see pharmacists in industry taking responsibility for leading change and being at the cutting edge of all relevant scientific, professional, environmental and political ventures and promoting unity in our profession”.

QUADPHARMA C.C.

Training consultants to the pharmaceutical manufacturing industry. Extract as from the website

(www.quadpharma.com)

Quad Pharma cc specializes in training on Medicine Registration in South Africa, Regulatory affairs for the pharmaceutical industry and GMP.

Mission: To provide quality practical ongoing training in the pharmaceutical industry in medicine registration and related fields.

To sustain a standard of excellence that will be valued by the industry through personal contact with and individual tuition of our learners.

To provide a consulting service of value to the pharmaceutical industry by remaining topical and current with regard to both local and international trends.

Background: Quad Pharma c.c. was established in October 1995 as a consulting company to the Pharmaceutical industry by John Alexopoulos. John, although still a member officially retired in June 2016.

Joy Berry-Baker joined in 1996 and launched the training arm of the company with the first training workshop being held in March of that year.

Quad Pharma c.c. has kept pace with the changing focus in education and training and was first approved by the South African Pharmacy Council as a provider of education and training in February 2001. Review by SAPC is conducted every 5 years and Quad Pharma c.c. has maintained its accreditation status over the years.

Quad Pharma cc has increased its level of expertise through associations with other professionals in the Pharmaceutical Industry and is proud to have participated in the development of the eQALs CTD and eCTD building software in association with Robin Baker of Automated Logic Solutions and Computer Den.

LENERI DU TOIT CONSULTANTS CC

Extract as provided from the CV:

A self-motivated successful regulatory consultant to the pharmaceutical industry (covering NCE, OTC, CAMs, Medical Devices and other health products) with more than 27 years' experience. Driven by ensuring I provide strategic vision and leadership to my stakeholders. I have played an active role in influencing, promoting and supporting the evolution of legislation and key guidelines. I have grown a sustainable and standalone business in South Africa with a successful track record in obtaining registrations, claims initiatives, classification, training and mentoring junior regulatory personnel. Excellent people skills.

TWINZ FOUNDATION CC

Extract as taken from the website (www.twinz.co.za):

Twinz Pharmaceutical Regulatory Affairs Consultants' wide range of experience and extensive network of pharmaceutical registration experts provide the talent to ensure all the needs of your regulatory department are thoroughly addressed. Make Twinz the ideal partner in all your Pharmaceutical Regulatory Affairs.

APPENDIX 8: Email request for interview with questions for semi-structured interviews – non-statutory bodies

Dear

Thank you very much for granting me an appointment, I really look forward to speaking with you.

The suggested questions in the attachment were directed at the MCC and SAPC, the regulator and professional council; you may discuss any of these questions. In addition, below are my proposed questions for a trainer to the pharma industry, a slightly different slant.

From the attachment enclosed, you will see that I require your consent; I will use a dicta-phone to record our discussion. Your identity will remain strictly confidential. Should I quote you I will ensure this through use of a pseudonym.

My aim is to explore your views as a trainer to the industry. The scope of my inquiry will be limited to the RP in the manufacturing sector of the pharma industry; I will not address the RP role in other sectors such as wholesale, retail, clinics/hospital. I hope to be able to identify common themes across interviews, which I would support from quotes by the interviewee.

These are the questions I have in mind: As a trainer to the pharma industry including the Quality Assurance and Regulatory Affairs functions:

- Which key competencies would you consider to be essential for the RP role? You may also comment on other competencies which, in your opinion, are highly recommended.
- Which courses are you aware of which cover training on these competencies?
- What do you think would be the ideal training program for a newly qualified RP with limited experience in manufacturing e.g. approximately 3 years' experience which included QA, and/or Production and may or may not include regulatory affairs and pharmacovigilance?
- How best do you think the newly registered RP can be supported by the SAPC, the MCC, SAAPI, the RP's employer, or others, to acquire and develop the necessary competencies for their role?
  CPD is a professional responsibility, however, it is also necessary that the RP understand what is missing from their experience to make inquiry and effort to develop further necessary skills.

- Do you think academia can play a role in preparing the pharmacy student for the role of RP in the future?

These are suggestions, I am open to other lines of inquiry too, as I'm sure over time, with your training course, you've had other questions regarding the RP role and I would really appreciate a discussion on those too.

Another angle may also be to discuss factors you may consider as essential to ensure that the RP attains success, for example experience, attitudes, skills, and trainings, or the support of the employer, or the level of authority the RP has within the organization.

Also, please feel free to change the question if you like, approach it from another perspective or skip it.

Thank you in advance. I look forward to seeing you soon.

CONSENT TO PARTICIPATE IN RESEARCH

Dear

Title of Study: AN INVESTIGATION INTO THE COMPETENCY FRAMEWORK REQUIRED FOR THE RESPONSIBLE PHARMACIST IN THE PHARMACEUTICAL MANUFACTURING SECTOR IN SOUTH AFRICA

Researcher: Leila Dockrat

Please read this form carefully and feel free to ask any questions you may have before deciding whether or not to participate in this study.

This research aims to explore the views, perceptions and attitudes of Responsible Pharmacists (RPs) about their role in the pharmaceutical manufacturing sector. Inquiry will be made through an anonymous questionnaire, into whether RPs consider themselves to be adequately equipped for their role and responsibilities at the time of registration and thereafter, whether they consider themselves to have acquired the necessary training to fulfil their CPD requirements. Part of the broader aim of this research is to identify ways in which the RP could be better supported in the CPD training context.

You are invited to participate in an interview to explore your views of the current process for registration of RPs, the CPD requirements, ongoing training requirements for RPs. In addition, I hope to discuss your future vision for these aspects, whether there are plans to devise guidelines and standards and mandatory annual CPD for RPs in the pharmaceutical manufacturing sector.

Participation entails an interview of approximately 60 minutes which will be audio-taped (with your permission), and transcribed verbatim for the purposes of analysis.

Benefits to Participants: the study will contribute to the body of knowledge regarding the competencies and authority levels of RPs in the pharmaceutical manufacturing sector, and their CPD in this regard. Interviewees' contributions may potentially influence the aforementioned key focus areas of this study.

Potential Risks to Participants: the interviews will present minimal risk and discomfort to participants in terms of their wellbeing, no more so than would be ordinarily encountered in daily life. Participants are free to decline to answer certain questions if they so wish.

Confidentiality: All information provided in the interview will be kept strictly confidential. The audio files and transcripts will be password protected and labeled with pseudonyms to protect your identity, and will only be directly accessible by the researcher.

Voluntary Participation: Participation is entirely voluntary and no person will be advantaged or disadvantaged in any way for choosing to participate or not to participate in this study. You are under no obligation to answer questions that cause discomfort and you are free to end the interview or withdraw from the study at any time.

Dissemination of Results: Insights gained from you and other participants will be used in writing a dissertation, which will be available to read after the examination process. Findings may also be published in academic journals. Though direct quotes from you may be used, your identity will be protected through the use of a pseudonym and no other identifying information will be included.

Contacts and Questions: If you have any further questions or concerns please feel free to contact me:

Leila Dockrat

RPSurveyLD@gmail.com 082 xxx xxxx

Statement of Consent

Your signature below indicates that you have read and understood the information provided above, have had an opportunity to ask questions, and agree to participate in this research

Participant's Signature	**Place**	**Date**
Participant's Unique Identifier:		
Researcher's Signature	**Place**	**Date**