National Research Foundation
iThemba LABS
Laboratory for Accelerator Based Sciences

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REQUEST FOR QUOTATION (RFQ)

Supplier Name: .....

GOODS [X] **SERVICE** [ ]

Request for Quotation Number	iLABS/RFQ 2025/26:247
Date Issued:	05 March 2026
Description of Services/ Goods:	Supply and installation of an Electronic Quality Management System (EQMS) for the Nuclear Medicine Department, iThemba LABS, Cape Town. Full Specification on page 4
Closing Date:	19 March 2026
Closing Time:	11:00 am
E-submission	**Bids may be submitted via e-submission. e-Tenders e-submission platform: This link helps for e-submission:** https://www.youtube.com/watch?v=x9DDXBTUOAw or email to: scm2@tlabs.ac.za
Date Goods or Service Required:	ASAP
For More Information (Technical):	Email: scm3@tlabs.ac.za Tel: 021 843 1000
For More Information (Supply Chain Management):	Email: scm3@tlabs.ac.za Tel: 021 843 1345

THE FOLLOWING CONDITIONS WILL APPLY:

- **Where quotations/proposals are R 2 000.00 or more, the preferential Procurement System Applicable is 80/20**
- Price(s) quoted must be valid for at **least sixty (60) days from closing date of the RFQ**.
- Price(s) quoted must be firm and must be inclusive of VAT.

PAYMENT CONDITIONS:

- For Any advance payments: A payment guarantee approved by iThemba Labs Finance will be accepted.
- Payment terms are 30 days from date of invoice received date
    - As schedule 3A public entity: Payments terms are 30 days from date of invoices (should you be awarded).
    - Should your conditions differ i.e. shorter payment terms, your organisation will be requested to submit a Payment Guarantee to mitigate all risks.
    - Or shorter payment of 7/14days from delivery date mutually agreed between both parties, **at the time of submitting your pricing proposal.**
- A firm delivery period **must** be indicated.
- Late proposals/quotations / bids will be not be accepted.
- **Submit your B - BBEE Certificate as accredited with SANAS or Sworn affidavit if you are claiming for specific goals.**
- **Bidder / service provider / supplier that fails to provide mandatory RFQ requirements may be disqualified.**
- **Changes made by the / service provider/supplier to the RFQ template and its terms and conditions will not be considered after the closing date and time**
- Provide CSD Summary Report (www.csd.gov.za)
- The attached forms to be completed by the Bidder (where applicable):
    - SBD 4 – Bidder disclose
    - SBD 6.1 – Preference Points Claim (South African Companies Only)
- This request for formal quotation is subject to the Preferential Procurement Policy Framework Act (PPPFA) and The Preferential Procurement Regulations, 2022, **The General Conditions of Contract (GCC and, if applicable, any other special Conditions of Contract**.

REGISTRATION ON THE CENTRAL SUPPLIER DATABASE (CSD):
The bidder must be on the National Treasury's Central Supplier Database in order to do business with the NRF and for the NRF to award a bid and sign the subsequent contract. Registration on the CSD (www.csd.gov.za) is compulsory and bids from unregistered bidders are not considered.
National Treasury Contact Details: +27 (0) 12 406 9222 or email csd.support@treasury.gov.za

SCHEDULE 1 - SPECIFICATION

Introduction to the NRF

The National Research Foundation ("NRF") is a juristic person established in terms of the National Research Foundation Act, Act 23 of 1998, and a Schedule 3A Public Entity in terms of the Public Finance Management Act. The NRF is the government's national agency responsible for promoting and supporting research and human capital development through funding researchers, provision of the National Research Platforms, and science outreach platforms/programs to the broader community. The NRF provides these services in all fields of science and technology, including natural science, engineering, social science, and humanities.

The NRF is a schedule 3A entity under the PFMA (Act 29 of 1999), which is required to plan and report on its activities and organizational performance, and which is to be audited by the AGSA on an annual basis. As part of the AGSA audit requirements, the NRF has to collect / document and store details, data and/or information of all persons and activities that form part of its performance record as proof thereof. In terms of this requirement, all persons making use of NRF facilities, platforms, equipment, tools etc., for research and related purposes are required to provide their personal details/data/information as per the template below or other similarly appropriate format. By completing your information in the template/register/record below and appending your signature thereto, you confirm your consent, in line with the Protection of Personal Information Act 4 of 2013, whereby the NRF and any of its business units may process (collect, receive, record, organize, collate, share, store, update, modify, retrieve, alter, consult, use, disseminate, distribute,

merge, link, erase or destroy) the personal information you provide within and amongst its business units/functions for the purpose of fulfilling its statutory mandate, public accountability and other regulatory/legal requirements.

Introduction to the Business Unit responsible for this RFQ

iThemba LABS (Laboratory for Accelerator-Based Sciences) is a multi-disciplinary research laboratory based at two sites in the Western Cape and Gauteng respectively, these provide facilities for:

- Basic and applied nuclear physics research using particle beams
- Research Radiation Biophysics
- The supply of accelerator-produced radioactive isotopes for nuclear medicine and research

Evaluation Process

- Evaluation of proposals:

  All proposals will be evaluated by Supply Chain Management for administrative compliance, functionality, price and B-BBEE. Based on the results of the evaluation process and upon successful negotiations, iThemba LABS will approve the awarding of the contract to the successful bidder.

- Preference points system:

  The 80/20 preference point system will be used where 80 points will be dedicated to price and 20 points to B-BBEE status. **"**If all bids received are more than R 1 000 000.00, this request is automatically cancelled''.

  Subject to section 2(1)(*f*) of the PPPFA, the contract will be awarded to the tenderer scoring the highest points.

Supplier Response

Name of Supplier:	
Address of Supplier:	
Contact Person:	
Contact Tel:	
Email Address:	
CSD Supplier Number:	MAAA……
Lead Time for delivery	
Currency:	ZAR
Payment terms:	30 days from the date of receiving the invoice

Administrative Compliance Returnable Documents (M – Mandatory); (O – Optional)	Submitted	
Bidders Disclosure (SBD 4), signed and completed.	**M**	❑ Yes ❑ No
Preference Points Claimed (SBD 6.1), signed and completed with BBBEE certificate or sworn affidavit (applicable for local bidders).	**O**	❑ Yes ❑ No
Bidders must provide list (minimum three (3)) of contactable references where the bidder has successfully implemented similar systems	**M**	❑ Yes ❑ No
Bidders must provide a letter confirming that they are authorised to sell the Electronic Quality Management System on behalf of the Vendor.	**M**	❑ Yes ❑ No
Bidders are required to complete the User Requirement Specifications (URS) as per specifications. If any response is NO then an alternative to meet the requirement must be stipulated by the bidder. Failure to completely respond to the URS elements will be seen negatively	**M**	❑ Yes ❑ No
Presentation of the proposed systems elements from the bidders is required if 1.3 successful (met the URS).	**M**	❑ Yes ❑ No
The successful bidder must agree to complete the URS again on the Quality Assurance template for validation purposes. The identical URS v 1.3 will be used	**M**	❑ Yes ❑ No
(M – Mandatory); (O – Optional)	**Submitted**	
Pricing completed	**M**	❑ Yes ❑ No

SPECIFICATIONS:

1. OBJECTIVE

The User Requirement Specification (URS) is a key document to specify the functional and operation requirements that the electronic Quality Management System (EQMS) should comply with, to fulfill the needs of iThemba LABS. The URS shall provide the Vendor clarity on the technical, quality and documentation requirements of iThemba LABS. The URS is required to contain clear, concise and testable requirements to serve as a baseline for validation and qualification for the successful compilation and implementation of the Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) of the EQMS Software.

Accept: Yes/No		Comment:	

2. SCOPE

2.1. Governance

The URS will be applicable to govern and outline the requirements of the following EQMS software modules to comply with 21CFR Part 11 and cGMP requirements:

- Change Controls

- Deviations
- CAPA
- Customer Complaints
- Audit Management
- Documentation Management (SOPs, Batch books, Drawings, Protocols and Reports)

Accept: Yes/No		Comment:	

2.2. Implementation

This system must be implemented at the following iThemba LABS Site:

- iThemba Labs, Nuclear Medicines Department, Old Faure Rd, Cape Town, South Africa

Accept: Yes/No		Comment:	

3. RESPONSIBILITIES

3.1. Quality Assurance (System Owner)

The System Owner for this EQMS software is the Quality Assurance department. The System Owner is responsible for assisting for the development of the URS and reviewing and approving the final URS to ensure that it accurately reflects the requirements of the system intended, to users. Quality assurance verifies cGMP requirements, as well as applicable validation guidelines for qualification and provides feedback to subsequent qualification protocols. The System Owner is also the owner of the URS document.

3.2. Implementation Team

The Implementation Team Users will be responsible to conduct the User Acceptance Testing as per the site's requirements. All Users will receive training from the service provider or bidder as and when required.

4. OVERVIEW

4.1. Background

The EQMS software system must be an integrated Quality Assurance Management System which will provide iThemba LABS with a highly configurable, workflow driven process automation with 21CFR Part 11 and cGMP compliance.

Accept: Yes/No		Comment:	

4.2. Project Overview

4.2.1. Project Summary

The EQMS system must be developed and configured as part of iThemba LABS commitments. The EQMS

must enable the Applicant, iThemba LABS, to process Change Controls, Deviations, CAPAs, Customer Complaints, Audits and documentation in an electronic validated environment.

Accept: Yes/No		Comment:	

4.2.2. Key Objectives

The key objective is to provide an electronic Quality Assurance Management System with the required functionality while simultaneously meeting the requirements of ISPE GAMP 5, cGMP, FDA's 21 CFR Part 11.

Accept: Yes/No		Comment:	

4.2.3. Anticipated Benefits

The EQMS must be able to integrate with other products, or future products, to further improve the overall compliance to the required regulatory requirements throughout iThemba LABS with products such as (electronic Batch Records Management System, LIMS (Laboratory Information Management System) and (Training Management System).

Accept: Yes/No		Comment:	

The EQMS system must be highly configurable, quick to implement, and can mimic the current formats and workflow, thereby reducing training needs and process changes

Accept: Yes/No		Comment:	

The system must be a pre-validated central framework that will reduce validation efforts during and after its implementation.

Accept: Yes/No		Comment:	

To improve Regulatory Compliance

To implement a core Quality Management System within the iThemba LABS that will promote a high standard across all areas of the business.

To have a tool that consolidates all information and can provide an overview to the Quality Assurance of all QA activities across the iThemba LABS.

Accept: Yes/No		Comment:	

To increase the effectiveness, efficiency and turn-around time of the QA processes as manual systems are more time consuming with authenticated electronic signatures.
To identify trends within each QA process that will identify areas for improvement and promote continuous improvement.

Accept: Yes/No		Comment:	

To have real-time validated data you can trust and which you can access from any location through being connected to the internet.
To promote a consistent format of capturing data across all iThemba LABS sites.
Traceability if changes are made.
To generate consistent month end reports across all iThemba LABS sites and spend less time to consolidate data for reporting purposes.

Accept: Yes/No		Comment:	

To be able to export data from system in a report *.pdf format as well as raw data in MS Excel format.

Accept: Yes/No		Comment:	

To automatically send initial and reminder notifications to users to perform activities on records.

Accept: Yes/No		Comment:	

To escalate records to the approving manager or senior management for records nearing due dates and those passing due dates.

Accept: Yes/No		Comment:	

Provide secure access to non-iThemba LABS affiliated contract manufacturers to upload and comment and approve customer complaints.

Accept: Yes/No		Comment:	

4.3. Facility Overview

4.3.1. Existing Facilities and Equipment

The iThemba LABS Facilities as identified in section 2.2, are a combination of manufacturing, distribution, research and development and administration facilities. The introduction of the electronic Quality Management System will have no little to no impact on the existing physical facilities and/or equipment. The existing server room located within iThemba LABS will house the new equipment "Database Server" for the EQMS system.

4.3.2. New Facilities and Equipment

The introduction of the electronic Quality Management System does not require a new facility to house the new Database Server. All other facilities will have access to the new Database Server through existing connections within the iThemba LABS Network.

4.3.3. Modifications to Existing Facilities and Equipment

No major modifications of the existing facilities and/or equipment is required except to connect the new Database Server with the existing iThemba LABS Network.

4.4. Automated Overview

4.4.1. Existing Systems

The iThemba LABS Facilities as identified in section 2.2, are a combination of manufacturing, distribution, research and development and administration facilities. The introduction of the electronic Quality Management System will have no little to no impact on existing systems within the facilities identified as these facilities don't have any existing electronic EQMS to replace or migrate data from. The EQMS system is a stand-alone web-based software application and can operate on its own.

Accept: Yes/No		Comment:	

4.4.2. New Systems

None

4.4.3. Modifications to Existing Systems

No major modifications of the existing systems are required except to connect the new Database Server with the existing iThemba LABS Network. As part of iThemba LABS's requirements, selected product and vendor information from The MRP system will be integrated into EQMS.

4.5. Main Functions and Interfaces

4.5.1. Functions

Management Change Controls

Accept: Yes/No		Comment:	

Management of Deviations

Accept: Yes/No		Comment:	

Management of CAPAs

Accept: Yes/No		Comment:	

Management of Customer Complaints

Accept: Yes/No		Comment:	

Management of Audits

Accept: Yes/No		Comment:	

Management of documentation

Accept: Yes/No		Comment:	

4.5.2. Interfaces

MRP System

Accept: Yes/No		Comment:	

4.6. Applicable GxP requirements

USFDA: 21CFR Part 11

Accept: Yes/No		Comment:	

SAHPRA: Guide to Good Manufacturing Practice for Medicines in South Africa (Jun 10 v5)

SAHPRA: Good Wholesaling Practice for Wholesalers, Distributors and Bonded Warehouses (March 12 v2)

SPE GAMP 5

Accept: Yes/No		Comment:	

4.7. Other Applicable regulations

EudraLex: The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

WHO: Quality Assurance of Pharmaceuticals, a compendium of guidelines and related materials, Volume 2, 2nd updated edition, Good Manufacturing Practices and inspection.

5. OPERATIONAL REQUIREMENTS

5.1. Functions

5.1.1. Management Change Controls

Refer to Annexure 1 for more details.

5.1.2. Management of Deviations

Refer to Annexure 2 for more details.

5.1.3. Management of CAPAs

Refer to Annexure 3 for more details.

5.1.4. Management of Customer Complaints

Refer to annexure 4 for more details

5.1.5. Management of Audits

Refer to annexure 5 for more details

5.1.6. Management of Documentation

Refer to annexure 6 for more details

5.1.7. Reporting Requirements per function

Refer to Reporting sub-sections within Annexures 1 – 6.

5.2. Modes of operations

The system should provide 2 operation modes:1. Testing/Simulation Environment and Production Live Environment

Accept: Yes/No		Comment:	

5.2.1. Testing / Simulation Environment

The system shall allow users to simulate each process function which includes

Accept: Yes/No		Comment:	

The ability to work through a workflow, by selecting the appropriate users to review, testing the system to assign records automatically to the relevant approvers (as pre-defined).

Accept: Yes/No		Comment:	

The ability to test all possible scenarios within the system.

Accept: Yes/No		Comment:	

The ability to temporarily force input errors and return the process to a previous state where inputs can be corrected.

Accept: Yes/No		Comment:	

The ability to set and configure the frequency of notifications and escalations in accordance with the configured workflows for each module

Accept: Yes/No		Comment:	

5.2.2. Production / Live Environment

During normal operation, the system shall enable the user to perform required operations based on privileges associated with the user's account.

Accept: Yes/No		Comment:	

5.3. Performance and timing requirements

5.3.1. EQMS Performance

The system should perform at adequate levels to provide an effective and responsive system. The following guidelines are intended to indicate performance expectations:

Activity/Event	Performance Expectation
Process Monitoring and Basic Controls	EQMS should be monitoring each record generated in any Module in accordance with the workflow to indicate the process status and overall progress.
Process Input Display	EQMS display should be immediate as typing and drop-down fields are selected. Where information is collected from an integrated system i.e. MRP, the information retrieval and input generated into the form fields should be reflected immediately without delay.

Activity/Event	Performance Expectation
User Control Command	Evidence of EQMS response to user commands (e.g., submitting comments, approving activities/processes) and the status change where applicable of the record should be presented to the user within one (1) second (e.g., by changing from "pending Approval" to "QA Approved").
Display Navigation	Evidence of EQMS response to a user command to change displays between screens of the workflow should be presented to the user immediately without delay.
Workstation Synchronization	When a process attribute is changed from one workstation, the attribute change must be reflected on another workstation displays. Such attribute changes should be reflected on all workstations within three (3) seconds and or after the display is refreshed.

Accept: Yes/No		Comment:	

5.3.2. Date and Time

Data integrity is of utmost importance and the time an entry was made. The time of all actions need to be standardized and aligned across all users and take into consideration when users work on the system across different time zones.

Accept: Yes/No		Comment:	

Users should not be able to change the date and time of their operating system to influence the date and time of actions being recorded.

Accept: Yes/No		Comment:	

The EQMS shall be designed to minimize and, as necessary, compensate for differences in date and time values amongst different workstations used by different users.

Accept: Yes/No		Comment:	

Date/time compensation will be periodically reconciled to a known accurate date/time source. The date/time value should not normally deviate from the known accurate date/time source value by more than ten (10) seconds between periodic reconciliations

Accept: Yes/No		Comment:	

All date/time reconciliations shall be recorded in the EQMS event log(s) in a way that allows determination of the pre-reconciliation date/time value offset.

Accept: Yes/No		Comment:	

5.3.3. Action required in case of failure

If a power failure takes place, the system should enable the user to carry on with work from the last saved point

Accept: Yes/No		Comment:	

EQMS fault conditions (such as hardware anomalies; software failures and anomalies; communication failure and anomalies) that potentially impact data quality should be communicated by the system to the user and should be incorporated into the system's event log.

Accept: Yes/No		Comment:	

5.4. Safety

5.4.1. Desired Product / Process Safety Systems:

The System shall be protected with computer Anti-Virus software, Anti-Ransomware, Anti-Malware and adequate Firewalls to prevent data pilferage and misuse.

Accept: Yes/No		Comment:	

5.4.2. Any other specific requirements:

None.

5.5. Security

5.5.1. Desired Product/ Process Safety Systems:

All EQMS modules shall be designed to protect against deliberate and/or accidental activities that could potentially compromise electronic records.

Accept: Yes/No		Comment:	

Logical controls should include user authentication for any process control or modification activity. Refer to

the User Interfaces section (5.8) for additional descriptions related to logical controls.

Accept: Yes/No		Comment:	

The System shall be designed to allow the system administrator to control access of all users.

Accept: Yes/No		Comment:	

System access shall be restricted to authorized users only.

Accept: Yes/No		Comment:	

User permissions will be restricted in accordance with the level of authority assigned to a user. The User permissions are: “Initiator, Reviewer and Approver.

Accept: Yes/No		Comment:	

All the forms shall have the security statement that the forms are proprietary property of iThemba LABS and no part of the forms shall be reproduced in any form either electronic or manual mode.

Accept: Yes/No		Comment:	

5.5.2. Other specific requirements

The system should automatically identify the user access level based on the user’s role and restrict a user to either site specific user view or an unrestricted view for a Quality Assurance user.

Accept: Yes/No		Comment:	

5.6. Data

5.6.1. Definition

Data will be referred to all text entries entered into form fields by means of manually typing, selecting entries from a pre-defined dropdown list, or the uploading of file attachments as supporting documentation into defined fields.

Accept: Yes/No		Comment:	

5.6.2. Capacity requirements

None

5.6.3. Access speed requirements

Real-time Data

Access to real-time data, via the user interface displays, is a primary function of the PCS. Refer to the "Functions - Performance and Timing" subsection for a description of performance expectations including input display and workstation synchronization features.

Historical Data

EEQMS historical data includes all of the following:

- Process data records generated within of each of the 5 modules,
- File attachments,
- Alarm and event logs

Accept: Yes/No		Comment:	

The User interface to access historical data should include all of the following:

- Time-sequenced trending of values,
- Query-driven display of records,
- Pre-configured reports (which can also be exported into various file formats such as *.pdf, *.xlsx, *.tiff, *.docx)
- Access to historical data (i.e., not yet archived) should be optimized for efficient retrieval. However, no specific access speed specification is applicable due to the diverse nature of potential queries. Instead, the following interface guidelines are recommended:
  - For data retrieval that could take more than ten (10) seconds, an on-screen "in progress" indication should be provided.
  - For data retrieval that could take more than twenty (20) seconds, an ability to cancel the query should be provided.
  - For data retrieval that could take more than thirty (30) seconds, a rough progress indicator (e.g., percent complete bar graph) should be provided.

Accept: Yes/No		Comment:	

5.7. Archive requirements

EQMS historical data retention capabilities must conform to site and/or product data retention requirements.

In general, all historical data should be accessible for at least ten (10) years. Any robust archiving technology is acceptable; however, existing site archiving facilities, technologies, and procedures should be exploited if possible. Archive system design should consider the potential for having to migrate the historical data so that access can be preserved beyond the point of de-commissioning.

Accept: Yes/No		Comment:	

EQMS system manuals must include detailed procedures for committing historical data to archive and for retrieving historical data from archive. Retrieved historical data must include any and all data that was, or may have been, considered for verifying manufacturing and/or product quality. Retrieved data context, format, and/or access must be identical to, or at least comparable to, original data context, formats, and/or access. The EQMS system must provide the ability to retrieve archived data without interrupting ongoing process operations.

Accept: Yes/No		Comment:	

Back-up and recovery mechanism shall be in place to prevent a loss of data in case of power failure and data shall be stored on database with backup media for backup and archival.

Accept: Yes/No		Comment:	

5.8. Data security and integrity with regards to the requirements of 21 CFR Part 11

The EQMS data security and integrity features must be consistent with controls required by 21 CFR Part 11 to protect electronic records. The following table identifies anticipated EQMS design features intended to satisfy these requirements:

Part 11 Control	EQMS Compliance Feature(s)
System Validation	EQMS development lifecycle and documentation must be adequate to support system validation. This should include a specifications traceability matrix and/or similar quality control mechanism.
Copying Records	EQMS manuals should include detailed procedures for generating accurate and complete copies of records in both human readable and electronic form.
Protection through Retention Period	Refer to the 5.7. “Data - Archive Requirements” subsection of this document.

Part 11 Control	EQMS Compliance Feature(s)
Limiting System Access	Refer to 5.8 “Functions - Security” and 5.9 “User Interfaces - Security” subsections of this document.
Audit Trails	All EQMS historical records shall use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information.
Operational System Checks	EQMS specification documentation shall clearly identify permitted sequencing of steps and events that must be enforced, if any. The EQMS must be designed to enforce this sequencing, as appropriate.
Authority Checks	Refer to the 5.6 “Functions - Security” and 5.9 “User Interfaces - Security” subsections of this document.
Device Checks	EQMS specification documentation shall clearly identify restrictions to valid sources of data input or operational instruction, if any. The EQMS must be designed to enforce these restrictions, as appropriate.
System Documentation Controls	System operation and maintenance documentation must be included with the EQMS. Distribution of, access to, and use of this documentation must be adequately controlled and subject to revision and change control procedures that maintain an audit trail that documents time-sequenced development and modification of systems documentation.
Open System Controls	Systems with any component(s) that are not installed in an environment in which system access is controlled by persons responsible for the content of electronic records that are on the system are considered “Open Systems”. Open systems must include controls to ensure the authenticity and integrity of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include additional measures such as document encryption and use of appropriate digital signature standards.

Accept: Yes/No		Comment:	

5.9. User Interface

5.9.1. User Interface Design

User Interfaces are designed to facilitate both general process awareness and specific tasks. The EQMS software application is designed with a User Interface and is the backbone to login onto the software application, navigate between processes and tasks to capture data into the Database Server. The following table outlines the specific tasks accommodated by the EQMS user interface features:

Task	Description
Process Monitoring: Overview	Features designed to provide a rapid and accurate assessment of the status of a record within a specific process (Change Control, Deviation, CAPA, Customer Complaint and Audit Management). Overview displays the status of a record and this could be displayed graphically through a dashboard display. When a record is accessed the workflow view will be displayed to identify the state of the record.
Process Monitoring: Detail	Features designed to provide structured access to all important attributes. When a workflow is accessed to provide an overview of a record, the individual elements can be accessed to obtain further details on what actions are required to progress the records to next record state.
Process Monitoring: Analytical	Features designed to display historical and/or statistical information to users. These typically include a historical trend display of records.
Process Control	Features that provide for monitoring and control to initiate, review and approve records within each process module (Change Control, Deviation, CAPA, Customer Complaints and Audit Management). Process Control features typically include screens for workflow driven initiation of a record, review of records by various users and the ability for users to provide their comments, user prompts/responses, approvals by authorized personnel, rejection of records as a whole, or rejection of selected content by authorized personnel and reports.
Super Administrator Functions	Features, protected from normal user (initiator, reviewer and approver) access, designed to provide extraordinary process management controls. Super Administrator capabilities may include to re-open closed records when required, moving records to a previous state when additional information is required, etc. but doesn't include the capability to erase or change data without being logged in an audit trail.
Notification Management	Features designed to notify user of activities, records assigned to the user to be executed.
Reports	Features designed to select and display/print written summaries of historical production data.
Software Application Configuration	Features provided to allow for the customization and modification of the software application, i.e. identification of public holidays to calculate working day.

Accept: Yes/No		Comment:	

5.9.2. User Interface Hardware

User Interface hardware refer to the computer terminals/laptop, as the EQMS system is designed to be operated on a computer terminal/laptop.

Accept: Yes/No		Comment:	

5.9.3. Security

All EQMS user interfaces must be designed to control user access. Access controls must be consistent with 21 CFR Part 11 requirements for protection of computer systems that employ electronic records and electronic signatures. These include (but are not limited to) the following:

- User accounts shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
- User accounts not based on biometrics shall employ at least two distinct identification components such as a User ID and password. At least one of these components should be secret or otherwise guaranteed to be unique.
- Workstation logins should expire (e.g., by automatic logout) if no user activity occurs within a pre-determined, definable time period.
- Use of transaction safeguards to prevent unauthorized use of a user account, and to detect and report in an immediate and urgent manger any unauthorized access attempt to the system security unit, and, as appropriate, to organizational management.

Access level assigned to an individual will dictate which functions, interfaces, and displays a user has access to, and which operations the user can perform. Where feasible, user access administration should leverage existing site computer security policies and procedures (including security administration servers and existing user accounts).

Records of operator actions should include the operator's identity, as confirmed by user account login information. All access attempts and results must be recorded and accessible for review and/or reporting.

5.9.4. Workstation Display Navigation

Display navigation design should provide easy access to all user interface features. The following navigation characteristics should be provided:

	Navigation Attribute
☐	Display navigation should be limited, as appropriate, based on the user login and permission levels.
☐	A hierarchical menu system (e.g., in "site map" format and/or dropdown list) should be provided. Process Workflow displays should provide single keystroke/click navigation to this menu system.
☐	Process displays should provide single keystroke/click navigation to detail displays related to objects shown on the display (e.g., overview to detail).

	Navigation Attribute
☐	Process displays should provide single keystroke/click navigation to the previously viewed display(s) (e.g., a “Back” button).
☐	Process displays should provide single keystroke/click navigation to upstream and downstream process displays according to a comprehensive sequence, or sequences, of process displays within the workflow.

Accept: Yes/No		Comment:	

5.9.5. Reports

The user interface should provide the features needed to request, display, and print reports. A comprehensive process record report should be generated (per module / function i.e. Change Control, Deviation, CAPA, Customer Complaint and Audit Management) that includes all data entries made during the procedure (All required fields per workflow are stipulated within Annexure 1 - 5).

Additional required reports may include:

- Monthly and Quarterly Trend Analysis Reports per Process
- Efficiency Reports monitoring the time duration of records

Accept: Yes/No		Comment:	

5.9.6. Interfaces with other Systems

Communications to iThemba LABS’s ERP system is required to access Product Names, Batch Numbers and Vendor/Supplier Names. The intended communication mechanism will be through TCP/IP communication and will be communicated to EQMS on a daily basis to update the Database Server.

Accept: Yes/No		Comment:	

5.10. Environment

5.10.1. Location

The Server/s are located within iThemba Labs Server room.

Accept: Yes/No		Comment:	

5.10.2. Physical conditions

- Electrical power supply should be 230 V AC, three phase and 50 Hz.

- UPS (Un-interrupted power supply) connectivity
- Temperature controlled conditions to a set-point of 16 °C
- Raised floors

Accept: Yes/No		Comment:	

6. CONSTRAINTS

6.1. Timescales and milestones

The implementation of the 6 modules within EQMS will take place in 2026.

Accept: Yes/No		Comment:	

6.2. Compatibility

- Server PC
- User Terminal PC
- LAN Components
- File Attachments compatibility to new and older versions of Adobe Acrobat pdf. Files; MS Office *.docx files; MS Excel *.xlsx files throughout product lifetime to access historical data.

Accept: Yes/No		Comment:	

6.3. Availability

6.3.1. Reliability requirements

The maximum allowable period for maintenance or other downtime will should not interrupt daily operations at the designated sites. To prevent any disruptions any scheduled maintenance should take place outside of South African Office hours to ensure all process activities can take place without interruption. Maintenance should not take longer than 12 hours at a time.

Accept: Yes/No		Comment:	

6.4. Procedural constraints

6.4.1. Regulatory and statutory obligations

Regulatory and statutory obligations should be adhered to as set out in section 4.6 (21 CFR Part 11, GMP, and ISPE GAMP 5)

6.4.2. Workflows

Ensuring that the EQMS workflows are closely configured to current working methods and workflows to minimize training requirements.

Accept: Yes/No		Comment:	

6.4.3. Training requirements

Training manual from Vendor

Accept: Yes/No		Comment:	

Roll-out to all 20 users

Accept: Yes/No		Comment:	

6.4.4. Skill

Computer literacy user skill levels

Accept: Yes/No		Comment:	

6.4.5. Licenses

Impact if reduced licenses are procured and how this will limit the workflow to key users. Workflows will require a minimum of 3 users to participate (initiator, reviewer and approver).

The total number of licenses required for the EQMS system is 20 to allow all users to work without any constraint,

Accept: Yes/No		Comment:	

Vendor agreed to grant iThemba Labs free additional licenses for first year during implementation

Sites / Departments	Minimum Requirements for Functional Electronic EQMS®	Required Licence Numbers: Validated
QUALITY	**# Users**	**# Users**
Production	3	3
Quality Control	4	4
Quality Assurance	4	4

R&D	1	1
Procurement	1	1
Engineering	1	1
Radiation Safety	1	1
Admin	5	5
Total	**20**	**20**

Accept: Yes/No		Comment:	

6.5. Maintenance

Software updates and the ease thereof to update and enhance the software procured.

Expected lifetime and long-term support.

Accept: Yes/No		Comment:	

6.6. Vendor requirements

Documentation

Supply of user manuals

Supply of DQ IQ OQ PQ protocols and execution thereof with the iThemba team

Accept: Yes/No		Comment:	

With the iThemba IT team setup and installation of the EQMS® on server/s

Accept: Yes/No		Comment:	

7. Life Cycle

7.1. Development

The Supplier shall provide a Quality and Project Plan as part of their proposal. The Supplier shall have a quality system in place. Internal quality procedures shall be available for the User's review. The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.

Accept: Yes/No		Comment:	

The project shall utilize the GAMP methodology when developing the system and documentation.

Accept: Yes/No		Comment:	

Testing

To describe the Supplier testing requirements e.g. via remote/VPN

Accept: Yes/No		Comment:	

The EQMS will be validated in accordance with a Validation Test Plan before the system will be commissioned.

Accept: Yes/No		Comment:	

In order to verify system performance, the Users will take part in the User Acceptance Test procedure to verify the system workflows, configurations and all features as specified in the URS.

Accept: Yes/No		Comment:	

7.2. Delivery

The EQMS system, with all options, shall be installed onto the User's Database Server and the documents listed below delivered to the User during the implementation phase and site visits.

Accept: Yes/No		Comment:	

7.3. Documentation

Installation, operation, and maintenance instruction documentation for the system shall be developed to a level that is comprehensible to a high school graduate.

Accept: Yes/No		Comment:	

The Supplier shall use the formats described in the GAMP Supplier Guide, Current Version, to produce the documentation. The Supplier shall provide the documentation for preliminary review. The Supplier shall provide the final documentation in accordance with the agreed workflows and configurations made with final delivery.

Accept: Yes/No		Comment:	

All final documents shall be shipped with transmittals that identify them as contractually required documents.

Accept: Yes/No		Comment:	

All documents shall be in English and supplied with hard copies and electronic versions supplied in the format identified for each document:

Document	Format
Project Plan	Microsoft Projects Microsoft Word 2019 (*.docx)
User Requirements Specification	Microsoft Word 2019 (*.docx)
Impact/Risk Assessment	Microsoft Word 2019 (*.docx)
GAP Analysis	Microsoft Word 2019 (*.docx)
System Impact Assessment	Microsoft Word 2019 (*.docx)
Validation Plan	Microsoft Word 2019 (*.docx)
Qualification and Validation Protocols	Microsoft Word 2019 (*.docx)
Functional Specification/Requirements	Microsoft Word 2019 (*.docx)
Design Specifications	Microsoft Word 2019 (*.docx)
Hardware Installation Test	Microsoft Word 2019 (*.docx)
Operational Test	Microsoft Word 2019 (*.docx)
Operator, Maintenance and Service Manuals	Microsoft Word 2019 (*.docx)

Accept: Yes/No		Comment:	

7.4. Support

The following supporting activities will be required after acceptance:

7.4.1. Start-up Support

Training

Accept: Yes/No		Comment:	

Super User / Implementation team training on all modules within EQMS system

Accept: Yes/No		Comment:	

7.4.2. Post Start-up Support

Technical Support Telephone (Voice/modem/router/LAN connection/WIFI)

Accept: Yes/No		Comment:	

7.4.3. User Site Support

Preventative Maintenance (list maintenance contracts available)

Accept: Yes/No		Comment:	

System Improvements (supplier shall notify user of any improvements available on a regular basis)

Accept: Yes/No		Comment:	

8. RESOURCES AND PROJECT SUPPORT

8.1. Resources

The project will require a full-time Project Manager.

Accept: Yes/No		Comment:	

A resource from I.T. will be required to ensure proper installation and network configuration hardware.

Accept: Yes/No		Comment:	

During the implementation of EQMS the site's full-time support is required for the User Acceptance Testing, implementation and hand over.

Accept: Yes/No		Comment:	

The iThemba site will require an administrator to control the efficient running of the system.

Accept: Yes/No		Comment:	

Management of Change Controls

Change Control Form

Login/Initiator workflow and fields requirement

- Reference number shall be configurable and may be different for individual sites and corporate office. Number shall be allocated by QA department. Numbering shall be as follows: Department code/Sequential number/Year. The numbering shall be automatic once workflow has been initiated.
- Provision to enter Market/customer/country
- Generation of CC number is based on the selection of department.
- Provision to enter Date of initiation.
- Provision to enter Initiator name.
- Provision to enter Department.
- Provision to enter Title of the document.
- Provision to enter Document reference number.
- Provision to enter Details of change proposed:

  - Provision to enter the change related to: Master formula, BMR, BPR, Batch size, SOP, Specification, Test method, Facility, Utilities, Equipment, Artwork, Vendor, Product, Process and others (Multi selection).
- In case of Printed Material code/ Art work change, Provision to enter Ref. Art work Revision Number.
- Provision to enter details of Existing status (Option for file attachment)
- Provision to enter details of Change proposed (Option for attachment)
- Provision to enter details of Reason for change (Option for file attachment)
- Provision to attach supporting information (Option for file attachment)
- Initiator signature / date and time (electronically completed)
- Provision for user to review historical data. Documents upload - Provision to select requirement of documents as supporting data (Yes/No). If yes provision of file attachment. Format of files for attachments should include pdf, jpeg and tiff. To send mail alert in advance (at least 3 working days) to document controller and QA Manager/ Designate and Factory Manager for non-completion of identified actions.
- Continuous workflow requirement

- Initiator to Dept. Manager to complete Review and Evaluation comments.
- Form shall move Dept. Manager to QA/ EQMS® Manager to complete Review, Evaluation and Assessment of the change.
- Enter the classification of change like Critical, Major and Minor.
- Enter the documents affected by change or new documents to be prepared as a result of change like Artwork, BMR, BPR, Specification, Test Method, Validation Docs, SOPs, Vendors list, BOM and others (Multi selection). Integrating to CAPA module.
- Enter other departments whose approval and assessment is required (Multiple selection from a list).
- Form shall move to all selected department managers simultaneously for their comments.
- Form shall move to QA Manager/ Designate to enter the customer approval: Applicable/Not Applicable.
- If customer approval is applicable, the change request (updated till this stage) shall go to customer through e-mail along with supporting data (Optional file attachment). The form stays at QA Manager/ Designate ID.
- QA Manager/ Designate shall approve the change control behalf of the customer based on the supporting data/documents supplied. (Option for file attachment).
- The filled form shall move to QA manager/ designate to write summary of change control, enter certification of implementation of change control.
- In case of product related change final implementation date shall be entered.
- To decide further requirements like Validation, Stability, additional testing and Training.
- Identification of requirement of other actions triggered by the change controls e.g. other documents affected.
- After completion of identified other activities, provision to review all the revised documents, activities done.
- Provision to enter implemented activity details to give Implementation of change reviewed and verified comments. And closing of change control.

Form fields requirement for Initiator Department Manager

- Provision to give detailed description of the Review and Evaluation (Option for file attachment).
- Initiator Dept. Manager sign/date and time.

Form fields requirement for QA Manager/ Designate

- Provision to give detailed description of the Review, Evaluation and Assessment

- Provision to enter the documents affected by change or new documents to be prepared as a result of change like Artwork, BMR, BPR, Specification, Test Method, Validation Documents, SOPs, Vendors list, BOM and others (Multi-Selection).
- Provision to identify different departments to be affected by the change for their comments (Multi-Selection)
- Provision to select customer in a report.
- Provision to enter requirements for Validation, Stability, Training and others as separate fields with (Yes/No) option.
- Provision to enter the certificate of implementation of change control: Proposed actions subsequent to change, Responsibility, completed on, Ref.No. Reviewed by/date (Option for file attachment). Option to select more than one task and have each task owner notified via email
- In case of Product related change, provision to enter final implementation date.
- Verified by Sign. / Date
- Provision to enter Validation/Qualification completed (If applicable)
- Provision to enter Validation/Qualification Report No.
- Verified by Sign. / Date
- Training Completed (If Applicable)
- Verified by Sign. / Date
- Provision for Others to capture additional information.
- Verified by Sign. / Date
- Provision to enter Implementation of change reviewed and verified comments
- Change control closing date
- Manager sign/date and time with QA option

Form fields required to different Department Managers

- Provision to enter comments
- Department Manager sign/date and time

Form fields required to Customer (Provision shall be with QA Manager/ Designate)

- Mail based task intimation is required with receiver's selection option
- Provision to enter comments. (Option for file attachment)
- Customer sign/date and time

References

- SOP RPG-SOP-0006 Change Control Procedure

Reports

- Reports generated by the system shall be configurable. (Overdue, by department, by category)

Management of Deviations

Deviation Form

Login /Initiator workflow and form fields Requirement

- Initiator should have the provision to select planned deviation, unplanned deviation or Incident, based on the event.
- Reference No. shall be configurable and may be different from sites to corporate office (Sequential number for Deviation and Incident e.g. DEV/001/08/2024, where DEV - deviation, 001- sequential number for deviation, 08- represents the month deviation initiated, 2024- represents the year deviation logged).
- Allocation of the sequential number shall be automatically generated by the system.
- Provision to enter Initiation Date from the calendar.
- Provision to enter Initiator Department as drop-down menu.
- Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.
- Provision to enter Batch No. /Lot No
- Provision to enter Batch Size
- Provision to enter Mfg. Date
- Provision to enter Expiry Date
- Provision to enter A.R. No.
- Provision to enter other details (if any)
- Deviation Details (Provision to give detailed description of the deviation)
- Provision to attach any files/documents for reference (Option for file attachment)
- Initiated by signature / date and time.
-

Continuous Workflow Requirement

- Initiator to initiator Dept. Manager and subsequently to QA Manager. Justification/ Root Cause Investigation will be completed by Initiator and Initiator's Dept. Manager. (Option for file attachment)
- Initiator dept. manager will propose the CAPA.
- QA Manager / Manager shall complete assessment and approve the CAPA.
- Then it shall be linked to CAPA tracking based on target completion date.
- If the CAPA is proposed, for example training to be conducted then it shall be linked to the Training SOP (QA manager / Designate shall have the provision to select if it should be completed through CAPA or not).

- Flow of this form to Site Responsible Pharmacist or Plant Manager for comments.
- This form now moves to QA manager / Designate to directly approve or reject the deviation/incident.
- If required he should have the provision of notification to send to Regulatory /customer where applicable.
- After evaluation, if customer approval is required this information shall go to the customer through mail and the supporting data shall be attached. (Option for file attachment). The e- form stays at QA Manager ID.
- QA manager / Designate shall approve the deviation behalf of the customer on the basis of supporting data. (Option for file attachment)
- If the CAPA is generated it is tracked through the CAPA system and an ID of the issue stays at QA Manager ID. If no CAPA is selected then the issue closes at this point.
- Final closure: After implementation of the CAPA, QA manager / manager shall enter disposition comments and close the deviation.
- If deviation is permanent, it shall be linked to change control management but the deviation will be closed where necessary.

- Form fields requirement for Initiator dept. Manager
- Field required to enter detailed description of the Justification/Root cause investigation (Option for file attachment).
- Initiator Dept. Manager / Manager sign/date and time
- Field required to enter detailed description of the Corrective actions proposed (Option for file attachment)
- Field required to enter detailed description of the Preventive Actions Proposed (Option for file attachment)
- Initiator Dept. Manager / Manager sign/date and time

- Form fields requirement for QA dept. Manager / Manager
- Field required to approve the Justification/Root cause investigation
- QA Dept. Manager / Manager sign/date and time
- Field required to enter comments and approval of the corrective actions proposed
- Field required for entering comments and approval of the preventive actions proposed
- QA Manager / Designate sign/date and time
- Field required to enter comments (Approved/Rejected)
- Field required to Approve or Reject the deviation/incident

- QA Dept. Manager / Manager sign/date and time
- Field/notification required for selecting notification to: Regulatory/Customer/Contract giver/license holder (Yes/No).
- Field required for entering customer Approved/Rejected comments. (Field require in the name of customer but the provision should have the QA manager / manager)
- Field required to Approve / Reject the deviation/incident (on behalf of customer) (Option for file attachment).
- QA Dept. manager / manager sign/date and time
- Field required to enter disposition comments
- Deviation/Incident closed signature/date/time

- Form fields requirement for Plant Manager
- Field required to enter comments on the proposed Deviation/Incident
- Plant Manager/elevation to senior for sign/date and time

- Form fields requirement for Customer
- Field required to enter comments on the proposed Deviation/Incident
- Customer sign (or QA rep based on mail correspondence)/date and time

References

- SOP DEV-010 Handling of Deviations

Reports

- Reports generated by the system shall be configurable

Management of CAPA

CAPA Form

Login /Initiator work flow and form fields Requirement

- Initiator should have the provision to select planned deviation, unplanned deviation or Incident, based on the event.
- Reference No. shall be configurable (Sequential number for Deviation and Incident e.g. DEV/001/08/2024, where DEV - deviation, 001- sequential number for deviation, 08- represents the month deviation initiated, 2024- represents the year deviation logged).
- Allocation of the sequential number shall be automatically generated by the system.
- Provision to enter Initiation Date from the calendar.
- Provision to enter Initiator Department as drop-down menu.
- Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.
- Provision to enter Batch No. /Lot No
- Provision to enter Batch Size
- Provision to enter Mfg. Date
- Provision to enter Expiry Date
- Provision to enter A.R. No.
- Provision to enter other details (if any)
- Deviation Details (Provision to give detailed description of the deviation)
- Provision to attach any files/documents for reference (Option for file attachment)
- Initiated by signature / date and time.

Continuous work flow requirement

- Based on the significance respective Department Manager shall propose CAPA and target completion dates and assign responsible person.
- Proposed CAPA shall move to QA Manager for approval.
- QA Manager shall have the provision to evaluate and approve the CAPA.
- Based on origin of CAPA, QA Manager/Designate shall have the provision to allocate the unique CAPA tracking number and this number shall be configurable.
- CAPA/001/2024 where CAPA - Corrective and Preventive Action, 001=Sequential number, 2024 - shows the year CAPA initiated.
- CAPA shall move to the person responsible for implementation (Option for file attachment).

- Implemented CAPA shall be reviewed by respective dept. Manager.
- Form shall move to QA Manager for review and approval of implemented CAPA.
- QA Manager shall identify the department/regulatory body/auditor to whom the communication of compliance to be sent and provision to send mail communication.
- If CAPA is not completed in target completion dates, initiator dept. Manager shall request QA Manager for an extension for target completion along with justification.
- QA Manager shall give comments and extend the target completion date
- QA Manager sign/date.

Form field requirement for Initiator Department Manager

- Provision to propose CAPA and target completion dates.
- Initiator Dept. Manager sign/date
- Provision to assign the work to the person responsible.
- Initiator Dept. Manager sign/date
- Provision to review implemented CAPA.
- Initiator Dept. Manager sign/date
- Provision for mail alert to the department responsible person to comply with CAPA in advance to target completion date.
- Provision to request to increase target completion duration.
- Initiator Dept. Manager sign/date.

Form field requirement for Responsible person

- Provision to complete the work in target completion dates (option for file attachment)
- Responsible person sign/date

Form field requirement for QA Manager

- Provision to approve the proposed CAPA
- QA Manager sign/date
- Provision to approve the implemented CAPA
- QA Manager sign/date
- Provision to approve the request/justification from initiator dept. manager to increase the duration for target completion (Option for file attachment)
- QA Manager sign/date
- Provision for CAPA closure

- QA Manager sign/date
- Provision/notification to identify the department/regulatory body/auditor to whom the communication of compliance to be sent
- Provision to send a mail communication and option for file attachment.

4 Management of Complaints

Login /Initiator workflow and form fields Requirement

- Initiator should have the provision to select complaint, based on the event.
- Reference No. shall be configurable and may be different from departments (Sequential number for Complaint e.g. COMP/001/08/2024, where COMP - complaint, 001- sequential number for complaint, 08- represents the month complaint receieved, 2024- represents the year complaint logged).
- Allocation of the sequential number shall be automatically generated by the system.
- Provision to enter Initiation Date from the calendar.
- Provision to enter received by Function/Department as drop-down menu.
- Provision to enter received from whom and how (mail, fax, call, letter)
- Provision to enter sample recieved
- Provision to enter event related to: e.g. Product /Material /Document/Equipment etc.
- Provision to enter Batch No. /Lot No
- Provision to enter Batch Size
- Provision to enter Mfg. Date
- Provision to enter Expiry Date
- Provision to enter A.R. No.
- Provision to enter other details (if any)
- Provision for response and acknowledgement of complaint
- Deviation Details (Provision to give detailed description of the complaint)
- Provision to attach any files/documents for reference (Option for file attachment)
- Initiated by signature / date and time.

Continuous Workflow Requirement

- QA to allocate initiator Dept. Manager and subsequently to QA Manager. Justification/ Root Cause Investigation will be completed by allocated Dept. Manager. (Option for file attachment)
- Allocated dept. manager will propose the CAPA.
- QA Manager / Manager shall complete assessment and approve the complaint and the CAPA.
- QA manager to allocate classification
- Then it shall be linked to CAPA tracking based on target completion date.

References

- SOP RPG-QA-012 Complaints and recalls

Reports

- Reports generated shall be configurable

Management of Audits

Login /Initiator workflow and form fields Requirement

- Initiator should have the provision to select audit, based on the event.
- Audits can be internal, service, vendor, regulatory type audits
- Provision for Audit schedules to be uploaded.
- Provision for completed audits to be uploaded.
- Provision to enter Initiation Date from the calendar.
- Provision to attach any files/documents for reference (Option for file attachment)
- Initiated by signature / date and time.

Continuous Workflow Requirement

- QA to allocate initiator Dept. Manager and subsequently to QA Manager for response and capa (Option for file attachment)
- Allocated dept. manager will propose the CAPA.
- QA Manager / Manager shall complete assessment and approve the audit response.
- QA manager to allocate classification where applicable
- Then it shall be linked to CAPA tracking based on target completion date.

References

- SOP RPG-QA-022 Vendor audits, Self inspection, Regulatory audits

Reports

- Reports generated shall be configurable

Management of Documentation

Login /Initiator workflow and form fields Requirement

- Initiator should have the provision to select document by title or number.
- Provision for iThemba department numbering of documents
- Documents to have a prepared by reviewed by and approved by provision
- Document versions are controlled
- Provision for document effective dates and expiry dates
- New documents supersede previous versions with strict version control
- Provision for tracking of distribution of printed copies
- Withdrawal and printing of documents to have a withdrawn by and printed by and time stamp. Document to expire after 24hrs is also to be printed
- Documents to be created in word and saved as pdf
- Electronic signatures to be provided for document review and approval
- Provision for monitoring and notification of document pending expiry date

Continuous Workflow Requirement

- QA to allocate prepare, review and approve
- QA Manager / Manager shall complete assessment and review.

References

- SOP RPG-QA-022 Documentation

Reports

- Reports generated shall be configurable

Pricing Schedule:

Supplier Specifications include Model if applicable	**Quantity**	**Price per unit (Incl. VAT)**	**Total Price (Incl. VAT)**
EQMS Software licensing for 100 users	1	**R**	**R**
Server hardware and peripherals	1	**R**	**R**
Software licences (for operating system)	1	**R**	**R**
Installation, training (Operational and Technical) and validation	1	**R**	**R**
Support services Year 1	1	**R**	**R**
Support services Year 2	1	**R**	**R**
Support services Year 3	1	**R**	**R**
Support services Year 4	1	**R**	**R**
Support services Year 5	1	**R**	**R**
All the five (5) year Support services should include software and hardware maintenance			
TOTAL (VAT INCLUSIVE)		**R**	**R**

STANDARD BIDDING DOCUMENT (SBD) 4

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest1 in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	**Identity Number**	**Name of State institution**

1 the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

……

……

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? **YES/NO**

2.3.1 If so, furnish particulars:

……

……

3 DECLARATION

I, the undersigned, (name)…… in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read and I understand the contents of this disclosure;

3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;

3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium2 will not be construed as collusive bidding.

3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.

3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

2 Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

……	……
Signature	Date
……	……
Position	Name of bidder

STANDARD BIDDING DOCUMENT (SBD) 6.1

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

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1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 **To be completed by the organ of state**

a) The applicable preference point system for this tender is the 80/20 preference point system.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

(a) Price; and

(b) Specific Goals.

1.4 **To be completed by the organ of state:**

The maximum points for this tender are allocated as follows:

	POINTS
PRICE	80
SPECIFIC GOALS	20
Total points for Price and SPECIFIC GOALS	**100**

1.5 Failure on the part of a tenderer to submit proof or documentation required in terms of this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.

1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.

2. DEFINITIONS

(a) **"tender"** means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;

(b) **"price"** means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;

(c) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

(d) **"tender for income-generating contracts"** means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and

(e) **"the Act"** means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - P\,min}{P\,min}\right) \text{ or}$$

$$Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. **POINTS AWARDED FOR PRICE**

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 + \frac{Pt - P\,max}{P\,max}\right) \text{ or}$$

$$Ps = 90\left(1 + \frac{Pt - P\,max}{Pmax}\right)$$

Where

Ps	=	Points scored for price of tender under consideration
Pt	=	Price of tender under consideration
Pmax	=	Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:

4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—

(a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or

(b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,

then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.

***Note to tenderers: The tenderer must indicate how they claim points for each preference point system.*)**

The specific goals allocated points in terms of this tender (B-BBEE Status Level of Contributor)	Number of points allocated (90/10 system) (To be completed by the organ of state)	Number of points allocated (80/20 system) (To be completed by the organ of state)		Number of points claimed (90/10 system) (To be completed by the tenderer)	Number of points claimed (80/20 system) (To be completed by the tenderer)
1	10	20			
2	9	18			
3	6	14			
4	5	12			
5	4	8			
6	3	6			
7	2	4			
8	1	2			
Non-compliant contributor	0	0			

Bidders must submit B-BBEE certificates or sworn affidavit to claim points for specific goals.

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm…….

4.4. Company registration number: ……...

4.5. TYPE OF COMPANY/ FIRM

- ☐ Partnership/Joint Venture / Consortium
- ☐ One-person business/sole propriety
- ☐ Close corporation
- ☐ Public Company
- ☐ Personal Liability Company
- ☐ (Pty) Limited
- ☐ Non-Profit Company
- ☐ State Owned Company

[TICK APPLICABLE BOX]

4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that

the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;

iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –

(a) disqualify the person from the tendering process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution, if deemed necessary.

	…….
	SIGNATURE(S) OF TENDERER(S)
SURNAME AND NAME:	…….
DATE:	……
ADDRESS:	……
	……
	……
	……

Note: It is advised that documents be returned in PDF