ISO 15189:2012 Medical laboratories

Course outline

Module 1: Introduction to ISO 15189:2012

Module 1: Introduction to ISO 15189:2012 is an introductory course designed to provide an overview of the ISO 15189:2012 standard for medical laboratories. It covers the scope and purpose of the standard, the requirements for accreditation, and the benefits of accreditation. It also provides an overview of the quality management system and the roles and responsibilities of laboratory personnel.

Lessons

- Overview of ISO 15189:2012
- Quality Management System Requirements
- Personnel Requirements
- Premises and Equipment Requirements
- Process Control Requirements
- Measurement Traceability Requirements
- Validation and Verification Requirements
- Proficiency Testing Requirements
- Internal Audits Requirements
- Management Review Requirements
- Complaints and Nonconformity Requirements
- Documentation Requirements
- Corrective and Preventive Action Requirements
- Risk Management Requirements
- Lab Accreditation Requirements

After completing this module, students will be able to:

- Understand the purpose and scope of ISO 15189:2012 and its application to medical laboratories.
- Identify the requirements of ISO 15189:2012 and how they relate to the quality management system of a medical laboratory.
- Develop a plan for implementing ISO 15189:2012 in a medical laboratory.
- Implement the requirements of ISO 15189:2012 in a medical laboratory.

Module 2: Quality Management System Requirements

Module 2: Quality Management System Requirements for ISO 15189:2012 Medical Laboratories course provides an overview of the requirements for establishing and maintaining a quality management system for medical laboratories. It covers topics such as the scope of the standard, the structure of the quality

management system, the requirements for documentation, and the requirements for management review. It also provides guidance on how to implement the standard and how to assess the effectiveness of the quality management system.

Lessons

- Introduction to Quality Management System Requirements
- Quality Management System Documentation
- Quality Management System Planning
- Quality Management System Implementation
- Quality Management System Monitoring and Measurement
- Quality Management System Improvement
- Quality Management System Auditing
- Quality Management System Risk Management
- Quality Management System Training
- Quality Management System Communication

After completing this module, students will be able to:

- Understand the requirements of ISO 15189:2012 for medical laboratories.
- Develop a Quality Management System (QMS) that meets the requirements of ISO 15189:2012.
- Implement the QMS in a medical laboratory setting.
- Monitor and evaluate the effectiveness of the QMS in meeting the requirements of ISO 15189:2012.

Module 3: Personnel Requirements

Module 3: Personnel Requirements is a course designed to provide an overview of the personnel requirements for medical laboratories to meet the ISO 15189:2012 standard. It covers topics such as personnel qualifications, training, and competency assessment, as well as the roles and responsibilities of personnel in the laboratory. The course also provides guidance on how to develop and implement personnel policies and procedures.

Lessons

- Qualifications and Training of Personnel
- Responsibilities of Personnel
- Documentation of Personnel Qualifications
- Competence Assessment of Personnel
- Supervision of Personnel
- Personnel Records
- Personnel Health and Safety
- Personnel Security
- Personnel Performance Evaluation
- Personnel Development

After completing this module, students will be able to:

- Understand the personnel requirements for medical laboratories according to ISO 15189:2012.
- Identify the roles and responsibilities of personnel in medical laboratories.
- Develop strategies to ensure personnel are adequately trained and qualified for their roles.
- Implement personnel management systems to ensure compliance with ISO 15189:2012.

Module 4: Premises and Environment

Module 4: Premises and Environment provides an overview of the requirements for the physical environment of a medical laboratory, including the premises, equipment, and safety measures. It covers topics such as the design and layout of the laboratory, the requirements for the laboratory environment, and the safety measures that must be taken to ensure the safety of personnel and the accuracy of results.

Lessons

- Establishing and Maintaining a Safe and Secure Environment
- Ensuring Appropriate Premises and Facilities
- Ensuring Appropriate Equipment and Supplies
- Ensuring Appropriate Waste Management
- Ensuring Appropriate Transport of Samples
- Ensuring Appropriate Storage of Samples
- Ensuring Appropriate Access to Premises and Facilities
- Ensuring Appropriate Access to Equipment and Supplies
- Ensuring Appropriate Access to Waste Management
- Ensuring Appropriate Access to Transport of Samples
- Ensuring Appropriate Access to Storage of Samples
- Ensuring Appropriate Security of Premises and Facilities
- Ensuring Appropriate Security of Equipment and Supplies
- Ensuring Appropriate Security of Waste Management
- Ensuring Appropriate Security of Transport of Samples
- Ensuring Appropriate Security of Storage of Samples
- Ensuring Appropriate Cleaning and Disinfection of Premises and Facilities
- Ensuring Appropriate Cleaning and Disinfection of Equipment and Supplies
- Ensuring Appropriate Cleaning and Disinfection of Waste Management
- Ensuring Appropriate Cleaning and Disinfection of Transport of Samples
- Ensuring Appropriate Cleaning and Disinfection of Storage of Samples

After completing this module, students will be able to:

- Understand the requirements for premises and environment for medical laboratories according to ISO 15189:2012.
- Identify the necessary infrastructure and equipment for medical laboratories.
- Develop a plan for the implementation of the premises and environment requirements.
- Monitor and evaluate the premises and environment of medical laboratories to ensure compliance with ISO 15189:2012.

Module 5: Equipment

Module 5 of the ISO 15189:2012 Medical Laboratories course covers the equipment used in medical laboratories. It provides an overview of the types of equipment used, the requirements for their use, and the maintenance and calibration of the equipment. It also covers the safety and quality control measures that should be taken when using the equipment.

Lessons

- Introduction to Equipment Requirements for ISO 15189:2012
- Equipment Selection and Maintenance
- Equipment Calibration and Verification
- Equipment Troubleshooting and Repair
- Equipment Documentation and Record Keeping
- Equipment Safety and Risk Management
- Equipment Validation and Qualification
- Equipment Performance Monitoring
- Equipment Troubleshooting and Problem Solving
- Equipment Quality Assurance and Control

After completing this module, students will be able to:

- Understand the requirements for the selection, installation, validation, maintenance and operation of laboratory equipment.
- Develop a plan for the implementation of laboratory equipment.
- Identify the necessary safety measures for the use of laboratory equipment.
- Develop a system for the monitoring and calibration of laboratory equipment.

Module 6: Reagents, Consumables and Reference Materials

Module 6: Reagents, Consumables and Reference Materials is a course designed to provide an overview of the requirements for reagents, consumables and reference materials in medical laboratories according to ISO 15189:2012. It covers topics such as the selection, storage, handling, and control of reagents, consumables and reference materials, as well as the requirements for their traceability and documentation.

Lessons

- Selection and Qualification of Reagents and Consumables
- Quality Control of Reagents and Consumables
- Storage and Handling of Reagents and Consumables
- Calibration and Validation of Reference Materials
- Traceability of Reference Materials
- Documentation and Record Keeping of Reagents and Consumables
- Risk Management of Reagents and Consumables
- Quality Assurance of Reference Materials
- Quality Improvement of Reagents and Consumables
- Quality Assurance of Reagents and Consumables

After completing this module, students will be able to:

- Understand the requirements for reagents, consumables and reference materials in ISO 15189:2012 Medical laboratories.
- Identify the appropriate reagents, consumables and reference materials for a given laboratory test.
- Evaluate the quality of reagents, consumables and reference materials used in the laboratory.
- Develop and implement a system for the selection, procurement, storage and use of reagents, consumables and reference materials.

Module 7: Samples and Specimens

Module 7: Samples and Specimens covers the requirements for the collection, handling, and storage of samples and specimens in medical laboratories. It outlines the responsibilities of the laboratory personnel, the requirements for sample and specimen labeling, and the requirements for the transport of samples and specimens. It also covers the requirements for the storage of samples and specimens, including the requirements for the storage of biological samples and specimens.

Lessons

- Specimen Collection and Handling
- Specimen Labeling and Identification
- Specimen Transport and Storage
- Specimen Rejection Criteria
- Specimen Quality Control
- Specimen Validation
- Specimen Traceability
- Specimen Integrity
- Specimen Security
- Specimen Disposal

After completing this module, students will be able to:

- Understand the importance of sampling and specimen collection in medical laboratory testing.
- Identify the different types of samples and specimens used in medical laboratory testing.
- Develop and implement procedures for the collection, handling, and storage of samples and specimens.
- Understand the requirements for the traceability of samples and specimens.

Module 8: Test and Calibration Methods

Module 8: Test and Calibration Methods module for ISO 15189:2012 Medical laboratories course provides an overview of the principles and practices of test and calibration methods used in medical laboratories. It covers topics such as the selection of appropriate methods, the validation of methods, the use of reference materials, and the calibration of instruments. The module also covers the requirements for proficiency testing and the use of quality control materials.

Lessons

- Introduction to Test and Calibration Methods
- Quality Control and Quality Assurance
- Establishing and Maintaining Traceability
- Calibration of Test Equipment
- Validation of Test Methods
- Proficiency Testing
- Internal Quality Control
- External Quality Assessment
- Risk Management
- Documentation and Record Keeping

After completing this module, students will be able to:

- Understand the principles and requirements of ISO 15189:2012 for test and calibration methods.
- Develop and implement a quality management system for test and calibration methods.
- Identify and evaluate the accuracy and precision of test and calibration methods.
- Develop and implement a process for validating test and calibration methods.

Module 9: Reporting of Results

Module 9: Reporting of Results is a module in the ISO 15189:2012 Medical Laboratories course that focuses on the importance of accurate and timely reporting of laboratory results. It covers topics such as the types of reports, the format of reports, and the importance of quality assurance in the reporting process. It also covers the importance of communication between the laboratory and the requesting physician or other healthcare provider.

Lessons

- Overview of the Reporting of Results Module
- Quality Assurance Requirements for Reporting of Results
- Reporting of Results in the Laboratory Information System
- Reporting of Results to the Requesting Physician
- Reporting of Results to the Patient
- Reporting of Results to Other Laboratories
- Reporting of Results to Regulatory Agencies
- Reporting of Results to External Quality Assessment Schemes
- Reporting of Results to Other Health Care Providers
- Reporting of Results to Research Studies
- Reporting of Results to Public Health Agencies
- Reporting of Results to Other Relevant Stakeholders
- Documentation Requirements for Reporting of Results
- Training Requirements for Reporting of Results

After completing this module, students will be able to:

- Understand the requirements of ISO 15189:2012 for reporting of results.
- Develop a reporting system that meets the requirements of ISO 15189:2012.

- Implement a reporting system that meets the requirements of ISO 15189:2012.
- Monitor and evaluate the performance of the reporting system to ensure it meets the requirements of ISO 15189:2012.

Module 10: Proficiency Testing

Module 10: Proficiency Testing for ISO 15189:2012 Medical Laboratories course provides an overview of the requirements for proficiency testing (PT) as outlined in the ISO 15189:2012 standard. It covers the purpose of PT, the types of PT available, the requirements for participation, and the evaluation of results. It also provides guidance on how to develop and implement a PT program.

Lessons

- Overview of Proficiency Testing
- Types of Proficiency Testing
- Benefits of Proficiency Testing
- Proficiency Testing Requirements for ISO 15189:2012
- Proficiency Testing Strategies
- Proficiency Testing Documentation
- Proficiency Testing Results Analysis
- Proficiency Testing Quality Assurance
- Proficiency Testing Troubleshooting
- Proficiency Testing Best Practices

After completing this module, students will be able to:

- Understand the requirements of ISO 15189:2012 Medical laboratories for proficiency testing.
- Develop proficiency testing plans and procedures to ensure the accuracy and reliability of laboratory results.
- Evaluate proficiency testing results and take corrective action when necessary.
- Implement quality assurance measures to ensure the accuracy and reliability of laboratory results.

Module 11: Internal Quality Control

Module 11: Internal Quality Control for ISO 15189:2012 Medical Laboratories course provides an overview of the principles and practices of internal quality control (IQC) in medical laboratories. It covers topics such as the purpose of IQC, the components of IQC, the selection and use of IQC materials, and the evaluation of IQC results. It also provides guidance on the implementation of IQC in medical laboratories and the use of IQC to ensure the accuracy and reliability of laboratory results.

Lessons

- Understanding the Requirements of ISO 15189:2012
- Establishing an Internal Quality Control System
- Implementing Internal Quality Control Procedures
- Monitoring Internal Quality Control Performance
- Evaluating Internal Quality Control Results

- Corrective Action and Preventive Action
- Documenting Internal Quality Control
- Internal Quality Control Audits
- Internal Quality Control Reporting
- Continuous Improvement of Internal Quality Control

After completing this module, students will be able to:

- Understand the importance of internal quality control and its role in the laboratory.
- Develop and implement an internal quality control program that meets the requirements of ISO 15189:2012.
- Monitor and evaluate the performance of the internal quality control program.
- Identify and address any issues or discrepancies in the internal quality control program.

Module 12: External Quality Assessment

Module 12: External Quality Assessment module for ISO 15189:2012 Medical laboratories course provides an overview of the requirements for external quality assessment (EQA) for medical laboratories. It covers the principles of EQA, the roles and responsibilities of the laboratory and the EQA provider, and the requirements for the design and implementation of an EQA program. It also provides guidance on the interpretation of EQA results and the corrective action that should be taken when necessary.

Lessons

- Overview of External Quality Assessment
- Benefits of External Quality Assessment
- Types of External Quality Assessment
- Quality Assurance Programs
- Quality Control Programs
- Quality Improvement Programs
- Quality Management Systems
- Quality Assurance and Quality Control in Medical Laboratories
- Quality Assurance and Quality Control in ISO 15189:2012
- Quality Assurance and Quality Control in Clinical Laboratories
- Quality Assurance and Quality Control in Diagnostic Laboratories
- Quality Assurance and Quality Control in Research Laboratories
- Quality Assurance and Quality Control in Pathology Laboratories
- Quality Assurance and Quality Control in Blood Banks
- Quality Assurance and Quality Control in Microbiology Laboratories
- Quality Assurance and Quality Control in Molecular Diagnostics Laboratories
- Quality Assurance and Quality Control in Cytogenetics Laboratories
- Quality Assurance and Quality Control in Histology Laboratories
- Quality Assurance and Quality Control in Immunology Laboratories
- Quality Assurance and Quality Control in Toxicology Laboratories

After completing this module, students will be able to:

- Understand the requirements of ISO 15189:2012 Medical laboratories and how to apply them in practice.
- Develop an effective external quality assessment program for medical laboratories.
- Identify and address any non-conformities in the laboratory's quality management system.
- Implement corrective and preventive actions to ensure the laboratory meets the requirements of ISO 15189:2012.

Module 13: Complaints and Corrective Action

Module 13: Complaints and Corrective Action is a course designed to help medical laboratories understand and implement the requirements of ISO 15189:2012. It covers topics such as the importance of complaints and corrective action, how to identify and investigate complaints, and how to develop and implement corrective action plans. The course also provides guidance on how to document and report complaints and corrective action.

Lessons

- Understanding the Complaint Process
- Investigating Complaints
- Documenting Complaints
- Corrective Action Planning
- Implementing Corrective Action
- Monitoring Corrective Action
- Reporting Complaints and Corrective Action
- Root Cause Analysis
- Preventive Action
- Internal Auditing of Complaints and Corrective Action

After completing this module, students will be able to:

- Understand the importance of a complaints and corrective action system in a medical laboratory.
- Identify the different types of complaints and corrective actions that can be taken in a medical laboratory.
- Develop and implement a complaints and corrective action system in accordance with ISO 15189:2012.
- Monitor and evaluate the effectiveness of the complaints and corrective action system.

Module 14: Document Control

Module 14: Document Control module for ISO 15189:2012 Medical laboratories course provides an overview of the requirements for document control in medical laboratories. It covers topics such as document control procedures, document control systems, document control forms, document control registers, document control templates, document control policies, and document control audits. It also provides guidance on how to ensure that documents are properly controlled and maintained in accordance with the ISO 15189:2012 standard.

Lessons

- Document Control Procedures
- Document Identification and Traceability
- Document Change Control
- Document Distribution and Retrieval
- Document Archiving and Retention
- Document Security and Confidentiality
- Document Review and Approval
- Document Formatting and Layout
- Document Version Control
- Document Control Auditing

After completing this module, students will be able to:

- Understand the importance of document control in medical laboratories and its role in meeting the requirements of ISO 15189:2012.
- Develop and implement a document control system that meets the requirements of ISO 15189:2012.
- Establish procedures for the review, approval, and distribution of documents.
- Monitor and audit document control processes to ensure compliance with ISO 15189:2012.

Module 15: Records Management

Module 15: Records Management module for ISO 15189:2012 Medical laboratories course provides an overview of the requirements for records management in medical laboratories. It covers topics such as the purpose of records management, the types of records that must be kept, the importance of accurate and complete records, and the methods for storing and retrieving records. It also provides guidance on how to ensure that records are kept securely and are accessible when needed.

Lessons

- Understanding the Principles of Records Management
- Establishing Records Management Policies and Procedures
- Implementing Records Management Systems
- Managing Records Retention and Disposal
- Ensuring Records Security and Confidentiality
- Auditing Records Management Systems
- Training Staff on Records Management
- Developing Records Management Strategies
- Managing Electronic Records
- Managing Records in a Digital Environment

After completing this module, students will be able to:

- Understand the importance of records management in medical laboratories and its impact on quality assurance.
- Develop and implement a records management system that meets the requirements of ISO 15189:2012.

- Identify and classify records according to their importance and relevance.
- Develop and implement procedures for the secure storage, retrieval, and destruction of records.

Module 16: Management Review

Module 16: Management Reviewmodule for ISO 15189:2012 Medical laboratories course provides an overview of the management review process and the requirements of ISO 15189:2012. It covers topics such as the purpose of management review, the scope of the review, the review process, and the review criteria. It also provides guidance on how to document the review and how to use the results to improve the laboratory's performance.

Lessons

- Overview of the Management Review Process
- Establishing the Scope of the Management Review
- Preparing for the Management Review
- Conducting the Management Review
- Documenting the Management Review
- Follow-up and Improvement Actions
- Benefits of Management Review
- Challenges of Management Review
- Quality Improvement Strategies
- Risk Management Strategies
- Quality Assurance Strategies
- Quality Control Strategies
- Quality System Auditing
- Quality System Documentation
- Quality System Training
- Quality System Monitoring
- Quality System Improvement
- Quality System Maintenance
- Quality System Compliance
- Quality System Performance Measurement

After completing this module, students will be able to:

- Understand the purpose and scope of a management review in accordance with ISO 15189:2012.
- Identify the key elements of a management review and the associated documentation.
- Develop a plan for conducting a management review and identify the necessary resources.
- Analyze the results of a management review and develop corrective and preventive actions.

Module 17: Risk Management

Module 17: Risk Management for ISO 15189:2012 Medical Laboratories course provides an overview of the risk management process and how it applies to medical laboratories. It covers topics such as risk identification, risk assessment, risk control, and risk communication. It also provides guidance on how to develop and implement a risk management plan.

Lessons

- Introduction to Risk Management in Medical Laboratories
- Risk Identification and Analysis
- Risk Evaluation and Control
- Risk Communication and Documentation
- Risk Monitoring and Review
- Risk Management Strategies
- Risk Management Tools and Techniques
- Risk Management and Quality Improvement
- Risk Management and Regulatory Compliance
- Risk Management and Incident Reporting

After completing this module, students will be able to:

- Understand the principles of risk management and its application to medical laboratories.
- Identify potential risks and develop strategies to mitigate them.
- Develop a risk management plan for a medical laboratory.
- Implement risk management processes and procedures in a medical laboratory.

Module 18: Accreditation and Certification

Module 18: Accreditation and Certification module for ISO 15189:2012 Medical laboratories course provides an overview of the accreditation and certification process for medical laboratories. It covers the requirements of ISO 15189:2012, the accreditation process, and the certification process. It also provides guidance on how to prepare for and maintain accreditation and certification.

Lessons

- Overview of ISO 15189:2012 Medical Laboratories Accreditation and Certification
- Benefits of ISO 15189:2012 Medical Laboratories Accreditation and Certification
- Quality Management System Requirements for ISO 15189:2012 Medical Laboratories
- Documentation Requirements for ISO 15189:2012 Medical Laboratories
- Internal Auditing for ISO 15189:2012 Medical Laboratories
- Management Review for ISO 15189:2012 Medical Laboratories
- Corrective and Preventive Action for ISO 15189:2012 Medical Laboratories
- Risk Management for ISO 15189:2012 Medical Laboratories
- Competence and Training Requirements for ISO 15189:2012 Medical Laboratories
- Validation and Verification Requirements for ISO 15189:2012 Medical Laboratories
- Monitoring and Measurement Requirements for ISO 15189:2012 Medical Laboratories
- Nonconformity and Corrective Action Requirements for ISO 15189:2012 Medical Laboratories
- Continual Improvement Requirements for ISO 15189:2012 Medical Laboratories
- Accreditation and Certification Process for ISO 15189:2012 Medical Laboratories
- Legal and Regulatory Requirements for ISO 15189:2012 Medical Laboratories
- Challenges and Opportunities for ISO 15189:2012 Medical Laboratories Accreditation and Certification
- Best Practices for ISO 15189:2012 Medical Laboratories Accreditation and Certification

- Case Studies of ISO 15189:2012 Medical Laboratories Accreditation and Certification

After completing this module, students will be able to:

- Understand the requirements of ISO 15189:2012 Medical laboratories and how to apply them in practice.
- Develop a quality management system that meets the requirements of ISO 15189:2012 Medical laboratories.
- Prepare for and successfully complete the accreditation process for ISO 15189:2012 Medical laboratories.
- Demonstrate the ability to maintain and improve the quality management system in accordance with ISO 15189:2012 Medical laboratories.