1.0 Purpose

This Standard Operating Procedure is to ensure that:

1.1 All procedures required for the day-to-day operations of the Rwanda FDA are documented and controlled in a consistent and effective way.

1.2 All internal documents are reviewed, approved and authorized prior to issue and use.

1.3 Current documents are readily available at the respective points of use.

1.4 Changes and the current revision status of internal documents are identified.

1.5 The document control system meets the requirements of ISO 9001:2015 standard.

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all controlled internal documents (generated internally by Rwanda FDA) that form part of the quality management system of Rwanda Food and Drugs Authority.

2.2 Applies to controlled external documents with regard to the receipt and registration of new external documents (documents of external origin) and identification of those that are superseded.

2.3 Does not apply to records.

3.0 Policy

3.1 The Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in:

Article 27(1) … *"to monitor and coordinate daily duties and activities";* and

Article 28 (2) …. "*to monitor daily activities of Rwanda FDA*"

3.2 ISO 9001:2015 Clause 7.5.3.1 states that "*Documented information required by the quality management system and by this International Standard shall be controlled".*

3.3 ISO/IEC 17025:2017 Clause 8.3.1 states that *"The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document".*

3.4 WHO Good Practices for Pharmaceutical Quality Control laboratories WHO Technical Report Series N^{o} 957, 2010, Annex 1; sections 3 *"Control of documentation".*

4.0 Definition and Abbreviation

4.1 "**Author**" The Author shall be the person(s) who created a document or any subsequent revision of the controlled document.

4.2 "**Approved by**" Endorsement providing authority for a document to become officially valid and to be put into formal use.

4.3 "**Checked by/Authorised by**" Endorsement signifying that the internal document is ready for approval

4.4 "**Controlled Copy**" A document which is distributed to pre-determined persons or staff and if any change or revision is made on the document, the Quality Management Systems Specialist shall submit the revised document and make sure that the previous (superseded) document is retrieved,

4.5 "**Document**"

a) "Document" means readable information and its supporting medium.

b) A "document" describes any policy, procedure, work instruction or form that is to be controlled.

c) A "document" can be a Law, Regulation, standard, policy statement, manual, guideline, protocol, process flow outlines, standard operating procedure, work instruction, drawing, specification, form, record, chart, report, certificate, checklist, aide memoir, register, worksheet, textbook, poster, notice, memorandum, software, photograph, drawing, or plan.

d) A "document" may be on various media e.g. paper, magnetic, electronic or optical computer disc, and may be digital, analog, photographic or written.

4.6 "**Effective Date**" A date after the concerned staff or persons have been formally trained or notified or oriented on the use of the document and records maintained, but shall not be later than 15 working days from the revision date.

4.7 "**External Document**"

a) A legal, regulatory or technical document which is not written or created (not internally generated), issued or revised by Rwanda FDA.

b) "External document" can be used as reference in writing internal documents or as a manual for operating equipment.

4.8 "**Internal Document**": A document which is issued and revised by Rwanda FDA.

4.9 "**Master Document**" Original of a controlled internal document that contains original signatures of the authorities that checked/authorized and approved the document.

4.10 "**Objective**" A brief statement(s) describing the purpose of the document.

4.11 "**Policy**" A short statements derived from the applicable law(s), regulation(s), standard(s), resolutions(s), decision(s) or concept(s) that govern the document or provide a mandate or basis for the document.

4.12 "**Procedure**"

When used as a title, e.g. in a Standard Operating Procedure (SOP), or Work instruction, a procedure shall be written as follows:

1) Write clear, concise, step-by-step instructions on how to perform the procedure.
2) Write the instructions chronologically for the user to follow, without a lot of theoretical background.
3) Indicate the preliminary steps that must be done before beginning the actual procedure.
4) Number each step so that repeat steps can be referred to rather than making the SOP very long.
5) Number each sentence so as to make reference to it easy under document revision history when it is revised.
6) Include explanations and an example of how to do any required calculations.
7) Create and indicate the Form(s) where the results, observations or data should be recorded.

4.13 "**Responsibility**" indicates the designations or titles of the Rwanda FDA staff or member and briefly describe their specific responsibilities in performing the procedure in a document and in ensuring that the document is implemented and performed correctly and consistently.

4.14 "**Review Due Date**"

A date three years from the effective date, to ensure continued adequacy and suitability of a document. A document may remain valid beyond its review due date if no major change had happened in the process, until the revised document is authorized.

4.15 "**Review**"

Assessment of the correctness, suitability and adequacy of a document including technical, legal, regulatory, health, safety, and environment compliance issues.

4.16 "**Reviewer**"

The Reviewer shall be the person(s) who assesses a document for technical, legal, regulatory, health, safety, and environment compliance issues as per Section 9.3 of the Document Control SOP number QMS/SOP/001.

4.17 "**Revision Date**" The date when the document is approved and thereby becoming officially valid.

4.18 "**Revision Number**" A numerical figure that changes serially; the first document shall have revision number "0" and its first revision number "1", second revision number "2" and so on.

4.19 "**Safety Precautions**" When used in a procedure e.g. SOP, indicate all safety precautions that must be taken before the procedure is performed. Includes special precautions and protective garments (containment facility clothing, masks, hoods, goggles, gloves, cleanup of spills, etc.) for working with physical, chemical, radioactive, biological or microbiological hazards.

4.20 "**Scope**" A brief statement of where the document applies, when it need to be applied and any limitations of the document.

4.21 "**Title**" A title shall be a short, precise statement representing the contents of the procedures

4.22 "**Uncontrolled Copy**"
A document which is issued to persons or staff who are not part of the distribution list for that document for information purposes only and if any change or revision is made on the document, the Quality Management Systems Specialist is not in control of retrieval of the previous (superseded) document.

5.0 Responsibility

5.1 The Quality Management Systems Specialist is responsible for:

a) Ensuring that all internal documents are created, reviewed, authorized, approved, registered, identified, issued, distributed, revised, retrieved and maintained according to this SOP.

b) Ensuring that all external documents are received and registered by the user departments or Divisions or Units and those that are superseded are identified.

c) Notifying all applicable departments, divisions and directorates of superseded controlled copies of internal documents in advance.

d) Maintaining the master file for all master documents (originals of controlled internal documents) as well as a master list (register) of all current documentation (both internal and external documents) and history of changes to the documentation.

5.2 The designated quality management systems staff for each Department/Division/Unit is responsible for ensuring that all required documentation is received, is current and is available at each work location and that all affected employees are trained in the use of new or revised documents that apply to them.

5.3 The author of an internal document is responsible for providing training or orientation to staff, where necessary, before the document is used.

6.0 Distribution

6.1 Director General of Rwanda FDA

6.2 A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sops\)

6.3 Hard copies to staff that have no access to the Rwanda FDA server.

7.0 Safety Precautions

Not applicable to this SOP

8.0 Materials and equipment

8.1 Document identification stamps:

a) "**MASTER DOCUMENT**"

b) "**CONTROLLED COPY**"

c) "**CERTIFIED TRUE COPY**"

d) "**SUPERCEDED DOCUMENT**",

8.2 Colour printer

8.3 Colour Photocopier machine

8.4 Document scanner

8.5 Fire resistant filing cabinet

8.6 File folders

8.7 Shared folder on the Rwanda FDA Server

8.8 Suitable electronic data storage and back-up devices

9.0 Procedure

9.1 Writing a New Internal Document

9.1.1 The in charge of Quality Management Systems, Department/Division/Unit Head, Designated Quality Management Officer of each Department / Division/Unit or any officer shall identify the documents required by each Department, Division or Unit.

9.1.2 Internal documents shall be denoted by three letters (*YYY)* as below:

	Document Type	**Code**
1)	Authorization for Emergency Use	AEU
2)	Chart	CHT
3)	Checklist	CKL
4)	Client Service Charter	CSC
5)	Form	FOM
6)	Format	FMT
7)	Guidelines	GDL
8)	Internal Rules & Regulations	IRR
9)	Job Description	JOD
10)	Job Specification	JBS
11)	Manual	MAN
12)	Policy	POL
13)	Process Flow outline	PRF
14)	Protocol	PTC
15)	Standard Testing Procedure	STP
16)	Technical regulation	TRG
17)	Terms of Reference	TOR
18)	Work instruction	WOI
19)	Memorandum of Understanding	MOU
20)	Contract	CTC
21)	Concept Note	CTN
22)	Reports	REP
23)	Strategic Plan	SPL

9.1.3 The Author of a document will obtain an electronic copy of the approved format for that document from the in charge of Quality Management systems or the Designated Quality Management Staff of the Department or Division, and follow through it to write the new document. The list of approved formats is shown below:

#	**Name of Format**	**Format Number**
1	Format for Standard Operating Procedure	Doc No. QMS/FMT/001
2	Format for Forms	Doc No. QMS/FMT/002

3	Format for Guidelines	Doc No. QMS/FMT/003
4	Format for Internal Memorandum	Doc No. QMS/FMT/004
5	Format for Job description	Doc No. QMS/FMT/005
6	Format for Job Specification	Doc No. QMS/FMT/006
7	Format for Manuals	Doc No. QMS/FMT/007
8	Format for Power Point Presentation	Doc No. QMS/FMT/008
9	Format for Regulations	Doc. No. QMS/FMT/009
10	Format for Terms of Reference	Doc No. QMS/FMT/010
11	Format for Work Instruction	Doc No. QMS/FMT/011
12	Format for Memorandum of Understanding	Doc No. QMS/FMT/012
13	Format for Contract	DocNo. QMS/FMT/013

9.1.4 Page Setup to be used when writing a new document (with the exception of the Internal Memorandum, Power Point Presentation, agreements, forms and formats).

1) Margins

Top	0.5”	Bottom	0.3”
Left	0.5”	Right	0.5”
Gutter	0”	Gutter Position	Left

2) Header and Footer setup: Header from Top 0.3; Footer from Bottom 0.2

3) Orientation: Portrait to be used. Landscape to be used only in special circumstances (e.g. large tables) that cannot fit if set in Portrait.

4) Font Specifications for Header, Footer and Body Text

Font Type	Times new Roman
Font Size	12 *(Note1: Tables may be in font size 11 depending on size of the contents of the table.* *Note 2:The front and rear covers of manuals, strategic plan and other high level documents may be in other font sizes)*
Font Color	Black *(Note: manuals, strategic plan and other high level documents may have other font colors)*
Font Style	Regular for body text, italics for citations, bold for headings

5) Line Spacing: Single

6) Press “enter” after each line numbering to provide for space between numberings.
7) Indentation: Left 0.3” Right 0”

8) Alignment of text in the body of a document: Justify.

9) Alignment of text in a table: Left

9.1.5 The Author will forward the draft document, written in the approved format, to the in charge of Quality Management systems or the to the Designated Quality Management Systems Staff of the Department/Division/Unit, depending on the type and use level of the document.

9.1.6 The Designated Quality Management System Staff shall forward the draft document to the in charge of Quality Management Systems who will allocate it a document number and a revision number, and organize for the review and subsequent authorization and approval in accordance with the applicable scenario indicated under 9.4.1 of this document.

9.1.7 All Documents for which implementation depends on stakeholders other than Rwanda FDA staff, will pass through stakeholders validation workshop for their inputs before it is approved by the top Management of the Authority.

9.1.8 The source or originating department or division shall be indicated by three letter code *(XXX)* as assigned below:

Name of Source	**Code**
Chairman Board of Directors	CBD
Office of Rwanda FDA Director General	ODG
Department of Food & Drugs Assessment & Registration	DAR
Department of Food & Drugs Inspection & Safety Monitoring	DIS
Division of Drug & Health Technologies Assessment & Registration	DHT
Division of Drug and Food Inspection & Compliance	ICD
Division of Food Assessment & Registration	FAR
Division of Pharmacovigilance & Food Safety Monitoring	PSM
Division of Quality Control Laboratory	QCL
Finance Unit	FIN
Human Resource and Administration Unit	HRA
Legal Services Unit	LEG
Office of the Chief Finance Officer	CFO
Quality Management System Unit	QMS

9.1.9 The Document Number shall be indicated by *XXX/YYY/ZZZ* where: *XXX* denotes the source or originating department, division or unit; *YYY* denotes the document type; and ZZZ denotes the serialised document number. E.g. this document is an SOP; origination from The Quality Management System Unit and it's the first document to be registered, hence it is designated as Document N^{o}: QMS/SOP/001. The next SOP will take the Document N^{o}: XXX/SOP/002, where XXX is the assigned code of the source of that SOP, not necessarily from QMS.

9.2 Revising an Internal Document

9.2.1 Revising, or making changes to an existing approved document can be done for purposes of continual improvement of the quality management system, as a result of, for example, management review, internal and external audit, product complaint, new regulatory or new official standards requirement, suggestion, recommendation, and others.

9.2.2 Any person can originate a request for revising a document by filling the Change Control Form and forwarding it to the Designated Quality Management Staff of the concerned Department/Division/Unit.

9.2.3 Hand written corrections, changes or amendments and the use of correction fluid e.g. whiteout or similar medium on current controlled documents is strictly prohibited.

9.2.4 Any change or amendment in a controlled document shall only be effected by issue of a new revision of that document or an addendum to the original document and only after the change has been reviewed, approved and authorized as per 9.2.3 above.

9.2.5 Addendum shall only apply to Manuals but not to lower level documents like SOPs.

9.2.6 The Addenda shall be numbered serially, e.g. First Addendum, Second Addendum, and so on, but indicating the same document number and revision number of the original document to which the amendments in the addendum refer.

9.3 Reviewing an Internal Document

9.3.1 The author of a document has to ensure the correctness of a document prior to submission of the draft document to the Designated Quality Management Systems Staff of the respective Department/Division/Unit.

9.3.2 The Designated Quality Management Systems Staff submits the draft document to the Quality Management Systems Specialist

9.3.3 The Quality Management Systems Specialist shall distribute the draft document to the relevant officer(s) in the originating departments/unit and/or to any designated expert(s) in the

particular field covered by the document, for reviewing, using the Document Review, Checking and Authorization Circulation Form number QMS/FOM/001.

9.3.4 Such reviews can include technical, legal, regulatory, health, safety, and environment compliance issues.

9.3.5 The review process shall ensure that the document is:

a) Relevant and is actually required.

b) Suitable for its given purpose/objective

c) Complying with the approved format.

d) Consistent with the Rwanda FDA Law and other applicable laws, regulations, government policies, relevant standards and national and international guidelines.

e) Correct and adequate for its given function.

f) Having or not having an impact on any already existing document or operation; and that such impact is comprehensively evaluated, justified and approved before the document is authorized.

9.3.6 The reviewer(s) shall sign on the Document Review, Checking and Authorization Circulation Form (QMS/FOM/001) after the review.

9.4 Checking/Approving and Authorizing an Internal Document

9.4.1 Authorisation and approval of different types of a new or a revised document at different levels shall be done in accordance with any of the applicable scenarios shown below:

1) Document, e.g. Board Manual, that is approved by the Minister of Health

The cover page should have the logo of the Ministry of Health on the left hand side and the logo of the Rwanda FDA on the right hand side as shown below:

Ministry of Health

The following headings to be written on separate pages to designate adoption and approval:

Preface

Signature
The Minister of Health

Foreword

Signature
Chairman Board of Directors

2) Document, e.g. the Strategic Plan for Rwanda FDA, which is approved by the Minister of Health.

The following headings to be written on separate pages:

Foreword

Signature
Chairman Board of Directors

Message from the Director General

Signature
Director General
Rwanda Food and Drugs Authority

3) Document, e.g. organogram, Policy Manuals e.g. Human Resource Manual, Operations Manual, and other policy documents.

Adoption and Approval of the Manual

The Manual was Adopted and Approved by the Board of Directors of Rwanda Food and Drugs Authority, during the xx *(insert meeting N°)* meeting held on ……*(insert date).*

Signed by:

Signature		Date	
Names			
Title	**Chairman Board of Directors Rwanda FDA**		

4) Document, e.g. Guidelines, to be used to provide guidance information to the stakeholders, clients or customers of Rwanda FDA, e.g. Guideline on Import and Export of Pharmaceutical Products and Medical Devices.

	Author	Authorized by	Approved by
Title	Division Manager	Head of Department	Director General
Names			
Signature			
Date			

NB: All documents designed to provide guidance for stakeholders shall be signed only if a stakeholders' validation workshop was conducted and their inputs incorporated.

5) Document e.g. SOPs, to be used in all departments (Rwanda FDA Level)

	Author	Reviewed by	Authorized by			Approved by
Title	Division Manager	QMS Specialist	CFO	HoD F&D ISM	HoD F&D A&R	Director General

6) Document, e.g. SOPs, to be used in one **entire** department only (Department Level)

	Author	Checked by		Approved by
Title	Director	QMS Specialist	DM or Director of Unit in Finance Dept.	Head of Department or CFO
Signature & Date				

7) Document, e.g. SOPs, to be used in one Division only (Division Level)

	Author	Reviewed by		Approved by
Title	Officer	QM Specialist or Designated QM staff	Director of Unit	Division Manager
Signature & Date				

8) Document, e.g. SOP, to be used in one Unit only (Unit Level)

	Author	Authorized by		Approved by
Title	Officer	Designated QMS staff	Specialist/Officer	Director of Unit
Signature & Date				

9) Document, e.g. Laboratory Quality Manual for the QC Laboratory as per ISO/IEC 17025:2017, or Laboratory Information File as per WHO Good Practices for Pharmaceutical Quality Control Laboratories (*WHO TRS 957, Annex 1*).

	Author	Authorized by			Approved by
Title	Officer	Lab QM	QMS Specialist	DM QCL	Director General
Signature & Date					

10) Document, e.g. SOP, to be used only in the **entire** QC Laboratory

	Author	Reviewed by		Approved by
Title	Officer	Lab QM	Director of Unit	Manager QC
Signature & Date				

11) Document, e.g. Standard Test Procedure (STP), or Work Instruction (WOI), to be used only in one Unit of the QC Laboratory

	Author	Reviewed by	
Title	Officer	Lab QM	Director of Unit
Signature & Date			

9.5 Registering, Identifying and Issuing an Internal Document

9.5.1 The original of the authorized document shall be printed on one side only and stamped "**MASTER DOCUMENT**" in green color on the back side of every page.

9.5.2 The Quality Management Systems Specialist will issue and record the Master Document on the Master Internal Document Register number QMS/FOM/002

9.5.3 The issued Master Document will be kept in the Document Control Centre in a fireproof file cabinet.

9.5.4 Copies of the authorized Master Document shall only be made for workplaces or workstations or staff that strictly require hard copies or those that do not have easy access to the Rwanda FDA electronic QMS shared folder on the Rwanda FDA server.

9.6 Each copy of the authorized Master (Original) document shall be stamped "**CONTROLLED COPY**" in blue color, on every page, and allocated a copy number depending on where it is to be distributed.

9.6.1 Controlled copies shall be distributed to designated recipients and the Document Distribution Form number QMS/FOM/003 maintained.

9.6.2 For electronic documents, the Master document shall be scanned in PDF and posted on the Rwanda FDA QMS shared folder on the Rwanda FDA server (\\rwandafdaserver\qms\sops) as a read-only document, except for forms and formats.

9.6.3 All authorized guidelines and any other controlled documents that need to be disseminated to the public shall be uploaded on the Rwanda FDA Website.

9.6.4 Any controlled document printed from the QMS shared folder on the server by anybody shall be valid for only that day it is printed.

9.6.5 Any Rwanda FDA staff who needs a controlled document and is not part of the specified distribution, shall request for a copy of the document from the Quality Management Systems Specialist with approval from the Head of Department/Division/Unit where the document is to be used, and shall fill the Document Request Form number QMS/FOM/004 prior to document transmittal.

9.6.6 Any member of the Board of Directors, Advisory Committee and staff of the Rwanda Food and Drugs Authority and any outside persons, other institution or government agency who requests for a document, for whatever reason or purpose, shall provide information to be filled on the Document Request Form prior to document transmittal.

9.6.7 The Quality Management Systems Specialist shall transmit the document to the person requesting the document recipient and fill the Document Transmittal Form number QMS/FOM/005 which has to be signed by the recipient.

9.6.8 Any hard copy of a controlled document issued to any outside person, institution or organization, or a court of law shall be stamped “CERTIFIED TRUE COPY” in red color on the front of every page.

9.6.9 Any electronic document to be issued to any outside person shall be converted into PDF before it is transmitted electronically.

9.7 Retrieving a Superseded Internal Document

9.7.1 A controlled internal document that has been superseded by a new or revised document shall be removed from all work areas by the user; and from the QMS shared folder on the Rwanda FDA server by the Quality Management Systems Specialist; and destroyed in case of the hard copy, or transferred to the electronic folder for Superseded Documents on the QMS shared folder on the Rwanda FDA Server.

9.7.2 The user shall be responsible for checking on the QMS shared folder to ensure that the document he/she is using is still current (not superseded).

9.7.3 The in charge of Quality Management Systems shall send email to all recipients of the superseded document and notify them of the issue of the new or the revised document.

9.7.4 A superseded **Master Document** shall be stamped "**SUPERCEDED DOCUMENT**" in red ink on the front of the first page and put in the document archive for reference purposes.

9.7.5 Any controlled internal document that will not be further revised and its use terminated, e.g. a document that has been merged into another document, shall be stamped "**OBSOLETE DOCUMENT**" in red ink on the front of the first page.

9.8 Document Hierarchy and Storage System

9.8.1 All Master (original) documents shall be stored at the Document Control Centre under supervision of the Quality Management Systems Specialist and recorded in the Master Document Register.

9.8.2 The Designated Quality Management Staff of each Department/Division/Unit shall store and maintain all received hard copies of controlled external documents.

9.8.3 The Rwanda FDA documents hierarchy is shown in Figure 1 below:

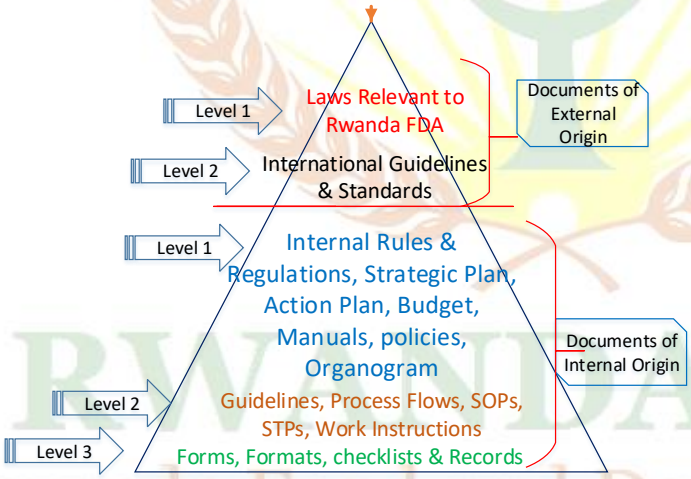


Figure 1: Document Hierarchy

9.9 Backup of Electronically Stored Documents

9.9.1 Electronic copies of documents shall be saved on the Rwanda FDA server, with periodic backup.

9.10 Document Review Frequency

9.10.1 All controlled documents shall undergo periodic reviewed every three years from the effective date indicated on each document, to ensure their continued adequacy and suitability.

9.10.2 Notwithstanding section 9.9.1 above, a document may remain valid beyond its review due date if no major change(s) have happened in the process, until the revised document is authorized.

9.10.3 A controlled document may be reviewed at any time, if required, as a result of internal audit, management review, decision made in response to a customer complaint or any other justifiable special circumstances.

9.10.4 Any changes to a controlled internal document as a result of the review shall be handled in compliance with part 9.2, 9.3, 9.4 and 9.5 above.

9.11 Receiving and Maintaining External Documents

9.11.1 All hard copies of external documents (documents of external origin) e.g. Laws, regulations, orders, pharmacopeias, international standards, policies and guidelines of external origin, etc, shall be received by the respective user Department/Division/Unit and stamped "**RECEIVED DATE…(DD/MMM/YYYY)**", register it, and notify the Designated Quality Management Staff of the respective Department/Division/Unit.

9.11.2 All electronic external documents shall be received by the respective user Department/Division/Unit and loaded on the QMS shared folder on the server for documents of external origin.

9.11.3 The Designated Quality Management Staff shall register the document in the Master External Document Register number QMS/FOM/006.

9.11.4 The Designated Quality Management Staff shall immediately submit the following details of the external document to the Quality Management Systems Specialist: version or edition number, author or publisher, effective date and date received.

9.11.5 When a new version or edition of an external document (document of external origin) is received, the previous (superseded) document shall be stamped "**OBSOLETE DOCUMENT**" on the first page and retained by the Designated Quality Management Staff of the respective Department/Division/Unit and kept for reference purposes.

10.0 References

10.1 The Rwanda FDA Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organisation and Functioning.

10.2 ISO 9001:2015 Quality Management Systems – Requirements.

10.3 ISO 9000:2015 Fundamentals and Vocabulary.

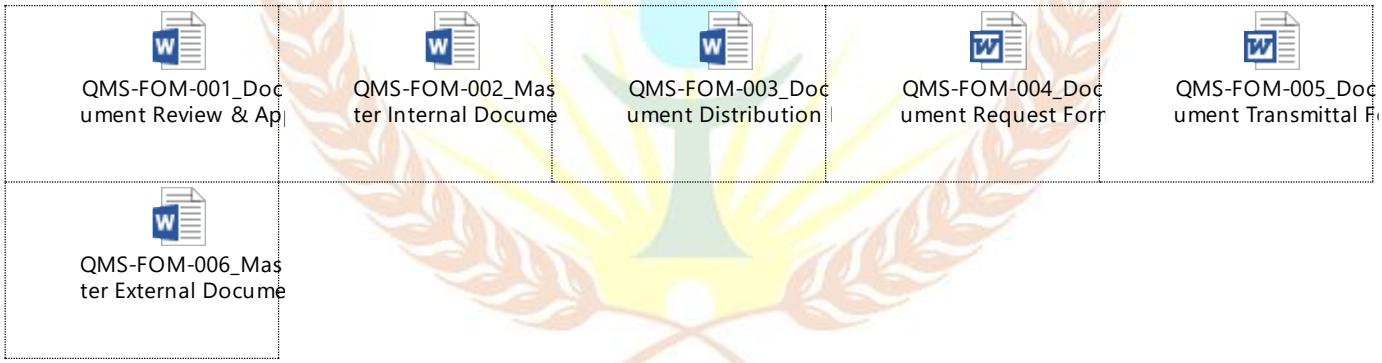
10.4 WHO Good Practices for Pharmaceutical Quality Control Laboratories, 2010, TRS 957 Annex1.

10.5 Change Control Procedure, for Rwanda FDA, document number QMS/SOP/002.

11.0 Appendices

The following list of appendices designates forms for use with this SOP but which may be revised at any time even if the SOP is not revised concurrently. In the MS Word file, the Appendices can be opened by double clicking on the file icon.

11.1 Document Review and Approval Circulation Form (QMS/FOM/001)
11.2 Master Internal Document Register Form (QMS/FOM/002)
11.3 Document Distribution Form (QMS/FOM/003)
11.4 Document Request Form (QMS/FOM/004)
11.5 Document Transmittal Form (QMS/FOM/005)
11.6 Master External Document Register Form (QMS/FOM/006)
11.7 Specimen document identification stamps.



12.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
29 Jan 2019	0	Rwanda FDA Staff	First Issue

End of Document