



TERMS OF REFERENCE

FOR THE PROCUREMENT OF A CONSULTING FIRM
TO SUPPORT THE AFRICAN MEDICINES AGENCY IN ATTAINING

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM CERTIFICATION

Reference Number:	AMA/QMS/TOR/2026/001
Issuing Authority:	African Medicines Agency (AMA)
Procurement Category:	Professional Advisory & Consulting Services
Assignment Duration:	18 Months
Classification:	PUBLIC TENDER
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African Medicines Agency

Kigali Heights Building
KG 7 Avenue
Kigali, Rwanda
Website: www.au-ama.africa
Email: info@au-ama.africa

X (TWITTER): @AU_AMAfrica **LINKEDIN:** African Medicines Agency (AMA)
YOUTUBE: African Medicines Agency **FACEBOOK:** African Medicines Agency

DOCUMENT CONTROL AND DISCLAIMER

This Terms of Reference (TOR) is issued by the African Medicines Agency (AMA) for the sole purpose of procuring a qualified consulting firm to support AMA in achieving ISO 9001:2015 Quality Management System (QMS) certification. The document is issued in the public interest and in strict compliance with AMA's Procurement Policy and applicable African Union (AU) procurement frameworks.

Responses to this TOR shall be submitted in accordance with instructions contained herein. AMA reserves the right to accept or reject any or all proposals, to annul the procurement process, and to reject all proposals at any time prior to award of contract, without thereby incurring any liability to the affected bidders.

All information furnished by Bidders in connection with this TOR shall be treated as confidential. Any misrepresentation or concealment of material information may result in disqualification and potential blacklisting from future AMA procurements.

ACRONYMS AND DEFINITIONS

AMA	African Medicines Agency
AU	African Union
CAB	Conformity Assessment Body
CB	Certification Body (accredited ISO registrar)
CAPA	Corrective Action and Preventive Action
GAP	Gap Analysis (current state vs. ISO 9001:2015 requirements)
ISO	International Organization for Standardization
KPI	Key Performance Indicator
MRM	Management Review Meeting
PDCA	Plan-Do-Check-Act cycle
QMS	Quality Management System
RBT	Risk-Based Thinking (ISO 9001:2015 Clause 6.1)
SOW	Statement of Work
TOR	Terms of Reference
WHO	World Health Organization
WLA	WHO Listed Authority

SECTION 1 - BACKGROUND AND ORGANISATIONAL CONTEXT

1.1 The African Medicines Agency

The African Medicines Agency (AMA) is a specialised agency of the African Union, established pursuant to the AMA Treaty adopted by the 32nd Ordinary Session of the AU Assembly in February 2019. The Agency's Treaty entered into force on 5 November 2021 following ratification by AU Member States. AMA is headquartered in Kigali, Rwanda.

AMA's core mandate is to facilitate the harmonisation of medicines regulation across Africa, strengthen the continent's medicines regulatory systems, and ultimately improve access to safe, effective, and quality-assured medical products for the African population. AMA works in close collaboration with National Medicines Regulatory Authorities (NMRAs), Regional Economic Communities (RECs), and international partners including the World Health Organization (WHO), European Medicines Agency (EMA) and US Food and Drugs Administration (US FDA).

As the Agency expands its operational footprint, institutionalises its governance structures, and prepares to assume treaty-mandated regulatory functions, it recognises that robust internal organisational systems are a prerequisite for institutional credibility, donor confidence, and sustained operational effectiveness. AMA has accordingly identified the attainment of ISO 9001:2015 QMS certification as a strategic organisational priority.

1.2 Rationale for ISO 9001:2015 Certification

ISO 9001:2015 is the world's most widely recognised Quality Management System standard, adopted by over one million organisations in 170 countries. For a regulatory and technical agency such as AMA, certification under ISO 9001:2015 will:

- Demonstrate to State Parties, partners, and donors that AMA operates to internationally recognised quality benchmarks;
- Establish a systematic, process-driven approach to planning, execution, monitoring, and continuous improvement of AMA's operations;
- Enhance institutional accountability through clearly defined roles, responsibilities, and quality objectives cascading from AMA's strategic plan;
- Embed risk-based thinking across all operational units, enabling proactive identification and mitigation of organisational risks;
- Provide a structured framework for managing stakeholder relationships and regulatory engagement commitments;
- Strengthen AMA's positioning as a peer partner to WHO and other international health regulatory agencies, all of which operate under stringent quality management regimes;
- Support AMA's long-term objective of achieving WHO Listed Authority (WLA) status, which will require evidence of robust institutional quality management.

1.3 Current Institutional Readiness

AMA is at an early but critical stage of institutional development. The Secretariat has established foundational governance structures, including a Director General and senior management team, and has begun operationalising key functional areas. However, a formal QMS does not yet exist and processes are not systematically documented against any recognised standard. A readiness assessment confirmed the need for substantive external technical assistance to guide the Agency through the full ISO 9001:2015 certification journey.

SECTION 2 - OBJECTIVES OF THE ASSIGNMENT

2.1 Overall Objective

The overall objective of this assignment is to support the African Medicines Agency in designing, implementing, and certifying an ISO 9001:2015-compliant Quality Management System, culminating in the award of certification from an accredited Certification Body within the assignment period.

2.2 Specific Objectives

1. Conduct a comprehensive baseline assessment against all ISO 9001:2015 clauses to establish a detailed gap analysis;
2. Design and develop a fit-for-purpose QMS tailored to AMA's mandate, size, and operational context, including all required documentation;
3. Support AMA senior management in embedding quality leadership, including development of strategic quality objectives;
4. Develop and implement a Risk and Opportunity Register aligned to ISO 9001:2015 Clause 6.1;
5. Build internal QMS capacity across all AMA functional units through targeted training programmes;
6. Establish and operationalise an internal audit programme and train a cadre of AMA internal auditors;
7. Support AMA management in conducting a formal Management Review Meeting (MRM) in compliance with Clause 9.3;
8. Manage the interface with the accredited Certification Body, including supporting Stage 1 and Stage 2 audits;
9. Deliver a post-certification sustainability roadmap to ensure ongoing QMS maintenance and surveillance audit preparedness.

SECTION 3 - DETAILED SCOPE OF WORK

3.1 Phase I - Inception and Baseline Diagnostic (Months 1-2)

KEY ACTIVITIES

- Prepare and present a detailed Inception Report including a refined project plan, risk register, communication matrix, and quality assurance plan for the assignment itself;
- Conduct structured interviews, workshops, and process observation sessions with AMA Senior Management and all functional unit heads;
- Review all existing documentation including the AMA Treaty, Strategic Plan, governance frameworks, HR policies, financial regulations, and any existing SOPs;
- Perform a detailed, clause-by-clause gap analysis against all ten (10) clauses of ISO 9001:2015;
- Develop a Gap Analysis Report with a traffic-light scoring system (Conforming / Partially Conforming / Non-Conforming) for each requirement;
- Present findings to AMA Senior Management and obtain formal approval to proceed.

3.2 Phase II - QMS Design and Documentation (Months 3-5)

KEY ACTIVITIES

- Facilitate senior management workshops to define, adopt, and cascade AMA's Quality Policy and SMART quality objectives;
- Map all core, management, and support processes using recognised business process modelling notation (BPMN or equivalent);
- Develop the full documentation suite, including: Quality Manual; documented information required by ISO 9001:2015; operational process procedures and work instructions; templates, forms, registers, and records; context of the organisation analysis (Clause 4) including interested party register;
- Design and implement AMA's document and records management framework ensuring version control, access management, and retention compliance;
- Develop the Risk and Opportunity Register (Clause 6.1) using a systematic risk assessment methodology;
- Establish a performance monitoring framework with KPIs for each core process aligned to AMA's strategic objectives;
- Submit all documentation to AMA for internal review and ensure formal approval by the Director General.

3.3 Phase III - Implementation and Capacity Building (Months 6-10)

KEY ACTIVITIES

- Develop a comprehensive training needs analysis and QMS training curriculum covering all staff levels;
- Deliver QMS Awareness Training to all AMA staff through classroom and e-learning modes as appropriate;
- Deliver ISO 9001:2015 Internal Auditor Training to a minimum of eight (8) designated AMA staff members;
- Provide targeted process-level coaching to process owners and functional managers;

- Support the operationalisation of all documented processes and procedures, including go-live support;
- Establish the Corrective Action and Preventive Action (CAPA) system;
- Design and operationalise the customer satisfaction measurement system, including survey instruments and feedback analysis mechanisms;
- Facilitate at least two (2) internal QMS progress reviews with AMA management.

3.4 Phase IV - Internal Audit and Management Review (Months 10-12)

KEY ACTIVITIES

- Plan, coordinate, and support execution of the first full internal audit cycle, covering all ISO 9001:2015 clauses and all AMA processes;
- Produce a comprehensive internal audit report with a log of all findings (conformities, observations, and nonconformities);
- Support AMA management in developing and tracking CAPA plans to address all identified nonconformities;
- Plan, facilitate, and document AMA's first formal Management Review Meeting (MRM) in compliance with Clause 9.3;
- Prepare a pre-certification readiness assessment documenting AMA's implementation readiness against all Stage 2 audit criteria.

3.5 Phase V - Certification Support (Months 13-15)

KEY ACTIVITIES

- Assist AMA in selecting and engaging an internationally accredited Certification Body (IAF member accreditation required);
- Prepare and submit the Stage 1 audit documentation package to the Certification Body;
- Review Stage 1 findings and ensure all issues are resolved prior to the Stage 2 audit;
- Provide on-site support during the Stage 2 certification audit, including document retrieval support and real-time technical advisory;
- Manage the CAPA process for any nonconformities raised during the Stage 2 audit;
- Facilitate the issuance of the ISO 9001:2015 certificate.

3.6 Phase VI - Post-Certification Sustainability (Months 16-18)

KEY ACTIVITIES

- Conduct a post-certification review to assess QMS performance and identify areas for improvement;
- Develop a three-year QMS Sustainability and Continuous Improvement Roadmap, including a surveillance audit preparation plan;
- Prepare and deliver a knowledge transfer report and handover sessions to the AMA QMS focal team;
- Develop and present the Final Assignment Report to AMA Senior Management.

SECTION 4 - DELIVERABLES AND ACCEPTANCE CRITERIA

All deliverables shall be submitted in English (and French where required by AMA) in both editable electronic format and signed hard copy. Deliverables are subject to formal review and written acceptance by AMA's designated Project Manager. AMA reserves the right to request revisions to any deliverable before acceptance is granted.

Ref	Deliverable	Timeline	Acceptance Criterion
D1	Inception Report & Project Charter	Month 1	Management-approved inception report with revised project plan
D2	Current State Gap Assessment Report	Month 2	Comprehensive clause-by-clause gap analysis report
D3	QMS Design Blueprint & Process Documentation	Month 4	ISO-ready process manual and full documentation suite
D4	Risk Register & Quality Objectives Framework	Month 5	Approved risk register and quality objectives
D5	Implementation Roadmap	Month 5	Management-approved 18-month implementation plan
D6	Staff Training Completion Report	Month 8	Signed attendance records and competency assessments
D7	Internal Audit Report	Month 10	Full internal audit report with CAPA log
D8	Management Review Documentation	Month 11	Approved MRM minutes and action register
D9	Pre-Certification Readiness Report	Month 13	Readiness scorecard and corrective action plan
D10	ISO 9001:2015 Certificate	Month 15	Certificate issued by accredited Certification Body
D11	Post-Certification Sustainability Roadmap	Month 18	3-year QMS sustainability and improvement plan

SECTION 5 - QUALIFICATIONS AND KEY PERSONNEL REQUIREMENTS

5.1 Firm Eligibility Requirements

Bidding firms must demonstrate the following at the time of proposal submission:

- Legal registration as a company or consulting firm with a minimum of seven (7) years of continuous operation;
- Demonstrated experience in at least five (5) successfully completed ISO 9001 implementation and certification assignments, of which at least two (2) must have been in public sector, international organisation, or multilateral agency contexts;
- At least one assignment in a sub-Saharan African or comparable developing-country institutional context;
- No conflict of interest with AMA or its funding partners;
- Current and satisfactory financial standing (audited accounts for the past three years to be provided);
- Compliance with applicable anti-bribery, anti-corruption, and integrity requirements.

5.2 Key Personnel - Minimum Requirements

The following key personnel are required. CVs and evidence of qualifications must be submitted with the technical proposal.

Position	Minimum Qualifications & Experience	Commitment
Team Leader / QMS Programme Director	Minimum 15 years experience; ISO 9001 Lead Auditor certified; experience in AU-affiliated institutions or multilateral organisations	Full-time, Months 1-18
ISO 9001 Lead Consultant	Certified ISO 9001:2015 Lead Auditor/Implementer; 10+ years QMS implementation; regulatory sector experience preferred	Full-time, Months 1-15
Process Documentation & Business Analysis Specialist	Strong process mapping and documentation skills; experience with healthcare or regulatory operations	Full-time, Months 2-8
Training & Change Management Specialist	Adult learning certification; experience delivering QMS awareness and internal auditor training in multi-cultural environments	Part-time, Months 4-12
Internal Audit Specialist	ISO 9001 Lead Auditor certified; experience developing and executing internal audit programmes	Part-time, Months 8-15
Risk Management & Compliance Advisor	Experience integrating ISO 9001 risk-based thinking with regulatory compliance frameworks	Part-time, Months 3-10

SECTION 6 - GOVERNANCE, REPORTING, AND QUALITY ASSURANCE

6.1 Reporting Lines

The Firm shall report to the Director General of AMA, or a designated staff as Project Manager. Day-to-day coordination shall be managed through the AMA QMS Focal Team (led by the Project Manager), to be constituted within the first month of the assignment.

6.2 Progress Reporting

- Monthly Progress Reports: submitted by the 5th working day of each month, covering activities completed, upcoming activities, issues, risks, and financial expenditure summary;
- Quarterly Review Meetings: formal progress review meetings with AMA Senior Management on a quarterly basis;
- Deliverable Review Periods: AMA shall have a minimum of ten (10) working days to review and comment on each deliverable before acceptance.

6.3 Assignment Quality Assurance

The Firm shall maintain an internal quality assurance plan for the assignment. All methodologies and approaches must be grounded in current ISO 9001:2015 requirements and recognised implementation practice. The Firm shall not substitute key personnel without prior written approval from AMA. Any substitution shall be with personnel of equal or superior qualifications.

SECTION 7 - PROPOSAL EVALUATION METHODOLOGY

AMA will evaluate proposals using a Quality and Cost Based Selection (QCBS) methodology in accordance with AMA's Procurement Policy. Technical proposals and financial proposals shall be submitted in separate sealed envelopes. Financial proposals will be opened only for firms achieving the minimum qualifying technical score.

#	Criterion	Weight	Description
1	Technical Approach & Methodology	35%	Quality and rigour of proposed approach; alignment with ISO 9001:2015 and African regulatory context
2	Firm's Relevant Experience & Track Record	25%	Demonstrated ISO 9001 implementation experience in public health, regulatory, or AU-affiliated institutions
3	Key Personnel Qualifications	20%	Credentials, certifications (Lead Auditor), and relevant CVs of proposed team
4	Understanding of Assignment Context	10%	Demonstrated understanding of AMA mandate, AU frameworks, and regulatory environments
5	Financial Proposal & Value for Money	10%	Reasonableness of fee structure, cost transparency, and value proposition
	TOTAL	100%	<i>Minimum qualifying technical score: 70 percent. Financial proposals opened only for technically qualified firms.</i>

SECTION 8 -- PROPOSAL STRUCTURE AND SUBMISSION REQUIREMENTS

8.1 Technical Proposal Contents

1. Cover Letter -- signed by an authorised representative of the firm;
2. Firm Profile -- overview, legal registration, and relevant organisational background;
3. Understanding of the Assignment -- demonstrated comprehension of AMA's institutional context;
4. Technical Approach and Methodology -- detailed phase-by-phase description including tools, frameworks, and work plan;
5. Implementation Plan -- Gantt chart detailing activities, milestones, and deliverables over 18 months;
6. Relevant Experience -- minimum five (5) reference assignments with comparable scope, including client contacts;
7. Team Composition -- proposed staffing plan, role descriptions, and percentage of time per team member;
8. CVs of All Key Personnel -- maximum four (4) pages per CV; must include verifiable ISO 9001 certifications;
9. Risk Management Approach -- how the Firm will identify and manage assignment-level risks;
10. Declaration of Integrity and Conflict of Interest -- signed statement.

8.2 Financial Proposal Contents

The Financial Proposal shall include a fully itemised budget broken down by phase, activity, personnel, and expense category. Daily rates for each team member must be stated. The Financial Proposal shall remain valid for a minimum of ninety (90) days from the submission deadline.

- All prices shall be quoted in US Dollars (USD);
- The budget shall distinguish between professional fees and reimbursable expenses;
- VAT and any applicable taxes must be stated separately;
- Certification Body fees should be included as an indicative line item; AMA will negotiate directly with the CB.

8.3 Submission Instructions

Proposals must be submitted electronically to the AMA Procurement Unit at amatender@au-ama.africa by the deadline specified in the Tender Notice. The subject line must read: "AMA/QMS/TOR/2025/001 -- [Firm Name] - ISO 9001 Consulting Proposal".

Technical and Financial Proposals must be submitted as separate password-protected PDF files. Passwords shall be communicated in a separate email no later than 24 hours after the proposal deadline. Late submissions will not be considered under any circumstances.

SECTION 9 - CONTRACT TERMS AND PAYMENT SCHEDULE

The assignment will be governed by AMA's standard Professional Services Contract. The following payment schedule will apply, with each payment triggered by formal written acceptance of the relevant deliverable:

#	Milestone / Trigger	% of Value	Timing
1	Contract signature and submission of Inception Report	10%	Month 1
2	Acceptance of Gap Analysis Report	15%	Month 2
3	Acceptance of QMS Design Blueprint and Documentation	20%	Month 5
4	Completion of Training Programme	15%	Month 8
5	Acceptance of Internal Audit Report and MRM Documentation	15%	Month 12
6	ISO 9001:2015 Certification Achieved	20%	Month 15
7	Acceptance of Final Report and Sustainability Roadmap	5%	Month 18

Payment will be made within thirty (30) calendar days of written acceptance of the relevant deliverable. AMA is not liable for any payment in respect of deliverables not formally accepted in writing.

SECTION 10 - ETHICAL STANDARDS, INTEGRITY, AND SAFEGUARDS

AMA is committed to the highest standards of transparency, accountability, and integrity in all its procurement activities. All Bidders and personnel engaged under this assignment are required to comply with AMA's regulations and the African Union's Anti-Corruption Policy Framework:

- No gift, benefit, or hospitality of any kind may be offered to or accepted by AMA personnel in connection with this procurement;
- Any real or perceived conflict of interest must be disclosed in writing at the time of proposal submission;
- AMA staff found to have improperly influenced the evaluation process will be subject to disciplinary action;
- The selected Firm must agree to AMA's right to audit all financial records related to the assignment;
- Sub-contracting of any portion of the assignment requires prior written approval from AMA;
- All information obtained in the course of the assignment is confidential and may not be disclosed to third parties without AMA's written consent.

SECTION 11 - QUERIES AND CLARIFICATIONS

Queries relating to this TOR must be submitted in writing to the AMA Procurement Unit at amatender@au-ama.africa no later than fourteen (14) calendar days before the proposal submission deadline. Written clarifications will be issued to all registered Bidders and posted on AMA's official website.

No verbal clarifications are binding. Only written clarifications issued by AMA's Procurement Unit carry official standing. AMA is not bound by any statement made by its staff outside the formal clarification process.

ANNEX A - ISO 9001:2015 CLAUSE MAPPING TO AMA FUNCTIONS

The table below maps each ISO 9001:2015 clause to the relevant AMA functional unit(s), to guide the Firm in scoping the QMS design and implementation activities. The Firm is expected to validate and refine this mapping during Phase I.

Clause	ISO 9001:2015 Requirement	AMA Functional Area(s)
4	Context of the Organisation	DG Office, Strategy & Planning, Legal & Governance
5	Leadership	Director General, Senior Management Team, Board
6	Planning	Strategy & Planning, Risk Management, All Units
7	Support	HR, Finance, IT, Administration, Communications
8	Operation	Scientific Affairs, Regulatory Harmonisation, Capacity Building, Member State Coordination, SMEs and Innovators support
9	Performance Evaluation	Monitoring & Evaluation, Internal Audit, All Process Owners
10	Improvement	All Units; QMS Management Representative; Internal Audit Function

ANNEX B - REFERENCE DOCUMENTS AND APPLICABLE STANDARDS

Bidders are expected to be familiar with the following documents. Key reference materials will be made available to the selected Firm in a data room upon contract signature:

- ISO 9001:2015 Quality Management Systems -- Requirements (latest edition);
- ISO 9000:2015 Quality Management Systems -- Fundamentals and Vocabulary;
- ISO 19011:2018 Guidelines for Auditing Management Systems;
- AMA Treaty (2019) and AMA Statute;
- AMA Strategic Plan;
- African Union Regulatory Harmonisation Framework and African Medicines Regulatory Harmonisation (AMRH) and AU3S Programme documentation;
- AU Commission Procurement Framework;
- WHO Global Benchmarking Tool (GBT) for National Regulatory Systems -- as contextual reference for regulatory system quality standards;
- AMA Headquarters Agreement with the Republic of Rwanda;
- AMA Human Resources Policy Framework and Financial Regulations.

END OF TERMS OF REFERENCE

AMA/QMS/TOR/2025/001 -- African Medicines Agency ISO 9001:2015 QMS Certification Assignment

Procurement enquiries: procurement@au-ama.africa | www.au-ama.africa