Basic Essentials and Applications of Quality Management System (QMS) in Biomedical Sciences

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2.1 What You Will Learn in This Chapter

- The importance of quality management system (QMS) in biomedical sciences
- The implementation of the international quality standards for laboratories
- The importance of implementing safety management programs
- The importance of trained and qualified personnel
- The implementation of quality control processes and quality assurance
- The importance of monitoring, analyzing, and managing of the QMS
- The necessity of continuous improvement
- The necessity of establishing a program to address user requirements and satisfaction
- The functions and requirements of the organizational process, management, and structure
- The necessity of the documentation including keeping records and documents
- The challenges in QMS and applying new techniques in the near future

2.2 Rationale and Importance

Although the essentials of the quality management system (QMS) were introduced in the 1920s, its implementation in the laboratory was started in the 1940s. Quality in the laboratory means to have a traceable and accurate test results. Accordingly, any level of inaccuracy should be avoided. On the other hand, in the field of biomedical product manufacturing, achieving a safe and efficient product needs implementing all of the aspects of the quality in the manufacturing process [1, 2].

Depending on the type of project, in all fields including diagnostic laboratory management, biomedical product management, scientific research, and clinical trials, the implementation of guidelines on good laboratory practice (GLP), good manufacturing practice (GMP), and good clinical practice (GCP) should be considered for achieving acceptable standards in the quality management process (Fig. 2.1) [3, 4]. GLP refers to the set of methods which regulates the processes and activities in the laboratory to ensure the reliability and safety of laboratory data [5]. On the other hand, GMP is the set of regulations that monitor the manufacturing processes to improve the quality, purity, and safety of products [6]. Finally, promoting the safety, reliability, and integrity of data reporting and methodology associated with clinical trials is implemented by GCP [7].

2.3 A Snapshot of the Quality Management System

The structure of the QMS is made of some essentials that should work together and be managed properly. QMS can control and direct an organization in accordance with quality features. In this organization, personnel are responsible for achieving the highest quality and continuous improvement in every organizational position [8, 9].

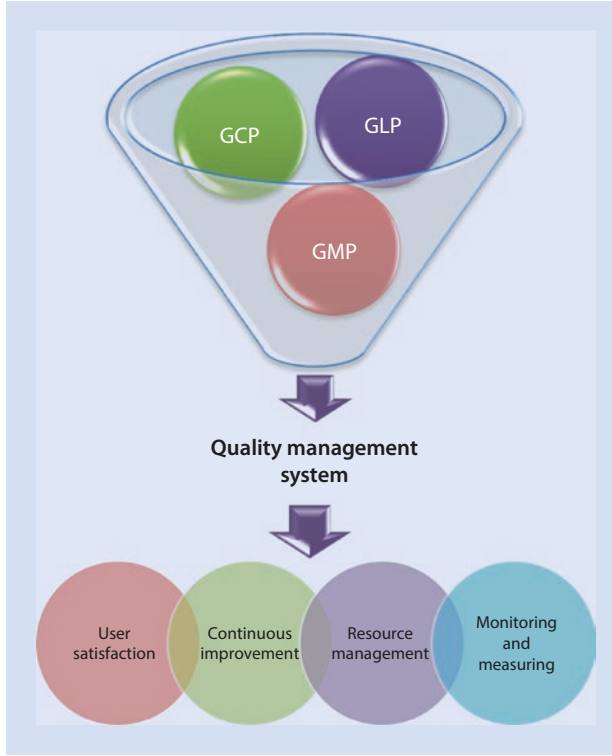

Fig. 2.1 Commitment to GLP, GMP, and GCP in biomedical projects can improve the quality of data and products as the final conclusion of QMS implementation

2.3.1 The Definition of the Quality Management System

QMS is a set of procedures, activities, resources, policies, documented information, and organized processes that help organizations to meet quality improvement, consistency, and good customer services. QMS regulates, coordinates, and directs the activities of the organization in order to meet regulatory and user needs, to improve its efficiency and effectiveness continuously [8, 9].

2.3.2 Quality Management System Principles in Biomedical Sciences

The aim of QMS implementation in biomedical sciences is to improve bioproduct characteristics, productivity, efficiency, public awareness, working atmosphere, continuous improvement, as well as lowering costs. In summary, commitment to the QMS principles can improve organizational performance. Some of the major principles of QMS are as follows [9, 10]:

- User focus
- Leadership
- People involvement
- Process approach
- System approach to management

- Continuous improvement
- Factual decision-making
- Mutually beneficial supplier relationships

2.4 An Introduction to International Organization for Standardization

In 1946, a meeting has been held between the International Federation of the National Standardizing Associations (ISA) and the United Nations Standards Coordinating Committee (UNSCC) about setting the International Organization for Standardization (ISO) to make worldwide series of international standards. These standards are known as ISO standards [11]. Then, in 1947, different countries decided to establish ISOs as nongovernmental organizations and set commercial and industrial standards to improve quality features of products and services and also to provide appropriate solutions for global challenges [9, 11]. In summary, ISO is a nongovernmental organization that develops a series of international standards and works with different institutes in around 150 countries [11].

2.5 International Quality Standards for Laboratories

Assessing performances according to quality standards has a crucial role in implementing QMS. Standards should be applied to meet the regulatory requirements and user needs for enhancing the safety, consistency, and also monitoring of laboratory performances [11]. Therefore, a group of standards has been published to ensure that the production of biomedical products is fit for their goals. Accordingly, ISOs have some different series based on their aims and scopes [12]:

- ISO 9000:2015 focuses on QMS fundamentals and vocabulary and also provides a guidance for different kinds of organizations to promote quality management and productivity as well as address user requirements [12].
- ISO 9001:2015 specifies QMS requirements as well as providing the standards for achieving user satisfaction [12, 13].
- ISO 15189:2012 defines requirements of competency and quality in medical laboratories [14].
- ISO 17025:2017 focuses on the general requirements of calibration laboratories and competence of testing [15].
- ISO 13485:2016 identifies the QMS requirements to provide medical devices [11].
- ISO 14644:2019 focuses on cleanroom classification and associated controlled environments [16].

2.6 Implementing of Safety Management Programs

Safety management programs as one of the essential parts of the QMS contain safety of personnel, facilities, equipment, and manufactured biomedical products. Safety equipment and facilities are used for achieving quality and safety of products, personnel, and

patients and also for preventing the chemical and biological hazards [9]. In this context, relevant policies and standard procedures must be established. Accordingly, personnel should be aware of the potential hazards and be trained for applying safety practices [2]. Additionally, laboratory safety program can optimize and improve health status of the patients and also working atmosphere [2]. On the other hand, the reputation of the institutes will be improved, and the income will be increased using QMS. Finally, QMS can help the organization to reduce its undue costs and negative effects [17].

2.7 Personnel Training Program

Personnel has a crucial role in every organization. Trained, qualified, and responsible personnel help organizations to achieve their goals such as high quality of biomedical products and services. As a result, health status of the patients will be improved [18]. Therefore, the accurate data and high-quality services depend on the competent personnel who have the ability to perform different tasks and procedures properly. Accordingly, training process should focus on personnel skills knowledge and behavior [18]. First of all, competency assessment such as evaluating education of all employees and also their knowledge and problem-solving skills must be assessed before starting training programs. In addition, it is necessary to write a policy for competency assessment. Further, all the personnel should know about the policy of the organization. Finally, all the procedures in the organizations should be documented [19].

2.8 Quality Control Processes

Quality control processes use monitoring to ensure the accuracy and reliability of process and include the quality control (QC) and sample management process [20].

- *Quality Control*
- QC is one of the main components of the process control. It can monitor, examine, and detect failures that may occur throughout the processes [20].
- *Sample Management Process*
- Accuracy and reliability of quality data and test results depend on the suitable management of samples. Subsequently, the quality of the results has a significant effect on clinical decisions, patient care, and good treatment [9]. Therefore, written protocols for sample management are necessary considering some important points such as [2] the following:
  - Sample collection
  - Sample preservation
  - Sample labeling
  - Sample storage and retention
  - Sample transport
  - Sample disposal

2.9 Quality Assurance

Quality assurance (QA) is a set of systematically structured plans and activities to ensure the quality of products and services. Implementing QA can reduce problems and defects in manufactured products and laboratory results [21]. Personnel should be aware of all the QA procedures and be committed to all relevant requirements and standards [9].

2.10 Monitoring Based on the Quality Management System

Monitoring, analyzing, and managing are pivotal in evaluating quality of an organization based on QMS features [2]. Further, monitoring in QMS should be performed in accordance with established standards such as ISOs. Therefore, each process should be monitored using some appropriate methods to increase its effectiveness [9].

2.11 Continuous Improvement

Since continuous improvement is critical in QMS, monitoring and evaluating the effectiveness and performances of all activities in organizations step by step are necessary for detecting weaknesses and errors and correcting them [11]. Continuous improvement mainly focuses on improving and increasing activities to fulfill quality requirements. Accordingly, all the processes should be better continuously [9].

2.11.1 Implementing Tools for Process Improvement

There are a lot of practical techniques that are used in process improvement to evaluate, control, and detect the problems and defects in the processes, using external and internal audits [22].

2.11.1.1 External and Internal Audit

According to ISOs that focus on assessment requirements, the organization performance is evaluated. Therefore, suitable and practical tools should be applied as audits. Audits have a regulated program which detects and evaluates problems throughout the whole organization using two approaches [23]: (1) internal audit and (2) external audit. Internal audit is a type of assessment conducted by organization with a group of personnel. External audit is conducted by groups and agencies from outside the organization for getting accreditation, approval, licensure, and certification [9, 11].

2.12 Good Customer Services

The main goal of the QMS is to meet the user requirements. Institutes should be aware of the user needs and try to meet them by focusing on the ISO series to improve the quality of products and achieve the satisfaction of the users (e.g., patients, communities, physicians, and public health agencies). It is essential to establish a program to address user

requirements and satisfaction [24]. In accordance with, all personnel should be committed to the system, using proper monitoring tools to collect necessary information. Therefore, they need to be trained for using these tools properly and also using technologies such as computer and Internet to document and save time [25].

2.13 Organizational Requirements and Functions of the Quality Management System

Organization includes management and organizational structure. Management should direct the organization by a visible support to show the importance of personnel efforts [26]. Its policies should be written according to the mission and factual-based decision-making. Moreover, the design of the organizational structure should meet all the quality requirements and be clearly defined. It is also important to ensure that all functions in the organization are performed properly in accordance with quality features [19].

2.14 Documentation

Documentation is a tool used for writing information about procedures, processes, and policies. Perfect documentation system needs clear, accurate, feasible, and practical documents and manuals which can be used by personnel easily [11]. By keeping records and documents, the information whenever is necessary will be available. Defining processes should be recorded to prove that they are being followed. Documentation has a pivotal role in objective evidences which can support personnel via manufacturing, design, and development of biomedical product to meet the requirements [9]. All the laboratories and manufacturing facilities should have clear standard operating procedures (SOPs) which are a type of document and instruction that should be followed by personnel. It is important to change and update the documents regularly [27]. Accordingly, policy is a type of fundamental document that includes main objectives which are defined in organizations and approved by the management system. It is necessary that each organization writes their specific policies according to national policies [19].

2.15 Challenges and Future Perspectives

Establishing a perfect QMS in an organization has some serious limitations. For instance, trained, expert, and committed personnel, implementing proper and up-to-date data protocols, easy access to suitable information, doing everything at the first time, avoiding time and budget waste, etc., are considerable challenges (Table 2.1) [28, 29].

Some new techniques have been developed to improve institutes and organizations according to QMS specifications continuously. Accordingly, using such new methods and tools will not be negligible in the near future. In this context, lean process [30, 31] and Six Sigma [32, 33] are the most commonly used tools. Both of them are used for optimizing all activities of the organization to save time and money and also to improve organizational performances by controlling, analyzing, and measuring as well as to reduce the mistakes and problems in the processes [30, 32, 33].

Table 2.1 Some important challenges of the QMS implementation and possible solutions

Challenges	Solutions
Not enough satisfying users	Focusing on the user requirements
Too much unnecessary documentation	Implementing useful documentation management procedures
Too much focus on theory which is not practical	Focusing on practical theories and putting them into practice
Wasting too much time and resources on unnecessary details	Using details which are based on your activities
Too inflexible program	Implementing changes that improve the process
Not enough support and communication	Defining leadership and personnel responsibility clearly

Take-Home Messages

- QMS is a set of procedures, activities, resources, and organized processes to achieve quality specifications and fulfill user requirements.
- Implementing guidelines on GLP, GMP, and GCP in institutes can increase quality of data and products in accordance with relevant standards.
- ISO series intends to promote the quality, efficiency, and safety of biomedical products and technologies for users.
- Safety management programs can improve the safety of manufactured products, personnel, and patients.
- Training program can develop the skills, knowledge, and behaviors of the personnel.
- Quality control processes can control activities and monitoring processes to ensure continuous improvement.
- Continuous improvement is a permanent objective of an organization.
- Internal and external audits are the important tools of continuous improvement.
- The organizational requirements include proper management and also clear organizational structure to meet all the quality requirements.
- Institutes and organizations should be aware of the user needs and try to meet them by focusing on the ISOs.
- Documentation is a set of documents that includes writing procedures, policies, and processes which record all the necessary information and should be clear and easily accessible.
- Establishing a perfect QMS includes some challenges.

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Further Reading

Books

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Online Resources

https://europepmc.org/abstract/med/15137330, Quality management system in the medical laboratory--ISO15189 and laboratory accreditation.
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