RECRUITMENT FOR THE BACKLOG CLEARANCE PROGRAM

One of the critical priorities of the South African Health Products Regulatory Authority (SAHPRA), since its launch, has been the clearance of its backlog of new medicine registration and variation applications. SAHPRA's Board is set to launch a Backlog Clearance Program to clear the backlog in two years. A dedicated Backlog Clearance Team will be responsible for achieving this ambitious goal. This document provides an overview of available positions, a description of the objectives and requirements of each, and how to apply.

[1] Posts for Medicines Evaluator cover:

- CER (Clinical Evaluation for Registration)
- PER (Pharmaceutical Evaluation for Registration, also known as pharmaceutical and analytical)
- Inspectorate
- Names and Scheduling

INSTRUCTIONS TO APPLICANTS

All applications must:

- Be made on Z83 forms (obtainable http://www.dpsa.gov.za/dpsa2g/documents/forms/employ.pdf or from any Government department)
- Be completed in full, clearly reflect the name of the position, name and date of the publication (candidates must use the post reference numbers), be signed, accompanied by a comprehensive CV, the names of 3 referees and certified copies of ID and qualification/s. Applications without the afore-mentioned will not be considered
- A separate application form must be completed for each post. SAHPRA will not be liable where applicants use incorrect or no reference number on their applications
- Applications must be submitted by email to recruitment@sahpra.org.za, including the required certified documentation as indicated. DO NOT MAKE ENQUIRIES TO THIS ADDRESS
- No late or faxed applications will be accepted. CVs will not be returned. Applications, which are received after the closing date, will not be considered
- Further communication will be limited to shortlisted candidates. If you have not received a response from SAHPRA within 3 months of the closing date, please consider your application as unsuccessful.
- It will be expected of candidates to be available for selection interviews on a date, time and place as determined by SAHPRA.

Applicants must note that further checks will be conducted once they are shortlisted and that their appointment is subject to positive outcomes on these checks, which include security clearance, qualification verification, criminal records, credit records and previous employment.

SAHPRA is guided by the principles of Employment Equity. Candidates with disabilities are encouraged to apply and an indication in this regard will be appreciated.

Closing date for applications:

2019/05/24

Enquiries:

Ms Setlola Molepo setlola.molepo@sahpra.org.za. DO NOT SEND APPLICATIONS TO THIS ADDRESS.

SAHPRA BACKLOG CLEARANCE PROGRAM

SAHPRA

The Republic of South Africa launched the South African Health Products Regulatory Authority (SAHPRA) as a Schedule 3A independent public entity in February 2018, replacing the Medicines Control Council (MCC).

SAHPRA's vision is to strive towards excellence in health product regulation with the aim of promoting and protecting human and animal health in South Africa, being recognised and respected both nationally and globally as a leading and exemplary health product regulator

The Backlog Clearance Program

At its formation, SAHPRA inherited a backlog of approximately 16,000 small molecule, veterinary and biological medicine applications for both new registrations and variations. Given the magnitude of this inherited backlog, if SAHPRA maintained current capacity and current processes, it would take eight years to clear the backlog – assuming no new applications were received. Therefore, SAHPRA intends to make an innovative step change to rapidly clear the inherited backlog whilst simultaneously reforming its operating model to turnaround 'business as usual' (BAU).

The Backlog Clearance Program has been created to fulfil the Board's commitment to clear the backlog in two years. This ambition highlights that this represents an exciting opportunity to dramatically improve access to medicines in South Africa and promote the growth of a thriving pharmaceutical industry. The Program will consist of a dedicated team, using completely re-engineered evaluation policies and processes, enabled by a newly implemented digital solution.

Your Invitation to Join the Backlog Clearance Team

You will be joining SAHPRA at a time when the regulation of health products and South Africa's public health system are offering unprecedented opportunities. SAHPRA, as the national regulator, serves such a critical role in safeguarding the health and wellbeing of all who live in South Africa.

You will bring your aspirations, talents and experiences to the regulator. In return, you will find new fulfilling opportunities for personal and professional development.

By joining the Backlog Clearance Team, you will enable SAHPRA to gain its place amongst the leading health product regulatory agencies in the world. SAHPRA looks forward to welcoming you as a colleague.

SAHPRA 083/2019 PORTFOLIO COORDINATOR

A JOB INFORMATION SUMMARY

1. JOB TITLE	Portfolio Coordinator
2. DESIGNATED UNIT:	Backlog Clearance Program (Seconded)
3. POST LEVEL	DPSA Level 11
4. COMPONENT	Medicines Backlog Project
5. POST REPORTS TO	Backlog lead
6. LOCATION	Pretoria

B JOB PURPOSE

The job exists to support SAHPRA clear the medicine application backlog through managing communication with the applicant throughout the end to end process and ensuring application evaluations are completed within the required timeframe.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Build and maintain relationships with applicants through constant communication** 1.1. Act as the primary point of contact for applicants, facilitating technical conversations with evaluators when deemed necessary 1.2. Capture details of application on system once allocated and update application status as it advances through the process 1.3. Consolidate queries and relay those to the applicant, communicate all subsequent responses to the evaluators 1.4. Consistently update applicants on the status of their applications as they advance through the process. This includes notifying applicants should their application be rejected by any division 1.5. Develop a finalised report for approved application by compiling all approval report summaries.
2.	**Facilitate the allocation of applications** 2.1. Develop a work-plan schedule that is in line with the backlog clearance strategy and use it to select the applications that are next in the queue to be evaluated and processed 2.2. Inform evaluator coordinators of the application type, skills required and expected time 2.3. Ensure all applications requiring a division's external committee review are forwarded to the relevant committee and reviewed at the next committee meeting 2.4. Receive committee recommendations should any department's committee be required to make final judgement on an application 2.5. Follow up on outstanding recommendations 2.6. Pass on recommendations to staff responsible for registration document preparation
3.	**Track and convey status to applicants** 3.1. Relay end to end schedule of applications to industry, as well as current status

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Sound working knowledge of document management and workflow management software
- Comfort working with computers and computer software packages
- Technical knowledge of the regulatory environment is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Display exceptional stakeholder management capabilities
- Ability to communicate fluently in English with both written and verbal communication
- Defines and prioritizes goals in the face demands to keep people focused on achieving business objectives
- Good leadership and decision-making ability.
- Critical thinking and problem-solving skills.
- Planning and coordination skills.
- Ability to manage conflict.
- Ability to tolerate stress

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 4-year Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA.
2. Proven experience.
   - Grade 2: Chemistry degree - 10 years, B Pharm Degree - 8 years, Registration as Pharmacist - none
   - Grade 3: Chemistry Degree - 18 years, B Pharm degree – 16 years, Registration as a Pharmacist - 8 years

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly communicate with evaluators
- Directly report to the Backlog Clearance Program lead
- Liaise with the evaluator coordinators

E.2 External

- Act as first point of contact for applicants
- Direct contact with external committees

SAHPRA 084/2019 Assistant Manager: Project Office Manager

A JOB INFORMATION SUMMARY

1. JOB TITLE	Assistant Manager Project Office Manager (Fixed term contract)
2. DESIGNATED UNIT	Medicines Clearance Backlog team
3. POST LEVEL	DPSA Level 11
4. COMPONENT	Program Management Office (PMO)
5. POST REPORTS TO	PMO Lead: Backlog Clearance Program
6. LOCATION	Pretoria

B JOB PURPOSE

The job exists to support SAHPRA clear the medicines application backlog through the project management of assigned modules.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Planning and support:** 1.1. Develop module based targets that are in line with the overarching target of clearing the application backlog within the required timeframe 1.2. Facilitate meetings to discuss performance of module against predetermined targets, key risks to progress and the development of potential solutions to those risks 1.3. Provide strategic, analytical, communication, and project management support to the relevant department heads with a focus on solution implementation to identified risks 1.4. Develop strong relationships with staff and department heads 1.5. Draft communications for presentations to external industry stakeholders, the Board and the CEO 1.6. Assist in the training and on-boarding of new staff 1.7. Additional duties as defined by the project management office team leader
2.	**Track and monitor progress of backlog team:** 2.1. Tracks and reports on performance of assigned module against predetermined targets identifying all shortfalls, surpluses and, defining the next steps

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Sound working knowledge of document management and workflow management software
- Technical knowledge of the regulatory environment is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Work effectively in high-pressure situations, handling multiple tasks simultaneously through prioritisation and organisation
- Ability to communicate fluently in English with both written and verbal communication
- Must be comfortable working with computers and computer software packages
- Exceptional stakeholder management capabilities
- Manages time in an efficient and effective manner
- Plans proactively and communicates potential roadblocks to Portfolio Coordinator timeously
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve
- Strong analytical skills

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year qualification. National certificate / National Diploma / Post Graduate certificate / Post graduate Diploma / Bachelors degree / BTech
2. Experience: Minimum requirement:
   - 3 years' work experience in high pressure roles requiring flexibility (e.g., consulting, investment banking, or similar environments)
   - A successful track record of engaging in cross-functional projects
   - Project management experience including managing teams, developing and evaluating budgets, creating and implementing work plans, and monitoring both project and staff performance

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly communicate with the evaluators
- Portfolio Coordinators
- Directly report to the Backlog lead

E.2 External

- None

SAHPRA 085/2019 Deputy Manager: PMO Lead

A JOB INFORMATION SUMMARY

1. JOB TITLE	Deputy Manager PMO Lead (Fixed term contract)
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA Level 12
4. COMPONENT	Program Management Office (PMO)
5. POST REPORTS TO	Head of the Backlog Clearance Team
6. LOCATION	Pretoria

B JOB PURPOSE

The job exists to manage the operational support for the clearance of the medicine application backlog at SAHPRA through the oversight of the project management team.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Stakeholder engagement:** 1.1. Act as a strategic thought partner to the head of the Backlog Clearance Team in matters relating to external industry communications, developing and implementing strategies and, overall project execution 1.2. Promote and manage effective communication between external industry stakeholders, the board, the CEO, the head of the Backlog Clearance Team and the staff 1.3. Manage relations between the Backlog Clearance Team and SAHPRA's routine work 1.4. Prepare frequent progress reports for external industry stakeholders, the Board, the CEO, the head of the Backlog Clearance Team and, potentially for Parliament
2.	**Project management oversight:** 2.1. Create and assign modules to the project management team that will enable end to end operational support of the medical drug application backlog 2.2. Lead a team of consultants to provide overall operational project support and ensuring high quality and timely team output. This includes the provision of mentorship and performance feedback to the consultants 2.3. Execute the backlog clearance project by designing and implementing project-wide strategies that are in line with the overarching target of clearing the medical application backlog 2.4. Identify key risks to the successful execution of the backlog clearance project and address these risks through the development and implementation of solutions 2.5. Regularly develop and implement ambitious work plans and budgets for the project, and monitor overall project progress to ensure that deliverables and milestones are met in a timely fashion. Address any deviations to progress timeously

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Sound working knowledge of computer software packages (MS word, excel, PowerPoint etc.)
- Deep understanding of core project management tools
- Comfortable working with document management and workflow management systems
- Technical knowledge of the regulatory environment is an added bonus

D.2 Skills

- Ability to solve complex problems and displays quantitative and qualitative analytical capabilities
- Strategic thinker able to think creatively around long-term program objectives and the detailed steps necessary to achieve these goals
- Strong interpersonal skills and ability to build relationships
- Self-driven team-player, that manages numerous modules simultaneously in high-pressure situations by setting priorities
- Communicates fluently in English with both written and verbal communication
- Detail-oriented with strong organizational and planning skills
- Ability to train, develop and, lead individuals

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year qualification. National certificate / National Diploma / Post Graduate certificate / Post graduate Diploma / Bachelors degree / BTech
2. Experience: Minimum requirement:
   - 5 years' work experience in high pressure roles requiring flexibility (e.g., consulting, investment banking, or similar environments)

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise with the head of the backlog clearance program
- Directly communicate with backlog division leads and indirectly the staff of each division in SAHPRA
- Directly report to the CEO

E.2 External

- Industry stakeholders will require progress reports and updates
- The South African Parliament may require updates

SAHPRA 086/2019 Snr Administrative Officer: Evaluator Coordinator

A JOB INFORMATION SUMMARY

1. JOB TITLE	Snr Administrative Officer - Evaluator Coordinator
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA Level 10
4. COMPONENT	Medicines Backlog Project
5. POST REPORTS TO	Backlog lead
6. LOCATION	Pretoria

B JOB PURPOSE

To manage the workflow of the medicine registration applications by assigning resources to applications based on the inputs given by Portfolio Coordinators.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Allocation of applications to evaluators** 1.1. Develop and consistently update staffing plan 1.2. Records the experience and available capacity of evaluators 1.3. Define and document the evaluator requirements in line with pre-determined backlog KPIs by identifying the necessary skill level and capacity requirements for future batches of applications 1.4. Allocate applications based on available evaluator experience and capacity to ensure evaluators are not overloaded
2.	**Tracking of application history** 2.1. Monthly reconciliation of applications assigned and successfully evaluated 2.2. Monitor progress against predetermined KPIs, and identify the root causes for any shortfalls and implement solutions to remove these 2.3. Identify low performing evaluators and alert Operations and administration divisional backlog department head for follow up
3.	**Ensure compliance with agreed-to timelines by both internal and external evaluators and expert committee processes.** 3.1. Assess and recommend the need for additional resources or expertise that may be required 3.2. Reassign applications if necessary

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Sound working knowledge of document management and workflow management software
- Comfort working with computers and computer software packages
- Technical knowledge of the regulatory environment is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Display exceptional stakeholder management capabilities
- Ability to communicate fluently in English with both written and verbal communication
- Defines and prioritizes goals in the face demands to keep people focused on achieving business objectives
- Good leadership and decision-making ability.
- Critical thinking and problem-solving skills.
- Planning and coordination skills.
- Ability to manage conflict.
- Ability to tolerate stress

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - An Appropriate three-year National Diploma/Degree. Preferably a bachelor's degree in natural or health sciences, or BPharm.
2. Proven experience: (please indicate if applicable)
   - Minimum of three years' work experience

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly communicate with the evaluators
- Portfolio Coordinators
- Directly report to the Backlog lead

E.2 External

- None

SAHPRA 087/2019 Technical Screener

A JOB INFORMATION SUMMARY

1. JOB TITLE	Technical Screener (Fixed Term Contract)
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA Level 8
4. COMPONENT	Medicines Backlog Project
5. POST REPORTS TO	1. Backlog P&A lead or 2. Backlog Clinical lead
6. LOCATION	Pretoria

B JOB PURPOSE

The job exists to offer technical assessment and evaluation of applications for registration of medicines to ensure that they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the relevant guidelines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Provide technical screening of applications to enable the further evaluation and subsequent registration:** 1.1. Assess each module of the application against the relevant technical screening checklist to ensure they are appropriate in terms of format and content as defined by the relevant guidelines 1.2. Write technical content queries for assigned applications and submit them to the relevant application manager 1.3. In the event of query responses, address query responses from applicants and inform application manager on the sufficiency of responses 1.4. Perform initial or secondary check on certificates for approved medicines and make corrections when necessary 1.5. Perform initial or secondary check on government gazettes and make corrections when necessary 1.6. Additional duties as defined by the Health Product Authorisation backlog department head
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Attend relevant training as may be necessary to support your function 2.3. Provide weekly progress reports to the Health Product Authorisation backlog department head

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Theoretical knowledge of technical aspects for evaluation of medicines across all fields, namely:
  - Safety and efficacy
  - Quality and bioequivalence
  - Naming and scheduling
  - Good manufacturing practice

D.2 Skills

- Comfort working with computers and computer software packages
- Displays a strong academic background
- Ability to communicate fluently in English with both written and verbal communication
- Ability to work precisely and efficiently
- Able to remain self-motivated with the ability to work independently
- Ability to prioritize and displays excellent time management skills
- Knowledge of the regulatory environment
- Positive attitude

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA.
2. Proven experience:
   - 3 years' experience after registration with SAPC.
   - Exposure to a medicines regulatory environment is an added advantage

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise with Portfolio Coordinators
- Directly report to Backlog P&A or Clinical lead

E.2 External

- None

SAHPRA 088/2019 Administration Clerk

A JOB INFORMATION SUMMARY

1. JOB TITLE	Administration Clerk (Fixed Term Contract)
2. DESIGNATED UNIT	Backlog Clearance Program (BCP)
3. POST LEVEL	DPSA Level 5-6
4. COMPONENT	Medicines Backlog Project
5. POST REPORTS TO	Backlog lead
6. LOCATION	Pretoria

B JOB PURPOSE

The job exists to offer administrative support for the assessment and evaluation of applications for registration of medicines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate applications for the registration of medicines:** 1.1. Receive and sort electronic applications from industry based on active pharmaceutical ingredient (API) 1.2. Perform validation of application (does application open, perform virus check etc.) 1.3. Assess application against the relevant electronic administrative checklist or ensure eCTD application has passed validation 1.4. Submit administrative queries resulting from screening to the relevant application manager 1.5. Address query responses to administrative queries from applicants and inform application manager on the sufficiency of responses 1.6. Organise logistics for committee meetings as and when they are required 1.7. Assist in the printing of certificates for approved medicines and subsequent distribution to applicants 1.8. Additional duties as defined by the Health Product Authorisation backlog department head
2.	**Conduct risk management and audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Attend relevant training as may be necessary to support your function
3.	**Provide weekly progress reports to the Health Product Authorisation backlog department head**

D INHERENT REQUIREMENT OF THE JOB

D.1 Skills

- Comfort working with computers and computer software packages
- Ability to communicate fluently in English with both written and verbal communication
- Flexibility in adopting to new processes
- Quality conscious and excellent attention to detail and accuracy
- Detail-oriented with strong organization skills
- "Can do" mentality

D.2 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Grade 12 minimum: An appropriate 3-year qualification. National certificate/National Diploma/Post Graduate certificate/ Post graduate Diploma /Bachelor's Degree /B-Tech is an advantage.
2. Proven experience:
   - 3 years' experience in a similar role
   - Exposure to a medicines regulatory environment is an added advantage

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise directly with the Portfolio Coordinators
- Directly report to Backlog lead

E.2 External

- None

SAHPRA 089/2019 Medicines Evaluator: Level 1-Foundation (CER)

A JOB INFORMATION SUMMARY

1. JOB TITLE	Medicines Evaluator (Level 1 Foundation) - CER
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA consultant rates – Level 10
4. COMPONENT	Clinical Evaluation for Registration (CER)
5. POST REPORTS TO	1. Supervised by Level 2 or 3 evaluators 2. Backlog clinical lead 3. Assigned peer reviewer
6. LOCATION	Remote / Pretoria

B JOB PURPOSE

To evaluate the clinical, safety and efficacy of generic applications for registration in compliance with the Medicines and Related substances Act (101 of 1965), as amended, as well as with the relevant guidelines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate the safety and efficacy of applications for the registration of medicines:** 1.1. Reviews and evaluates the proposed labelling submitted in support of generic drug applications against registered innovator labelling and other prescribed references and guidelines 1.2. Perform abridged and verified reviews for generic medicines 1.3. Consistently update the application manager and assigned peer reviewer on the progress of the application 1.4. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.5. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.6. Engages in technical conversations with the applicant should the application manager deem it necessary 1.7. Other responsibilities as identified by the clinical backlog divisional lead
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB

D.1. Knowledge

- Knowledge of technical aspects for clinical evaluation of safety and efficacy of medicines
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2. Skills

- Ability to communicate fluently in English with both written and verbal communication
- Ability to evaluate scientific evidence of the safety and efficacy of medicinal products
- Able to understand the clinical content knowledge of the therapeutic area under evaluation
- Understanding of the pharmacology of the chemical under evaluation
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve
- Plans proactively and communicates potential roadblocks to application manager timeously

D.3. Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA.
2. Proven experience:
   - At least 2 years relevant experience
   - Basic knowledge of medicines control and regulation

E COMMUNICATION/NETWORKING

E.1. Internal

- Directly report to the assigned peer reviewer
- Liaise with the assigned Portfolio Coordinator
- Liaise with the assigned Evaluator Coordinator
- Where applicable, reporting to the internal CET committee
- Where applicable, reporting to the backlog clinical lead

E.2. External

- None

SAHPRA 089/2019 Medicines Evaluator: Level 1-Foundation (PER)

A JOB INFORMATION SUMMARY

1.JOB TITLE	Medicines Evaluator Level 1 (Foundation) - PER
*2.*DESIGNATED UNIT	Backlog Clearance Program
3.POST LEVEL	DPSA consultant rates – Level 10
4.COMPONENT	Pharmaceutical Evaluation for Registration (PER)
5.POST REPORTS TO	1. Supervised by Level 2 or 3 evaluators 2. Backlog PER lead 3. Assigned peer reviewer
6.LOCATION	Remote / Pretoria

B JOB PURPOSE

The job exists for the incumbent to offer technical support for the assessment and evaluation of applications for registration of medicines to ensure that they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. These duties are to be performed as an evaluator of the quality and bioequivalence of drugs

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate new applications for the registration of medicines:** 1.1. Evaluates the quality and bio-equivalence aspects of new chemical entities and generics for the registration of medicines. 1.2. Consistently update the application manager and assigned peer reviewer on the progress of the application 1.3. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.4. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.5. Engages in technical conversations with the applicant should the application manager deem it necessary 1.6. Other responsibilities as identified by the PER backlog divisional lead
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Knowledge of technical aspects for evaluation of quality and bioequivalence of medicines
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding and experience of the evaluation of quality and bioequivalence of medical drug applications
- Ability to communicate fluently in English with both written and verbal communication
- Manages time in an efficient and effective manner
- Plans proactively and communicates potential roadblocks to application manager timeously
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve

D.3 Learning Field and Indicators

1. Qualifications: Minimum requirement of:
   - B.Pharm
   - MSc in chemistry
2. Proven experience:
   - At least 2 years of work experience within the pharmaceutical industry
   - Exposure to a medical drug regulator is an added bonus

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise with the assigned Portfolio Coordinator
- Liaise the assigned Evaluator Coordinator
- Directly report to the assigned peer reviewer
- Where applicable, report to the internal CET committee
- Where applicable, report to the backlog PER lead

E.2 External

- None

SAHPRA 090/2019 Medicines Evaluator: Level 2-Specialisation (CER)

A JOB INFORMATION SUMMARY

1. JOB TITLE	Medicines Evaluator (Level 2 Specialised) - CER
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA consultant rates – Level 11
4. COMPONENT	Clinical Evaluation for Registration (CER)
5. POST REPORTS TO	1. Supervised by Level 2 or 3 evaluators 2. Backlog clinical lead 3. Assigned peer reviewer
6. LOCATION	Remote / Pretoria

B JOB PURPOSE

To evaluate the clinical, safety and efficacy of NCE and generic applications for registration in compliance with the Medicines and Related substances Act (101 of 1965), as amended, as well as with the relevant guidelines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate the safety and efficacy of applications for the registration of medicines:** 1.1. Reviews and evaluates the applicant reports relating to evaluation of preclinical pharmacological studies submitted in support of NCEs and generic drugs 1.2. Review of non-clinical and clinical data to support labelling of medicines for regulatory purposes 1.3. Consistently update the application manager and assigned peer reviewer on the progress of the application 1.4. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.5. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.6. Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary 1.7. Other responsibilities as identified by the CER backlog divisional lead
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB (Competency profile)

D.1 Knowledge

- Knowledge of technical aspects for evaluation of safety and efficacy of medicines
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Ability to evaluate scientific evidence of the safety and efficacy of medicines application
- Ability to communicate fluently in English with both written and verbal communication
- Clinical content knowledge of the therapeutic area under evaluation
- Understanding of the pharmacology of the chemical under evaluation
- Understanding of bio statistical principles of medical research
- Understanding of clinical study design principles and impact on study results
- Ability to interpret results of clinical studies and make clinical practice and labelling recommendations
- Able to understand the clinical content knowledge of the therapeutic area under evaluation
- Plans proactively and communicates potential roadblocks to Portfolio Coordinator timeously

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA.
2. Experience: Minimum requirement:
   - At least 2 years relevant experience. Good working knowledge of 1 or more areas of regulatory activity. Evaluate full, abridged and verified applications independently.

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly report to the assigned peer reviewer
- Liaise with the assigned Portfolio Coordinator
- Liaise with the assigned Evaluator Coordinator
- Where applicable, reporting to the internal CET committee
- Where applicable, reporting to the backlog clinical lead

E.2 External

- None

SAHPRA 090/2019 Medicines Evaluator: Level 2-Specialisation (PER)

A JOB INFORMATION SUMMARY

1. JOB TITLE	Medicines Evaluator (Level 2 Specialised) - PER
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA consultant rates – Level 11
4. COMPONENT	Pharmaceutical Evaluation for Registration (PER)
5. POST REPORTS TO	1. Supervised by Level 2 or 3 evaluators 2. Backlog clinical lead 3. Assigned peer reviewer
6. POST REPORTS TO	Remote / Pretoria

B JOB PURPOSE

The job exists for the incumbent to offer technical support for the assessment and evaluation of applications for registration of medicines to ensure that they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. These duties are to be performed as an evaluator of the quality and bioequivalence of medicines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate new applications for the registration of medicines:** 1.1. Evaluates the quality and bio-equivalence aspects of new chemical entities and generics for the registration of medicines. 1.2. Consistently update the Portfolio Coordinator and assigned peer reviewer on the progress of the application 1.3. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.4. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.5. Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary 1.6. Other responsibilities as identified by the P&A backlog divisional lead
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB (Competency profile)

D.1 Knowledge

- Knowledge of technical aspects for evaluation of safety and efficacy of medicines
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding and experience of the evaluation of quality and bioequivalence of medicines applications
- Ability to communicate fluently in English with both written and verbal communication
- Manages time in an efficient and effective manner
- Plans proactively and communicates potential roadblocks to application manager timeously
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - BPharm
   - MSc in chemistry
2. Experience: Minimum requirement:
   - At least 2 years relevant experience. Good working knowledge of 1 or more areas of regulatory activity. Evaluate full, abridged and verified applications independently.

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly report to the assigned peer reviewer
- Liaise with the assigned Portfolio Coordinator
- Liaise with the assigned Evaluator Coordinator
- Where applicable, reporting to the internal PER lead

E.2 External

- None

SAHPRA 090/2019 Medicines Evaluator: Level 2-Specialisation (Inspectorate)

A JOB INFORMATION SUMMARY

1.JOB TITLE	Medicines Evaluator (Level 2 Specialisation) - Inspectorate
2.DESIGNATED UNIT	Backlog Clearance Program
3.POST LEVEL	DPSA consultant rates – Level 11
4.COMPONENT	Inspectorate and Law Enforcement
5.POST REPORTS TO	Backlog inspectorate lead
6.LOCATION	Remote / Pretoria

B JOB PURPOSE

The job exists to ensure manufacturing sites comply with good manufacturing practice (GMP) for the registration of medicines to ensure they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. This is done through the inspections conducted on these sites and the evaluations of the dossiers submitted by applicants. These duties are to be performed as a primary inspector of the inspection reports

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Evaluate medical applications** 1.1 Inspect pharmaceutical local manufacturing sites for compliance with Good Manufacturing Practices (GMP) by evaluating standard operating procedures (SOP's) of manufacturing sites for compliance with GMP Guidelines as accepted by the SAHPRA 1.2 Consistently update the application manager and assigned peer reviewer on the progress of the application 1.3 Evaluate the dossiers submitted by applicants to ensure documents to be relied upon accurately reflect that the site is adequate to produce the product they applied for 1.4 When an inspection occurs the inspector prepares an inspection report to be peer reviewed 1.5 Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.6 Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary 1.7 Other responsibilities as identified by the backlog clearance inspectorate backlog divisional lead
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and Guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB (Competency profile)

D.1 Knowledge

- Deep knowledge of technical aspects for inspection of sites for GMP approval
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding and experience in the evaluation of the quality and bioequivalence of Manages time through working efficiently and prioritising effectively
- Ability to communicate fluently in English with both written and verbal communication
- Excellent planning as the job requires trips to perform inspections and simultaneously perform evaluations
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve

D.3 Learning Field and Indicators

1. Qualifications:
   - An appropriate recognised three year Bachelor's degree in natural sciences or NQF 6 certificate in pharmacy
2. Proven experience in:
   - At least 3 years' experience as a GMP inspector for a medicines regulator
   - Experience working for a health regulator in South Africa would be an added advantage
3. A valid driver's license
4. Willing to travel

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly communicate with assigned Portfolio Coordinator
- Directly communicate with assigned Evaluator Coordinator
- Where applicable, reporting to the external committee
- Where applicable, the backlog inspectorate lead

E.2 External

None

SAHPRA 090/2019 Medicines Evaluator: Level 2-Specialisation (N&S)

A JOB INFORMATION SUMMARY

1.JOB TITLE	Medicines Evaluator Level 2 (Specialisation) - N&S (Names and Scheduling)
*2.*DESIGNATED UNIT	Backlog Clearance Program
3.POST LEVEL	DPSA consultant rates – Level 11
4.COMPONENT	Names and Scheduling (N&S)
5.POST REPORTS TO	Backlog N&S lead
6.LOCATION	Remote / Pretoria

B JOB PURPOSE

The job exists to offer technical support for the assessment and evaluation of applications for registration of medicines to ensure that they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. This is to be done as the technical screening of generic and NCE medicines applications and the primary evaluator of generic medicines applications in the names and scheduling department.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Screen, Assess and evaluate applications for the registration of medicines:** 1.1. To screen the generic and NCE medicines applications 1.2. To assess and evaluate the schedule status for generic medicines applications 1.3. To assess and evaluate the proprietary names of new medicines applications and the proprietary name changes of post registration amendments 1.4. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the Team Leader reviewer 1.5. Consistently update the Portfolio Coordinator and assigned Team Leader reviewer on the progress of the application 1.6. Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary 1.7. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.8. Submit report to BAU N&A staff member for updating of the schedules in the Government Gazette
2.	**Risk Management and Audit:** 2.1. Standard operating procedures and guidelines must be adhered to 2.2. Assesses applicant responses to queries on applications for registration of medicines 2.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Knowledge and application of the Medicines and Related Substance Control Act, 101 of 1965 and related regulations.
- Sound working knowledge of computer software packages
- Technical knowledge of the safety, quality and efficacy of medicines and their application in medicines evaluation is an added bonus
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding of the requirements and process to schedule a drug
- Ability to communicate fluently in English with both written and verbal communication
- Willingness to receive feedback, dedicated to learning and, striving to continuously improve
- Ability to work precisely and efficiently
- Able to work under time pressure and a stressful environment

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Bachelor's degree in Pharmacy (BPharm) plus adequate experience gained after obtaining the aforementioned qualification. (completion of Community service)
2. Proven experience in:
   - Previous experience within a medicines regulatory environment is required
   - At least 2 years of experience within the pharmaceutical industry

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly report to the assigned Team Leader reviewer
- Liaise with the assigned Portfolio Coordinator
- Liaise with the assigned Evaluator Coordinator
- Where applicable, reporting to the internal N&S committee
- Where applicable, the backlog N&S lead

E.2 External

- None

SAHPRA 091/2019 Medicines Evaluator: Level 3 –Advanced (CER)

A JOB INFORMATION SUMMARY

1. JOB TITLE	Medicines Evaluator Level 3 (Advanced) - CER
2. DESIGNATED UNIT	Backlog Clearance Program
3. POST LEVEL	DPSA consultant rates – Level 12
4. COMPONENT	Clinical Evaluation for Registration (CER)
5. POST REPORTS TO	1. Backlog clinical lead 2. Assigned peer reviewer
6. LOCATION	Remote / Pretoria

B JOB PURPOSE

To evaluate the clinical, safety and efficacy of NCE and generic applications for registration in compliance with the Medicines and Related substances Act (101 of 1965), as amended, as well as with the relevant guidelines. In addition, the job will require technical oversight of the assessment and evaluation of applications for registration to be performed as a peer reviewer.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate the clinical safety and efficacy of applications for the registration of medicines:** 1.1. Reviews and evaluates the applicant reports relating to preclinical and clinical studies submitted in support of the labelling of NCE and generic medicines 1.2. Review of non-clinical and clinical data to support labelling of medicines for regulatory purposes 1.3. Consistently update the application manager and assigned peer reviewer on the progress of the application 1.4. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.5. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.6. Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary 1.7. Other responsibilities as identified by the clinical backlog divisional lead
2.	**Technical oversight of the assessment and evaluation of the safety and efficacy of applications for the registration of medicines:** 2.1. Provide guidance to primary evaluators whist they conduct reviews. 2.2. Reviews primary evaluator's reports relating to evaluation of preclinical pharmacological studies submitted in support of NCEs and generic drugs 2.3. Consistently update the application manager on applicant information 2.4. Provide input into review results for the technical committee should the review provide a different outcome to that of the primary evaluator 2.5. Provide input into report results for the technical committee

OBJECTIVES AND ACTIVITIES	
3.	**Risk Management and Audit:** 3.1. Standard operating procedures and guidelines must be adhered to 3.2. Assesses applicant responses to queries on applications for registration of medicines 3.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Knowledge of technical aspects for evaluation of safety and efficacy of medicines
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Ability to evaluate scientific evidence of the safety and efficacy of medicines application
- Ability to mentor a team of evaluators and develop them from a technical standpoint
- Ability to communicate fluently in English with both written and verbal communication
- Clinical content knowledge of the therapeutic area under evaluation
- Understanding of the pharmacology of the chemical under evaluation
- Understanding of bio statistical principles of medical research
- Understanding of clinical study design principles and impact on study results
- Ability to interpret results of clinical studies and make clinical practice and labelling recommendations
- Able to understand the clinical content knowledge of the therapeutic area under evaluation
- Plans proactively and communicates potential roadblocks to Portfolio Coordinator timeously

D.3 Learning Field and Indicators

1. Qualifications:
   Minimum requirement of:
   - Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA.
2. Proven experience:
   - At least 8 years relevant experience. Recognised within SAHPRA and internationally as an expert. Detailed knowledge of one or more areas of regulatory activity. Evaluate novel or complex APIs; peer review evaluations; mentor lower level evaluators.

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise with assigned Portfolio Coordinator
- Liaise with assigned Evaluator Coordinator
- Where applicable, directly report to the assigned peer reviewer
- Where applicable, reporting to the CET committee
- Where applicable, reporting to the backlog CER lead

E.2 External

- None

SAHPRA 091/2019 Medicines Evaluator: Level 3 –Advanced (PER)

A JOB INFORMATION SUMMARY

1.JOB TITLE	Medicines Evaluator Level 3 (Advanced) - PER
2.DESIGNATED UNIT	Backlog Clearance Program
3.POST LEVEL	DPSA consultant rates – Level 12
4.COMPONENT	Pharmaceutical Evaluation for Registration (PER)
5.POST REPORTS TO	Backlog PER lead
6.LOCATION	Remote / Pretoria

B JOB PURPOSE

The job exists to offer technical support for the assessment and evaluation of applications for registration of medicines to ensure that they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. These duties are to be performed as an evaluator and a peer reviewer of the quality and bioequivalence of medicines.

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Assess and evaluate new applications for the registration of medicines:** 1.1. Evaluates the quality and bio-equivalence aspects of new chemical entities and generics for the registration of medicines. 1.2. Consistently update the application manager and assigned peer reviewer on the progress of the application 1.3. Prepares a comprehensive summary of the data reviewed and submits conclusions for approval by the peer reviewer 1.4. Provide input into report results for the technical committee when evaluation result differs to that of the peer reviewer 1.5. Engages in technical conversations with the applicant should the application manager deem it necessary 1.6. Other responsibilities as identified by the PER backlog divisional lead
2.	**Review and provide opinion on the primary evaluator's application report** 2.1. Provide guidance to primary evaluators whist they conduct reviews. 2.2. Review primary evaluator reports concerning the quality and bio-equivalence aspects of variations and new registrations of medicines applications 2.3. Update application manager as to the result of the primary evaluator report review 2.4. Provide input into review results for the technical committee should the review provide a different outcome to that of the primary evaluator 2.5. Other responsibilities as identified by the backlog clearance PER team lead

OBJECTIVES AND ACTIVITIES	
3.	**Risk Management and Audit:** 3.1. Adhere to all standard operating procedures and guidelines 3.2. Assesses applicant responses to queries on applications for registration of medicines 3.3. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB

D.1 Knowledge

- Knowledge of technical aspects for evaluation of quality and efficacy (bioequivalence) of medical drug applications
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding and experience in the evaluation of the quality and bioequivalence of medicines application
- Ability to communicate fluently in English with both written and verbal communication
- Ability to mentor a team of evaluators and develop them from a technical standpoint
- Manages time efficiently through efficient work and effective prioritisation

D.3 Learning Field and Indicators

1. Qualifications: Minimum requirement of:
   - BPharm
   - MSc in chemistry
2. Proven experience in:
   - At least 8 years' proven experience as an evaluator for a health regulator

E COMMUNICATION/NETWORKING

E.1 Internal

- Liaise with assigned Portfolio Coordinator
- Liaise with assigned Evaluator Coordinator
- Where applicable, report to assigned peer reviewer
- Where applicable, reporting to the external committee
- Where applicable, the backlog PER lead

E.2 External

- None

SAHPRA 091/2019 Medicines Evaluator: Level 3 –Advanced (Inspectorate)

A JOB INFORMATION SUMMARY

1.JOB TITLE	Medicines Evaluator (Level 3 Advanced) - Inspectorate
2.CORE:	Backlog Clearance Program
3.POST LEVEL	DPSA consultant rates – Level 12
4.COMPONENT	Inspectorate and Law Enforcement
5.POST REPORTS TO	Backlog inspectorate lead
6.LOCATION	Remote / Pretoria

B JOB PURPOSE

The job exists to offer technical oversight of the inspections conducted by primary inspectors for the registration of medicines to ensure they are compliant with the Medicines and Related Substances Act (101 of 1965) as amended and the subscribed guidelines. These duties are to be performed as a peer reviewer of the inspection reports

C MAIN OBJECTIVES

OBJECTIVES AND ACTIVITIES	
1.	**Evaluate medical applications** 1.1 Provide inspectors with guidance throughout the inspection process 1.2 Reviews primary inspector site evaluation reports 1.3 Provide input into review results for the technical committee should the review provide a different outcome to that of the primary evaluator 1.4 Consistently update the application manager on the status of applications 1.5 Conduct evaluations of sites that are deemed to have preliminary GMP approval from the technical screening phase 1.6 Other responsibilities as identified by the inspectorate divisional backlog lead
2.	**Risk Management and Audit:** 2.1. Adhere to all standard operating procedures and guidelines 2.2. Attend relevant training as may be necessary to support your function

D INHERENT REQUIREMENT OF THE JOB (Competency profile)

D.1 Knowledge

- Deep knowledge of technical aspects for inspection of sites for GMP approval
- Sound working knowledge of computer software packages
- Working knowledge of document management and workflow management software is an added bonus
- Knowledge of CTD and eCTD software applications is an added bonus

D.2 Skills

- Deep understanding and experience of the inspection of manufacturing sites and the underlying principles of good manufacturing practice
- Ability to mentor a team of evaluators and develop them from a technical standpoint
- Manages time efficiently through efficient work and effective prioritisation
- Ability to communicate fluently in English with both written and verbal communication
- Excellent planning skills

D.3 Learning Field and Indicators

1. Qualifications:
   - An appropriate recognised three year Bachelor's degree in natural sciences or NQF 6 certificate in pharmacy
2. Proven experience in:
   - At least 10 years' experience as an inspector for a medicines regulator
   - Leadership positions that dealt with the mentoring and development of inspectors through performance management and on the job training
3. A valid driver's license
4. Willing to travel

E COMMUNICATION/NETWORKING

E.1 Internal

- Directly communicate with assigned Portfolio Coordinator
- Directly communicate with assigned Evaluator Coordinator
- Where applicable, reporting to the external committee
- Where applicable, the backlog inspectorate lead

E.2 External

- None