



MiChem Dynamics
LEADING CHANGE

INTERNAL AUDITING OF BIOBANKING ORGANISATIONS TRAINING

This training course is designed to provide participants with a comprehensive understanding of internal auditing principles aligned with ISO 19011 and ISO 20387 standards. Tailored for professionals in the biotechnology and healthcare sectors, the course aims to equip participants with the skills and knowledge needed to conduct robust internal audits within the framework of quality management systems for clinical laboratories.

This course provides a specialized focus on internal auditing in the healthcare and biobanking sectors, integrating the foundational principles of ISO 19011 with the specific requirements of ISO 20387. Participants will leave equipped to navigate the unique challenges of clinical laboratory operations and contribute to the continual improvement of healthcare quality management systems.



THE COURSE WILL RUN OVER A PERIOD OF 3 DAYS

LEARNING OUTCOMES:

- Understand the principles and importance of internal auditing as per the ISO 19011.
- Exploring the role and responsibilities of an internal auditor.
- Learning the audit process, from planning to reporting.
- Developing skills in conducting risk-based audits.
- Preparation and conduct of internal audits based on requirements of ISO 20387:2018 and additional accreditation requirements.

WHO SHOULD ATTEND THIS COURSE:

- Quality assurance professionals in healthcare and biobanking
- Clinical laboratory managers and personnel
- Internal auditors specialising in ISO standards in the healthcare sector
- Anyone involved in the management and improvement of organizational processes

MINIMUM ENTRY REQUIREMENTS

- Fluency in English writing and reading skills

TUITION

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

PRE-REQUISITE:

- The delegate should have successfully completed an ISO 20387:2018 Quality management system course.

COURSE CONTENT

DAY 1

- Introduction to internal auditing and ISO 19011
 - Overview of internal auditing principles.
 - Introduction to ISO 19011 and its relevance.
 - Roles and responsibilities of internal auditors.
- Plan for and perform an audit within a quality management system
 - Risk-based audit planning.
 - Developing audit checklists and criteria.
 - Understanding the audit scope and objectives.
- Conducting the audit
 - Results of the audit are evaluated and interpreted
 - Techniques for effective information gathering.
 - Interview skills and effective communication.
 - On-site observation and evidence collection.
- Reporting and follow-up
 - Writing effective audit reports.
 - Communicating findings to stakeholders.
 - Follow-up procedures and corrective actions.

DAY 2

- Practical demonstration
 - Auditing of management systems based on ISO 20387:2018

DAY 3

- Practical demonstration
 - Auditing of technical activities based on ISO 20387:2018

