



Laboratory Quality management system

MODULE 13 Assessment

Part 13.0: Assessment



OBJECTIVE: To provide the participants with an overview of laboratory assessment, and information about external and internal audits.

Learning Objectives

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

- develop a process to prepare your laboratory staff for an external audit;
- plan and manage an internal audit;
- discuss how to use results from a laboratory audit;
- Advocate for the importance of taking corrective actions.

MATERIALS:

1. Handouts,
2. Slides
3. Computer
4. Over head projector
5. Flip chart
6. Markers and pens
7. Note books
8. Exercise: stickers for equipment placement and lab flow diagram
9. Additional handouts as required.

TIMELINE: 90 Minutes

METHODOLOGY:

- 1.** Lectures
- 2.** Discussion
- 3.** Group exercise

ADVANCE PREPARATION:

1. Ensure that adequate exercise materials are available, i.e each group should have at least two exercise materials
2. Make sure that adequate instructions are printed and issued out to the various groups, i.e. each group member should have a copy of the exercise instructions.
3. Confirm that the stickers are appropriate and adequately stick onto the diagrams prior to starting the class

FACILITATORS STEP-BY STEP INSTRUCTIONS:

1. Welcome and Introduction
2. Present module overview
3. Break the class into 5 groups composed of not more than 5 participants each at least and issue out the exercise sheets.

4. Ask each group representative to come up and present to the class the audit process

FACILITATORS NOTES

Refer to the trainers notes attached

Refer to the trainers activity guide attached

SLIDE OF POWERPOINT PRESENTATION



SITUATION ANALYSIS/ EXERCISES

- 1) Give the participants a copy of the following scenario and/or show it as a slide (Presentation 13, Activity 13-1)
- 2) Allow 2 minutes for them to read.
"You are the quality manager in your laboratory and you want to organize an internal audit."
- 3) **Ask the question:**
- 4) What steps will you take?
- 5) A presentation will then be made to the class from each of the group representatives.

(Refer to the facilitators activity guide attached)

ASSESSMENT REVIEW

LQMS/FG/013

Version 1.0

Effective date: 01-Jun-2019

1. Outline the process to prepare your laboratory staff for an external audit.
2. Describe how to use results from a laboratory audit.
3. What is the importance of taking corrective actions after the assessment?

REFERENCES

- GLI TB training package (<http://www.stoptb.org/wg/gli/trainingpackages.asp>)
- 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