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Practice Analysis for mid-level Pharmacy Workers in South Africa

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Abstract

Background: In South Africa, educational programmes are being developed for new cadres of mid-level pharmacy workers. Therefore, a practice analysis was needed to ensure that these programmes address workplace needs.

Aims: To determine and verify, in accordance with published scopes of practice, the responsibilities (*i.e.*, what they will do) and the competencies (*i.e.*, knowledge, abilities, and skills) that pharmacy technicians will need to practice successfully.

Methods: The study used the "Job Analysis at the Speed of Reality" (JASR) method in which focus groups of subject matter experts (SMEs) developed categorised lists of job functions. The SMEs represented both pharmacists and mid-level workers from a range of practice sites.

Results: A task list for pharmacy technicians was developed from focus group data.

Conclusions: Results of the practice analysis provide valuable information for educators, employers, and other stakeholders to ensure that curricular content are practice-related and relevant to all practice settings.

Keywords: *pharmacy technician, practice analysis, pharmacy education*

Introduction

Prior to the 1994 democratic election, the South African health system was designed along racial lines. The white minority benefitted from a highly resourced system while the black majority was served by a system that was under-resourced (Kon & Lackan, 2008). Since the new constitution which outlawed racial discrimination was promulgated, several attempts to transform the healthcare system and introduce healthcare financing reforms have been unsuccessful. The resultant healthcare system is a two-tiered health system - public and private - based on socioeconomic status (Kon & Lackan, 2008).

Between 2009 and 2013, South Africa has annually spent more than 8% of its gross domestic product (GDP) on healthcare expenditure (World Bank, 2014). Despite this high expenditure, health outcomes remain poor. This poor performance has been attributed to the inequalities that exist between the public and private sectors. The 8.3% of GDP spent on health is split as 4.1% in the private sector and 4.2% in the public sector. The 4.1% of the GDP spent on health care in the private sector provides for 16.2% of the population (8.2 million people), who are largely on medical benefit schemes. The remaining 4.2% is spent on 84% of the population (42 million people) who mainly utilise the public healthcare sector (Department of National Treasury, 2011).

Among the challenges faced by the current healthcare system in South Africa are the worsening burden of disease and shortage of key human resources. These challenges, together with poor management, under-staffing, and deteriorating infrastructure, have led to poor performance amongst public sector healthcare institutions. South Africa is introducing a new system of health care, known as the National Health Insurance (NHI). The pilot phase of NHI commenced in April 2012 (Department of Health, 2014). The intent of the NHI is to ensure access to appropriate, efficient, and quality health services. The successful provision of this improved level of care relies on a re-engineered primary healthcare system. The delivery of pharmaceutical services within the new system will be dependent upon an adequate supply of pharmacy mid-level workers (Department of Health, 2011a).

There is a marked shortage of mid-level pharmacy workers in South Africa. The Human Resources for Health planning framework (Department of Health, 2011b) identified the need for mid-level workers in all

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professional areas to meet the country's ever increasing demand for healthcare services. In a one-year period, from 2012 to 2013, approximately 750 new, post-basic pharmacist's assistants registered with the South African Pharmacy Council. This number is considerably less than the projected 2500 additional mid-level workers per annum that will be required to achieve optimal levels of pharmacy mid-level workers by 2020 (Office of the Registrar, 2011).

Pharmacy Mid-Level Workers in South Africa

Pharmacy mid-level workers (basic and post-basic pharmacist's assistants) were introduced in South Africa in 2000. The basic and post-basic pharmacist's assistant qualifications are workplace-based and require pharmacists in the workplace to act as tutors for the learner pharmacist's assistants (South African Qualifications Authority, 2012a). As these first cadres of pharmacy mid-level workers became integrated into the workplace, it became evident that the qualification was not providing the knowledge and skills required to meet the demands of the published scopes of practice. Thus, in 2011, the South African Pharmacy Council, in consultation with the National Department of Health and relevant stakeholders, developed new mid-level worker qualifications at a higher educational level. These qualifications are for the Pharmacy Technical Assistant (PTA) and the Pharmacy Technician (PT) (South Africa, 2011).

The candidate for the PTA must complete two full semesters at a university. The candidate for the PT must complete an additional two semesters of university education upon successful completion of the PTA programme. A six-month traineeship (supervised practice as prescribed by the South African Pharmacy Council) must be completed prior to registration as either a PTA or PT. The new PTA and PT programmes provide generalist training for practice in community (retail), hospital, primary care, industry, and wholesale practice sites in both the private and public sectors (South Africa, 2011).

According to the scope of practice, a PTA may only work under the direct personal supervision of a pharmacist. In addition to directly supervised practice, the PT may – in a primary healthcare setting – function under the indirect supervision of a pharmacist who is not physically present in the pharmacy. In manufacturing and wholesale pharmacies, a PT is able to perform certain defined functions without the direct oversight of a pharmacist. Such functions will be performed in accordance with the batch manufacturing documents and standard operating procedures approved by the responsible pharmacist (South Africa, 2011).

Nelson Mandela Metropolitan University (NMMU) was the first institution to be accredited to present the new pharmacy mid-level worker programmes. The PTA programme commenced in 2013, followed by the PT training in 2014. The first PT graduates will, therefore, enter the workplace in 2015.

Purpose of the Practice Analysis

Presentation of the PT qualification is still in the early stages. To ensure that the programme is responsive to the needs of both the profession of pharmacy and healthcare consumers in South Africa and reproducible at other higher education institutions, NMMU decided to analyse the workplace requirements for the PT. Since the scope of practice of the PTA is a subset of the scope of practice for the PT, this practice analysis concentrated on the role of the PT in the workplace.

Thus, a practice analysis was conducted to determine and verify, in accordance with the published scopes of practice (South Africa, 2011), the responsibilities (*i.e.*, what they will do) and the competencies (*i.e.*, knowledge, abilities and skills) that the PT will need to practice successfully. The results of the practice analysis may be used to:

- inform the didactic and educational programs for the PTA and PT;
- identify and remedy any gaps in the PTA and PT curricular content;
- ensure that respective curricular content is practice-related and relevant to all major practice settings;
- serve as a guide for creating training manuals and other instructional materials; and
- communicate PTA and PT competencies and training to various stakeholders.

Background

According to Hartley (1999), several different methods have been used to conduct practice analyses, including combinations of the following:

- self-reports
- direct observations
- interviews (including behavioural event interviews)
- procedural reviews
- document reviews
- checklists
- critical incidents and work diaries
- questionnaires and surveys.

These methods have been used to collect data to create job descriptions, measure performance, self-assess, assist with organisational planning, develop competencies, and create standardised competency examinations. There are a variety of methods used to develop curricula for educational and training programs, each with its own set of advantages and disadvantages. For the purposes of this job analysis study, the team selected a method known as 'Job Analysis at the Speed of Reality' (JASR). The JASR method is relatively efficient, consistent, reliable and valid, and involves both job incumbents and managers to provide checks and balances and instil ownership of the process (Hartley, 1999).

Methods

The JASR Method was adopted for this practice analysis. Focus group sessions were conducted with subject matter experts (SMEs) to develop and categorise a list of job functions. A purposive, stratified sampling technique was employed to ensure that the focus groups included representatives from all areas of pharmacy practice. Further stratification ensured representation from both private and public sectors. The sample included both pharmacists and post-basic pharmacist's assistants within each stratum. As the practice settings in the pharmaceutical environment are diverse, two separate focus groups were formed to represent: (1) community and hospital pharmacy practice sites (four representative from the private sector and eight from the public sector); and (2) manufacturing (there is no public manufacturing thus all six representatives were from the private sector) and wholesale practice sites (one representative from the private sector and two from the public sector).

The practice analysis was conducted at the offices of the South African Pharmacy Council on 31st March, 2014. A modified nominal group technique (which employed consensus building as opposed to voting) was used to develop lists of knowledge, skills and abilities needed by mid-level pharmacy workers in order to practice successfully in diverse settings. Two focus groups were developed: one representing traditional pharmacy practice (*i.e.*, hospital, primary care and retail pharmacies) with four post-basic pharmacist's assistants and eight pharmacists; and the other panel representing manufacturing and distribution pharmacy with five post-basic pharmacist's assistants and four pharmacists. Each focus group was led by a facilitator who was a South African pharmacist. Co-facilitators with expertise in focus group methodologies served as notetakers. The focus group data were recorded, tabulated, and condensed to eliminate duplicate items. These lists were distributed to participants so that comments could be incorporated into the final document.

Ethical approval was obtained from Nelson Mandela Metropolitan University [H13-HEA-PHA-009] and the St. Louis College of Pharmacy [IRB-03-08-2013] and written, informed consent was obtained from each participant. This study was conducted in compliance with the ethical principles for medical research with human subjects as outlined in the Declaration of Helsinki (World Medical Association, 2014).

Results

The task lists that emerged from the focus groups are presented in Appendices A and B of this report. Both panels described specific tasks and skills needed for the mid-level roles as well as the knowledge base required to perform these tasks and skills.

In addition to listing knowledge, skills, and tasks, the participants of both focus groups emphasised numerous abilities that they felt were essential for the mid-level worker role. The identified abilities corresponded with the Critical Cross-Field Outcomes listed in the South African Qualifications Authority (2012b) qualification for the PT. The fact that panellists emphasised the need for achieving these outcomes may indicate that there is a gap between the practice of the current mid-level pharmacy cadres (basic and post-basic pharmacist's assistants) and what is required in the workplace; hence, the need for the new PTA and PT qualifications. The list of knowledge, skills, tasks, and requisite abilities was disseminated to the focus group participants for comment and no changes were required.

When practice analyses are used to develop a standardised competency examination, rather than a curriculum, there is often a follow-up survey of a large representative sample of stakeholders to rank essential job functions in terms of 'importance' of the function and 'frequency' with which the function occurs so that each domain could be properly weighted for the examination. Areas that rank higher would be represented on the examination by a larger proportion of examination items. Since the purpose of this practice analysis is curriculum development rather than licensure or competency examination development, such a survey was not necessary for this project.

Discussion

The scope of practice for mid-level pharmacy workers had already been established by the South African Pharmacy Council (South Africa, 2011). However, the methodology utilised for this study was an efficient and effective method for determining, in accordance with the published scopes of practice, the responsibilities and competencies that pharmacy technicians will need to practice successfully.

Participants in this practice analysis emphasised the need to prepare mid-level workers who have specific knowledge and abilities and who demonstrate professional behaviours and competencies necessary to perform successfully in the contemporary health environment. Of particular importance to the focus group participants was the ability of pharmacy mid-level workers to clearly understand their scope of practice and be able to communicate their skills – and limits thereof – to the public. It is crucial that employers, pharmacists, and other supervisors in the workplace have clearly delineated expectations for the new pharmacy mid-level workers to maximise the utility of the PTA and PT in practice.

As with any study, there are some limitations to this practice analysis. It should be noted that this practice analysis reflects the collective thinking of a group of subject matter experts about the knowledge, skills, and abilities needed for mid-level pharmacy workers to effectively perform within their scope of practice. The task list is not intended to be an exhaustive record of all of the individual tasks that mid-level workers may perform now, or in the future. Since there are not yet any individuals registered to practice as a PT in South Africa, this practice analysis is based on current practices of post-

basic pharmacist's assistants with reference to the PT scope of practice.

This practice analysis was designed to develop a task list for the PT role; the PTA scope of practice is a subset of that for a PT. The next step in the process will be to extract the PTA task list from that developed for the PT.

Conclusions

The results of this practice analysis may be valuable to educators, employers, and other stakeholders as the initial PT graduates leave the training institutions and enter the workforce in the private and public sectors. Educators may apply these findings to the design of mid-level pharmacy training programmes or to identify gaps in current curricula. This may help educators ensure that training programmes are practice-related and help students develop the knowledge, skills, and abilities that are relevant to the workplace. Furthermore, the results of this practice analysis may serve as a guide for the creation of manuals and other instructional materials for initial training programmes or continuing professional development modules. This practice analysis may inform the development of other training programmes for mid-level pharmacy workers in South Africa and other parts of the world.

Since pharmacy is a dynamic profession, it is recommended that a practice analysis be conducted on a periodic basis to ensure that education is responsive to workplace needs. Furthermore, South Africa is currently developing a National Health Insurance system and it is expected that workplace requirements for the PT may change as NHI evolves.

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Appendix A

Practice Analysis for Hospital and Community Pharmacy

NOTE: For all tasks, pharmacy mid-level workers must follow standard operating procedures (SOPs) and practice in accordance with minimum standards as prescribed in rules relating to Good Pharmacy Practice (GPP) published in terms of Section 35A of the Pharmacy Act. Pharmacy mid-level workers may not practice outside of their approved scope of practice (*Government Gazette,* 2011).

Task List
Area 1. Dispensing Process
1.1 – Prescription Information
Check validity of patient information on prescription or medical record labels
Confirm patient medical information (allergies, etc.) on/in written prescriptions/ records
Verify legality of prescriptions
Confirm for compliance with formulary requirements
Confirm the identity of the patient for whom the prescription is written
Verify validity of prescribers and relevant registration numbers
Verify original prescriptions for S5 medications
Identify fraudulent prescriptions
Verify that chronic prescriptions are within date range for repeat dispensing
Interpret prescription abbreviations
1.2 – Preparing/Dispensing Prescriptions
Confirm medical aid clearance
Capture prescription information
Perform drug utilisation review (DUR) and refer to pharmacist, if required
Pick items
Select appropriate containers for items
Label items properly
Sign for completion of each step
Refer potential medication interactions to the pharmacist
Inform patients whether prescription may be repeated and the relevant date for the repeats
Confirm duration of therapy
Calculate appropriate number of units
Check calculations with pharmacists
Confirm that consent has been obtained for generic substitution
Check for type of prescription (i.e., inpatient or discharge medications)
Supply medications to patient following verification by pharmacists
Provide relevant information and instructions to patients
Check expiry dates
Verify patient medical information for repeat prescriptions
Comply with GPP standards for environment and equipment
Distribute prescription items to wards
Answer telephonic queries from clinics and outpatient departments
1.3 – Preparing/Dispensing Over-the-Counter (OTC) Medications
Collect relevant information required to determine appropriate management of patients' medical conditions
Monitor for abuse potential
Obtain patient consent when required
Ask relevant questions to assist in selection of appropriate products
Verify schedule 2 OTC item selection with pharmacists
Update knowledge base regularly (S1 and S2 products)
Apply knowledge of medical aid benefit packages relevant to OTC prescribing
1.4 – Calculations
Perform and verify calculations with the pharmacist including, but not limited to: • dosages (e.g., mg per kg prescribed and body surface area) • quantities to be dispensed • percentage concentrations (i.e., w/w, w/v, v/v) • flow rates and infusion times for intravenous medications • ratios and proportions • conversion between measurement units (i.e., mg to g to kg) for dilutions and alligation

Task List
1.5 – Extemporaneous Compounding of Non-Sterile and Sterile Products
Compound prescription orders according to SOPs
Prepare environment and equipment appropriately
Verify phases of compounding with pharmacist
Operate equipment appropriately including, but not limited to: mortars and pestles, graduated cylinders, spatulas, scales, etc.
Weigh or measure ingredients accurately
Complete documentation of compounding
Assign batch numbers and expiry dates
Check and verify yield
Dispose of waste properly
Maintain sterile environment using aseptic technique when appropriate
Prepare sterile products (including intravenous admixtures, parenteral solutions, total parenteral nutrition and cytotoxic medications) according to SOPs and GPP
1.6 – Patient and Professional Communications
Consult appropriate resources as needed
Report adverse drug reactions to the pharmacist
Communicate professionally and effectively with members of the health team and patients
Apply principles of health and illness behavior when communicating with patients
Demonstrate effective customer service skills
Demonstrate effective anger/conflict management skills and access assistance as needed
Demonstrate basic telephone communication skills
Demonstrate basic electronic communication etiquette
Area 2. Stock Control
2.1 – Ordering
Check stock levels according to minimum/maximum levels and adjust orders as needed to satisfy changes in demand
Request pharmacist to authorise orders when appropriate
Submit requisitions per ordering schedule
Collect required data for submission of Section 21 orders
Select appropriate generic or therapeutic alternatives
Create an action plan to manage out-of-stock items
Submit emergency orders
Process transfers/borrowing of stock
2.2 – Receiving
Check delivery address and batch numbers prior to accepting orders
Receive and handle stock appropriately (e.g., hazardous substances, S5 and S6 substances, refrigerated substances)
Store items in appropriate environment and location
Perform administrative/documentation tasks associated with receipt of stock
Confirm maintenance of cold chain
Check for, and return short-dated stock
Check for, and return damaged stock
Capture invoices and perform related administrative tasks
Enter items into stock control system and, if necessary, create or update bin number/stock entry file/stock cards for new items
Manage receipt discrepancies appropriately
Process items to be returned and process credits
2.3 – Storage and Maintenance
Apply first-in-first-out (FIFO) stock rotation principles
Pack refrigerator appropriately in order to maintain cold chain
Document and maintain proper environmental storage conditions

Task List
Remove expired stock items and prepare them for waste disposal
Quarantine recalled goods for removal
2.4 – Stock Control
Perform stock counts, comparing to minimum and maximum stock levels per item
Report out-of-stock items and elevate the enquiry
Assess stockholding for overstock items
Manage short-dated items
Ensure movement of slow-moving stock
Determine reasons for out-of-stock items
Disseminate out-of-stock information to relevant healthcare providers
Perform stock takes as scheduled
Area 3. Supervisory and Other Duties
3.1 – Monitoring the Work Team
Monitor and supervise staff including, but not limited to: cleaning staff, healthcare aisle assistants/front shop assistants, and other mid-level workers
Handle complaints and, if needed, refer appropriately
Create a schedule for staff training sessions
Respond to audit team queries
Manage the queuing of prescriptions
Monitor the delivery of patient medications by home-based carers
Monitor workflow in team situations while identifying, resolving, and reporting problems
Serve as safety officer or first aid officer
3.2 – Training of Staff
Assist with training and orientation of staff including, but not limited to: mid-level worker staff, stock controllers, cleaning staff, and pharmacy students/ interns
Manage personal continuing professional development (CPD)
3.3 – Housekeeping
Perform administrative tasks
Clean shelves, equipment, and specialised storage areas
Perform electronic administrative duties (e.g., medical aid updates, cash out)
Maintain supply of medicine containers (e.g., bottles, poly-vials and tablet boxes)
Manage duty rosters for mid-level workers
Arrange for personal leave replacement
Area 4. Practice Under Indirect Supervision
Note: A PT may provide or perform the following services or acts under the supervision of a pharmacist who is physically not present in the dispensary in a primary healthcare clinic and in accordance with minimum standards as prescribed in the rules relating to GPP (Government Gazette, 2011).
Order and receive S1 to S5 medicines provided that orders for S5 medications are validated by a pharmacist
Manage stock of S1 to S5 medicines provided that orders for S5 medications are validated by a pharmacist
Assess, select, manipulate, compound, label, pack, and provide patient information for prescription medicines that appear on the primary health care essential medicines list and which are prescribed in accordance with standard treatment guidelines
Provide patient information to optimise therapeutic outcomes for medications dispensed at a pharmacy and sent to the primary healthcare clinic for supply to the patient
Manage the dispensary
Conduct general housekeeping and administrative tasks in the dispensary as specified by the supervising pharmacist
Area 5. Health Science and Drug Therapy
Apply basic medical and pharmaceutical terminology
Apply knowledge of Standard Treatment Guidelines and Essential Medicines List

Task List
Apply basic concepts of physiology and pathophysiology
Apply basic pharmaceutics principles and differentiate between various dosage forms
Identify medications according to therapeutic classes and schedules
Apply basic principles of pharmacology
Area 6. Laws and Regulations
Explain and comply with the critical elements of laws, regulations and standards applicable to manufacturing and distribution including but not limited to: • Good Pharmacy Practice (GPP) standards • Good Manufacturing Practice (GMP) standards • Good Wholesale and Distribution Practice (GWDP) standards • Pharmacy Act no. 65 of 1974 and applicable regulations • Medicines and Related Substances Act no. 101 of 1965 and applicable regulations • Consumer Protection Act no. 68 of 2008 • Hazardous Substances Act no. 15 of 1973 • Occupational Health and Safety Act no. 85 of 1993
Apply basic ethical principles including, but not limited to the Code of Conduct (Board Notice no. 108 of 24 October 2008)
Apply principles of patient confidentiality, including confidentiality of electronic data
Demonstrate professional behavior and professional dress
Respond with an appropriate explanation of scope of practice when asked to perform outside of scope
Select appropriate recourse upon being asked to practice out of scope by an employer
Area 7. Clinical Skills – Screening and Testing
7.1 – Relevant History Taking
Collect and record patient demographic data
7.2 – Skills Performance
Perform clinical tests accurately including, but not limited to: • blood pressure • blood glucose • cholesterol • HbA1c • urine screen • pregnancy test • HIV antibody test • peak flow assessment
Handle body fluids/waste, etc. appropriately
Demonstrate appropriate patient care skills
Refer test/assessment results to pharmacist for interpretation

Appendix B

Practice Analysis for Pharmaceutical Manufacturing and Wholesaling

NOTE: For all tasks, pharmacy mid-level workers must follow standard operating procedures (SOPs) and practice in accordance with minimum standards as prescribed in rules relating to GPP published in terms of Section 35A of the Pharmacy Act and the GMP and the GWDP as applied by the Medicines Control Council in terms of the Medicines and Related Substances Act no. 101 of 1965. Pharmacy mid-level workers may not practice outside of their approved scope of practice (*Government Gazette,* 2011).

Task List
Area 1. Pharmaceutical Products, Dosage Forms and Pharmaceutics Principles
Differentiate between different types of dosage forms
Apply basic pharmaceutics concepts (e.g., tableting, friability, dissolution, moisture content, thickness, lyophilisation, freeze drying, diluent, surfactant, binding agents, sterilisation, thermal labile, compatibility of product with container, sterilisation, contamination, and reconstitution)
Differentiate between brand-name products and generic equivalents
Apply basic microbiological principles related to sterility, contamination, spoilage, and expiration of medicines
Differentiate between sound-alike and look-alike medication names
Area 2. Laws and Regulations
• Apply the critical elements of – and apply laws, regulations and standards applicable to – manufacturing and distribution including but not limited to: • Good Pharmacy Practice (GPP) standards • Good Manufacturing Practice (GMP) standards • Good Wholesale and Distribution Practice (GWDP) standards • Pharmacy Act no. 65 of 1974 and applicable regulations • Medicines and Related Substances Act no. 101 of 1965 and applicable regulations • Consumer Protection Act no. 68 of 2008 • Hazardous Substances Act no. 15 of 1973 • Occupational Health and Safety Act (OHSA) no. 85 of 1993
Explain why and how various regulatory bodies conduct inspections
Area 3. Manufacturing and Packaging Process
Receipt of raw materials and components including, but not limited to: • confirmation against certificate of analysis • verification that stock was received from an approved supplier • transfer of materials to and from quarantined area
Secure raw materials and printed packaging
Sample materials and explain purpose of assays (chemical and microbiological)
Check storage conditions
Describe the need for and procedure for quarantining materials
Check expiration dates
Check item code, full description and lot number, quantity and weight
Book materials into inventory and assign in-house lot numbers
Identify those scheduled substances that require direct pharmacist supervision during the receipt of active pharmaceutical ingredients and throughout the manufacturing process
Comply with the personal protective equipment and personal hygiene procedures
Properly store and maintain stock in the raw materials/component warehouse (e.g., verify document against physical stock, unblock product pursuant to an approved quality assurance assay, etc.)
Monitor environmental conditions (e.g., temperature, humidity, pressure)
Rotate materials on a FEFO (first-expiry-first-out) or FIFO (first-in-first-out) basis
Write SOPs and apply correctly
Calibrate scales and weigh materials properly
Apply GMP
Check product/batch integrity and transfer to suspect cage if necessary
Conduct cycle counts and annual stock takes

Task List
Demonstrate the additional security required for S5 and S6 products and properly maintain a register for S5 and S6 products
Maintain proper cold storage of products
Dispense raw materials or release components and/or bulk products, including but not limited to: • creating production orders with item numbers • issuing and verifying batch books • creating picking/packing lists/orders and verifying • picking raw materials/components and/or bulk products according to picking/packing list/order • checking picked/packed items against batch book and picking/packing list/order for accuracy • securing and sealing picked/packed items • recording of seal numbers in batch book • transferring raw materials/components to dispensary • weighing raw materials • sealing and transferring raw materials to production area
Perform aseptic technique and maintain sterile area
Perform and check calculations including, but not limited to: • purity percentages • percentage yield • expiration dates • proportions • mass (w/v, w/w) • molar concentrations • ratios • dilutions
Prepare for the manufacturing process including, but not limited to: • verifying receipt of product – checking and signing seals • calibrating scales and enter into log book • conducting line clearance and opening line
Perform manufacturing process including, but not limited to: • verifying and signing for correct addition of materials • conducting in-process checks
Describe specification tests and in-process checks, interpret results (e.g., pH, conductivity, spectrophotometry, viscosity, friability, spreadability, hardness testing) and raise a deviation to the appropriate supervisory person, if necessary
Explain importance of and perform line closure including, but not limited to: • cleaning equipment and area • swabbing samples • calculating percentage yield • reconciling components
Prepare for the packing/repacking process including, but not limited to: • verifying receipt of bulk product and components – check and sign seals • calibrating scales and enter into log book • conducting line clearance and opening line
Calculate expiration dates and describe shelf life
Label products properly and explain the risk if something is mislabelled
Close packaging line
Explain importance of and procedures for proper destruction or disposal of waste products

Task List
Area 4. Wholesaling
Receive products including, but not limited to: • checking if order exists • checking that stock was received from an approved supplier • following SOPs • ensuring product integrity • transferring materials to and from quarantined areas
Identify products that need special handling (e.g., scheduled and hazardous substances and products that need to be refrigerated)
Differentiate between various dosage forms (e.g., tablet vs. capsule, ampoule vs. vial)
Explain the pharmaceutical manufacturing process (e.g., batches, lot numbers, expiration dates, etc.)
Resolve discrepancies (e.g., quantities, labelling)
Monitor and maintain stock including, but not limited to: • monitoring environment (e.g., temperature, humidity, pressure), • describing and implementing FEFO/FIFO, • maintaining integrity of stock, • conducting stock take and cycle counts, • explaining procedures that require special handling (e.g., S5 and S6 substances, hazardous substances and products that require refrigeration) • describing the process for storing products in bin locations
Receive orders from customers
Prepare and pack orders including, but not limited to: • generating a picking list • describing correct packing principles and selecting correct packing materials for products requiring special handling (e.g., fragile items, products requiring refrigeration, hazardous materials) • describing security requirements and procedures • verifying picked products against documentation
Dispatch orders
Provide quality customer service and fulfil customer needs
Explain record keeping requirements and terminology (e.g., invoices, waybill, trip sheets)
Area 5. Quality Assurance (QA)
Develop QA documentation
Issue correct QA documentation
Report deviations
Verify manufacturing or packaging process by auditing batch documents
Receive retention samples
Describe the importance of stability and retention sampling
Write reports
Area 6. Supervisory and Other Duties
6.1 – Monitoring and Training the Work Team
Identify ways of improving productivity
Demonstrate basic management skills including, but not limited to: • personnel management (e.g., delegation, performance appraisal) • basic financial management • conflict management • time management
Plan a series of complex tasks to achieve a desired goal
Conduct meetings

Task List
Apply basic computer literacy skills
Train workers on proper application of SOPs
Conduct on-the-job training,
Conduct orientation for new employees
Conduct safety training
6.2 – Housekeeping
Maintain proper housekeeping by performing the “5 Ss” (sort, set in order, shine, standardise, and sustain)
Conduct self-inspection or internal audits