



Laboratory Quality Management System (LQMS)

(Module 3)

Organization

Part 3.0: Organization



PURPOSE: To describe the organizational structure, management roles and responsibilities, and other factors needed for a successful laboratory quality management system.

LEARNING OBJECTIVE:

At the end of this module, participants will be able to:

- describe organizational elements needed for a quality management system;
- discuss management roles and responsibilities in a quality system;
- explain the process for designing, implementing, maintaining, and improving the laboratory quality system;
- explain the purpose of a quality manual.

MATERIALS:

1. PowerPoint slides or transparencies
2. Overhead projector or computer with an LCD projector
3. Prepared flipchart, white board, or chalk board
4. Paper cards, markers, and tape
5. Additional handouts as required.

TIMELINE: 135 Minutes

METHODOLOGY:

1. Lecture
- 2.** Discussion
- 3.** Exercise

ADVANCE PREPARATION:

1. Printing Activities 3-1 and 3-2
2. Familiarize oneself with the slides
3. Read facilitators Notes and ISO 15189 Standard

FACILITATORS STEP-BY STEP INSTRUCTIONS:

1. Welcome and Introduction
2. Present module overview
3. Ask Questions in between the presentation to actively involve participants.
4. Continue the presentation
5. Recap presentation using the Assessment questions

6. Ask if there is any question.

FACILITATORS NOTES

1. Refer to the Facilitator notes attached and participant and facilitator activities for this module 18.
2. Use relevant examples and illustrations from the slides to help participants understand.

SLIDE OF POWERPOINT PRESENTATION



SITUATION ANALYSIS/ EXERCISES

1. Provide participants with Activity 1-2- Organization, attached.
2. Divide participants into two groups and each handles one scenario, and present their answers.

ASSESSMENT REVIEW

1. What are the organizational elements needed for a quality management system?
3. List the management roles and responsibilities in a quality system.
4. Explain the purpose of a quality manual

REFERENCES

- CLSI – Standards, guidelines, and best practices for quality in medical testing
- WHO – Laboratory Quality Management System - Handbook
- ISO 15189 – Medical laboratories – Requirements for quality and competence