

**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

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PREFACE

This Manual has been developed to enable uniform interpretation and application of the Quality Management System (QMS) requirements and guidelines that apply to the regulation of the quality and standards of all kinds of drugs including biologics, vaccines, blood products, alternative medicines, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement, and cosmetics. An effective QMS can help to ensure that the services of Directorate General of Drug Administration (DGDA) comply with applicable laws, acts, rules, regulations, ordinances, and regulatory authority advisory guidelines. It is designed as an operational instrument for personnel and staffs involved in the inspection, assessment, testing, quality control, quality assurance, market control surveillance and enforcement of quality standards and procedures applicable to all kinds of drugs and cosmetics manufactured, produced, imported, exported, or traded and donated in Bangladesh. It is also intended to make manufacturers, traders, and other stakeholders understand the procedures and requirements for pharmaceutical and other health related products.

The Quality Manual contains the required policy for smooth functioning of DGDA's QMS. Quality system implementation has three goals:

1. To provide product and services that are fit-for-use.
2. To satisfy customer's requirements and
3. Provide a mechanism for continual improvement of DGDA and its services, operations, and management.

To meet these goals, DGDA has set up functional procedures for which the functional heads are accountable. These functional procedures define the responsibilities of functional head for organizational structure, processes, and resources optimization. The QMS is aligned with the organization's strategic direction and strategic plan to ensure proper planning, monitoring and improvement of regulatory processes and services. Periodic review of the manual will be done to ensure its consistency with any changes in the established QMS and standards both at international and national level.

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ACRONYMS AND ABBREVIATIONS

The following acronyms and abbreviations are used throughout the quality manual:

| | | |
|-------|---|--|
| AEFI | - | Adverse Events Following Immunization |
| API | - | Active Pharmaceutical Ingredients |
| BP | - | British Pharmacopoeia |
| CAR | - | Corrective Action Request |
| NDCL | - | National Drug Control Laboratory |
| CAPA | - | Corrective and Preventive Actions |
| CPP | - | Certificate of Pharmaceutical Product |
| DCC | - | Drug Control Committee |
| DGDA | - | Directorate General of Drug Administration |
| DTL | - | Drug Testing Laboratory |
| FSC | - | Free Sale Certificate |
| GCP | - | Good Clinical Practice |
| GDP | - | Good Distribution Practice |
| GMP | - | Good Manufacturing Procedure |
| HQ | - | Head Quarter |
| HR | - | Human Resources |
| HQM | - | Head of Quality Management |
| IEC | - | International Electro-technical Commission |
| ISO | - | International Organization for Standardization |
| LR | - | Lot Release |
| NRA | - | National Regulatory Authority |
| NRS | - | National Regulatory System |
| PDCA | - | Plan-Do-Check-Act |
| PIC/S | - | Pharmaceuticals Inspection Cooperation Scheme |
| PV | - | Pharmacovigilance |
| QMS | - | Quality Management System |
| QM | - | Quality Management |
| SF | - | Substandard and Falsified |
| SMS | - | Short Message Service |
| SOP | - | Standard Operating Procedure |
| TM | - | Top Management |

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USP - United States Pharmacopoeia
WHO - World Health Organization

1. INTRODUCTION

1.1. Purpose

Directorate General of Drug Administration (DGDA) is the National Regulatory Authority (NRA) of all kinds of drugs including biologics, vaccines, blood products, alternative medicines, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement, and cosmetics in Bangladesh. It ensures the quality of its regulatory services through the establishment of an effective QMS aligned with the requirements of ISO 9001:2015 - quality management systems. To protect public health, the quality manual demonstrates DGDA's responsibility to establish and enforce quality standards required for all kinds of drugs and cosmetics and services in Bangladesh.

Quality Manual is used to document how DGDA established an effective QMS. This manual also defines how the policies, procedures and processes established, implemented and maintained to assure the quality of all kinds of drugs and cosmetics in Bangladesh. To build an integrated quality system into the organization, DGDA plans, implements, documents, and assesses for continual improvement. DGDA's goals are to ensure its services and decisions fit for their intended use, and to align the resources and processes with DGDA's strategic plan and legislations.

1.2. DGDA Overview:

Directorate General of Drug Administration (DGDA) under Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh is the only National Regulatory Authority of the country. It was founded in 1974 by the Government of Bangladesh to plan, investigate, regulate, organize, direct and control activities to ensure the quality, safety and efficacy of all drugs and to ensure that all drugs for research and public consumption comply with the laws in force in Bangladesh as well as the guidelines and standards set by ISO, WHO or other international organizations.

DGDA acts to serve its customers who are:

- Manufacturers, suppliers, importers, exporters, marketing agents and distributors of drugs, biologics, vaccines, blood products, alternative medicines, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement, and cosmetics in Bangladesh.
- Consumers and other stakeholders.

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All activities of DGDA are governed and guided by:

- The Drug and Cosmetics Act 2023
- The Drug Rules, 1945
- The Bengal Drug Rules, 1946
- The Drug (Control) Ordinance, 1982 and its amendments
- National Drug Policy, 2016

DGDA supervises and implements all prevailing drug regulations in Bangladesh and regulates all activities related to import, export, and procurement of raw and packaging materials, and production, pricing and import of finished drugs, vaccines, blood products, biologics, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement, and cosmetics.

The Director General of Drug Administration is empowered by the Government to act as National Regulatory Authority (NRA) for issuing licenses and monitoring of drugs, vaccines, blood products, biologics, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement and cosmetics. The National Drug Control Laboratory (NDCL) of DGDA, Mohakhali, Dhaka and Drug Testing Laboratory (DTL), Chittagong are responsible for the analysis of product quality.

At present, there are 55 district offices of Directorate General of Drug Administration in Bangladesh. All officers of DGDA function as "Inspector of Drugs" as per clause-47 of the Drug and Cosmetics Act-2023 and assist the Licensing Authority to discharge DGDA's responsibilities properly. They work to prevent the manufacture, sale, store, or distribute of any misbranded, counterfeited and adulterated drugs and cosmetics etc.

Several committees, such as the National Drug Advisory Council, Drugs Control Committee (DCC), and a number of other relevant committees comprised of experts, advise the Regulatory Authority on matters related to drugs, vaccines, blood products, biologics, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement and cosmetics.

Vision:

The DGDA shall strive to ensure the quality, efficacious and safe drugs and cosmetics for all.

Mission:

- To safeguard the health of humans and animals by ensuring all kinds of drugs and cosmetics meet applicable standards of safety, quality and efficacy.
- To ensure the safety and security of supply chain for all kinds of drugs and cosmetics.
- To ensure availability including accessibility and affordability and rational use of essential drugs.

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- To foster a regulatory environment that supports research and innovation and thereby ensures moving towards global standards for quality products.

1.3. Scope

The scope of this Quality Manual covers all activities that fall under the responsibility of the DGDA mandate to plan, investigate, regulate, organize, direct and control activities to ensure quality of all kinds of drugs and cosmetics. This manual is applied across all regulatory functions and activities, including National Regulatory System; Registration and Marketing Authorization; Pharmacovigilance; Market Surveillance and Control; Licensing Establishments; Regulatory Inspections; Laboratory Access and Testing; Clinical Trials Oversight; and NRA Lot release to implement DGDA's vision and mission. For ensuring the safety, efficacy and quality of drugs and cosmetics supplied in Bangladesh, DGDA regulates finished pharmaceuticals products, Active Pharmaceutical Ingredients (APIs), vaccine, blood products, biologics, medical devices, dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or food supplement, cosmetics, and veterinary medicines.

This manual can be used for other regulatory activities that are mandated by the national laws and regulations to ensure public health safety, by assuring the quality, safety, and effectiveness of all kinds of drugs and cosmetics. This extends to areas of all kinds of drugs and cosmetics such as pricing, professional training, and regulation, as well as to other areas within the legislative mandates and functions of the DGDA.

Activities covered by the DGDA-

- Marketing Authorization/Product Registration for all kinds of drugs and cosmetics.
- Source validation of imported raw materials.
- Approval of blocklist for imported raw materials and packaging materials of drugs.
- Approval of all kinds of drugs and cosmetics manufacturing at new facility or site.
- Approval of Indent or Proforma invoice of imported drugs.
- Approval of manufacturing process for Investigational drugs.
- Issuance and renewal of licenses for pharmaceutical manufacturing plants, retail, and wholesale pharmacies, etc.
- Performing regulatory inspection for evaluating manufacturing facilities of all kinds of drugs and cosmetics against requirements or standards such as to issue or renew manufacturing licenses, to approve new dosage forms or to examine new production processes or production facilities,
- Issuance of GMP Certificates to manufacturing facilities.
- Issuance of CPP/ FSC for export purpose.

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- Registration and control of imported pharmaceuticals and approval APIs and Packaging materials.
- Oversight of clinical trials, monitor GCP compliance and approve CRO and protocols.
- Monitor product quality, safety, efficacy of all kinds of drugs and cosmetics. Control of advertisement for all kinds of drugs.
- Monitoring Pharmacovigilance and AEFI.
- Monitor and inspect pharmacies and wholesalers for good pharmacy practice.
- To conduct planned operation, mobile court, or raid against Substandard and Falsified (SF) drug manufacturers and sellers based on reliable information, and to take legal or administrative action against perpetrator/offender.
- Approval of packaging and promotional materials of all kinds of drugs and cosmetics.
- Issuance of no objection certificate for unregistered products to be imported or brought to the country for research on emergency and other valid reasons.
- Fixation of price and issuance of maximum retail price (MRP) certification for listed drugs.
- Lot release of Vaccines.
- Analysis of all kinds of drugs and cosmetics in NDCL and Drug Testing Laboratory.
- Analysis of pre-registration samples of INN listed drugs.
- Conducting post market surveillance.
- Conducting anti-microbial consumption surveillance to prevent and control of anti-microbial resistance.
- Filing lawsuits in drug court, magistrate court or mobile court against those violating Drug and Cosmetics act-2023.
- Issuance of Emergency Use Authorization (EUA) of drugs, vaccines, medical devices etc. in case of emergency situation in Bangladesh.

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1.4. Terms and Definitions

The following terms and definitions relevant with this manual are taken from ISO 9001:2015 and Drugs and Cosmetics act-2023.

Drugs: Drug includes

- a) All kinds of drugs including vaccines and biological drugs for internal or external use in humans or animals, and all kinds of substances useful for the treatment, and mitigation, cure or prevention of human or animal diseases;
- b) Medical Devices;
- c) Any substances (other than food) intended to change the human anatomy or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals;
- d) Any substance mentioned as monograph in any editions of the British Pharmacopoeia, the United States Pharmacopoeia, the United States National Formulary (USNF), European Pharmacopoeia or in any International Pharmacopoeia;
- e) Any substance of unani, ayurvedic, herbal, and homoeopathic or biochemic system of drug or any substance used for preparing the same;
- f) Dietary supplement, herbal supplement, nutritional supplement, medical nutrition or therapeutic nutrition or foodstuff or food supplement; and
- g) Any other substance which the Government may, by notification in the official Gazette, declare as a drug for the purposes of Drug and Cosmetics act 2023;

Cosmetics: Cosmetics means any cosmetics applied by rubbing, pouring and spraying that claims to effect any biological change in the human body or human body thereby.

Quality management system: An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.

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. Customers of an NRA include individuals or parties who receive or could receive and use products and services that are provided and offered by the NRA. These parties include the public, patients, manufacturers, distributors, health practitioners, researchers, the ministry of health and other individuals and institutions that rely on the NRA's products and services to make public health decisions.

NOTE 1: A customer can be internal or external to the organization.

NOTE 2: "Regulated Customer": Organization or person who by the nature of their business are subject to regulation by the NRA

NOTE 3: "Unregulated Customer": Organization or person who is not subject to regulation by NRA.

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Customer satisfaction: A customer's perception of the degree to which the customer's expectations have been fulfilled. The expectations include assurance that safe, efficacious and high-quality drugs and cosmetics will be available under the NRA mandate to regulate, and that the NRA will provide other products such as guidelines, public reports and related regulatory services that meet the expectations of different types of customers.

Top management: Person(s) or group of people who direct and control an organization at the highest levels and who have the authority and responsibility to mobilize resources within the organization.

Internal audit: A planned examination and assessment of the quality management system to include administrative and operational functions of DGDA conducted/performed at regular intervals defined and approved by top management or part of a QMS with the specific purpose of improvement. An internal audit should be conducted by an independent (i.e., of the function to be audited) team of competent auditors as designated by the management for this purpose.

Process: A set of interrelated or interacting activities that use inputs to deliver an intended result. In the context of NRAs, the production and service provision processes should coincide with basic regulatory functions.

Quality: The total set of characteristics of an entity that affect its ability to satisfy stated and implied needs and to ensure the consistent and reliable performance of services or products in conformity with specified requirements.

Quality policy: A brief statement that describes the organization's purpose, overall intentions, and strategic direction; provides a framework for quality objectives; and includes a commitment to meet applicable requirements.

Services: Output of an organization with at least one activity necessarily performed between the organization and the customer. Services of NRAs are also called regulatory services in this guideline. This includes, for example, activities such as evaluation of applications for market authorizations, inspections of facilities, testing of health product samples, etc.

2. QUALITY MANAGEMENT SYSTEM REQUIREMENTS

DGDA demonstrates its ability to provide services that meet the needs of its internal and external customers by implementing a quality management system based on compliance with the principles and requirements of ISO 9001:2015 - Quality management systems.

The Quality Management System of DGDA is based on the realities and needs of the organization, to lay the groundwork for greater credibility in their decisions, greater strength and stability of its functions, to execute a systematic planning and monitoring, and to improve the quality of processes as well as the higher levels of efficiency and effectiveness.

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according to the established QMS. Processes and procedures are designed to meet its intended purpose without making it unnecessarily complex. The QMS is simple, fit for the purpose and understandable.

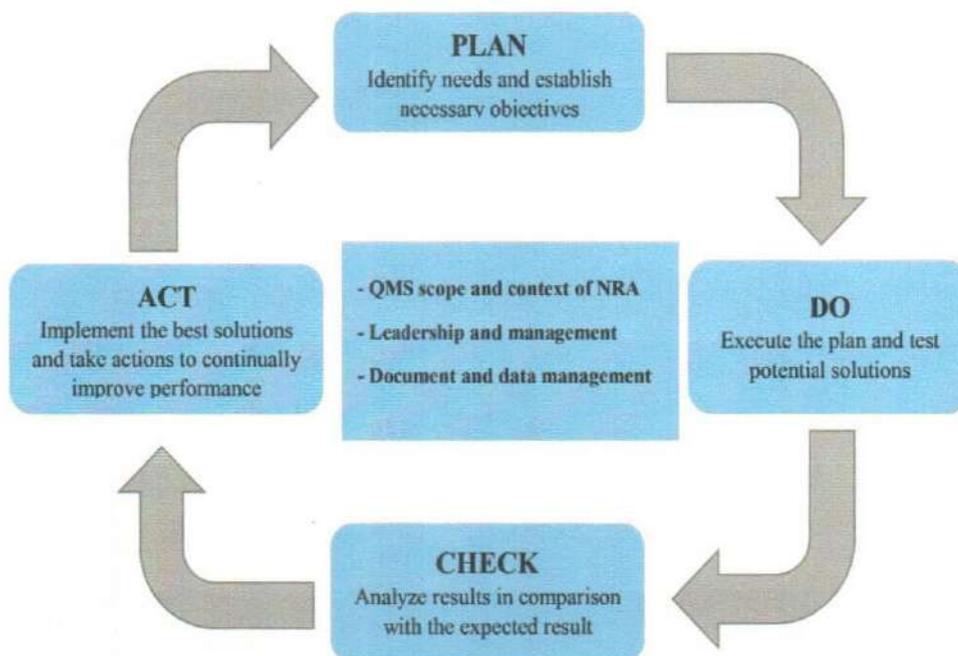


Fig 1: Applied PDCA Cycle

2.1 General Requirements

The DGDA has:

- Determined processes needed for the QMS and their applications throughout its nine regulatory functions.
- Determined sequence and interactions of these functions.
- Determined criteria and methods needed to ensure that the operation and control of the functions are effective, and has documented them in manuals, guidelines, procedures, work instructions, forms and other controlled documents.
- Provided the necessary financial, human and technological/physical resources and information necessary to achieve planned results and continual improvement of these functions.
- Established key performance indicators that monitor, measure and analyze the performance of these functions.
- Institutionalized the actions to achieve the planned results and to ensure continual improvement of the functions.

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DGDA has established control over outsourced processes that affect product conformity to requirements describing the outsource processes.

2.2 Document requirement

2.2.1 General

DGDA uses documents and evidentiary records to establish and maintain a quality system and to support effective and efficient work processes among the functions.

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

- Quality policy (Annexure-I)
- Quality objectives (Annexure-II)
- Guidelines and manuals
- Regulatory framework and process interaction
- Standard Operating Procedures , protocols and work instructions
- Organogram
- Job description
- Records and process flow charts
- Forms, annexures, etc.

2.2.2 Quality Manual

This Quality Manual is the first level of internal document in the DGDA QMS that describes internal functions, structure, and process.

In addition of this manual, the DGDA has developed other relevant manuals or procedures with specific title and identification numbers.

2.2.3 Control of documents and records

DGDA has developed a document control procedure to control internal and external documents and records. (SOP No: NRA-RS-004: procedure for control of documents)

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3. QUALITY MANAGEMENT PRINCIPLES

The QMS requirements that are described in this manual are based upon the below quality management principles-

3.1 Top Management (TM) commitment

Top management of DGDA is committed to support and ensure the effectiveness of administrative and operational activities within all its regulatory functional processes, from planning up to acting for continuous improvement of regulatory services. Top Management actively involved in implementing an effective QMS and provides the vision, strategic direction and support for the improvement of QMS, and establish quality objectives and the quality policy.

TM provides the necessary human, financial, physical, technical, and technological resources for the successful implementation of DGDA's QMS.

3.2 Customer focus

The top management identifies customers along with their needs associated with product and services. The main customers of the DGDA are all kinds of drugs and cosmetics manufacturers, importers, exporters, seller, medical practitioner, research institutions, and patients.

3.3 Engagement (involvement) of person

Competent, motivated, empowered and engaged person at all levels throughout the organization are essential to enhance the organization's capability to create and deliver valued services. DGDA formed nine functional unit with skilled and competent staffs along with supporting staffs to provide services to the recipients and stakeholders. An independent QMS unit is formed to oversee the quality of each functional activities.

3.4 Process approach

DGDA ensures the consistent and predictable results through effective and efficient system development and prepare skilled workforce to perform activities with better understanding and managed as interrelated processes that function as a coherent system. DGDA shall develop its systems and implement the systems as per ISO 9001:2015, WHO and other relevant international standards. A comprehensive training plan shall be prepared to make the staffs competent in their functional areas.

3.5 Improvement

DGDA ensures continuous improvement of its processes, products, and services and the QMS. The QMS unit develops internal audit and CAPA management program to ensure continual improvements.

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3.6 Evidence-based decision-making

Decisions based on the analysis and evaluation of data and information are more likely to produce the desired results. DGDA implements measures for monitoring, analyzing, and evaluating the collected data, to assess whether the processes are delivering the desired results or not.

3.7 Relationship management

For sustained success, DGDA maintain relationship with relevant stakeholders. DGDA is implementing an effective QMS to ensure that its relationships are managed strategically for continuous operations. The relationship includes management of contractual agreements between DGDA and sub-contracted individuals and institutions (e.g., DGDA maintain relationship with Health Engineering Department, third-party laboratory, vendors, etc.)

3.8 Quality policy

DGDA is committed to meet the needs and expectations of customers through continual improvement of its processes and quality services by implementing an effective QMS aligned with ISO 9001, WHO and/or any other relevant international standards. DGDA's goal is to establish processes that ensure the quality, safety, and efficacy of all kinds of drugs and cosmetics in compliance with Drug and Cosmetics Acts and rules. Objectives of DGDA is to establish QMS at all functional level that ensure the requirements of this policy. Top Management is committed to provide the necessary resources to ensure maintenance and continuous improvement of QMS.

DGDA has developed a quality policy (Reference: NRA-QP-001) which outlines its commitment to implementation of QMS into all function of DGDA and ensuring customer satisfaction. The quality policy has been formulated in the fulfillment of the DGDA's mission in an efficient, effective, and consistent way. (Annexure I: Quality Policy)

3.9 Planning

3.9.1 Quality objectives

DGDA has developed quality objectives including those needed to meet requirements for product and has aligned with strategic objectives of DGDA. The quality objectives are reviewed annually for continuing suitability. (Annexure II: Quality Objectives)

3.9.2 Quality management system planning

DGDA has developed a strategic plan (Reference: DGDA's 5-year strategic plan) to give directions to the achievement of the mission and implementation of QMS.

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3.10 Responsibility, authority, and communication

3.10.1 Responsibility and authority

Top management has defined and communicated responsibilities and authorities throughout DGDA. The current functional structure that clearly shows the inter-relationship and reporting mechanism of the personnel among the DGDA nine functions.

TM of DGDA approves current job descriptions for all members and staff in which the responsibilities and authorities of each of the employee positions on the organizational chart is defined.

3.10.2 Management representative

TM of DGDA has appointed the Head of Quality Management System (HQMS) who reports directly to the DG of DGDA and with the responsibility and authority to:

- Ensure that all the elements of QMS are established, implemented and maintained;
- Resolve matters pertaining to quality;
- Report yearly a review of the performance of the Quality Management System to TM and any need for improvement and maintain records of those reviews;
- Liase with customers, Government and regulatory agencies on matters relating to the QMS; and
- The Head of QMS has the overall responsibility and mandate on matters related to QMS in all DGDA functions.

In addition, DGDA TM appoints quality officers as Quality Representative in each function. The Quality officers functionally report to the Head of Quality Management System.

3.10.3 Communication

Internal and external communication in the DGDA, Aushad Bhaban, Mohakhali, Dhaka-1212 is through:

- Telephone: 02222280964/02222280897/02222280924), Fax: 02222280854
- Intranet and email (dgda.gov@gmail.com)
- Social media-facebook, What's App
- Website- <https://dgda.portal.gov.bd>
- Stakeholders meeting
- Senior management, departmental and general staff meetings
- Management review meeting,
- Performance data posted on the dash boards;

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- i) Annual performance report
- j) Office order/notification

3.11 Management review

3.11.1 General

Head of QMS is responsible to make plan for management review meeting and organize the meeting. The agenda items, frequency of meeting, rotation of functional areas, and involvement of staffs are determined by the QMS team as per the Management Review SOP (SOP No: NRA-RS-005, Procedure for Management Review). In the management review meeting, the TM reviews the last action items and discuss on the current agenda items and make decision. Also, the TM check the compliance of all functions to ensure its performance and effectiveness. An expected outcome of these reviews is the determination of the need for any changes to the QMS, including changes to the quality policy and quality objectives. The reports of management reviews are kept by the Head of Quality Management. Records of the management reviews are filled and maintained in accordance with record control procedure (SOP No: NRA-RS-012, Procedure for record control and monitoring).

3.11.2 Review input

The input to management review includes information on the following;

- a) Result of internal and external audits
- b) Customer feedback
- c) Processes performance and product conformity
- d) Status of preventive and corrective actions
- e) Follow-up actions from previous management review meeting
- f) Strategic or operational changes that could affect QMS
- g) Recommendations for improvement
- h) Effectiveness of the training activities for staff of DGDA.

3.11.3 Review output

The output from the management review includes decisions and actions related to the following;

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs

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4. RESOURCE MANAGEMENT

4.1 Provision of resources

TM ensures that adequate staff, equipment, and materials are available for all functional areas in order to:

- a) Implement, maintain and improve the QMS processes.
- b) Ensure customer service and satisfaction.
- c) Meet the quality objectives.

DGDA reference documents that provide evidence of resources that have been provided (e.g. budget, staff, establishment, scheme of service, no. of districts offices, asset register, etc.)

4.2 Human resources

4.2.1 General

TM is responsible to work with Ministry of Health and family Welfare, Ministry of Finance and Public Service Commission for recruiting/hiring new staff to fulfill the need of adequate workforce at DGDA. TM will be responsible to arrange adequate training for the existing and new staff to build their capacity and skill to achieve expected result or outcome. The TM also encourage, motivate, facilitate, and empower the staff to implement the system as per ISO 9001:2015, WHO or any other international standards as applicable.

Each employee in DGDA having an assignment associated with any of the processes of the QMS is competent through education, skill, training, and experience as necessary. Requirements for education, skill, training, and experience are found in the job descriptions maintained by the HR (admin) department.

4.2.2 Competence, training, and awareness

DGDA has:

- a) Determined the necessary competence for personnel performing work affecting conformity to product requirements. DGDA follows a determined competency matrix (SOP No: NRA-RS-029, Procedure for Competency Assessment, performance evaluation and staff appraisal).
- b) The training needs are identified. The employee's performance review is also used to identify specific individual training as well as evaluate effectiveness of actions taken to satisfy competency needs. (SOP No: NRS-RS-002, SOP for employee training)
- c) Training needs are summarized in the DGDA's Training Plan. This plan is reviewed to determine accuracy of process and incorporation of new areas at least once a year and proceed to provide that training is established and maintained.

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- d) DGDA staff receive general on boarding, orientation, induction, on-the-job training and regular refresher training for the staff to be aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,
- e) Provide local, regional and international training to achieve the necessary competency of staff in all directorates / departments,
- f) Develop key performance indicators to evaluate the effectiveness of the trainings,
- g) Formal training records are maintained by the QMS department. Admin department maintains educational and experience records of the employees in the personnel files.

4.2.3 Impartiality and independence

DGDA identifies risks to its impartiality that arises from its activities, or from its relationship, or from the relationship of its personnel with its stakeholders.

Top management adopts a code of conduct for all employees of DGDA which is in line with national public service code of conduct and professional bodies (indicate document title and the year) and each employee has signed Legally enforceable commitments necessary for confidentiality and conflict (SOP No: NRS-RS-014: Standard procedure for Confidentiality Management, and SOP No: NRS-RS-015: Procedure for Handling Conflict of Interest). The conflict-of-interest agreement (Annex) shall be followed by DGDA as per the mentioned SOP.

4.2.4 Confidentiality

The staff of DGDA and members of the committees have signed legally enforceable commitments for the management of all information obtained or created during the performance of activities. A confidentiality agreement is maintaining for all the members of DGDA.

4.3 Infrastructure

DGDA provides adequate offices at the head quarter, district, and regional offices throughout the country. All the offices are equipped with the necessary utilities, process equipment (both hardware and software), and supporting services (such as transport, communication, or information systems, etc.).

The infrastructure is continually maintained to achieve conformity to product requirements.

4.4 Work environment

DGDA maintains suitable work environment in all its offices needed to achieve conformity to product requirements.

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5. WORK PROCESS, CONTROLS, AND EXECUTION

5.1 Work Planning

All functions of DGDA work as a system of integrated process. In DGDA, any single work can be the result of a series of activities, e.g., a seizure enforcement action may result from an assignment, investigation, sample collection, sample analysis, and/or compliance evaluation. Alternatively, any single process may be involved in multiple works, e.g., a sample analysis may result in recalls, warning letter, new compliance programs, denial of entry applications, etc.

- (a) DGDA senior management ensure that functional activities are planned, developed, and documented consistent with the needs of the QMS. Changes in plans are appropriately controlled.
- (b) DGDA management ensure necessary process criteria. The criteria consider the quality objectives for the product based on known requirements, directives, resources including facilities, process verification and validation activities, and product acceptance measures.
- (c) DGDA senior management ensure that the design and development of new work processes and products are planned and controlled to assess the impact on related work and the ability to meet customer requirements for subsequent approval or review responsibilities.

5.2 Work plans and assignments

Once the work processes are planned, DGDA work with their set standards (WHO, ISO9001, PIC/S, etc.) to meet the customer requirements. The set standards are formally reviewed, and any concerns discussed with the customer. DGDA has provisions to arrange agreements with other NRA to get services as required.

- a) After completion of series of planning activities, DGDA respective personnel accept work and assignments.
- b) The following activities are managed by HQ officials:
 - i. Collaboration with the DGDA HQ and divisions/districts offices to develop specific work based on standard procedure;
 - ii. Development of an annual work plan with DGDA HQ and divisions/districts offices;
 - iii. HQ review certain work assignment and send to division /district officials.
- c) Divisions/districts officials accept plans and specific assignments from headquarters and implements as instructed.
- d) DGDA headquarter ensure guidance procedures and communication channels for work planning and the review, issuance, and acceptance of certain assignments are followed. The functional head ensures guidance needed to communicate information between DGDA components are used, and records kept including:

- ✓ Assignment status and outcomes,

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- ✓ Changes/amendments made to plans or assignments,
- ✓ Competing plan or assignment priorities between HQ and divisional/district offices
- ✓ Complaints and actions relating to non-conformances, and
- ✓ Feedback relating to DGDA performance.

5.3 Sub-Contracting work

DGDA sub-contracts with another organization to do work on behalf of DGDA. DGDA is responsible to monitor the activities of its subcontractors and are accountable for the services and products provided. To meet work quality requirements, DGDA controls contracts and evaluates the contractor's performance.

- a) DGDA's respective personnel ensure contracting processes and keep records as appropriate to assure that contractor-produced work conforms to DGDA requirements.
- b) DGDA's is responsible to place respective personnel in contracts with a competent contractor in order to achieve equivalent level of work quality.
- c) DGDA's respective personnel ensure:
 - ✓ Contracts are reviewed and approved based on adequate specification of work and quality requirements,
 - ✓ Arrangements are planned for verification of work quality, and
 - ✓ Verification is implemented and records of the contractor's performance are maintained.
- d) DGDA's respective personnel ensure the contractor is advised and notified. i.e., in writing, verbally, electronically, and, when appropriate, gain the approval of the contractor; DGDA work reports clearly identify any contributions from contracts.
- e) DGDA's respective personnel are accountable for the contractor's work quality. The contractor may share accountability if arrangement or oversight responsibilities are shared.

5.4 Control of equipment and materials

DGDA uses some equipment or materials in their work processes. If these items impact the quality of regulatory services provided, then they are controlled appropriately.

- a) DGDA respective personnel ensure equipment and materials needed to meet work and method requirements are identified and selected.
- b) DGDA respective personnel ensure staff is provided with methods of handling, preservation, and storage to protect equipment and materials from damage and to maintain their integrity.

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- c) DGDA respective personnel ensure equipment and materials are uniquely identified as needed to meet traceability requirements.
- d) If equipment or materials are found to be improperly functioning, DGDA respective personnel assess the validity of the work previously performed, and appropriate actions are taken if fitness for use is compromised.
- e) DGDA respective personnel ensure staff uses procedures for control of equipment used for measurement, sampling, and analysis, and for control of reference materials and standards.

5.5 Operations

DGDA plans and controls its work processes in order to add value, create effective products, and improve efficiencies. DGDA gathers data to evaluate services that are met customer requirements (i.e., are fit for their intended use) and to continually improve in meeting customer requirements.

DGDA assigned personnel and staff use defined procedures for performing work, for assuring work is reproducible, and for maintaining information integrity.

5.5.1 Work and method controls

DGDA performs and controls the work processes according to plan. DGDA assigned personnel to ensure work activities are performed according to established procedures and methods. These procedures and methods are readily available (SOP No: NRA-RS-004: Procedure for control of documents) and

- ✓ Define work requirements;
- ✓ Specify procedural steps to a degree necessary for proper performance by competent personnel;
- ✓ Describe equipment used for processing, measuring, or monitoring; and,
- ✓ Instruct how product is delivered to the customer.

5.5.2 Verification and validation of work processes

Verification under conditions of use is demonstrated by meeting criteria established for the process, as well as the accuracy and precision or other parameters for the type of work performed.

- a. DGDA ensures respective personnel can follow standard procedure to an acceptable level of performance.
- b. When a work process or product does not meet standard practice, or is significantly modified due to unusual circumstances, then DGDA ensure the impact of the non-conformity is evaluated in regards to meeting customer needs.
- c. In situations where the work product cannot be verified by monitoring and measurement, DGDA ensure the work process is validated by a combination of training and process controls.

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5.5.3 Integrity, traceability and identification

DGDA performs work, it tracks who does what, where, when, and how—or, as sometimes stated, manpower, materials, machinery, methods, and environment. As National regulatory authority, DGDA has a particular interest in maintaining the integrity of its work information and products.

- a) DGDA respective personnel ensures established procedures are used to maintain the integrity of:
- ✓ information provided to regulated stakeholder, industry, consumers, and other NRA employees;
 - ✓ physical or documentary samples collected for regulatory test or examination; and,
 - ✓ DGDA -created data and work products.
- b) As appropriate, DGDA respective personnel ensure work products and components are clearly identified and clearly noted the interim and final status to prevent misuse.
- c) As appropriate for traceability, DGDA respective personnel ensure relevant information is recorded regarding the personnel, materials, equipment, chronology, methods, and environment associated with a work activity.
- d) To the extent integrity is compromised or uncertain, DGDA respective personnel ensure relevant information is recorded and the customer is informed of the issues relating to fitness-for-use and regulatory compliance.

5.6 Reporting results

DGDA established standardized formats, content guidelines, delivery methods, and storage conditions to meet the customer's requirements effectively and efficiently.

- a) DGDA respective personnel ensures requirements for reports are established so that:
- 1) work results are reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific directives;
 - 2) reports account for all information requested by the customer and necessary for the interpretation of results;
 - 3) procedural non-conformances are identified in the report; and
 - 4) Reports that express opinions and interpretations also contain the basis upon which the opinions and interpretations have been made.
- b) As needed, designated HQ personnel control report formats to
- 1) Accommodate different types of results,
 - 2) Minimize the possibility of misunderstanding or misuse,
 - 3) Provide unique identification as needed for traceability, and
 - 4) Ensure identification of responsible individual(s).

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c) DGDA's assigned personnel ensure.

- 1) Information needed for traceability or evaluation not included in a report is readily available in the performing department (e.g., log books, notes, quality control records, etc.), and
- 2) Reports that are stored other than with the performing department are readily retrievable.

d) To maintain the integrity and accountability of reports, DGDA respective personnel ensure:

- 1) Information other than DGDA used in reports is clearly identified.
- 2) This section's requirements are met when transmission of reports is made by telephone, email or other electronic or electromagnetic media; and,
- 3) Amendments to an issued report are made as an additional report:
 - ✓ Amendments meet this section's requirements; and,
 - ✓ When it is necessary to issue a new report, it is uniquely identified and contains a reference to the original that it replaces and includes the reasons for replacement.

6. MEASUREMENT, ANALYSIS AND IMPROVEMENT

6.1 General

A system to monitor, measure, analyze and improve processes for the QMS is in place. Product quality plans are used for planning and defining the necessary monitoring and measurement techniques, including statistical techniques. Implementation according to the defined plans, the resulting data is analyzed.

6.2 Monitoring and measurement

6.2.1 Customer satisfaction

DGDA products and services are evaluated on a regular basis to meet customer satisfaction following criteria.

- a) in-service performance monitoring,
- b) customer complaint analysis,
- c) regular customer satisfaction surveys, at least once a year

The results are presented to TM during the annual management review meetings.

An efficient method of handling customer inquiries is established to provide a rapid response to customers who have an urgent need for assistance. (e.g. DGDA website, social networks, etc.)

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6.2.2 Internal audit

Internal audits are conducted to ensure that DGDA's quality system complies with specified requirements and is implemented effectively. The internal audits assess compliance of each functional area's processes and related procedures, approach, and deployment, identify any non-conformity, opportunities for improvements, and initiate preventive and corrective action where required. The internal audit process is reviewed as required to ensure that it is effective and that all contractual and regulatory requirements are met.

The internal audits are conducted according to an established schedule. An audit plan is maintained to ensure that all aspects of the Quality System are properly addressed. The frequency and scope of the audits take into consideration the significance of the process and results of previous audits. A documented procedure for internal audits process (SOP No: NRA-RS-011: Standard operating procedures for internal audit) has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

The auditors are selected to ensure objectivity and impartiality of the audit process. This is achieved by selecting a team of auditors from cross-functional departments who have received the appropriate training or have knowledge and experience on the subject matter in the auditing process.

The audit is conducted according to a documented Internal Audit procedure (SOP No: NRA-RS-011: Standard operating procedures for internal audit) and to ensure that timely corrective actions are implemented to eliminate the cause of any nonconformity found (SOP No: NRA-RS-016: Procedure for Corrective and Preventive Action). The results of the audits are recorded and submitted to the personnel responsible in the area audited. Audit results become part of the quality records and are presented at management review.

The tools and techniques are used in Internal Audit procedure. The acceptability of the selected tool is measured against the effectiveness of the internal audit process and overall organization performance. The following purposes shall be fulfilled through internal audit:

- Provide assurance to TM that the management system is implemented and maintained as intended.
- Investigate the cause(s) of quality problems; determine why the management system allowed such problem(s) to occur and identify corrective actions to prevent recurrence.
- Identify opportunities for improving the management system itself and its effectiveness.

6.2.3 Monitoring and measurement of processes

DGDA established the monitoring and measurement process to achieve customer requirements such as internal audit and management review. The resulting information is reported to TM to assist in decision making process. The processes are monitored to ensure their continuing ability to achieve the

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planned results. If the planned results are not achieved, corrective and preventive action (CAPA) are taken to ensure the product and service conformity.

In the event of process nonconformity, appropriate actions are taken to eliminate the cause of nonconformance. If service nonconformity has resulted this service is identified and controlled according to documented procedures. (SOP No: NRA-RS-016: Procedure for Corrective and Preventive Action)

6.2.4 Monitoring and measurement of Service

DGDA monitors the key features to verify the service requirements have been met. Key features and specification of the services identified, monitored, and controlled at appropriate stages of service with planned arrangements.

DGDA keeps records that indicate the person(s) authorizing for delivery of services to the customer. The delivery of service to the customer does not proceed until the planned arrangement has been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

6.3 Control of non-conforming Service

Control of Nonconforming service procedure defines the responsibilities, authorities and methods used for the identification, segregation, review and disposition of nonconforming services, as well as the implementation of corrective action in order to prevent recurrence of the nonconformity. (SOP No: NRA-RS-016: Procedure for Corrective and Preventive Action)

Records, clearly identifying the service, the nature and extent of nonconformity, the approved disposition and corrective action taken are maintained and form part of the quality records. Note: Parties requiring notification of nonconforming services may include stakeholders, internal organizations, customers, distributors, and relevant government agencies.

6.4 Monitoring the activities:

QMS unit shall be responsible to govern, manage all the activities. It can ensure, define, establish guidelines, detail processes, etc. The following items shall be monitor in this regard-

- a) To assess customer satisfaction levels
- b) To determine success rates in fulfilling customer needs.
- c) Internal and external audits reports
- d) Customer satisfaction surveys reports

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6.5 Improvement

6.5.1 Continual improvement

The DGDA continually improves the effectiveness of quality management system through the use of quality manual, quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The DGDA's continual improvement is:

- a) A part of the quality policy
- b) Reflected in the quality objectives
- c) A part of the actions taken upon audit results
- d) Driven by opportunities surfacing from data analysis
- e) A result of corrective action
- f) A result of preventive action
- g) A required output from management review

6.5.2 Corrective action

DGDA ensure corrective action are documented on a Corrective Action and submitted to the respective function, for the identification of the root cause and to initiate appropriate corrective action. (SOP No: NRA-RS-016: Procedure for Corrective and Preventive Action)

The corrective action is inserted in a central database for tracking and follow-up. The originator ensures that the corrective action is implemented in timely manner. Corrective action requests that are closed and opened are discussed at the management reviews.

The TM takes necessary action to eliminate the root causes of nonconformities in order to prevent recurrence. Records of corrective action taken are maintained by the respective department and QMS.

6.5.3 Preventive action

DGDA determine action to eliminate the causes of potential nonconformities to prevent their occurrence. A documented procedure for preventive action has been established to define requirements for determining potential nonconformities and their causes, evaluating the need for action to prevent occurrence of nonconformities, determining, and implementing action needed, and reviewing the effectiveness of the preventive action taken. (SOP No: NRA-RS-016: Procedure for Corrective and Preventive Action)

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Records of results taken are maintained by the respective departments and QMS

Non-conformities are analyzed to determine the preventive actions needed to avoid re-occurrence. The depth of the analysis is related to the criticality of the nonconformity, the impact on performance, reliability, customer satisfaction, safety and the risk involved. Relevant information on preventive actions taken is submitted for management review.

6.6 Risk Management

Risk management provides a range of qualitative and quantitative approaches for an organization to make decisions and set priorities. Through the use of risk-based information, DGDA optimizes its performance and resource allocation. Risks are reviewed and assessed in the context of their impact on the organization's mission and strategic objectives. (SOP No: NRA-RS-026: Quality Risk Management)

- a) TM ensures evaluated risks are considered (e.g., determining the appropriate response to non-conformance with work product requirements).
- b) To use risk-based information in its programs, TM considers problem context and definition, costs and benefits, options for action, and ex-post evaluation of outcomes. This is supplemented by seeking new data, models, and tools that may improve risk management.

6.7 Audits and assessments

Functional departments undergo audits and/or assessments to determine if their quality system conforms to planned requirements and are effectively implemented and maintained. Audits measure the robustness or conformity of the quality system.

Audits may be internal among the functions or imposed by an external party. QMS department maintains the audit-plan and ensures audits are conducted according to documented procedures.

- a) TM ensures:
 - ✓ Established process for facilitating audits from external sources.
 - ✓ Internal audit program for conducting audits among the nine functions covered by QMS

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DIRECTORATE GENERAL OF DRUG ADMINISTRATION



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7. REFERENCES

- **Drugs and Cosmetics act, 2023.**
- **ISO 9001:2015** – Quality Management Systems-Requirements.
- **WHO TRS 1025, Annex-13** Implementing quality management systems in national regulatory authorities.

8. REVISION HISTORY

Any Changes/review to this document will be recorded and tracked on this section:

| Version No. | Date | Reason |
|-------------|-----------------|---|
| 00 | September, 2012 | Newly developed |
| 01 | September, 2017 | Updated to comply with WHO GBT indicators requirement |
| 02 | December, 2021 | Updated as per WHO audit observation through incorporating QMS principles of WHO guideline. |
| 03 | March, 2024 | Updated to make it align with new Drug and Cosmetic Act, 2023 |

9. ANNEXEURE

- 9.1 Annexure-I Quality Policy
- 9.2 Annexure-II Quality Objectives

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DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure-II

| | | | | | | |
|---|--------------------------------------|----------------|-------------|--|------------|---|
|  | FORM Title: QUALITY OBJECTIVE | | | | |  |
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH



Document No.:

Revision Date:

Version:

Date of Issue:

Quality Objective

Write the objective in line with QM and DGDA's set strategic vision, mission and plan:

.....
....
.....
....

Date:

**Director General of Drug Administration
And
Licensing Authority (Drugs)**
Ministry of Health and Family Welfare,
Government of the People's Republic of Bangladesh

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure – I

| | | | | | | |
|---|-----------------------------------|----------------|-------------|---|------------|---|
|  | FORM Title: QUALITY POLICY | | | | |  |
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH



Document No.:

Revision Date:

Version:

Date of Issue:

Quality Policy

Write QP in line with QM and DGDA's set standards i.e., WHO, ISO and or PIC/S guideline:

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**Director General of Drug Administration
And
Licensing Authority (Drugs)
Ministry of Health and Family Welfare,
Government of the People's Republic of Bangladesh**

Date:

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