

18-1: Organizational requirements for a quality management system

Definition

The term **organization** in the context of a quality management model is used to indicate the management and the supporting organizational structure of the laboratory.

Organization is one of the essential elements of the quality system, and is intimately related to all the other elements in the model.



Characteristics essential to success

The principal element for a successful quality management system is **managerial commitment**.

- Management at all levels must fully support and actively participate in the quality system activities.
- Support should be visible to staff so that there is an understanding of the importance of the effort.
- Without the engagement of management, including the decision-making level of the organization, it will not be possible to put in place the policies and the resources needed to support a laboratory quality management system.

A second vital element is that the **organizational structure** must be designed to ensure that the quality goals of the organization are met.

- The laboratory must be a legally structured entity according to local requirements.
- All the organizational elements required to ensure a properly functioning quality management system must be in place.

Key
organizational
components

The important organizational requirements for achieving a successful quality system include the following:

- **Leadership**—laboratory leaders must be fully committed to implementation of the system, and these leaders will also need vision, team-building and motivational skills, good communication techniques, and the ability to use resources responsibly.
- **Organizational structure**—the structure of the organization should be clearly defined, and this should be reflected by a functional organizational chart with clear assignment of responsibility.
- **Planning process**—skills for planning are needed, and planning should address a time frame, responsibility for conducting the activities, the availability and use of human resources, management of workflow and financial resources.
- **Implementation**—implementation requires that a number of issues must be addressed by the management staff. These include management of projects and activities, directing resources to accomplish plans, and ensuring that timelines are met and goals achieved.
- **Monitoring**—as components of the quality management system are put in place, processes for monitoring will be needed to ensure that the system is working, and that benchmarks and standards are being met. This element is essential to the primary goal of a quality system, which is **continuous improvement**.

Providing leadership

18-2: Management role

Leadership can be defined in many ways, but it is an important factor in the success of any organization's efforts for improvement.

A good leader will exercise responsible authority. Important roles for a leader include:

- providing vision
- giving a direction for goal-setting
- motivating staff
- providing encouragement.

A strong leader will help staff understand the importance of the task at hand.

Responsibilities of managers

ISO 15189 [4.1.5] states that "Laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system".

A quality management system outlines specific responsibilities of managers. Management must be responsible for:

- establishing the policies and processes of the quality system;
- ensuring all policies, processes, procedures, and instructions are documented;
- making sure that all personnel understand documents, instructions, and their duties and responsibilities;
- providing personnel with the appropriate authority and resources to carry out their duties.

Management is charged with providing a quality manual which describes the quality management system. The quality manual is the means by which the policies are established and communicated to the staff and the users of the laboratory.

Laboratory directors have the principal responsibility for setting up an organization that can support the quality system model. They are responsible for developing policies, assigning authority and responsibility to the appropriate persons, ensuring resources and reviewing the organizational aspects of the system for optimal functioning of quality processes. Laboratory directors must ensure that staff follow the quality policies established by the quality manual.

Quality managers assist in developing policies, planning and implementing the quality management system. They are usually responsible for many of the implementing and monitoring processes, and must communicate all aspects of the quality management system processes to the laboratory director or head of the laboratory.

Commitment of
management

Laboratory staff (laboratorians) are responsible for understanding the organizational structure of the laboratory, including where authority and responsibility are assigned. The laboratory staff will follow all of the quality policies in their daily work routine.

Most critical in beginning any new programme is to seek approval from the top. Management needs to be involved at a sufficiently high level to assure success of the programme. When implementing a quality system, determine what the “sufficiently high level” is; be sure to include those who make decisions as their approval and support is vital. Finally, it is important that laboratory managers communicate their commitment to the entire laboratory staff. Managers must show the way, and encourage and foster the “spirit” of the organization.