QUALITY Manual

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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1. Introduction

1.1 Quality Control of Drugs at DGDA

Pharmaceutical and biopharmaceutical industries worldwide are strictly regulated, with requirements growing more and more demanding for the manufacture and marketing of their products. That is why every country must consider this element in the law relating to public health to ensure, among other things, compliance with the regulations established for these industries.

Directorate General Of Drug Administration (DGDA), National Regulatory Authority for drugs in Bangladesh, was created in 1976 by Government of Bangladesh to plan, investigate, regulate, organize, direct and control activities to ensure that all drugs, vaccines and drug for research, public consumption and exports comply with the laws in force in the country and the recommendations set by WHO or other international organizations, so that drugs are available with the required quality.

Mission:
To ensure the protection of public health by ensuring, through a system of regulation and control of health, drugs and diagnostics those are available for human use, whether imported or domestically manufactured, for the safety, efficacy and quality requirements.

Vision:
To consolidate as a National Regulatory Authority for drugs and vaccines, and recognized for its international counterparts, working to accomplish their mission with efficiency and transparency In fulfilling its mission, the functions performed by DGDA are evaluation, registration, inspection, control and surveillance of drugs and vaccines. DGDA defines the general and specific functions of the national control of drugs, which cover all stages of the cycle of drugs and diagnostics for human use, i e from research and product development to its post-marketing surveillance.
In fulfilling its functions, the DGDA performs services for the industry and population, which may be identified as their external customers:

- Manufacturers, marketers and distributors of drugs and vaccines or its domestic and international sales representatives in the country.
- People.
- Other stakeholders.

Some of the services provided are subject to payment by applicants of the same. Rates are stated in the Regulations for the Implementation of the official list prices for technical services productive. The regulation sets out all services and forms of payment if required.
DGDA has been proposed to demonstrate its ability to provide services that meet the needs of our internal and external customers by implementing a system of quality management based on compliance with the principles and requirements of international regulations.

The System of Quality Management by DGDA is based on the realities and needs of the organization, so as to lay the groundwork for greater credibility in their decisions, greater strength and stability of its functions and a systematic planning, monitoring and improving the quality of processes, as well as the higher levels of efficiency and effectiveness.
The DGDA in its development process, influencing its internal environment to improving the organizational structure (Annex 1) and the interrelationships between processes, the establishment of policies and objectives and defining new strategies.

1.2 Objective and Scope of Quality Manual

This document aims to establish and describe the quality system requirements based on international standard Quality Management – Requirements.

The scope of quality management involves the processes of realization of services of DGDA:

— Receipt and delivery procedures
— Register
— Pharmaceutical Inspection
— Release
— Authorization of clinical trials
— Monitoring Post
— Analytical control

The services offered meet the functions to be developed by drug regulatory authorities in any country, so they are already designed and are controlled by specific indicators previously established by international agencies.

1.3 Terms and Definitions

For a better understanding of this Manual, the terms and definitions in the International Quality Management – Vocabulary are applicable.

2. System of Quality Management

2.1 General System Requirements

The system of quality management is comprised of personnel, processes, documentation, interfaces, as well as the resources we use to ensure the quality of our services. These resources are allocated by the DGDA for the conduct of the processes of the QMS.
The implementation of quality management means that:

— Identify and assess the processes involved in it
— Determine the sequence and interaction of these
— Determine criteria and methods required to ensure its effective operation and control
— Ensure availability of information needed to support and monitor its operation and its measurement
— Provide monitoring and analysis and implemented, where required, the necessary actions to achieve planned results and continuous improvement

2.2 Documentation

For our system to operate consistently maintained and improved, we have established and implemented to provide us documents to ensure effective operations, process control and implementation of improvement actions.

The documentation of the QMS, in hierarchical order, consists of the following elements:

In addition to the Quality Manual, the DGDA has the Quality Manual for Inspectorate, in accordance with Annex No.8 of the Technical Report Series No.902 WHO, which makes references to the common requirements of the Manual of Quality Management System; there is no contradiction between them.

The external documentation necessary for the performance of the different activities of each process is identified, and is kept updated by the heads of departments and areas. It is formed mainly by the pharmaceutical regulations and national standards and international pharmacopoeia and reference guides that are applicable to the control of drugs.

Documents produced as part of the system are compatible with the established regulations.
The documentation is kept in safe places that allow access to specialists for consultation.

2.3 Control of Documents

In DGDA, documents including records relating to quality are identified, developed, reviewed, approved, recorded, archived, distributed, updated and removed by the procedure of control documents in force.
The area of Quality Management is responsible for establishing and maintaining the control system documentation regarding the quality.

Changes made to the documents are controlled by established procedures for each document.

3. Responsibility of the Directorate General of Drugs Administration - DGDA

3.1 Commitment by the DGDA

Services provided by DGDA for the protection of public health, development and continuous improvement of a System of Quality Management, as a way to achieving the quality policy and objectives established by involving all staff in their implementation, as well as meeting customer requirements, legal and regulatory compliance of our functions.

3.2 Quality Policy

The Quality Policy set by the DGDA expresses a commitment to implement a system of quality management based on continuous improvement. It is also disclosed, known and understood by all workers.

Quality Policy

Directorate General of Drugs is committed to protect the health of people of Bangladesh and fulfill their duties with professional and scientific rigor, while ensuring safety, efficacy and quality of Allopathic, Ayurvedic, Unanani, Homeopathic and Herbal medicines, vaccines, and biological according to the Drugs Acts, Rules, Ordinance and the amendments made there under.

DGDA shall work through effective, transparent and timely manner, ensuring implementation of Quality Management system which is continuously improved.

To meet our commitment, we must:

- Foster a team approach.
- Emphasize appropriate training for all employees.
- Recognize each employee's responsibility for quality.
- Provide regulations with timely written corrective actions.
- Earn recognition of our quality process and progress.
- Provide a framework for establishing and reviewing quality objectives.
- Develop and achieve Quality Improvement Goals.
- Maintain our honesty and integrity by following our Code of Conduct.
- Review and renew this Quality Policy on a regular basis.

3.3 Planning

Work objectives are expressed in a separate document and are reviewed periodically to ensure compliance. These objectives are deployed for specific and general tasks that are taken into account when drawing up the plans a month of work.

3.4 Responsibility and authority

The responsibilities and authorities of managers involved in the System of Quality Management DGDA are clearly mentioned in this manual. However Job responsibilities for each individual are well documented explained and clearly understood by each individual.

3.5 Representative of the DGDA

The Deputy Director of DGDA has been designated as representative of the DGDA of the area of Quality Management who has the additional responsibility and authority which includes:

— Ensure that the necessary processes for the system of quality management establishes, implements and maintains.
— Inform senior management of system operation, including the needs for improvement
— Promote awareness of customer requirements at all levels of the organization.

The responsibility of the management representative includes relationships with external parties on matters related to the system. **He is the designated Quality Assurance Manager.**

3.6 Internal Communication

As a minimum internal communication is done through the following channels:

— Meeting with Ministry-Joint Secretary (Once in a quarter)
— Senior Staff meetings (Monthly)
— Full Departmental meetings (weekly)
— Daily operational meeting of the departments and administrative areas
— Email
— Internet
— Telephone

3.7 Management review

The review by management is planned by the DGDA twice a year, the report resulting from this review is presented and discussed by the Board which includes an assessment of opportunities for improvement and the need for changes in the system, from the information obtained from:

— Results of internal and external audits conducted in the period being evaluated.
— Performance and compliance processes of the service.
— Status of corrective and preventive actions.
— Follow-up reviews by the previous.
— Results of customer feedback.
— Changes required for making the System.
— Recommendations for improvement

4. Resource Management

4.1 Provision of resources

Based on identified needs, the Department determines and provides the necessary resources to implement, maintain and continually improve the effectiveness of the processes of the System of Quality Management and achieving customer satisfaction.

4.2 Human Resources

The institution has a description of the skilled jobs, which declared the general and specific requirements to occupy the same.
The process of planning, development and evaluation of training and competence of staff, to ensure their performance in each job is carried out according to the standards.
It is the responsibility of the Department of Human Resources organization and coordination of activities related to this process

4.3 Infrastructure

DGDA manages the infrastructure necessary to achieve compliance with requirements of the service including:

- Working space
- Equipment for the processes that require
- Maintenance of facilities through the maintenance plan and control them

DGDA will also ensure compliance with national regulations for the protection and health at work and protection against disasters to prevent the occurrence of possible accidents

4.4 Work Environment

DGDA ensure a work environment that is conductive to improving the performance of workers providing adequate working conditions (lighting, atmosphere, climate, hygiene and cleaning) and ensures the systematic maintenance of the facilities of the institution.

5. Completing the Service

5.1 Planning the performance of the service.

In DGDA for planning the execution of the service there are determined and strategic goals are set according to customer requirements, as well as those of a regulatory requirement that govern the activity in the country with proper documentation.
This documentation process includes information sheets, procedures, instructions and records. To verify compliance with service requirements are determined and established control methods are planned and the self, internal audits and management reviews. Department heads of each branch is responsible for service planning and monitoring their compliance.

5.2 Customer related processes

5.2.1 Requirements related to the client

Customer requirements are identified taking into account, information obtained from interviews and surveys, in addition to those set out in legal documents and regulations related to service provision.

Requirements related to the client are based in:
— Compliance with the service with the established deadline.
— Prioritization and streamlining of procedures for the products of impact to human health and the economy.
— The offer of support guides for organizing the necessary documentation according to the services requested.
— The clarification of doubts with regard to services.
— Updating information on pharmaceutical regulation.
— Professionalism and confidentiality
— Comfort and good treatment in the service.

All requirements, including requirements not specified by the customer but necessary for the provision of service and regulatory requirements are processed and reviewed in the process of receiving and delivery, before engaging with the client to provide the service, and ensure that:
— It has complied with the requirements for the application of the service.
— Identify new requirements stated by the customer if any
— We resolve differences between the requirements of the request and expressed by the client.
— We have the ability to comply with the requirements defined for the product to the customer.

5.2.2 Communication with the customer

Communication with customers is maintained through:
— Internet
— Fax
— Email
— Post
— Surveys and interviews
— Meetings and exchanges between specialists and managers

Complaints and grievances are handled in the area of quality management through the provisions of the instructive addressing complaints and grievances.

5.3 Identification and traceability

The process of receipt identifies each service request with a unique code which is maintained throughout the process of providing the service, as described in the Fees Regulation.
The background paper delivered by customer for the analysis and making final decisions regarding the service and documentation issued as a result of the service are kept in a secure and reliable ensuring traceability for the service performed.

5.4 Ownership of the customer

The documentation provided by the client to carry out the service becomes the property of DGDA, should preserve any necessary documentation in adequate space to ensure the secure archiving of the same

5.5 Preservation of product

Products linked to the achievement of the processes are stored to ensure their identification, protection, and suitable conditions for preservation.

5.6 Control of monitoring and measuring devices

The DGDA service line ensures that the tracking devices used for measuring and testing of analytical process control at National Control Laboratory or used by its staff elsewhere, are properly calibrated or verified as appropriate, at intervals, adjusted or readjusted as necessary. This activity is ensured by the area of Quality Management.

6. Measurement, analysis and improvement

6.1 Monitoring and measurement

6.1.1 Customer Satisfaction

The evaluation of customer satisfaction is through the perception that has the same service, which expressed through interviews, surveys, meetings, visits to its facilities, attention to complaints and grievances, is determined annually in Quality Management and the number of customers to apply the methodology to assess their satisfaction and acceptance criteria for considering responses to the analysis of customer satisfaction.
The information collected is processed in the area of Quality Management and the results are analyzed for taking corrective actions and / or preventive.

6.1.2 Internal Audit

The audits are conducted taking into account the provisions of execution of internal audit in the DGDA, which state the responsibilities, requirements for conducting and planning, as well as the mechanism for reporting results and maintaining records.
Audit teams are content with selected specialists in the various processes of the center.
The planning, coordination and conduct of audits is the responsibility of the area of Quality Management

6.1.3 Monitoring and measurement of processes and services

The processes of quality management are measured systematically by using the following methods:
— Management review
— Evaluation of the Effectiveness

— Internal audits

The identification of performance indicators for each process and its evaluation is the responsibility of the heads of each process together with the head immediately above. The analysis of the monitoring is carried out through the measurement, analysis and improvement area of quality management.

6.2 Control of non-conforming services

Conformity assessment of the outcome documents of the service provided is done at an early stage by the managers and finally by the receiving and delivery ensures that non-conforming services are identified and controlled to prevent a delivery to customer. Corrective and preventive actions are taken. The system is continuously improved based on feed back.

6.3 Data Analysis

The data analysis provides information on the behavior of the customer satisfaction, compliance with service requirements, characteristics and trends of processes

The information sources used for this analysis are:
— Verification of provided services,
— Evaluation of advisory experts in the committee or any down the chain service provider,
— Monitoring and measurement of processes and service
— Audit results
— Results of management reviews,
— Complaints, compliments, opinions and suggestions from customers,
— Monitoring and measuring customer satisfaction.

As a result of the analysis are identified and planned actions for improvement.

6.4 Continuous Improvement

The implementation of the improvement is ensured through verification of compliance goals, checking the effectiveness of actions for improvement, corrective and preventive action and improvement of customer perception.

6.5 Control Change

— It describes the processes that are included in the scope of the Quality Manual
— An insight into the reasons for exclusion from the requirement
— Drafting of the Quality Policy
— It explicitly describes the procedure with regard to ownership of the customer and the preservation of the product
— Review of draft document

Annexure 1

ORGANIZATION CHART