QUALITY MANUAL

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Doc. No. QMS/MAN/001	Revision Date: 18 Mar 2020	Review Due Date: 23 Mar 2023
Revision No.: 3	Effective Date: 23 Mar 2020	

Writing, reviewing, checking and authorisation of this Manual

This Manual was prepared by the National Drug Authority (NDA) Secretariat and checked by the Secretary to the Authority.

The Manual was authorised by the Chairperson of the **Seventh Drug Authority** and is effective from the **23rd March 2020**

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Abbreviations and acronyms

Drug Authority	The governing body of the National Drug Authority set up by the NDPA Act [cap 206] of the laws of Uganda
CAR Form	Corrective Action Request Form
CTD	Common Technical Document
EAC MRH	East African Community Medicines Regulatory Harmonization
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISO	International Organization for Standardization
NDA	National Drug Authority (of Uganda)
NDPA	National Drug Policy and Authority
Pharmaceutical Inspectorate	The National body responsible for coordinating and carrying out GMP inspections, including inspections of pharmaceutical manufacturers and/or wholesale distributors. If relevant, this could include making decisions concerning the issue or withdrawal of establishment licences or authorisations for their activities, the issue or withdrawal of GMP certificates, providing advice and handling suspected quality defects[1].
PIC/S	Pharmaceutical Inspection Co-operation Scheme
Secretary to the Authority	The Head of the NDA Secretariat, as established by Section 54(2) of the NDPA Act
SIPOC	Supplier-Input-Process-Output-Customer
WHO	World Health Organization

[1] *Ref: PIC/S pi 002-3 2007 recommendations on quality system requirements for pharmaceutical inspectorates.*

Introduction

0.1 Background

This Manual and its provisions shall be cited as the "Quality Manual".

One of the goals of NDA is to have a functioning Quality Management System (QMS) in accordance with national and internationally recognized standards. This document provides requirements for implementing quality management systems in accordance with ISO 9001: 2015 and PIC/S (P1 002-3) Quality System Requirements for Pharmaceutical Inspectorates.

Correspondence between the requirements of PIC/S 002-3 and the sections in this Manual with respect to ISO 9001:2015 is shown in Appendix 1.

The Manual defines:

a) the scope of the quality management system, including details of, and justification for, any exclusions;

b) the documented information established for the quality management system, or reference to them;

c) description of the interaction between the processes of the quality management system; and

d) nominal reference to the quality system requirements for a Pharmaceutical Inspectorate.

0.2 Objectives of this Manual

a) To define and describe the quality management system, authorities and responsibilities of the management personnel involved in the operation of the system, and provide references to the general procedures for all activities comprising the quality system of the entire NDA, based on ISO 9001:2015 quality management systems requirements and PIC/S recommendation for quality system requirements for pharmaceutical inspectorates.

b) To communicate the quality management system to the NDA staff, members of the Drug Authority, customers, stakeholders, development partners and other interested parties and to inform them of the specific controls that are implemented by NDA to assure the highest standard of drug regulatory service to the population of Uganda.

QUALITY MANAGEMENT SYSTEM

1.0 Scope of the quality management system

This manual meets the requirements of ISO 9001:2015 International Standard and applies to all services provided by NDA. These include key drug regulatory services of NDA like: inspection and licensing, product assessment and registration, control of import and export, post marketing surveillance, pharmacovigilance, control of drug adverts and promotion materials, and quality control of drugs.

The quality management system described in this manual applies to all directorates, departments and units of NDA at all its geographical locations.

All clauses of ISO 9001:2015 Quality Management Systems Requirements apply except Section 8.3 (Design and development of products and services) which is excluded from this Manual because NDA does not engage in design and development work. NDA uses drug regulatory guidelines described in the National Drug Policy and Authority Regulations, and in international guidelines from World Health Organisation, International Council for Harmonisation of Technical Requirements for pharmaceuticals for Human Use (ICH), East African Community (EAC) Medicines Regulatory Harmonization (MRH), and other international bodies.

Clauses for impartiality and independence, and confidentiality have been included in this Manual as sections 7.7 and 7.8, respectively, to fulfil the requires of section 7.1 in the PIC/S PI 002-3 2007 recommendations on quality system requirements for pharmaceutical inspectorates.

2.0 Normative References

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

The ISO 9001:2015 Quality Management Systems — Requirements

In addition, the following referenced documents are indispensable for the application of the QMS in NDA:

a) ISO 9000:2015, Quality Management Systems – Fundamentals and Vocabulary;

b) PI 002 PIC/S- Recommendations on Quality System Requirements for Pharmaceutical Inspectorates; and

a) Oaths Act 1963.

3.0 Terms and Definitions

The terms and definitions given in ISO 9000: 2015 Quality management systems — Fundamentals and Vocabulary, shall apply for purposes of this Manual.

Drug	:	means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes.
Top management	:	a person or group of people who directs and controls an organization at the highest level. In the case of National Drug Authority, top management is The Drug Authority.
Organization	:	a person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives
Context of the organization	:	the combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives
Interested party (stakeholder)	:	a person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity
Customer	:	*a* person or organization that could or does receive a product or a service that is intended for or required by this person or organization
Provider (supplier)	:	an organization that provides a product or a service
External provider (external supplier)	:	a provider that is not part of the organization
Improvement	:	any activity to enhance performance
Continual improvement	:	any recurring activity to enhance performance
Management	:	coordinated activities to direct and control an organization
Quality management	:	management with regard to quality
Quality assurance	:	*a* part of quality management focused on providing confidence that quality requirements will be fulfilled
Quality control	:	a part of quality management focused on fulfilling quality requirements

Quality improvement	:	a part of quality management focused on increasing the ability to fulfil quality requirements
Change control	:	activities for control of the output after formal approval of its product configuration information
Activity	:	*the* smallest identified object of work in a project
Process	:	a set of interrelated or interacting activities that use inputs to deliver an intended result
Procedure	:	a specified way to carry out an activity or a process
Outsource	:	to make an arrangement where an external organization performs part of an organization's function or process
Contract	:	a binding agreement
Design and development	:	a set of processes that transform requirements for an object into more detailed requirements for that object
System	:	a set of interrelated or interacting elements
Infrastructure	:	a system of facilities, equipment and services needed for the operation of an organization
Management system	:	a set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives
Quality management system	:	the part of a management system with regard to quality
Policy	:	the intentions and direction of an organization as formally expressed by its top management
Quality policy	:	a policy related to quality
Vision	:	an aspiration of what an organization would like to become as expressed by top management
Mission	:	the organization's purpose for existing as expressed by top management
Object	:	an entity, item, anything perceivable or conceivable
Quality	:	the degree to which a set of inherent characteristics of an object fulfils requirements
Requirement	:	a need or expectation that is stated, generally implied or obligatory

Quality requirement	:	a requirement related to quality
Statutory requirement	:	an obligatory requirement specified by a legislative body
Regulatory requirement	:	an obligatory requirement specified by an authority mandated by a legislative body
Product configuration information	:	the requirement or other information for product design, realization, verification, operation and support
Nonconformity	:	non-fulfilment of a requirement
Defect	:	a nonconformity related to an intended or specified use
Conformity	:	fulfilment of a requirement
Traceability	:	ability to trace the history, application or location of an object
Innovation	:	new or changed object realizing or redistributing value
Objective	:	a result to be achieved
Quality objective	:	an objective related to quality
Output	:	the result of a process
Product	:	an output of an organization that can be produced without any transaction taking place between the organization and the customer
Service	:	an output of an organization with at least one activity necessarily performed between the organization and the customer
Performance	:	a measurable result
Risk	:	the effect of uncertainty
Effectiveness	:	the extent to which planned activities are realized and planned results are achieved
Data	:	facts about an object
Information	:	meaningful data
Information System	:	a network of communication channels used within an organization
Document	:	information and the medium on which it is contained
Documented information	:	information required to be controlled ad maintained by an organization and the medium on which it is contained
Specification	:	a document stating requirements

Quality manual	:	a specification for the quality management system of an organization
Record	:	a document stating results achieved or providing evidence of activities performed
Verification	:	confirmation, through the provision of objective evidence, that specified requirements have been fulfilled
Feedback	:	opinions, comments and expressions of interest in a product, a service or a complaints-handling process
Customer satisfaction:	:	a customer's perception of the degree to which the customer's expectations have been fulfilled
Complaint	:	the expression of dissatisfaction made to an organization, related to its product or service, or the complaints-handling process itself, where a response or resolution is explicitly expected
Characteristic	:	a distinguishing feature
Competence	:	the ability to apply knowledge and skills to achieve intended results
Configuration	:	interrelated functional and physical characteristics of a product or service defined in product configuration information
Review	:	the determination of the suitability, adequacy or effectiveness of an object to achieve established objective
Monitoring	:	determining the status of a system, a process, a product, a service or an activity
Measurement	:	a process to determine a value
measuring equipment	:	a measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process
Inspection	:	determination of conformity to specified requirements
Test	:	determination according to requirements for a specific intended use or application
Preventive action	:	an action to eliminate the cause of a potential nonconformity or other potential undesirable situation
Corrective action	:	an action to eliminate the cause of a nonconformity and to prevent recurrence

Correction	:	action to eliminate a detected nonconformity
Release	:	permission to proceed to the next stage of a process or the next process
Audit	:	systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
Audit plan	:	description of the activities and arrangements for an audit
Audit criteria	:	set of policies, procedures or requirements used as a reference against which objective evidence is compared
Auditee	:	organization being audited

4.0 Context of National Drug Authority

4.1 Understanding the context of NDA

The NDA has determined, monitors and reviews the external and internal issues that affect its ability to achieve the intended result(s) of its quality management system. This is through its periodic performance reviews.

4.2 Understanding the needs and expectations of interested parties

NDA has determined its interested parties and their requirements that are relevant to the quality management system through development of a stakeholders' analysis and mapping report.

4.3 Determining the scope of the quality management system

This manual applies to all activities that affect the quality of services delivered by NDA. These include the following key regulatory activities:

a) inspection and licensing of pharmacies, drug shops, medicine shops and local pharmaceutical manufacturers;
b) GMP inspection of domestic and foreign manufacturers of pharmaceutical products;
c) control of pharmaceutical imports and exports;
d) pharmacovigilance;
e) clinical and field trials;
f) vetting of publications and advertising relating to drugs;
g) post-marketing surveillance;

h) QC laboratory testing of samples; and

i) enforcement processes.

It also includes support functions of NDA such as finance and audit, procurement, information communication technology (ICT), legal services, human resource and administration, public relation and others as applicable.

The quality management system described in this manual shall apply to all directorates, departments, units and sections of NDA at all their geographical locations.

4.4 Quality management system and its processes

The Plan-Do-Check-Act cycle is applied to all processes and the quality management system as a whole as shown in appendix 2 (Level 1)

The sequence and interaction of the drug regulatory processes have been optimised through Supplier-Input-Process-Output-Customer analysis. The interactions of these processes at macro-level are shown in Appendix 2 (Level 2 and 3).

The criteria and methods needed to ensure that the operation and control of the processes are effective are documented in manuals, guidelines, standard operating procedures, forms, formats, checklists, aide memoires, flow charts and other controlled documents.

The necessary resources needed have also been included in NDA approved annual budgets;
The key performance indicators used to monitor and measure these processes are established and contained in the NDA strategic plan.

There are controls over externally provided processes, products and services that include specialised quality control testing for some of the drug samples which on a case by case basis are outsourced, cleaning and security services for office and laboratory premises, catering services, and expert reviewers.

5.0 Leadership

5.1 Leadership and Commitment

5.1.1 General

The Drug Authority is the "top management" of NDA with respect to ISO 9001:2015 requirements. This is because it's the body that directs and controls NDA at the highest level. Evidence for this can be from section 5 of the National Drug Policy and Authority Act and from section 2.7.3 of the NDA Authority Manual 2018 Doc. No. AUT/MAN/007

The Drug Authority is committed to the implementation of QMS. The Authority has approved the quality policy and provided the vision and mission; and the necessary human, financial, physical, technical and technological resources for the successful implementation of QMS.

5.1.2 Customer focus

The Drug Authority demonstrates leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met through annual work plans and budgets that are consistent with the strategic plan and the NDA mandate;

b) any risks and opportunities with the potential to impact the NDA's ability to provide drug regulatory services that conform the requirements, or that may affect customer satisfaction, are being identified and addressed; and

c) the focus on enhancing customer satisfaction is maintained.

5.2 Quality Policy

5.1.1 Establishing the Quality policy

The Drug Authority authorised a Quality Policy (Doc. No. QMS/POL/001) which is shown in Appendix 3.

5.1.2 Communicating the Quality Policy

The Quality Policy has been availed to the staff through the shared folder on the NDA server and displayed at several eye-catching locations at the NDA main office, at the NDA Laboratory and at the NDA regional offices. It has also been uploaded on the NDA Website.

5.3 Organizational roles, responsibilities and authorities

It is therefore the responsibility of the Drug Authority to assign the responsibility and authority for ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented and for ensuring the promotion of customer focus throughout the organization.

A policy on NDA organizational structure is described in the Human Resource Manual Doc. No. HRA/MAN/003. The current NDA organizational structure (Doc. No. HRA/POL/003) is shown in Appendix 4. The GMP structure is shown in Appendix 5.

There are approved current job descriptions clearly stating the role, duties and responsibilities of each member of staff.

6.0 Planning

6.1 Actions to address risks and opportunities

NDA has used different formats to determine the risks that need to be mitigated and opportunities to be harnessed.

During strategic planning, SWOT analysis is conducted to identify the potential risks and opportunities.

The SIPOC (Supplier-Input-Process-Output-Customer) analysis is used to identify the potential risks and opportunities during process planning and rationalization in the different departments / units.

NDA has also conducted an overall business risk analysis and maintains a Risk Register, (Doc. No. FIN/FOM/169) where monitoring and reporting on the progress of the risks is done by each directorate/department/unit.

Risk identification, rating and mitigation are part of the management and Authority papers.

6.2 Quality objectives and planning to achieve them

NDA has a strategic plan for the period July 2016 through June 2021. Quality objectives (QMS/FOM/248) that are in line with the strategic plan have been developed.

6.3 Planning of changes

An SOP for change control (Doc. No. QMS/SOP/003) is used for control of changes within NDA.

7.0 Support

7.1 Resources

7.1.1 General

The necessary resources are determined for each financial year during the planning and budgeting period (between October and February). This results in a recurrent and capital expenditure budget estimate for the entire NDA that is approved by the Honorable Minister of Health.

7.1.2 People

The required staffing levels are available across the NDA establishment. Recruitment is progressively made, year to year, with respect to the establishment. The employee contracts range from 4 years to 5 years.

7.1.3 Infrastructure

NDA has provided adequate offices at the head office on Lumumba Avenue; at the NDA Quality Control Laboratory at Mulago Hill, at the seven NDA regional offices; and the Nakawa inland port, Busia/Malaba port at the Uganda/Kenya boarder; and at Entebbe international airport. These offices have been provided with the necessary utilities, process equipment (both hardware and software), and supporting services (such as transport, communication and information systems).

The infrastructure is continually maintained in order to improve service delivery to the customers.

7.1.4 Environment for the operation of processes

The offices, storage areas and laboratory have been provided with adequate lighting, cold storage for samples; noise-protection and air-conditioning, where necessary.

7.1.5 Monitoring and measuring resources

Approved annual work plans are the basis for the quarterly, semi-annual and annual performance reporting against the targets. Process data is captured and analysed to reveal

any process trends that can be the basis for planning and improvement during the coming period.

7.1.6 Measurement traceability

Measuring equipment used in NDA is verified and/or calibrated against international or national measurement standards at specified intervals or prior to their use in order to provide confidence in the measurement results.

Measuring instruments are identified with calibration stickers so as to determine their calibration status and are protected to prevent them from being adjusted, damaged or subjected to deterioration or anything that would invalidate their correct calibration status and therefore jeopardise any future measurement results. Verification and/or calibration records are kept.

7.1.7 Organizational knowledge

Organizational knowledge specific to NDA is gained through experience of the staff and through specialised on-the job training and mentoring over the years; and from surveys, studies, operational research; and from conferences, seminars, workshops, benchmarking study visits and meetings with stakeholders, interested parties; regional and international bodies.

An assessment of organizational knowledge is done prior to making any changes (as part of change control) to the quality management systems in response to changing needs or trends in the operational environment. This is to ensure that informed decisions are made in respect of the changes to the quality management system.

7.2 Competence

Competence is defined as the *"ability to apply knowledge and skills to achieve intended results"*.

The employees of NDA are competent through education, skill, training and experience as necessary. Requirements for education, skill, training and experience are documented in the job descriptions. Training of employees is done in accordance with approved annual training plan.
The necessary competence for specific tasks is determined for employees and for contracted external experts that are required to perform work affecting conformity to product and/or service requirements (refer to scheme of service, job specifications, competence matrix, and terms of references for committees and for outsourced external experts).

A training plan is developed on annual basis and training records are maintained.

7.3 Awareness

All employees of NDA, and all persons doing work for, or on behalf NDA, are made aware of the NDA's quality policy and any quality objectives that are relevant to them.

7.4 Communication

A communication manual (PRS/MAN/007) has been developed for both internal and external stakeholders. The manual shows information like: what will be communicated; when to communicate; with whom to communicate; how to communicate; and who communicates.

Communication channels that are mainly organised for the external stakeholders include: press conferences and press releases, radio and television talk shows, emails, circulars, public alerts, seminars, workshops and consultative meetings; while for internal stakeholders (staff and members of Drug Authority and its committees), emails, meetings, and retreats are organised.

7.5 Documented information

This is information that NDA is required to control, to maintain (to document) and to retain (to keep records). Control of documentation is described in the SOP for Document Control (QMS/SOP/002).

NDA has established the following categories of documents of internal origin for the quality management system:

a) quality policy;
b) strategic plan in which quality objectives are contained;
c) guidelines;
d) manuals;
e) SIPOCs, process flowcharts
f) standard operating procedures, protocols;
g) forms, checklists, aide memoires; and
h) records.

Document registers for internal documents (Doc. No. QMS/FOM/007) and external documents (Doc. No. QMS/FOM/006) are maintained.

7.6 Creating, updating and control of documented information

The SOP for Document Control (QMS/SOP/002) describes the procedure for creating, updating and control of internal and external documents that are maintained while the for Control of Records (QMS/SOP/004) describes the procedure for control of records i.e. documents that are retained.

7.7 Impartiality and independence

The Drug Authority has adopted a code of conduct for all employees of NDA, which is in line with national public service code of conduct and professional bodies. Each employee has signed legally enforceable commitments necessary for impartiality and objectivity. (NDA code of conduct form HRA/FOM/089 and declaration of conflict of interests for NDA staff form QMS/FOM/112.

7.8 Confidentiality

The members of the Drug Authority and Authority Committees and staff of NDA have signed legally enforceable commitments which are in line with national public service code of conduct and professional bodies (Oaths Act 1963 [cap 19]) for the management of all information obtained or created during the performance of their duties. The members of the Drug Authority, advisory committees and chairperson complete Declaration of interest prior to Authority meetings using Form QMS/FOM/140. Subcontracted personnel and experts are also required to sign the Oath of Secrecy before commencement of their assignments.

8.0 Operation

8.1 Operation planning and control

NDA ensures that all human and veterinary drugs used in Uganda are of good quality, safe and effective through the following processes:

a) Inspection and Licensing of Pharmacies and Drug Shops;

b) Inspection of Pharmaceutical Manufacturing Plants (Good manufacturing practice);

c) Assessment & Registration of Drugs (Evaluation of product dossiers for quality, safety and efficacy of drugs; evaluation of publications and advertisement related to the drugs);

d) Control of Imports & Exports (verification of pro-forma invoices, Inspection of consignments at ports of entry into Uganda);

e) Quality Control Lab Testing (Testing of suspect, spurious, and random samples from ports of entry and from drug outlets) at the NDA laboratory by the Directorate of Laboratory Services, located at Mulago Hill;

f) Post Marketing Surveillance and Enforcement (sampling of suspect, spurious, and random samples from drug outlets (Doc. No. INS/SOP/044 for Sampling of Drugs including Medical Gloves, Male Latex Condoms and Long Lasting Insecticide-Treated Mosquito Nets) ; instruction for product recall by product license holder/applicant);

g) Pharmacovigilance and Clinical Trials (Monitoring of Adverse Drug Events [safety and efficacy of drugs]); and

h) Control of publications and advertising relating to drugs (including promotional materials).

Process flows, in terms of SIPOC analysis have been developed, outlining the activities involved at each stage and the required controls in terms of documented information that should be maintained (as a document) and retained (as a record).

Quality control and quality assurance measures at different stages of service provision have been established, e.g. first and second assessors for the evaluation of product dossiers; peer review of assessment reports and peer-review of GMP reports; and acceptance criteria based on applicable standards to be met, e.g. pharmacopeia specifications, requirements by WHO, ICH, PIC/S, EACMRH and other international organizations that related to the regulation and control of drugs.

The following procedures are established for the control of GMP Inspections, in accordance with PIC/S requirements:

a) Planning of GMP Inspection of a Pharmaceutical Manufacturing Facility for Medicinal Products (INS/SOP/012);

b) Preparation for GMP Inspection of a Pharmaceutical Manufacturing Facility for Medicinal Products (INS/SOP/013);

c) Conducting a GMP Inspection of a Pharmaceutical Manufacturing Facility for Medicinal Products (INS/SOP/014); and

d) Writing and Peer-Review of GMP Report, and Follow-Up of Non-Compliances (INS/SOP/015); and

e) GMP desk Assessment of Applications for GMP Inspection for Pharmaceutical Manufacturing Facilities (INS/SOP/045).

8.2 Requirements for products and services

8.2.1 Customer Communication

NDA communicates to its customers of the specific service requirements e.g. annual licensing requirements for pharmacies and drug shops, product registration requirements in the Common Technical Document (CTD) dossiers, requirements for amendments to a registered product, etc.., by sharing the information in draft guidelines with the respective customer/clients for consultation and input before the guidelines are finalised and approved.

Channels used for communication with the NDA clients (importers, manufacturers, distributors, wholesalers and retail of the pharmaceutical products), stakeholders, other interested parties and the general public include the following:

a) NDA website where guidelines and drug registers are posted;
b) face-to-face consultative and awareness meetings, workshops and seminars; and
c) print and electronic media.

Feedback from the clients, customers, stakeholders and interested parties is through market complaint handling system and periodic customer satisfaction surveys.

Customer satisfaction surveys shall be done at least once every two years using structured survey tools (questionnaires).

8.2.2 Determining the requirements for products and services

Requirements specified by the customer have been determined through consultative meetings with customers (e.g. manufacturers, importers, exporters, wholesalers and retail operators, practitioners, consumer organizations), and feedback mechanisms. This mainly affects the information to be included in new or revised guidelines, e.g. Annual licensing guidelines, Common Technical Document (CTD) guidelines, and others.

In developing such guidance documents, NDA also takes into account national, regional (EAC MRH) and international guidelines and best practices.

A service delivery timeline showing the regulatory area, action and timelines has been developed for all the drug regulatory functions of NDA. It is posted on the NDA website so as to communicate it to the clients and other interested parties.

8.2.3 Review of requirements for products and services

When applications for GMP inspection of local and foreign pharmaceutical manufacturers; or inspection for suitability of premises for wholesale and retail pharmacies, and drug shops are received; or supervision of clinical or field trial, etc.., they are reviewed by the respective process owners. Inspection schedules are developed and communicated to the applicants for consenting before the inspection takes place. However, un-announced inspections are also done under special circumstances.

8.2.4 Changes to requirements for products and services

Changes to the inspection schedules are made whenever justified and mutually agreed upon between NDA and the applicants. Applicants and the general public are notified of the changes in the requirements for licensing, inspection, product registration, sample size for laboratory testing purposes, etc...

8.2.5 Complaints and appeals

NDA has established documented procedures (Receiving, Handling and Feedback of Service related compliments, complaints and appeals Doc. No. QMS/SOP/009 and Management of Consumer Complaints on Suspected Defective Medicinal Products Doc. No. DPS/SOP/076) for investigation and handling of market complaints and appeals from customer. There are two committees with documented terms of reference; the Drug Complaints Investigation Committee (Doc. No. QMS/ToR/002) and the Service Related Complaints and Appeals Investigation Committee (Doc. No. QMS/ToR/012) that are designated to provide oversight over the complaint management process.

8.3 Design and Development of products and services

This section is not applicable because NDA is not involved in design and development work as justified under section 1.0 (Scope of the Quality Management System) of this Manual.

8.4 Control of externally provided processes, products and services

Externally provided processes, products and services include cleaning of office and laboratory premises, security of premises and catering services. In rare cases, outsourcing of laboratory testing is done for tests that cannot be done by the NDA laboratory. The necessary control for the latter are described in the Laboratory Manual. Procurement of all externally provided processes, products and services is governed by Public Procurement and Disposal of Public Assets (PPDA) Act and its regulations.

Records arising out of the procurement process including product/service specifications, procedures, evaluation of suppliers and selection criteria are maintained by the Procurement Department.

8.4.1 Type and extent of control

A list of prequalified suppliers of services, works and supplies was developed in accordance with the PPDA regulations. NDA ensures that purchased products are inspected and verified against the purchase order before they are accepted. Goods Receipt Notes are kept as evidence of inspection and verification of the purchased product.

8.4.2 Information for external providers

NDA develops and maintains purchasing information describing the product, service or works to be procured. This information includes specifications, procedures and acceptance criteria.

8.5 Production and service provision

8.5.1 Control of production and service provision

NDA carries out service provision under controlled conditions following the NDPA Act, regulations, guidelines, SOPs, checklists/aide memoires and qualified equipment. Additional controls include quality assurance measures like peer-review of reports (e.g. GMP reports reviewed by the Good Manufacturing Practice Peer Review Committee (GPRC)), first and second assessors for product dossier evaluation, checking by supervisors at different levels, approval by the Secretary to the Authority or by the relevant Authority Committee, and authorization by the Authority, where required. NDA established a procedure for issuance and withdrawal of licences and GMP certificates.

8.5.2 Identification and traceability

NDA uses unique identification numbers to customer property e.g. product dossiers, drug samples, and to the outputs e.g. marketing authorization number, permit number, license number, GMP certificate number, adverse event report number, poor quality medicine report number.

8.5.3 Property belonging to customers or external providers

NDA identifies, verifies, protects and safeguards customer property provided for use during services realization while it is under the NDA's control.

Customer property includes product dossiers for marketing authorization, samples, site master files for pharmaceutical manufacturing facilities, pro-forma invoices for importers of pharmaceuticals, medicine samples collected/taken for QC laboratory testing, confiscated medicines, medicine promotional materials, certificates.

8.5.4 Preservation

NDA preserves the conformity of product during internal processing and delivery to the intended destination; including preservation of samples taken during post marketing surveillance or exhibit samples taken during GMP inspection.

Preservation includes identification, handling, storage and protection. Preservation of product includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

a) prevention from contamination and deterioration;
b) marking and labelling including safety warnings; and
c) special handling and storage for temperature-sensitive materials and products.

8.5.5 Post-delivery activities

NDA monitors product safety with respect to pharmaceutical products that are in use by patients in Uganda by carrying out pharmacovigilance and other post-marketing activities.

8.5.6 Control of changes

NDA follows the SOP for change control (QMS/SOP/003) to ensure that changes made do not adversely affect the specifications and quality of the products and services delivered. Records of change controls are maintained.

8.6 Release of products and services

Reports, certificates, licences, permits and authorization letters are checked by the respective supervisors and signed by the Secretary to the Authority or by other senior officers authorised by the Drug Authority to do so as per section 4(3) of the National Drug Policy and Authority (NDPA) Act Cap.206. The list of authorised persons (Authorised Persons to Release NDA Outputs to Customers, QMS/FOM/249) is updated from time to time.

The release of reports, certificates, licences, permits and delivery to the customers does not proceed until the requirements have been satisfactorily met (e.g. GMP certificates are not issued until the evidence of corrective and preventive actions by the manufacturer are submitted and evaluated by NDA and found to be satisfactory).

8.7 Control of non-conforming outputs

Whenever a non-conforming output is identified, it is registered by the process owner and an investigation form e.g. the OOS investigation form (in case of the QC Laboratory) or complaint investigation in-process form (in case of market/customer complaints) or corrective action request (CAR) form (QMS/FOM/015) (for others e.g. arising out of quality

audits), is raised for investigation to be initiated in order to find out the root cause or assignable cause. Corrective action is then taken by the respective process owner.

Non-conforming outputs may include any of the following:

a) Erroneous verification certificate, GMP certificate, permit, or licence (from the GMP and GDP inspection processes; and control of imports and exports of drugs);
b) Erroneous registration of a product on the drug register (from the product assessment and registration processes);
c) Erroneous published adverse event report (from the pharmacovigilance processes);
d) Erroneous clinical / field trials assessment monitoring report (from the clinical/field trials monitoring processes);
e) Erroneous promotional material vetting report (from the control of publications and advertisement relating to drugs processes; and
f) Out-of-specification (OOS) test result (from the quality control laboratory processes).

9.0 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

A monitoring and evaluation framework that tracks process activities, targets, key performance indicators, and outputs is used to monitor progress of processes. Performance reports (quarterly, semiannual, and annual) are made and their information analyzed and used as input in management reviews.

9.1.1 Customer satisfaction

Customers' perceptions of the degree to which their needs and expectations have been fulfilled with respect to the services they receive from NDA is monitored using customer complaint analysis, and customer satisfaction surveys using a structured questionnaire that is administered to the respective stakeholder groups during meetings and workshops.

The Market Complaint Report Form (QMS/FOM/013) is available on the NDA website, at the reception and with the support supervision team to enable interested parties to fill and submit them to NDA.

Inquiries are also received via email (ndaug@nda.or.ug), toll free telephone line (+256 800 101 999), and social networks like WhatsApp (+256 791 415 555), short message service (SMS) services, NDA website (www.nda.or.ug), Twitter (@UNDAuthority) and Instagram (Uganda National Drug Authority).

9.1.2 Analysis and evaluation

NDA analyses and evaluates appropriate data and information for a variety of pre-defined purposes. These include: to demonstrate that the NDA's services conform to requirements; to assess customer satisfaction; to ensure the conformity and effectiveness of the quality management system; to evaluate the performance of external providers, to determine the need for improvements within the quality management system; and to demonstrate that planning has been successfully implemented.

9.2 Internal audit

Internal quality audits are conducted according to an approved schedule. Audit plans are developed to ensure that all aspects of the QMS are addressed. The frequency and scope of the audits are determined on the basis of the significance/sensitivity of a process and results of previous audits.

The SOP for internal quality audit (Planning, Conducting & Reporting Internal Quality Audits, Doc. No. QMS/SOP/006) is established to define the responsibilities and requirements for planning and conducting quality audits, establishing records and reporting results.

Reports of internal quality audits are submitted to the Secretary to the Authority and to the auditee. The auditee also receives the corresponding Corrective Action Request (CAR) forms (QMS/FOM/015). The audit is considered closed when the implementation and effectiveness of corrective actions has been verified and recorded.

Audit results become part of the quality records and are presented at management review.

9.3 Management review

Management conducts management review of the QMS at least once in a year in order to ensure its continuing suitability, adequacy and effectiveness. Management review can be done at directorate level and a report aggregated and submitted to top management. The records of management reviews are maintained.

Management review inputs include the following:

a) Review of the status of any actions identified at previous reviews.

b) consideration of any changes in the organization's context.

c) consideration of the QMS performance and effectiveness. Here, specific reference is made to the need for trends relating to nonconformities and corrective action, monitoring and measurement results, audit results, customer satisfaction as well as

relevant interested parties' feedback, process performance and conformity of the services; also external providers' performance and how well quality objectives are being achieved;

d) information on opportunities for improvement;

e) the adequacy of resources; and

f) if the actions to address risks and opportunities have been effective.

10.0 Improvement

The effectiveness and performance of the respective processes and the resulting services, are reviewed so as to identify and address unwanted effects, whatever they are and whatever the cause. Improvements can then be pursued by correction, prevention or reduction, as appropriate.

10.1 Nonconformity and corrective action

NDA investigates and takes action towards a nonconformity that has occurred, including those resulting from market complaints, and licensing complaints and appeals. The actions that relate to the registered product, can include suspension, or deletion of the product from the register, and/or to direct for quarantine and recall of the affected batches of product by the license holder, applicant or local technical representative.

Corrective action can also be required internally in NDA within the concerned processes. The needs for corrective action are documented on a Corrective Action Request (CAR) and submitted to the process owner for the identification of the root cause and to prevent recurrence.

10.2 Continual improvement

NDA adopts various forms of improvement, such as correction, corrective action, preventive action, breakthrough change, innovation and reorganization. Other approaches include addressing both risks and opportunities associated with its context, objectives and strategic
direction and enhancing customer satisfaction.

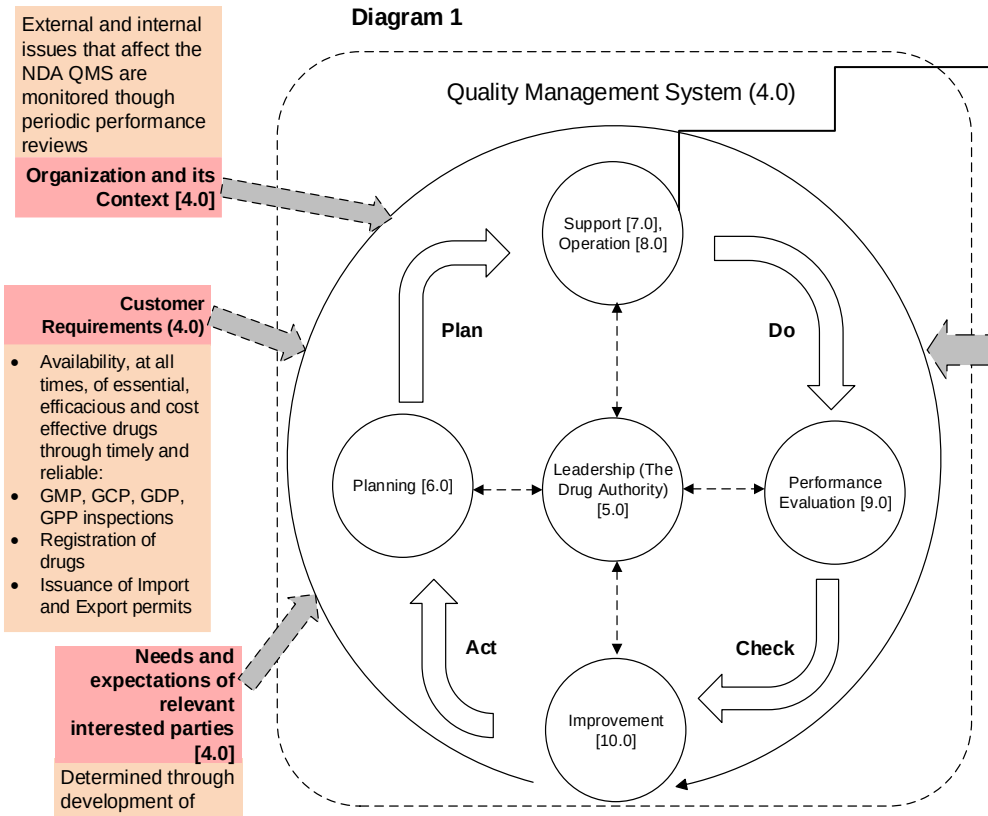
As part of continual improvement, NDA uses the results of analysis and evaluation of data from key processes and from management review to determine areas of underperformance and to identify any opportunities for improvement.

Appendix 1: Correspondence between PIC/S 002-3 and this Manual

PIC/S PI 002-3 2007	Section		NDA Quality Manual
Introduction	2	0.1	Introduction
Purpose	3	0.2	Objectives
Scope	4	1.0	Scope of the quality manual
Definitions	5	3.0	Terms and definitions
Quality Manual	6	7.5	Documented information
Administrative Structure (include GMP structure)	7	7.1.2	Human resources
Organization and Management	8 8.5	5.3 7.1 9.3	Responsibility and authority Resource provision Management review
Documentation and Change control	9	7.5	Documented information
Records	10	7.5	Documented information
Inspection Procedures	11	8.1	Operation planning and control
Inspection Resources	12	8.1	Operation planning and control
Internal Audit	13	9.2	internal audit
Quality Improvement and Corrective /Preventive Action	14	10.1 10.2	Nonconformity and corrective action Continual improvement
Complaints	15	8.2.5	Complaints and appeals
Issue and withdrawal of Licenses and GMP certificates	16	8.1 8.5.1	Operation planning and control Control of production and service provision
In the Inspection report format	11.4	8.5.	Preservation
Handing suspected Quality Defects and Rapid Alert System	17	8.7 7.4	Control of non-conforming product/outputs Communication
Liaison with the official Medicine Control Laboratory	18	8.1	Operation planning and control
Sub-Contracting and Assessing	19.1 19.2	8.4	Control of externally provided processes, products and services

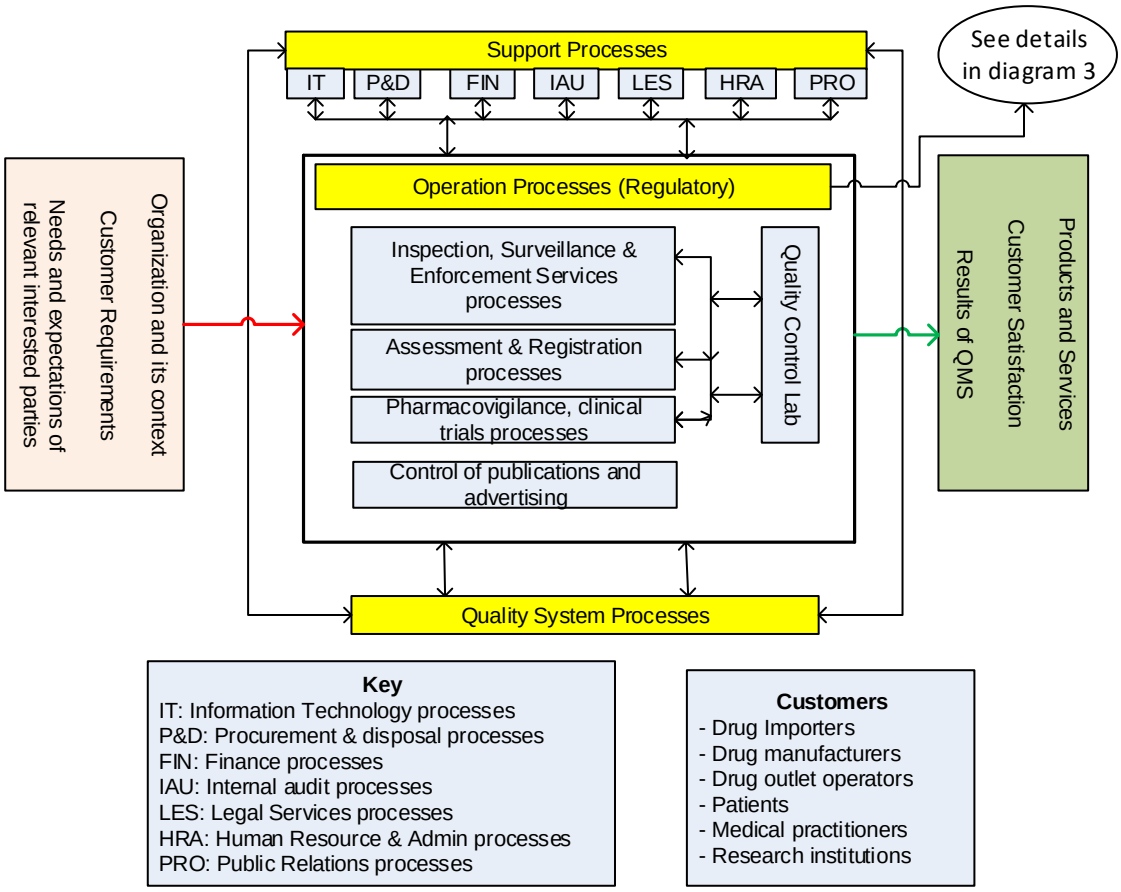
Appendix 2: Interaction of Processes

Level 1: NDA PDCA Cycle



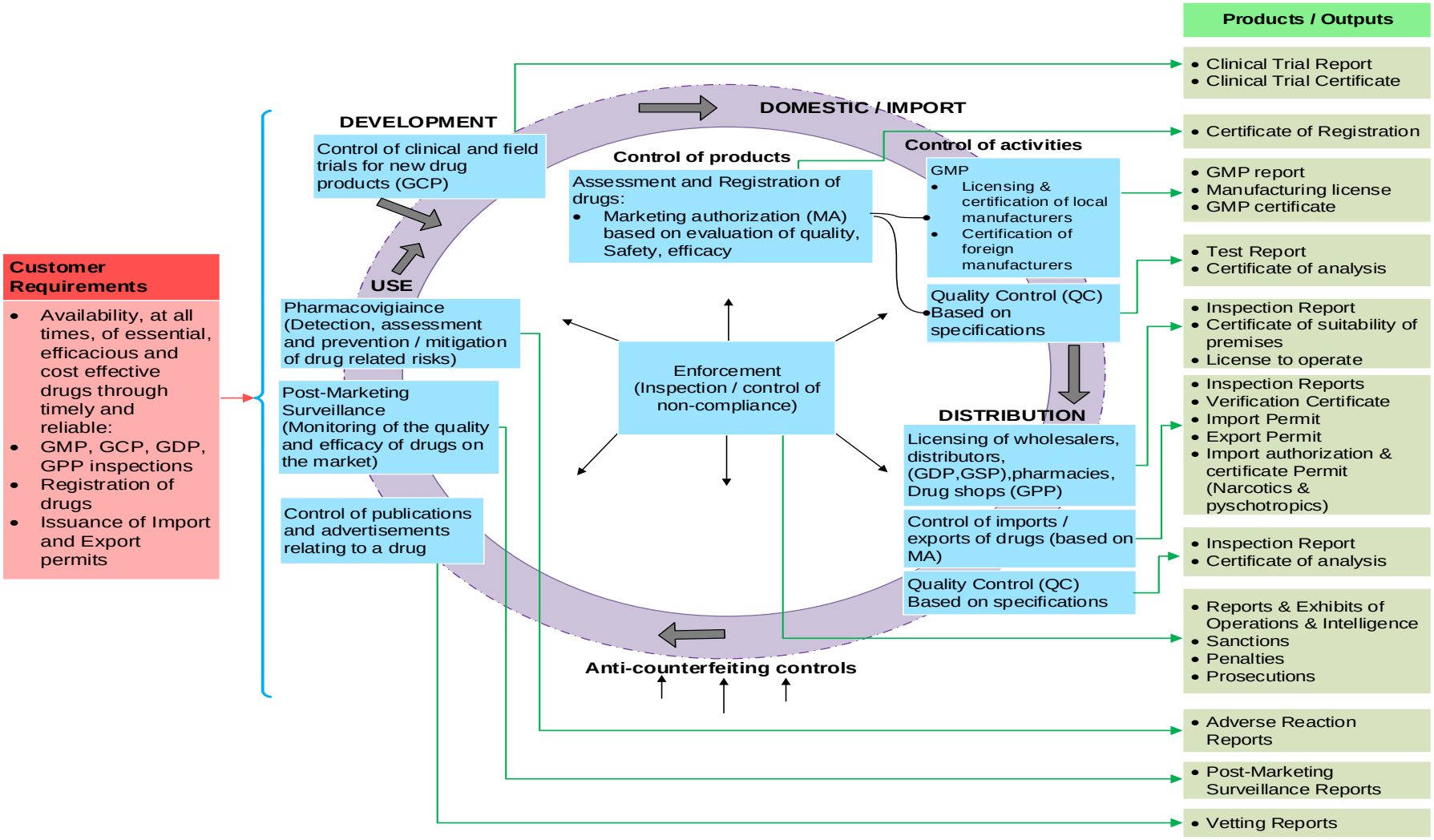
Level 2: NDA Interaction of Processes: Support and Operations

Diagram 2



Level 3: Sequence and Interaction of NDA Drug Regulatory Processes

Diagram 3



Appendix 3: Quality Policy

The Drug Authority is committed to providing the highest standard of drug regulatory service to all customers.

Timely and reliable service, compliance to all applicable statutory and regulatory requirements, and meeting customer requirements underlie all our effort in ensuring quality, safety and efficacy of all drugs and healthcare products used in Uganda. This is done through regulation and control of drug production, importation and distribution.

We are committed to implement a quality management system that complies with ISO 9001:2015 for the whole organization; WHO Good Practices for Pharmaceutical Quality Control Laboratories 2010 for the testing of drugs; ISO/IEC 17025:2017 for testing healthcare products; PIC/S 002 for pharmaceutical inspectorates; and maintaining an adequate workforce that is trained, motivated, facilitated and empowered to achieve intended results.

Quality objectives, processes, systems and procedures that support this quality policy are established and reviewed periodically for continuing suitability. The Drug Authority shall therefore commit adequate financial, human, physical and technological resources for implementing, maintaining and continually improving the quality management system to achieve set objectives.

Doc. No. QMS/ POL/001
Revision No. 3
Effective date 21 January 2020

Authorized by

Chairman
National Drug Authority

Note: Signed Quality Policy kept on file

Appendix 4: Organisational structure of National Drug Authority

See separate file for current organizational structure in document number HRA/POL/003

Appendix 5: The GMP Structure

See separate file for current GMP Structure in document number INS/FOM/004

Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
27th Aug 2009	0		Hope Kansiime	First issue
July 2013	1	QMS/MAN/001	Peter Ssali	1) Merged all 40 MS Word files into one file. 2) Changed document numbering system as per Quality Management system format, including new numbers for the SOPs that are referenced to in this manual. 3) Replaced Quality Policy with revised one. 4) Revised the quality objectives in line with the NDA Strategic Plan July 2011-June2016. 5) Replaced the process interaction with level 1 and level 2 process interactions. 6) Attached new responsibility matrix.
12 Feb 2017	2	QMS/MAN/001	*Author:* Peter Ssali *Reviewers:* Ramathan Mutungirehi Denis Mwesigwa Rogers Kayita	**Description of Change** / **Reason for change** Aligned entire Manual to ISO 9001:2015 Standard / To march with the new Standard Include subcontracted personnel and experts in confidentiality clause. / PIC/S requirement 7.2 Added reference to NDA code of conduct form / For reference purpose

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
				HRA/FOM/089 and declaration of conflict of interests for NDA staff form QMS/FOM/112 Added reference to Oaths Act 1963 — As a reference for confidentiality clause Added procedures for guiding GMP Inspections — To meet PIC/S requirements section 11 a) Planning GMP Inspection (INS/SOP/012) b) Preparation for GMP inspection (INS/SOP/013) c) Conducting GMP inspection (INS/SOP/014) d) Writing and Peer-Review of GMP Report, and Follow-Up of Non-Compliances (INS/SOP/015) and procedure for sampling of Drugs including Medical Gloves, Male Latex Condoms and Long Lasting Insecticide-Treated Mosquito Nets; Doc. no. QMS/SOP/044 — To meet PIC/S requirements section 11

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
				Included reference to procedure for Issue and withdrawal of licences and GMP certificates. To meet PIC/s requirements section 16 Added table of correspondence between PIC/S PI 002-3 2007 and this Manual (Appendix 1). So that this Manual can also serve as a quality manual for NDA Inspectorate Quality System.
14.01. 2020	3	QMS/MAN/001	*Author:* Dora Namyalo *Reviewers:* Peter Ssali Ramathan Mutungirehi Denis Mwesigwa	a) Section 3.0: Applicable terms and definitions from ISO 9000:2015 standard for Quality Management Systems – Fundamentals & Vocabulary have been added b) Section 4.3 subsection a): Drug shops and medicine shops added c) Section 4.4: Reference made to PDCA cycle which has been included in appendix 2 d) Subsection 5.1.1: Statement on the Drug Authority being top management and justification for the same added e) Section 6.1, paragraph 4: directorate added f) Section 7.5 Subsection e: Sipocs added and section moved above Standard Operating Procedures g) Section 7.7: Form number changed from 0112 to 112 h) Section 8.1: Titles of procedures established for the control of GMP inspections, in accordance with PIC/S requirements revised

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision
				i) Subsection 8.2.1: Frequency for conducting customer satisfaction surveys added j) Subsection 8.2.5: SOP for handling of drug related complaints added and SOP title for QMS/SOP/009 revised k) Subsection 8.2.5: Title of QMS/ToR/012 revised l) Appendix 2: Level 1 changed to PDCA Cycle and a PDCA cycle added as diagram 1 m) Appendix 2: Support and Operations processes changed from level 1 to level 2 and inputs and outputs added n) Appendix 2: Diagram 3 added for interaction of NDA regulatory processes o) Appendix 3: Quality Policy revised

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