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MTaPS trains Rwanda FDA staff on dossier assessment and evaluation, August 11, 2020. Photo credit: Rwandenzi Eugene Abimana, MTaPS

Supporting Rwanda FDA to Strengthen its Regulatory Services

Technical Brief | November 2024 | Rwanda

Implementing a Quality Management System (QMS) for the Rwanda Food and Drugs Authority (Rwanda FDA)

Background

In recent decades, Rwanda's total expenditure on health has progressively increased and, at 6.4% (2019) of the country's gross domestic product, is relatively high in relation to other East African Community countries, including Kenya at 4.59%, Uganda at 3.83%, and Tanzania at 3.83%.[1] As a result, Rwanda has seen significant improvement in health care. The Government of Rwanda is committed to the sustainability of the community-based health insurance scheme, which covers more than 90% of the Rwandan population and has increased access to a full range of essential health services without causing financial hardship.[2] To continue to improve the health of its people, Rwanda is committed to building a strong pharmaceutical system that can ensure continuous access (availability, affordability, acceptability, accessibility) and appropriate use of safe, effective, and quality-assured medical products.

[1] Rwanda - Total Health Expenditure as a Share of GDP. Available from: https://knoema.com/atlas/Rwanda/topics/Health/Health-Expenditure/Health-expenditure-as-a-share-of-GDP.

[2] Rwanda Health Sector Performance Report 2020–2021. Available from: https://www.moh.gov.rw/publications/reports.

In June 2019, the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program began to support pharmaceutical systems strengthening in Rwanda. Since that time, MTaPS has worked with Rwanda Food and Drugs Authority (FDA) to improve the effectiveness of the country's regulatory system.

Problem Statement

Rwanda established the Rwanda FDA in 2018 as a government agency that serves as a national regulatory authority for specified medical products. Rwanda FDA's regulatory functions include registration of pharmaceuticals and processed food products, inspections for good manufacturing practices, quality control, licensing of establishments and enforcement, post-market surveillance, pharmacovigilance, regulating the advertising/promotion of medicines, and the conduct of clinical trials for medical products. The Authority operates autonomously under the governance of a board of directors and is responsible for protecting public health through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco, and tobacco products.

As a recently established agency, Rwanda FDA had to establish its capacity to ensure the quality, safety, and efficacy of health products and technologies on the Rwandan market. Following a 2018 assessment of Rwanda FDA using the World Health Organization (WHO) Global Benchmarking Tool (GBT), the Authority developed a 5-year institutional development plan which would allow it to achieve a maturity level of 3 (a stable, well-functioning, and integrated regulatory system) on a scale of 1 (existence of some elements of a regulatory system) to 4 (operating at an advanced level of performance and continuous improvement).[3] Initially, Rwanda FDA started implementation of some elements of a regulatory system but was not effective in fully delivering its mandate. When MTaPS began its work in Rwanda, Rwanda FDA was starting to operationalize its 5-year plan and was recruiting staff and developing the technical resources and tools required to reliably meet its public health mandate.

A quality management system (QMS) is a collection of business processes designed to continuously satisfy the needs of customers (both internal and external) and raise their level of satisfaction. It is in line with the goals and strategic orientation of an organization. It comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results. It enables top management to optimize the use of resources considering the long- and short-term consequences and provides the means to identify actions to address intended and unintended consequences in providing products and services (risk-based thinking). An effective QMS is a prerequisite for attainment of maturity level 3 according to the WHO GBT, for ISO 9001:2015 certification, and to facilitate regional medicines harmonization initiatives. As revealed by the 2018 GBT assessment, Rwanda FDA had not yet established a QMS, a key pillar to ensuring effective provision of regulatory services.

Technical Approach

To build its institutional capacity, MTaPS is supporting the Rwanda FDA in implementing a QMS. Through the QMS implementation, MTaPS aims to strengthen the Rwanda FDA by systematically addressing the following key sub-indicators: RS05.01 (top management demonstrates commitment and leadership to develop and implement QMS), RS05.07 (requirements for documentation management as well as traceability of regulatory activities is established), and RS05.11 (internal and/or external audits of the QMS are established and conducted at planned intervals) identified as partially or not implemented in the November 2018 WHO GBT assessment, as well as other gaps noted in the subsequent 2021 WHO-assisted self-benchmarking assessment such as the partially implemented sub-indicator RS05.04 (enough competent staff is assigned to develop, implement, and maintain the QMS).

In a country's national medical regulatory authority such as Rwanda FDA, QMS contributes to higher-quality

[3] WHO. 2018. Benchmarking of the National Regulatory Authority (NRA) Global Benchmarking Tool Rev V. Rwanda, Date of visit: Nov. 6–9, 2018.

regulatory services and improved regulatory maturity. This promotes good governance, transparency, harmonization of service delivery, and adherence to international regulatory standards enhancing customer satisfaction. Thus, QMS fosters risk-based management and improves overall performance, thus contributing to a strong organizational reputation.

Building on the GBT 2018 assessment findings, MTaPS and Rwanda FDA developed an implementation plan for the establishment of an effective QMS. Initially, MTaPS facilitated sessions to raise awareness on QMS implementation and related benefits at all levels within Rwanda FDA, followed by capacity-building workshops to train staff on QMS. MTaPS also organized and conducted an internal audit. This ensured that all staff members were equipped with the necessary knowledge and skills to effectively implement and maintain the QMS. Additionally, MTaPS supported development of a QMS documentation management system, including manuals, regulations, technical guidelines, and procedures to strengthen compliance with the ISO 9001:2015 and WHO Global benchmarking Tool (GBT) maturity level 3 (ML3) requirements.

MTaPS collaborated with the MOH, WHO, regional regulatory authorities, and Bureau Veritas, among other partners, to guide QMS establishment and implementation at Rwanda FDA. Relevant policies and guidelines required for establishing the national regulatory agency were obtained from WHO and the MOH.

Intervention

QMS Preparation and Development/Implementation		
QMS document review	Meeting to review the plan	✓
	Conduct a situational analysis and identify gaps	✓
	Review of quality policy and objectives	✓
	Review and map QMS process for key regulatory functions	✓
	Review of procedures and instructions	✓
	Incorporate the quality policy and objectives, processes, and procedures in a quality manual	✓
QMS development	QMS implementation awareness training	✓
	QMS internal quality auditor training	✓
	Establishment of QMS documents	✓
	Conducting a first internal quality audit to identify the need for corrective actions	✓
	Implement corrective actions	✓

Table 1. MTaPS' stepwise approach to QMS preparation and development

MTaPS' support for Rwanda FDA in undertaking these steps is further detailed above (table 1).

Conducted a situational analysis of relevant procedures, manuals, and guidelines

- Conducted a situational analysis of all Rwanda procedures, manuals, and guidelines to identify gaps and opportunities for improvement, in accordance with ISO 9001:2015 Standard.
- Assessed the efficacy of the QMS, which involved:
  - Identifying existing quality policies and procedures
  - Reviewing job descriptions and organizational charts to define responsibilities
  - Identifying the designated Quality Champion for overseeing quality initiatives
  - Verifying the existence of a document control system for document maintenance and updates
  - Evaluating the system for managing suppliers and process mapping
- Evaluating methods for measuring customer satisfaction
- Ensuring the use of quality tools for continuous improvement
- Assessing the system's ability to track, measure, and report on QMS performance
- Ensuring a systematic approach for continuous improvement, including preventive and corrective measures
- Rwanda FDA, with technical assistance from MTaPS, reviewed its draft strategic plan 2021–2024 and other documents, including Law N° 003/2018 of 09/02/2018, policies, regulations, manuals, guidelines, and procedures, to compare how they aligned with clauses in the ISO 9001:2015 standard

and the WHO GBT. The review focused specifically on the following points: organizational context, leadership, quality policy, planning, support, operations, and performance evaluation and improvement. This review noted the gaps in ISO standard implementation, noting for example that Rwanda FDA did not demonstrate sufficient competency in planning and executing audits in compliance with ISO 9001:2015 requirements.
- Following the situational analysis, Rwanda FDA drafted recommendations to address the identified gaps.

Developed documentation to support capacity development and sustainability of the Rwanda FDA

- Contributed to finalizing the draft 4-year Rwanda FDA Strategic Plan (2021–2024). The strategic plan was approved in June 2021 by the chair of the Rwanda FDA's board of directors. Among its other strategic goals are to guide the Authority on implementing the QMS as well as strengthening the Authority's role to ensure compliance to specified standards and requirements for regulatory processes.
- Rwanda FDA developed a 5-year business plan and financial sustainability strategy (2021–2026) that is aligned with the 4-year strategic plan. The business plan's 5 strategic objectives include developing an organization that aligns with its ambitions, digitalizing services and operations, increasing revenue to maintain financial sustainability, improving the QMS, and introducing a customer-oriented culture.

Raised awareness on QMS

- Held meetings and orientation sessions with 12 members of the top leadership and executive organ of Rwanda FDA to explain the QMS process and boost leadership support for implementing QMS. The sessions served to clarify the role of leadership in QMS implementation, including in audit and risk assessment for QMS implementation.
- Facilitated a capacity-building and awareness session on the purpose, process, and requirements of QMS implementation based on ISO 9001:2015, with participation of 28 Rwanda FDA operational staff. These sessions helped raise awareness among Rwanda FDA personnel on the need to implement a QMS based on ISO 9001:2015 requirements.

Implemented QMS requirements

- Developed an internal quality management manual (which includes a client service charter and risk management framework), corresponding standard operating procedures (SOPs) and other support documents to be used to guide QMS implementation:
  - To support the pharmacovigilance function, four SOPs are in place to guide the assessment of products before registration, to conduct supportive supervision during active surveillance monitoring, to report adverse drug reaction at the facility level, and to use good review practices.
  - Developed a checklist for assessing the quality of active surveillance data.
  - To enhance Rwanda FDA's key regulatory functions such as market surveillance and control (MC) and medicines registration and market authorization (MA), seven process flow documents were developed: for disposal of medicines, medical devices, and diagnostics; product promotion and advertisement; import visa applications; voluntary recall; nonvoluntary recall; import license applications; and drug registration.
- Conducted a stakeholder validation workshop to validate documents that provide guidance and establish guidelines for the requirements for obtaining services within Rwanda FDA.

Supported internal quality audit of the Rwanda FDA to guide performance improvement

- Supported an internal audit to determine the level of conformance by Rwanda FDA to QMS requirements (June 2021).
- Participated as an observer during the WHO-led Rwanda FDA self-benchmarking assessment to measure progress against the WHO GBT (rev_VI_2021) and to identify remaining gaps in the Rwanda FDA's progress toward maturity level 3.

Developed capacity in conducting QMS internal audits

- Trained 28 Rwanda FDA staff through a 14-day course on QMS principles and internal auditing to achieve the following:
  - Build their understanding of QMS requirements in accordance with ISO 9001:2015

- Enable them to conduct internal QMS audit (gap analysis audits, system audits, and process audits)
- Foster their understanding of the roles and responsibilities of an auditor to plan, conduct, report, and follow up on a QMS audit in accordance with ISO 9001:2015 and ISO 19011:2018 Guidelines for Auditing Quality Management Systems

- MTaPS worked with Rwanda FDA to plan and conduct a five-day training of one QMS analyst and nine QMS focal staff nominated by Rwanda FDA from various departments and units on "ISO 9001:2015 QMS Lead Auditors Course." Those who completed the course were eligible to receive certification as lead auditors and contribute to implementation of QMS quality internal audits in all regulatory functions of the Rwanda FDA. The training was led by a trainer from an external accredited firm, Bureau Veritas, and emphasized various aspects required to meet the ISO 19011:2018 standards during the QMS audit. The course was certified by the Chartered Quality Institute and International Register of Certificated Auditors, and those who took part in the course were eligible to take exams to qualify as QMS ISO 9001:2015 Lead Auditors.

Results and Achievements

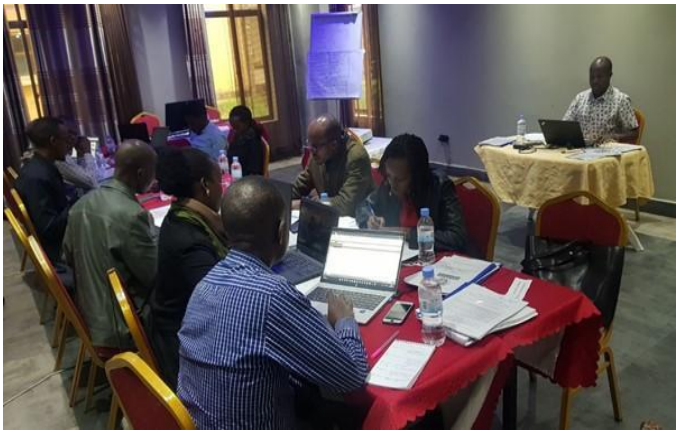
With support from MTaPS and other partners, Rwanda FDA has undertaken all the steps under Phase 1 of QMS preparation and implementation and paved the way to implement Phase 2, which is the external audit required for ISO 9001:2015 certification. With MTaPS support, Rwanda FDA has raised awareness of its leadership and personnel on QMS and their roles in QMS and has built staff capacity for QMS implementation. Rwanda FDA now maintains an Internal Quality Manual and has a team trained to conduct internal audits to determine readiness for ISO 9001:2015 certification. Standardization and training of Rwanda FDA staff has contributed to improved knowledge of Rwanda FDA quality officers on QMS principles and has enabled Rwanda FDA to implement a QMS.

As a result, Rwanda FDA's service delivery has become more organized and structured, with consistent delivery of regulatory services. The registration process for medical products now follows a more consistent process, rather than an ad hoc process for handling evaluation of product dossiers. Furthermore, through published guidelines, clients have a better understanding of when to submit their applications and what to expect once they have done so. The support provided to Rwanda FDA to implement the QMS has contributed to significant increase in the maturity score for the regulatory system according to the WHO GBT. The QMS is contributing to the overall goal of ensuring that the medical products that are on the market in Rwanda meet the safety, efficacy, and quality requirements.

Lessons Learned

- **A systematic, phased approach enables successful implementation.** Using a stepwise approach can enable successful implementation of a QMS. This is especially important when starting from the foundation, with an Authority where no QMS is in place. This approach allowed MTaPS to gradually introduce the concept of QMS to the regulatory body, obtain the required buy-in by the top leadership, and ensure that the new system was not only understood but also embraced by all stakeholders. By engaging in ongoing dialogue and sensitization of Rwanda FDA leadership, accompanied by training and a collaborative process to update policy documents, MTaPS built an understanding for a QMS which resulted in ongoing strong support and commitment from Rwanda FDA management.
- **Engagement of competent staff and engendering commitment from leadership contributes to successful QMS implementation.** By working collaboratively with Rwanda FDA from the preliminary phase and gaining commitment from top leadership, MTaPS was able to ensure that all regulatory requirements were met, and that the implementation of the QMS was aligned with their expectations. MTaPS made sure that Rwanda FDA was involved in planning activities and worked with the Authority to identify QMS focal points who would serve as champions. Regular communication and training sessions with staff members allowed the program to address any issues or concerns that arose during the implementation process. The approach helped

Rwanda FDA drive QMS implementation across its various departments.



MTaPS trains Rwanda FDA internal auditors on ISO 9001: 2015, September 2022. Photo credit: Jean Mirimo, MTaPS

- **Advocacy for sufficient resources can facilitate QMS implementation.** A QMS cannot be effectively implemented without adequate staffing in place. In low- and middle-income countries such as Rwanda, national regulatory agencies are often short-staffed. By setting clear objectives, providing resources, and regularly reviewing performance, top management can ensure that the QMS is aligned with the organization's strategic goals and objectives. Following MTaPS' work with senior leadership to gain support for the QMS, Rwanda FDA was able to reallocate job responsibilities between staff and even find ways for the Authority to bring on additional staff to fill crucial roles. The increase of Rwanda FDA staff (from 9 staff in July 2018 to 187 staff in October 2024) has contributed to ensuring a more flexible and conducive environment to conduct dossier evaluations, issue marketing authorizations and implement other regulatory functions.
- **Recommendations need to be realistic given the operational context.** Following their assessments of QMS implementation, assessors provide recommendations for solutions to address system gaps. These recommendations are typically tailored to the specific needs and goals of the organization, considering factors such as industry regulations, improved operational efficiency, increased customer satisfaction, and a stronger competitive advantage in the marketplace. By implementing these recommendations, organizations can further enhance their QMS and ensure ongoing compliance with standards and best practices. However, some recommendations like certifying the Authority under the ISO 9001:2015 standard, as made by two internal audits, may face implementation challenges due to resource constraints or other obstacles. Through discussion with the leadership, assessors can identify alternative recommendations that can be implemented given the available resources and the institutional context. For example, as Rwanda FDA lacked a staffed QMS division with certified internal auditors, MTaPS provided "ISO 9001:2015 QMS Lead Auditors Course" training for selected staff. This strengthened the QMS system and established a team of auditors with internationally recognized credentials.
- **External partnerships are key to establish QMS capacity**. MTaPS was able to leverage its technical and external expertise (through consultancies), partnerships, and twinning with other national regulatory authorities with effective QMS, such as the Tanzania Medicines and Medical Devices Authority (TMDA), to provide training and technical support to Rwanda FDA, namely, assessing the Authority's gaps to achieve WHO maturity level 3 and ISO 9001:2015. Ongoing collaboration with external experts and stakeholders will be crucial in supporting the Rwanda FDA in maintaining and continuously improving their QMS capacity.
- **Continual improvement is crucial in revising documents and processes.** Efforts should be made to sensitize partners to the need for regular review and update of documents to establish an understanding that a QMS is built on a commitment to continual improvement, focused on identifying areas for enhancement and implementing changes to increase efficiency and effectiveness. This can involve seeking feedback from stakeholders, conducting research on best practices, and staying current with industry trends. It is important to engage appropriate experts for document review to ensure that revised documents best meet country needs. However, all parties should understand that gaps will be identified during audits and changes will need to be made on an ongoing basis.

Pathway to Sustainability

Rwanda FDA has the ownership of a QMS, and the required tools for implementing it, including the Quality Manual and accompanying technical regulations, guidelines and guidance, SOPs, and related forms and formats, among others, are in place. The leadership has demonstrated a strong and continuing commitment to improve the regulatory services taking into consideration harmonizing with international standards. Today, Rwanda FDA QMS focal points are knowledgeable about QMS implementation and guide QMS implementation and awareness in the Authority. The Rwanda FDA also has a cadre of trained QMS internal auditors, and the country has a team of external QMS auditors. Rwanda FDA has a four-year business plan undergoing approval, which aims at strengthening financial management, enhancing accountability, and ensuring financial sustainability, with the long-term objectives of reducing Rwanda FDA's dependence on government and donor funding and attaining financial autonomy. With its much-improved human resource capacity, Rwanda FDA is now able to implement the QMS. The planned QMS automation will enable Rwanda FDA to manage all regulatory processes and ensure document control in a harmonized, efficient, and transparent manner, which will improve provision of services to clients and ensure a sustainable availability of quality medicines and other medical products on the Rwandan market.

"Rwanda FDA established a QMS to ensure a sustainable achievement of the mission of ensuring the availability of safe, effective, and quality regulated products on the Rwandan market . . . we now have the required tools and knowledgeable staff that implement QMS and we are committed to maintaining and continually improving our systems to meet regulatory and international a requirements."

—Professor Emile Bienvenu, Director General, Rwanda Food and Drugs Authority

Conclusions

Rwanda FDA has demonstrated its commitment for a QMS in strengthening the regulatory processes towards improved client services. With QMS implementation, Rwanda FDA has improved regulatory functions and service provision to clients. In response to the gaps identified in the WHO-led 2022 self-assessment of the Rwanda FDA, MTaPS supported certification of QMS "quality officers" (auditors and QMS focal points), and over 2023–2024, is supporting the introduction of a QMS module to enhance digitalization of the Rwanda FDA's regulatory system. This will help ensure that processes are implemented consistently and that any changes in procedures and updates in documents are communicated immediately to Rwanda FDA clients. It is recommended that the Authority conduct an external quality audit for determining the readiness of the Rwanda FDA for ISO 9001:2015 certification with support from implementing partners. The implementation of QMS at Rwanda FDA has demonstrated evidence of enhanced efficiency in service delivery and increased customer satisfaction. This improvement is further supported by the Authority's successful alignment with the WHO GBT, which underscores the system's role in achieving higher operational functionality and performance.

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About USAID MTaPS:

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.