

Terms of reference (ToR) for the procurement of services below the EU threshold

CONFIDENTIAL

Promoting Local Manufacturing of SRH Commodities in the SADC Region – GMP Readiness and Capacity Strengthening	Project number/ cost centre:
RAISE SRH Project	G-011806-040.00

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0. List of abbreviations

AG	Commissioning party
AIDS	Acquired Immunodeficiency Syndrome
AN	Contractor (Auftragnehmer)
API	Active Pharmaceutical Ingredient
AVB	General Terms and Conditions of Contract for supplying services and work (Allgemeine Vertragsbedingungen)
BMZ	German Federal Ministry for Economic Cooperation and Development (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung)
CAPA	Corrective Action and Preventive Action
CESARE	Cooperation for the Enhancement of SADC Regional Economic Integration
CEFR	Common European Framework of Reference for Languages
CO₂	Carbon Dioxide
CTD	Common Technical Document
DC	Development Cooperation
DQ	Design Qualification
EML	Essential Medicines List
EU	European Union
FK	Expert (Fachkraft)
FKT	Expert days (Fachkrafttage)
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
GMP	Good Manufacturing Practice
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IQ	Installation Qualification
ISO	International Organization for Standardization
KZFK	Short-term expert (Kurzzeitfachkraft)
M&E	Monitoring and Evaluation

NRA	National Regulatory Authority
OQ	Operational Qualification
OU	Organizational Unit
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PQ	Performance Qualification
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RAISE	Regional Approach to Improving SRH Commodity Security and Equity
SADC	Southern African Development Community
SMF	Site Master File
SOP	Standard Operating Procedure
SPPS	SADC Pooled Procurement Services
SRH	Sexual and Reproductive Health
SRHR	Sexual and Reproductive Health and Rights
STE	Short-Term Expert
STIs	Sexually Transmitted Infections
TEI	Team Europe Initiative
ToRs	Terms of Reference
WHO	World Health Organization
WHO PQ	WHO Prequalification Programme

1. Context

1.1. Programme Background

The Programme ("Fighting Harmful Practices, Improving Access to and Deepening Accountability for Sexual and Reproductive Health and Rights") (RAISE), implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) on behalf of German Federal Ministry for Economic Cooperation and Development (BMZ) and co-financed with the European Union (EU), supports the Southern African Development Community (SADC) in improving equitable access to quality-assured sexual and reproductive health (SRH) commodities. The Project is within the programme "Cooperation for the Enhancement of SADC Regional Economic Integration" (CESARE III), owned by the SADC Secretariat in Gaborone and implemented with SADC Member States, private sector, and civil society to strengthen regional economic integration through value chain development in agro-processing, pharmaceutical, and other medical products.

As part of its Value Chain Development component, the RAISE component is implementing the Team Europe Initiative on Sexual and Reproductive Health and Rights (TEI SRH) in the SADC region. This initiative aims to advance the realisation of sexual and reproductive health and rights by addressing key barriers to access and strengthening regional coordination mechanisms.

Within this framework, the project focuses on increasing the availability and use of essential, underused, or hard-to-access, quality-assured SRH commodities. These include family planning products, maternal health supplies, treatments for sexually transmitted infections (STIs) including HIV/AIDS, critical medical devices as well as diagnostic tests.

1.2. Sexual and Reproductive Health Commodities Challenges in the SADC Region

SRH is vital to the well-being and sustainable development of the SADC region. Over the past two decades, Member States have made significant progress in reducing maternal and child mortality, increasing contraceptive use, and lowering HIV infections and AIDS-related deaths. These achievements have been guided by regional strategies such as the SADC SRH Strategy (2006–2015) and the current Strategy for Sexual and Reproductive Health and Rights in the SADC Region (2019–2030).

The SADC region continues to face significant challenges in ensuring consistent access to these commodities. High maternal mortality rates, frequent stockouts of essential commodities in public health facilities, and elevated adolescent pregnancy rates highlight persistent gaps in availability, affordability, and quality. Despite ongoing regional initiatives like the SADC Pooled Procurement Services (SPPS), many countries experience stockouts lasting several days each month, undermining effective service delivery. These challenges are compounded by declining donor funding and insufficient domestic financing, which strain procurement and supply chain systems.

Underlying these issues are systemic root causes including weak health systems with under-resourced procurement and regulatory capacities, fragmented regional coordination, and

limited local manufacturing capabilities. Inefficient supply chain management, regulatory bottlenecks, and reliance on imports make the region vulnerable to disruptions and price fluctuations. Additionally, the lack of harmonized regulatory frameworks also hinders the effective implementation of pooled procurement mechanisms. Addressing these root causes through strengthened regional procurement collaboration, regulatory harmonization, and support for local production is essential to improve SRH commodity security across the SADC region.

1.3. Local manufacturing challenges of SRH commodities in the SADC Region

Local manufacturing of SRH commodities in the SADC region remains limited due to structural, technical, financial, and market constraints. The region relies on imports for about ninety percent of its pharmaceutical needs, creating major vulnerabilities in SRH commodity availability and exposing Member States to global supply disruptions and volatile procurement markets. Although some countries possess manufacturing capacity, many pharmaceutical companies struggle to meet core Good Manufacturing Practice (GMP) requirements, including quality management systems, documentation, sanitation, validation, and quality control. These gaps limit the production of stringent sterile formulations such as oxytocin, magnesium sulfate, tranexamic acid, as well as heat-sensitive contraceptive products such as implants. Heavy dependence on imported active pharmaceutical ingredients, excipients, and packaging materials further raises production costs and contributes to frequent delays across manufacturing processes.

Investment in SRH commodities local production is further constrained by fragmented and unpredictable markets across the region. Differences in essential medicines lists, weak demand forecasting, and limited implementation of regional pooled procurement mechanisms result in markets that are too small to generate economies of scale. As a result, manufacturers are often unable to justify capital-intensive investments in specialised SRH commodities production lines. Inadequate technology transfer mechanisms, limited availability of skilled technical personnel, and restricted access to modern production technologies further weaken competitiveness. Regulatory pathways remain slow, uneven, and costly, with prolonged registration timelines and inconsistent technical requirements contributing to delays in product introduction. Products such as heat-stable carbetocin, misoprostol, and medical abortion combination packs continue to face heightened regulatory scrutiny and socio-cultural sensitivities, which discourage private-sector engagement. Variations in the capacity of national regulatory authorities compound these challenges and undermine the pace of regional regulatory harmonisation.

Beyond technical and regulatory constraints, local manufacturers face significant commercialisation challenges. Limited access to market intelligence, underdeveloped marketing capabilities, absence of structured go-to-market strategies, and weak linkages to regional procurement mechanisms including SPSS constrain their ability to translate production capacity into sustainable market share. Many manufacturers lack the business development, pricing strategy, and product positioning expertise required to compete effectively in the SADC region's public and donor-funded procurement channels.

Broader infrastructure and financing constraints further impede manufacturing feasibility. Many SRH commodities require advanced sterile manufacturing environments, reliable power supply, efficient water systems, and stable cold-chain infrastructure. These remain inadequate or unevenly distributed across SADC Member States. Manufacturers also struggle to access affordable capital for infrastructure upgrades and quality systems, and there are limited incentive structures to de-risk investment in maternal health and family planning product lines. Local producers face strong price competition from low-cost imports, while persistent stockouts, inefficiencies in distribution systems, and limited visibility of consumption data reduce market confidence and deter long-term private investment. As a result, local production of family planning products, maternal health medicines, STI and HIV treatments, and reproductive health devices remains limited despite existing capacity.

These combined constraints highlight the need for targeted interventions to strengthen local manufacturing ecosystems, including enhanced regulatory reforms, dedicated financing instruments, expanded GMP capacity-building, improved technology transfer mechanisms, and deeper regional market integration. Addressing these challenges will not only improve the security and resilience of SRH commodity supply but will also contribute to industrial development, cost efficiencies, and employment creation across the SADC region.

1.4. Rationale for the Assignment

Addressing these combined constraints requires targeted interventions to strengthen local manufacturing ecosystems for SRH commodities. This assignment aims to provide comprehensive technical assistance to selected manufacturers in the SADC region to enhance their capacity to produce quality-assured SRH commodities in compliance with international standards and support them meet the quality and compliance requirements needed to qualify for regional pooled procurement mechanisms, including SPPS. Regulatory readiness support helps manufacturers close regulatory compliance gaps, respond to regulatory queries, and prepare for inspections to accelerate product registration.

This assignment operationalises recommendations from the RAISE SRH pharmaceutical manufacturing assessment by strengthening GMP compliance, regulatory readiness and technology adoption among selected manufacturers, while supporting the SPPS Steering Committee's decision to enhance regional pharmaceutical manufacturing in a manner that maintains transparency and value for money.

The intervention will address the constraints identified above through the following support to the manufacturers:

- a) Build capacity to meet World Health Organization (WHO) GMP requirements and self-assess GMP compliance
- b) Provide technical assistance for facility upgrades and quality system improvements
- c) WHO Pre-qualification (WHO PQ) readiness support

- d) Strengthen regulatory readiness support, including assistance with regulatory queries and inspection preparation

1.5. Objectives of the Assignment

The overall objective is to strengthen WHO GMP compliance and WHO Pre-qualification readiness in the SADC pharmaceutical industry to improve the availability, accessibility, and affordability of quality-assured SRH commodities.

1.6. Specific Objectives

- a) Enhance GMP compliance and quality management systems of selected manufacturers producing or intending to produce SRH commodities
- b) Assess regulatory readiness of manufacturers for WHO prequalification (where applicable), GMP standards applied by authorities participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) or SADC regional regulatory approvals for priority SRH products
- c) Support local manufacturers' readiness to participate in the SADC Pooled Procurement Services (SPPS), in line with the Steering Committee's decision on regional pharmaceutical manufacturing, through strengthened quality, regulatory and operational readiness
- d) Strengthen regulatory readiness support to manufacturers, including assistance with regulatory queries and inspection preparation
- e) Support manufacturer readiness for WHO PQ of priority SRH products, including readiness screening, gap identification against WHO PQ requirements, and facility-specific readiness roadmaps for interested companies
- f) Build capacity of national regulatory authorities through dedicated, structured training for regulators (e.g. on GMP inspection, dossier review and CAPA assessment)

2. Tasks to be performed by the contractor

The contractor is responsible for providing comprehensive technical assistance to strengthen local manufacturing of SRH commodities across selected SADC Member States

The RAISE seeks to engage a qualified consulting company with the requisite technical expertise, experience, and capacity to successfully deliver this assignment. The contractor's role is limited to technical advisory support. Infrastructure upgrades and equipment procurement are outside the scope of this assignment.

The Team Leader shall personally lead and deliver all technical and field activities under Work Packages 1 to 5, including the on-site baseline assessments, GMP training workshops, CAPA implementation clinics, regulatory readiness support and WHO PQ readiness support. Key Expert 1 and Key Expert 2 support the Team Leader in their respective areas of specialisation; their inputs complement, and do not replace, the Team Leader's on-site presence and lead role in these activities.

2.1. Preparatory Phase and Inception

- a) Conduct an inception meeting with RAISE component and the SADC Secretariat within two weeks of contract signature to finalise the work plan, confirm the participating manufacturers identified through the Expression of Interest (EoI) process and agree on coordination mechanisms.
- b) Establish communication protocols with participating manufacturers, including designation of facility focal persons, data sharing agreements, and confidentiality arrangements
- c) Review existing documentation including previous GMP inspection reports, regional pharmaceutical sector studies, SADC SRH strategy documents, and relevant regulatory frameworks
- d) Develop instruments to assess the quality of the manufacturers production processes, in consultation with GIZ, including a GMP compliance checklist aligned with WHO GMP guidelines

2.2. Work Package 1: Baseline Assessment and Gap Analysis

- a) Under the lead of the Team Leader, conduct comprehensive baseline assessments of 6-8 selected pharmaceutical manufacturers in SADC Member States currently producing or planning to produce SRH commodities, prioritising manufacturers with potential to supply SPPS and national pooled procurement mechanisms. Participating manufacturers will be identified through an Expression of Interest (EoI) process conducted by GIZ and the SADC Secretariat ahead of inception. Expressions of interest will be assessed against existing manufacturing capacity, relevance to priority SRH commodities, demonstrated commitment to GMP improvement, and potential participation in regional procurement mechanisms. Additional selection factors will include documented management commitment, the manufacturer's willingness to participate, availability of relevant technical and quality documentation, and commitment to implementing CAPA recommendations arising from the assessment.
Tentative countries of assignment: Based on the findings of the RAISE SRH inception report, the assignment is tentatively expected to cover seven manufacturers in four SADC Member States: Zambia, Mozambique, Malawi and Zimbabwe. These countries are indicative only; the participating manufacturers will be identified through the EoI, and the final list of manufacturers and countries will be confirmed at inception.
- b) Perform desk reviews of latest regulatory inspection reports, site master files, and product registration documentation as provided by manufacturers and/or regulatory authorities
- c) Conduct on-site GMP compliance assessments, led on site by the Team Leader with the support of Key Expert 1 (and Key Expert 2 at sterile manufacturing sites), using standardized tools developed in consultation with GIZ, based on WHO GMP guidelines and relevant international standards and applicable SADC regional harmonisation frameworks.
- d) Prepare detailed gap analysis reports for each manufacturer identifying technical, infrastructure, quality systems, and regulatory compliance gaps. Prioritize identified gaps and develop facility-specific roadmaps for achieving GMP compliance and product registration

- e) Roadmaps shall specify critical gaps, medium-term improvements, investment priorities, CAPA actions, regulatory milestones, and indicative implementation timelines for each manufacturer

2.3. Work Package 2: GMP Capacity Building and Training

- a) Develop comprehensive training materials on WHO Good Manufacturing Practices principles and requirements specific to SRH commodity manufacturing, including: (a) Participant manuals with case studies; (b) Trainer guides; (c) Presentation materials; (d) Practical exercise templates; (e) Assessment tools and checklists; (f) Reference materials and job aids
- b) Conduct initial GMP training workshops, led and facilitated by the Team Leader with Key Expert 1 (2 workshops, 2-3 days each) using a train-the-trainer approach targeting key personnel from quality control, quality assurance, production, and warehouse departments. The modules for training to be determined based on the GMP Gap Analysis reports or previous inspection reports from local NRA
- c) NRA inspectors may, subject to agreement, participate in selected GMP training workshops alongside manufacturers or attend a dedicated regulator track (e.g., GMP inspection, dossier review, and CAPA assessment), within the workshop numbers and duration specified above.
- d) Provide specialized **virtual** training modules on:
 - Sterile manufacturing and aseptic processing (for injectables like oxytocin, magnesium sulfate)
 - Cleanroom management and environmental monitoring
 - Equipment qualification (IQ, OQ, PQ) and calibration
 - Process validation and cleaning validation
 - Analytical method validation
 - Stability studies design, execution, and data analysis for SRH products
 - Risk management applications
- e) Deliver practical, hands-on training sessions at manufacturing sites, led by the Team Leader and combined with the CAPA implementation clinic missions
- f) Conduct follow-up refresher training sessions to reinforce learning and address emerging challenges
- g) The contractor shall be responsible for technical preparation, expert facilitation and development of training materials for the workshops. All conferencing services, venues, logistics, catering and participant-related costs shall be organised and funded separately by GIZ.

2.4. Work Package 3: Technical Assistance for CAPA Implementation

- a) Facilitate development of facility-specific CAPA plans addressing critical and major gaps identified in assessments, including clear objectives, responsible persons, timelines, resource requirements, and success criteria, aligned with WHO GMP and applicable SADC regulatory requirements. The contractor shall provide technical advisory support to manufacturers in prioritising and implementing CAPA actions; responsibility for implementation remains with participating manufacturers.

- b) The Team Leader shall personally lead and deliver on-site CAPA implementation clinics at each participating facility (1-2 days per facility), supported by Key Expert 2 at sterile manufacturing sites, providing hands-on technical assistance including: (a) Priority setting and sequencing of corrective actions; (b) Root cause analysis techniques; (c) Effectiveness verification methods; (d) Documentation and record-keeping
- c) Following each clinic, the Team Leader shall provide remote follow-up to track progress on agreed CAPA actions and verify their effectiveness, drawing on technical input from Key Expert 1 and Key Expert 2 as required
- d) Support development and revision of critical Standard Operating Procedures (SOPs) including:
 - a. Manufacturing procedures for SRH products
 - b. Quality control testing procedures
 - c. Equipment operation and maintenance SOPs
 - d. Cleaning and sanitation procedures
 - e. Personnel hygiene and gowning procedures
- e) Support preparation of validation protocols (process validation, analytical method validation, cleaning validation)
- f) Provide guidance on stability study protocol development and data analysis

2.5. Work Package 4: Regulatory Readiness Support

- a) Under the lead of the Team Leader, assist manufacturers in responding to regulatory queries and deficiency letters from NMRA. The contractor shall provide technical support for up to two rounds of deficiency-letter responses per manufacturer, while building manufacturers' capacity to manage subsequent responses independently. Responsibility for dossier content and submission remains with the manufacturers.
- b) Support preparation for regulatory inspections, led on site by the Team Leader, including inspection readiness assessments, benchmarking against current GMP standards and regional inspection practices.

2.6. Work Package 5: WHO Pre-qualification Support

- a) Under the lead of the Team Leader, conduct a WHO PQ readiness screening among participating manufacturers to identify companies and priority SRH products with WHO PQ potential
- b) Benchmark facility quality systems, manufacturing processes and product dossiers of shortlisted manufacturers against WHO PQ requirements, and identify critical gaps
- c) Provide targeted technical guidance to interested manufacturers on closing priority gaps (e.g. quality management systems, site master file, dossier compilation in CTD format)
- d) Support WHO PQ pre-assessment and inspection readiness for shortlisted manufacturers

This work package is limited to readiness assessment, gap identification and technical guidance. It does not include submission of the WHO PQ dossier itself, which remains the responsibility of the manufacturer

2.7. Reporting and Knowledge Management

- a) Prepare an inception report outlining detailed work plan, methodology, and timeline within 2 weeks of contract commencement
- b) Submit quarterly progress reports documenting activities completed, challenges encountered, and recommendations
- c) Record and report project indicators as required by GIZ, in line with the EU and BMZ project logframe, using GIZ-compatible reporting formats (e.g. Monitoring forms) and/or directly in the M&E tool used by GIZ CESARE
- d) Prepare individual facility assessment reports with detailed gap analyses and CAPA plans
- e) Develop an anonymized regional capacity assessment report highlighting strengths and weaknesses of the pharmaceutical sector's SRH manufacturing capabilities, suitable for sharing with SADC Secretariat, regulatory authorities, and development partners
- f) Prepare a final comprehensive report documenting all activities, achievements, lessons learned, and recommendations for sustainability
- g) Participate in monthly or bi-weekly monitoring calls with GIZ project team
- h) Document best practices and develop case studies for knowledge sharing within the region, covering GMP improvement journeys and lessons from CAPA implementation. The contractor shall develop templates, tools, checklists and training materials that remain available to GIZ and the SADC Secretariat for future use after completion of the assignment.

2.8. Project Management Requirements

The contractor is responsible for:

- a) Coordinating closely with participating manufacturers and relevant stakeholders
- b) Managing timelines, deliverables, and quality of outputs
- c) Ensuring effective communication and reporting to GIZ in accordance with GIZ AVB requirements
- d) Managing costs and expenditures and invoicing in line with GIZ requirements
- e) Liaising with the SADC Pooled Procurement Services (SPPS), the RAISE coordinator and the Private Sector focal persons embedded at SADC Secretariat on manufacturer readiness and coordination matters relevant to pooled procurement
- f) Support other ongoing RAISE interventions by information sharing, meetings, advise etc. as per guidance and request of GIZ colleagues.
- g) Recording and reporting on project indicators in accordance with the M&E requirements

2.9. Risk Management

The contractor shall identify implementation risks, propose mitigation measures, and notify GIZ promptly of any risks that may affect timelines, access to manufacturers, or delivery of outputs.

Certain milestones, as laid out in the table below, are to be achieved during the contract term:

Milestone	Timeline	Responsible
Inception Report	Week 2	Team Leader
WP1: Baseline assessments (6-8 manufacturers), including GMP compliance	Months 1-7	Team Leader (lead), supported by KE1
WP2: Training materials and 2 GMP workshops	Months 6-9	Team Leader (lead), KE1 & KE2
WP3: CAPA support & technical assistance	Months 9-14	Team Leader (lead), supported by KE2
WP4: Regulatory support	Months 15-18	Team Leader (lead), supported by KE1
WP5: WHO Prequalification (WHO PQ) readiness support	Months 7-16	Team Leader (lead), supported by KE1
Final Comprehensive Report	Month 19	Team Leader

Deliverables and Acceptance Criteria

The table below summarises the key deliverables, timing and acceptance criteria for this assignment. The Team Leader is accountable for all deliverables.

Deliverable	Timing	Acceptance Criteria
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1. Inception Report	Week 2	Endorsed work plan, methodology and timeline; incorporates GIZ/SADC comments
2. Facility Baseline Assessment Reports & GMP Improvement Roadmaps (6-8 manufacturers)	Following each assessment	Complete gap analysis per manufacturer; roadmap specifies critical gaps, timelines and CAPA actions
3. GMP Training Package and workshop delivery (2 workshops)	Before each workshop	Materials cover required topics; includes assessment tools
4. Facility-Specific CAPA Plans	Following assessments	Facility-specific; includes objectives, responsible persons, timelines; aligned with WHO GMP
5. Regulatory readiness assessment reports	Months 15-18	Facility-specific; identifies regulatory gaps against national (NMRA) and applicable SADC regulatory requirements; includes inspection-readiness benchmarking findings;
6. WHO PQ readiness roadmaps for shortlisted manufacturers	Month 16	Facility-specific; identifies WHO PQ gaps and prioritised actions per shortlisted manufacturer
7. Quarterly progress reports	Quarterly	Documents activities, challenges and recommendations; submitted within agreed timelines
8. Regional capacity assessment report	Month 17	Anonymised; suitable for sharing with SADC Secretariat, regulators and development partners
9. Final Comprehensive Report	Month 19	Documents all activities, achievements, lessons learned

		and recommendations; approved by GIZ and the SADC Secretariat
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Period of assignment: from 1st January 2027 until 31st July 2028 (19 months), with the option of prolongation subject to prolongation of the RAISE component.

3. Concept

In the tender, the tenderer is required to show *how* the objectives defined in Chapter 2 (Tasks to be performed) are to be achieved, if applicable under consideration of further method-related requirements (technical-methodological concept). In addition, the tenderer must describe the project management system for service provision.

Note: The numbers in parentheses correspond to the lines of the technical assessment grid.

3.1 Technical-methodological concept

Strategy (Evaluation Grid # 1.1): The tenderer is required to consider the tasks to be performed with reference to the objectives of the services put out to tender (see Chapter 1 Context) (1.1.1). Following this, the tenderer presents and justifies the explicit strategy with which it intends to provide the services for which it is responsible (see Chapter 2 Tasks to be performed) (1.1.2).

The tenderer is required to present the actors relevant for the services for which it is responsible and describe the **cooperation (Evaluation Grid # 1.2)** with them.

The tenderer is required to present and explain its approach to **steering** the measures with the project partners (**Evaluation Grid # 1.3.1**) and its contribution to the **results-based monitoring system** (1.3.2).

The tenderer is required to describe the key **processes** for the services for which it is responsible and create an **operational plan** or schedule (Evaluation Grid # 1.4.1) that describes how the services according to Chapter 2 (Tasks to be performed by the contractor) are to be provided. In particular, the tenderer is required to describe the necessary work steps and, if applicable, take account of the milestones and **contributions** of other actors (partner contributions) in accordance with Chapter 2 (Tasks to be performed) (Evaluation Grid # 1.4.2).

The tenderer is required to describe its contribution to knowledge management for the partner (1.5.1) and GIZ and to promote scaling-up effects (1.5.2) under **learning and innovation**.

3.2 Project management of the contractor

Compare Evaluation Grid #1.6

The tenderer is required to explain its approach for coordination with the GIZ project. In particular, the project management requirements specified in Chapter 2 (Tasks to be performed by the contractor) must be explained in detail.

The tenderer is required to draw up a **personnel assignment plan** with explanatory notes that lists all the experts proposed in the tender; the plan includes information on assignment dates (duration and expert days) and locations of the individual members of the team complete with the allocation of work steps as set out in the schedule.

The tenderer must describe how light-touch project management and quality assurance will be ensured through its standing team (Team Leader, Key Expert 1, Key Expert 2 — see Chapter 4), with the Team Lead providing at least the following support:

- Service-delivery control
- Managing adaptations to changing conditions
- Ensuring the flow of information between the tenderer and GIZ
- Assuming personnel responsibility for the contractor's experts
- Process-oriented steering for implementation of the commission
- Securing the administrative conclusion of the project

Further requirements (1.7)

The tenderer should address how gender considerations will be integrated into the assignment, including ensuring gender-balanced participation in training activities where feasible and considering gender dimensions in capacity building approaches

4. Personnel concept

The tenderer is required to provide personnel who are suited to filling the positions described, on the basis of their CVs (see Chapter 7), the range of tasks involved and the required qualifications.

The below specified qualifications represent the requirements to reach the maximum number of points in the technical assessment.

4.1. Team leader/ Senior GMP Expert

Tasks of the team leader

- Overall responsibility for the advisory packages of the contractor (quality and deadlines)
- Overall coordination and management of the assignment
- Coordinating and ensuring communication with GIZ, SADC Secretariat, and participating manufacturers
- Coordinating and cooperating with Luvent team and any other consultants engaged by GIZ or the SADC Secretariat, to avoid duplication of tasks
- Personnel management including planning and steering short-term expert assignments
- Leading inception activities and finalizing work plans in coordination with GIZ
- Personally lead and deliver all technical activities under Work Packages 1 to 5, in the field and remotely, with the Key Experts in a supporting role
- Lead and conduct the on-site baseline assessments and gap analyses at all participating manufacturers and sign off facility reports and roadmaps (WP1)
- Lead and facilitate the GMP training workshops and on-site hands-on training (WP2)
- Personally lead and deliver the CAPA implementation clinics at every participating facility and follow up on CAPA progress and effectiveness (WP3)

- Lead regulatory readiness support, including deficiency-letter responses and on-site inspection preparation (WP4)
- Lead the WHO PQ readiness screening, benchmarking and development of WHO PQ readiness roadmaps (WP5)
- Overseeing delivery of all work packages and ensuring quality of deliverables
- Prepare and submit all reports in accordance with deadlines (inception, quarterly progress, facility assessment, regional capacity assessment and final reports)
- Participating in monthly coordination calls with GIZ project team
- Ensure all project management tasks under 3.2. are delivered

Qualifications of the team leader

- **Education/training (grid 2.1.1):** university degree (German 'Diplom'/Master) in Pharmacy, Pharmaceutical Sciences, Chemical Engineering, Industrial Pharmacy, or related field. Additional qualifications in Quality Management, GMP, or Regulatory Affairs highly desirable
- **Language (grid 2.1.2):** C1-level language proficiency in English (**CEFR**). French or Portuguese language skills an asset
- **General professional experience (grid 2.1.3):** 12 years of professional experience in the pharmaceutical sector, with significant experience in pharmaceutical manufacturing and quality systems
- **Specific professional experience (grid 2.1.4):** 8 years in GMP compliance, quality assurance/quality control, pharmaceutical manufacturing, or regulatory affairs; experience with WHO GMP guidelines and WHO prequalification requirements; familiarity with SADC pharmaceutical regulatory harmonisation frameworks
- **Leadership/management experience (grid 2.1.5):** 6 years of management/leadership experience as project team leader or manager in a company
- **Regional experience (2.1.6):** 5 years of experience in projects in SADC region, understanding of pharmaceutical manufacturing landscape in developing countries
- **Development cooperation (DC) experience (grid 2.1.7):** 5 years of experience in DC projects, preferably with GIZ, EU, WHO, or similar international development organizations
- **Other (grid 2.1.8):** Experience conducting GMP audits and assessments; familiarity with PIC/S guidelines; experience in capacity building and training delivery; strong report writing and presentation skills. Experience in regional pharmaceutical manufacturing programmes, WHO GMP inspections, WHO PQ; demonstrated stakeholder engagement skills; hands-on experience leading CAPA development, root cause analysis and CAPA effectiveness verification at pharmaceutical manufacturing sites

4.2. Key expert 1: GMP and Quality Systems Specialist

Tasks of key expert 1

- Support the Team Leader in implementing technical activities

- Support the Team Leader in baseline assessments and gap analyses, and draft the facility baseline assessment reports, GMP improvement roadmaps and CAPA plans for the Team Leader's review and sign-off
- Develop training materials and co-facilitate GMP training workshops and virtual training modules
- Contribute to quality assurance of technical deliverables
- Draft the regional capacity assessment report and provide inputs to the inception, progress and final reports, for the Team Leader's review and sign-off
- Provide remote technical support to the Team Leader on CAPA follow-up (WP3) and regulatory dossier and deficiency-letter responses (WP4)
- Participate in coordination meetings with GIZ as required

Qualifications of key expert 1

- **Education/training (grid 2.2.1):** Advanced university degree (Master's or PhD) in Pharmacy, Pharmaceutical Sciences, Chemical Engineering, or related field. Additional qualifications in quality management, GMP auditing, or regulatory affairs preferred
- **Language (grid 2.2.2):** C2 -level language proficiency in English. French or Portuguese an asset
- **General professional experience (grid 2.2.3):** 10 years of professional experience in pharmaceutical manufacturing or quality assurance
- **Specific professional experience (grid 2.2.4):** 6 years of experience in GMP compliance, quality systems implementation, or pharmaceutical regulatory inspections, including familiarity with equipment qualification (IQ/OQ/PQ) and process/cleaning validation
- **Leadership/management experience (grid 2.2.5):** 4 years of experience leading or supervising technical teams
- **Regional experience (grid 2.2.6):** 3 years of experience working with pharmaceutical manufacturers in SADC or developing countries
- **Development Cooperation (DC) experience (grid 2.2.7):** 2 years of experience in DC projects related to pharmaceutical sector development
- **Other (2.2.8):** Demonstrated experience in regulatory affairs, including dossier preparation, inspection readiness, and engagement with National Regulatory Authorities

4.3. Designation of Key Expert 2 (Sterile Manufacturing Specialist)

Tasks of Key Expert 2

- Support the Team Leader in technical activities related to sterile manufacturing
- Support baseline assessments and gap analyses at manufacturing facilities as assigned
- Deliver specialized training modules in areas of expertise (sterile manufacturing, validation, QC, etc.)
- Support the Team Leader during CAPA implementation clinics at sterile manufacturing sites
- Assist in developing and revising SOPs, protocols, and technical documentation
- Support preparation for regulatory inspections in specialized areas

- Contribute to knowledge products and best practice documentation
- Support facility-level technology transfer processes, including formulation/process transfer planning, equipment and technology sourcing, and advice on relevant intellectual property and licensing matters

Qualifications of Key Expert 2 (Sterile Manufacturing Specialist)

- **Education/training (grid 2.6.1):** University degree (Master's preferred) in Pharmacy or Pharmaceutical Sciences, Chemistry, Chemical Engineering, Biotechnology, or related technical field
- **Language (grid 2.6.2):** B2-level or higher language proficiency in English
- **General professional experience (grid 2.6.3):** 8 years of professional experience in sterile/aseptic manufacturing
- **Specific professional experience (grid 2.6.4):** 3 years of professional experience in sterile manufacturing for injectables, cleanroom management, aseptic validation,
- **Regional experience (grid 2.6.5):** At least 2 years in SADC or developing country pharma contexts
- **Development cooperation (DC) experience (2.6.6):** At least 2 years DC experience
- **Other (2.6.7):** N/A

Soft skills of all team members

In addition to their specialist qualifications, the following qualifications are required of team members:

- Team skills
- Initiative
- Communication skills
- Socio-cultural skills
- Efficient, partner- and client-focused working methods
- Interdisciplinary thinking

The tenderer must provide a clear overview of all proposed short-term experts and their individual qualifications.

5. Costing requirements

5.1. Assignment of personnel and travel expenses

Per diem allowances are reimbursed as a lump sum up to the maximum amounts permissible under tax law for each country as set out in the country table in the circular from the German Federal Ministry of Finance on travel expense remuneration (downloadable from the [German Federal Ministry of Finance – tax treatment of travel expenses and allowances for international business travel as of 1 January 2025 \(GERMAN ONLY\)](#)).

Accommodation allowances are reimbursed as detailed in the specification of inputs below.

No budget amounts are prescribed for international flights, per diem allowances, accommodation or in-country ground transport. Tenderers shall price these items on the basis of the anticipated quantities specified in the table below (16 international return trips,

74 per diem days and 58 accommodation nights for three travelling experts) and propose their most competitive rates in the price schedule. Per diem and accommodation rates must not exceed the maximum amounts permissible under the BMF travel expense regulations.

With special justification, additional Accommodation costs up to a reasonable amount can be reimbursed against evidence.

All business travel must be agreed in advance by the officer responsible for the project

5.2. Sustainability aspects for travel

GIZ has undertaken an obligation to reduce greenhouse gas emissions (CO₂ emissions) caused by travel. When preparing your tender, please incorporate options for reducing emissions, such as selecting the lowest-emission booking class (economy) and using means of transport, airlines and flight routes with a higher CO₂ efficiency. For short distances, travel by train (second class) or e-mobility should be the preferred option.

CO₂ emissions caused by air travel must be offset. GIZ specifies a budget for this, through which the carbon offsets can be settled against evidence.

There are many different providers in the market for emissions certificates, and they have different climate impact ambitions. The [Development and Climate Alliance \(German only\)](#) has published a [list of standards \(German only\)](#). GIZ recommends using the standards specified there.

Specification of inputs

Fee days	Number of experts	Number of days per expert	Total	Comments
Designation of TL	1	80	80	Overall coordination and quality assurance; leads and delivers all work packages in person, incl. on-site baseline assessments, GMP workshops, CAPA implementation clinics, regulatory and WHO PQ readiness support; review and sign-off of all reports (indicatively 56 days on mission and 24 days remote)
Designation of Key Expert 1	1	65	65	Technical support to the Team Leader: baseline assessments, drafting of facility reports, CAPA plans and the regional report, training materials and workshops, remote CAPA follow-up and regulatory dossier support
Designation of Key Expert 2	1	25	25	Specialized support: sterile manufacturing, validation

Travel expenses	Quantity	Number per expert	Total	Comments
Per-diem allowance in country of assignment	74 mission days	TL: 50 KE1: 16 KE2: 8 (3 experts)	To be priced by tenderer	In line with BMF country ceilings; weekends reimbursed if between assignments
Overnight allowance in country of assignment	58 nights	TL: 44 KE1: 6 KE2: 8 (3 experts)	To be priced by tenderer	Overnight stays abroad: Please indicate in the price schedule whether your offer is on a lump-sum basis or against evidence.
Transport	Quantity	Number per expert	Total	Comments
International flights	16 return trips (economy class)	TL: 10 KE1: 4 KE2: 2 (3 experts)	To be priced by tenderer	Travel from the expert's home base to the place of service delivery in the SADC region. Missions will be to the SADC Member States where the 6–8 participating manufacturers are located, and to Botswana (SADC Secretariat, Gaborone) for workshops or coordination meetings where applicable. Participating manufacturers will be identified through an open Expression of Interest (EoI) and selected jointly by GIZ and the SADC Secretariat; the countries of travel will be confirmed to the contractor at inception. For pricing purposes, tenderers shall assume travel to any SADC Member State and price an average regional return economy fare. A return trip may include one intermediate leg between two SADC Member States where facilities are clustered.
Domestic flights	N/A	N/A	N/A	Flights within the country of assignment during service delivery
CO₂ compensation for air travel	1	EUR 800	EUR 800	A fixed budget of EUR 800 is earmarked for settling carbon offsets against evidence.
Travel expenses (train, car)	16 trips	TL: 10 KE1: 4 KE2: 2	To be priced by tenderer	Travel within the country of assignment, transfer to/from airport etc.

				One ground-transport allocation per mission (airport transfers and travel to/from manufacturing sites and venues).
Other travel expenses	N/A	N/A	N/A	e.g. visa costs
Fixed travel budget	N/A	N/A	N/A	N/A. No fixed travel budget is earmarked. Travel costs are priced by the tenderer on the basis of the quantities specified above.
Other costs	Number	Price	Total	Comments
Flexible remuneration	1	EUR 6000	EUR 6000	A budget of EUR 6000 is foreseen for flexible remuneration. Please incorporate this budget into the price schedule. Use of the flexible remuneration item requires prior written approval from GIZ.
Workshops	N/A	N/A	N/A	The budget contains the following costs N/A.
Subcontracts	N/A	N/A	N/A	The budget contains the following costs N/A.
Procurement of materials and equipment	N/A	N/A	N/A	The budget contains the following costs N/A.
Local contributions	N/A	N/A	N/A	The contractor administers the following local <i>contributions</i> in accordance with Section 2.7 AVB: N/A.
Other costs	1	1	EUR 2000	The budget includes printing costs for training materials, tools, and reports.

6. Inputs of GIZ or other actors

GIZ and/or other actors are expected to make the following available:

- Logistics for workshops: GMP trainings and CAPA workshops (conferencing, venue, catering)
- Facilitation of introductions and access to participating manufacturers
- Access to existing documentation
- Facilitation of NRA nominations and logistics, where NRA participation in trainings is agreed
- Review and approval of assessment tools and templates developed by the contractor prior to fieldwork

7. Requirements on the format of the tender

The structure of the tender must correspond to the structure of the ToR. In particular, the detailed structure of the concept (Chapter 3) should be organised in accordance with the positively weighted criteria in the assessment grid (not with zero). The tender must be legible (font size 11 or larger) and clearly formulated. It must be drawn up in English (language).

The complete tender must not exceed 10 pages (excluding CVs). If one of the maximum page lengths is exceeded, the content appearing after the cut-off point will not be included in the assessment. External content (e.g. links to websites) will also not be considered.

The CVs of the personnel proposed in accordance with Chapter 4 of the ToRs must be submitted using the format specified in the terms and conditions for application. The CVs shall not exceed 4 pages each. They must clearly show the position and job the proposed person held in the reference project and for how long. The CVs can also be submitted in English (language).

Please calculate your financial tender based exactly on the parameters specified in Chapter 5 Costing requirements. The contractor is not contractually entitled to use up the days, trips, workshops or budgets in full. The number of days, trips and workshops and the budgets will be contractually agreed as maximum limits. The specifications for pricing are defined in the price schedule.

8. Outsourced processing of personal data

During implementing this contract, the contractor will process personal data of the following categories of data subjects:

- Contact details (name, position, email, phone) of designated focal persons at participating manufacturing facilities, for coordination and communication purposes
- Names and contact details of manufacturer staff attending GMP training workshops and CAPA implementation clinics, for participation tracking and certification purposes

This data will be collected and used solely for the purposes of coordinating, delivering, and reporting on the services described in these ToRs, and will not be used for any other purpose. The contractor must handle all such data in accordance with Section 1.10 of the GIZ AVB and applicable data protection legislation, including secure storage, restricted access, and deletion or return of data upon contract completion.

9. Annexes

- SRH Inception Study for the SADC region report

