18-4: Organizational functions: planning

Once management is committed to instituting a quality system in the laboratory, a planning process is needed. Approaches used will vary, depending on many factors in the local situation.
- What quality practices are already in use in the laboratory?
- What is the level of knowledge of current staff?
- What resources will be available?

All elements of the quality system should be included in the planning process. It is not necessary (usually not possible) to implement all parts of the plan at once; a stepwise approach will often be more practical.

In many laboratories, the implementation of a quality system may involve many changes. It is therefore important to keep all staff involved, and to not proceed too rapidly, as personnel may find it difficult to meet the goals and can get discouraged. Communicate with staff frequently, clearly and positively; this will help to keep morale high.

During planning, priority areas will emerge as the bigger problems are identified. It will be important to keep objectives realistic and measurable. Inevitably, there will be some factors that are beyond the control of the laboratory. Recognize these and move on to other factors that can be addressed. If these factors are vital to the ultimate success of the quality programme, then look for ways to influence those who can control them. Always advocate for quality.

Establish a plan

In planning for implementation of a quality system, the first step is to analyze and understand the current practices. A useful way to accomplish this is the technique of **gap analysis**. To conduct a gap analysis:
- use a good quality systems checklist to evaluate the practices in the individual laboratory;
- identify gaps or areas where the laboratory is not using the good laboratory practices required in the quality system.

Using the information provided by the gap analysis, develop a task list of everything needing to be addressed, and then set priorities. In determining priorities, consider first addressing problems that can be easily fixed; this will give some early successes and boost staff morale. Also evaluate what would have the most impact on laboratory quality and give these factors high priority.

Problems commonly identified in laboratories using a gap analysis include:
- test ordering
- sample management
- incompetent technical staff
- quality control
- analytical process
- recording and reporting results
- reagent and equipment management.

The quality system plan

The implementation of a quality system in the laboratory requires a written plan. A written plan makes clear to all staff and all users of the laboratory how the process will proceed. The plan should contain the following components:
- objectives and tasks—what should be done;
- responsibilities—who will get the job done, who will be responsible;
- timeline—when will each task be worked on, when will it be completed;
- budget and resource needs—additional staff, training needs, facilities, equipment, reagents and supplies, quality control materials;
- benchmarks—essential for monitoring progress in implementation.

The written plan should be made available to all laboratory staff, as everyone must understand the plan and the process of implementation.

18-5: Organizational functions: implementation

Once a plan has been written and agreed upon, implementation will begin. These suggestions will help the laboratory in this process:

- **Commit** from the beginning to complete the project and achieve the established objectives. Go in with a positive attitude.
- **Prepare to implement in stages**. It is important to prevent staff from getting discouraged, so choose manageable "bites" at the beginning. Staggering start dates will also be helpful; use established priorities to determine start dates.
- **Determine resource requirements** early in the process, and secure the necessary resources before starting tasks. If working in a highly resource-limited environment, choose as initial activities those things that can be done with available funds and staff—there are many such activities, such as improving documents, records, or developing up-to-date and improved standard operating procedures.
- **Engage all staff** by communicating effectively. If training is needed to have personnel understand the quality system and its goals, this training should probably be done before starting other tasks.

As a part of the planning process, the laboratory will have established a timeline for tasks to be performed, including a projected completion date. This timeline is a critical part of the process, as it allows everyone in the laboratory to observe progress. A **Gantt chart** (shown below) is a very useful tool for visually representing the proposed timeline; it shows tasks to be done, with times of beginning and completion.
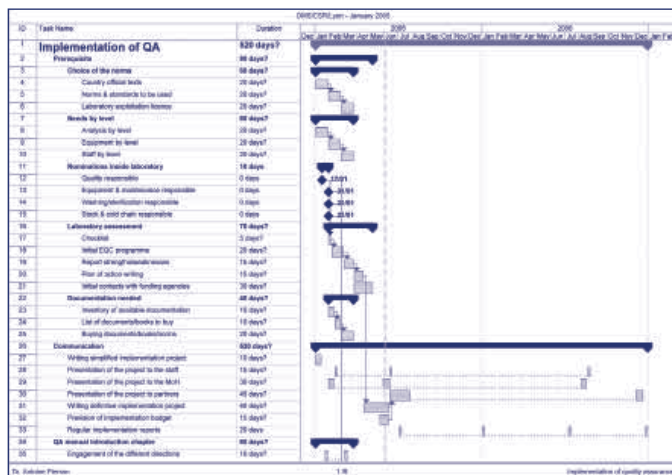
The timeline should be very carefully prepared, so as to allow appropriate times for completion. Do not let the laboratory staff become overwhelmed with the tasks that need to be accomplished.

Providing resources

During the planning process, all additional resources that are needed will have been identified. As implementation begins, be sure that these resources are in place and available. Several kinds of resources need to be considered:
• all financial requirements— establish a budget;
• personnel needs—are additional laboratory staff required, will training be needed for any of the staff?
• facilities, equipment, supplies, and computer needs.

Monitoring basics

Establishing a system for monitoring quality management is essential in implementing a quality system. It is the monitoring and maintenance part of the effort that will produce the continuous improvement that is the overall goal of a good quality system. Monitoring involves being able to check each part of the system to be sure that the system is working properly.

Establishing a monitoring programme

There are several steps in setting up a programme to monitor compliance to the quality system.
• Assign responsibility for the process. Usually the quality manager will be the person who is primarily responsible for the monitoring programme.
• Develop indicators or benchmarks using the laboratory quality policy. These indicators will be monitored over time.
• Develop a system for the monitoring process; establish time or frequency of checks, decide how the monitoring will be managed.
• Conduct an audit, followed by a management review; these constitute two important tools in monitoring compliance.

Internal audits should be conducted at regular intervals. They are valuable for evaluation, and they are required by ISO 15189.

Management reviews are a particularly valuable component of the monitoring process. It is the responsibility of management to review all appropriate quality systems information, and to look for opportunities for improvement.