

SIRIM LEAD AUDITOR ISO 15189:2022

Duration: 5 Days



PROGRAMME OVERVIEW

This course is designed to develop auditing skills of participants to conduct Quality Management System (QMS) audits against ISO 15189:2022, Medical laboratories – Requirements for quality and competence, in order to:

Objectively assess compliance of laboratories to meet accreditation body requirements

- Ensure auditors can support laboratory compliance and ensure competency of laboratory assured and improved
- Equip participants with an in-depth knowledge on the principles of the management system and technical requirements incorporated into ISO 15189
- Provide laboratory/quality practitioners and systems auditors with the understanding and skills necessary to professionally audit a laboratory management system
- Achieve the formal training requirements to allow progression to becoming a Registered Lead Auditor/Assessors.

Principles and practices of audit is based on ISO 19011:2018, Guidelines for auditing management systems, which forms the basis and reference document for this training course. At the end of the training, an examination will be conducted to assess the competency level of participants.

This course conforms to APAC Guidelines.

OBJECTIVES

- To understand the philosophy, concepts and techniques of auditing
- To understand principles and concepts of management system
- To understand the requirements and interpret ISO 15189:2022 revised standard.
- To acquire skills to undertake effective management system audits

COURSE OUTLINE

- Audit concepts
- ISO 15189:2022
- Interpretation
- Audit planning
- Conducting on-site audit
- Audit reporting and follow-up
- Accreditation
- Examination

WHO SHOULD ATTEND?

- Individuals wishing to perform audits to ISO 15189
- Companies seeking ISO 15189 accreditation
- Laboratory Managers and Supervisors
- Supplier quality auditors wishing to evaluate medical laboratory service suppliers
- Existing ISO 9001 auditors who are looking to expand their skills in the area of laboratory practices or who wish to audit medical laboratory environments
- Medical laboratory assessors

SIRIM STS Sdn Bhd

Building 3, SIRIM Complex,
1, Persiaran Dato' Menteri
P.O. Box 7035, Section 2,
40700 Shah Alam, Selangor
Tel : +603 5544 6200
Fax : +603 5544 6774
sirimsts@sirim.my
www.sirimsts.my

