

Postgraduate Certificate in Pathology Quality Assurance

## Quality Management Systems

Quality Management Systems (QMS) are a collection of business processes focused on achieving customer satisfaction by meeting customer requirements and striving for continual improvement. In the Postgraduate Certificate in Pathology Quality Assurance, it is essential to understand key terms and vocabulary related to QMS.

ISO 9001 is an international standard that outlines the requirements for a QMS. It is based on the Plan-Do-Check-Act (PDCA) cycle and provides a framework for organizations to ensure consistent performance and meet customer needs.

Key Terms and Vocabulary:

1. **Quality Management System (QMS):** A QMS is a collection of business processes focused on achieving customer satisfaction by meeting customer requirements and striving for continual improvement.
2. **ISO 9001:** An international standard that outlines the requirements for a QMS. It is based on the PDCA cycle and provides a framework for organizations to ensure consistent performance and meet customer needs.
3. **Plan-Do-Check-Act (PDCA) cycle:** A four-step model for continuous improvement. The steps are Plan, Do, Check, and Act.
4. **Plan:** Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.
5. **Do:** Implement the processes.
6. **Check:** Monitor and measure processes and products against policies, objectives, and requirements for the product.
7. **Act:** Take action to continually improve process performance.
8. **Quality policy:** A statement by the organization's top management, closely linked to the business and marketing plan and to customer needs. The Quality Policy is communicated and understood within the organization.
9. **Quality objectives:** Objectives set by the organization that can be measured. Quality objectives are consistent with the quality policy.
10. **Quality manual:** A document that describes the QMS and its implementation in an organization.
11. **Procedures:** Detailed, written instructions that describe the activities to be performed to achieve the desired results.
12. **Work instructions:** Detailed, written instructions that describe the activities to be performed at task level.
13. **Records:** Documented information to provide evidence of the performance of activities and the results obtained.
14. **Internal audit:** A systematic and independent examination to determine whether the QMS conforms to plan, to the requirements of ISO 9001, and to the organization's quality policy and objectives.
15. **Management review:** A review by top management of the performance of the QMS and of its continuing

suitability, adequacy, and effectiveness.

16. Non-conformity: A deviation from a specified requirement.

17. Corrective action: Action taken to eliminate the causes of an existing non-conformity or other undesirable situation.

18. Preventive action: Action taken to eliminate the causes of a potential non-conformity or other undesirable situation.

19. Continual improvement: Recurring activity to increase the ability to fulfill requirements.

Practical Applications:

A QMS can be applied in a pathology laboratory to ensure consistent performance and meet customer needs. The laboratory can establish a quality policy and quality objectives, and develop procedures and work instructions to guide the performance of activities. The laboratory can also conduct internal audits and management reviews to monitor the performance of the QMS and make improvements.

Challenges:

One challenge in implementing a QMS in a pathology laboratory is ensuring that all staff members understand and follow the procedures and work instructions. Another challenge is maintaining the QMS over time, as staff members may leave or new technologies may be introduced. To address these challenges, the laboratory can provide training and support to staff members, and regularly review and update the QMS to ensure its continued suitability, adequacy, and effectiveness.

Examples:

A pathology laboratory may have a procedure for processing tissue samples that includes work instructions for each step of the process. For example, the work instructions may specify the temperature at which the tissue samples should be stored, the equipment that should be used, and the steps for preparing the samples for analysis. The laboratory can conduct internal audits to ensure that the procedure is being followed and make corrections as needed. The laboratory can also conduct management reviews to evaluate the performance of the QMS and identify opportunities for improvement.

In conclusion, a QMS is a valuable tool for ensuring consistent performance and meeting customer needs in a pathology laboratory. By understanding the key terms and vocabulary related to QMS, laboratory staff can effectively implement and maintain a QMS and make continual improvements to the laboratory's performance.