CLSI Laboratory Quality Management System

Certificate Program Syllabus

Learning Objectives

At the conclusion of this course, you will be able to:

1. Demonstrate a basic understanding of the processes your laboratory needs to implement and maintain an effective QMS.
2. Determine your personal level of QMS knowledge and address any gaps.
3. Develop a foundation for pursuing more advanced quality certification.

How this Course Is Organized

Each QSE module contains all the following features:

A reference list points you to other sources for more detailed information. Additional resources are provided as separate documents throughout the course that you can use or customize as needed.

A set of learning objectives describes the outcomes you should achieve when the module is completed.

Descriptions of the requirements for that QSE.

Explanations of what your laboratory can do to meet the requirements.

Quiz questions to check your knowledge throughout the course.

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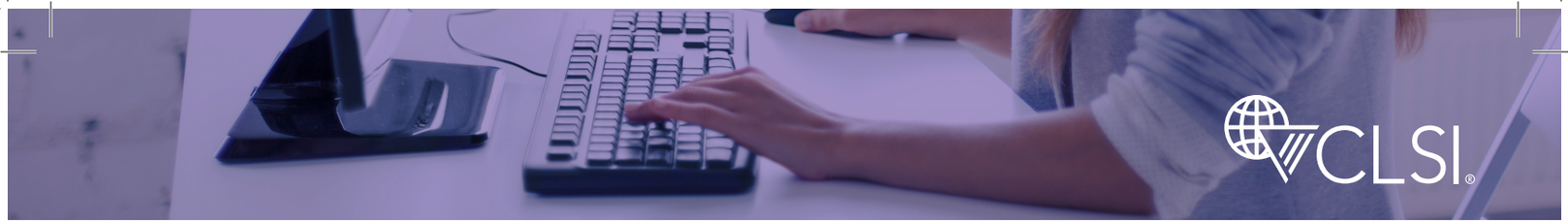


Module 1: Organization and Leadership

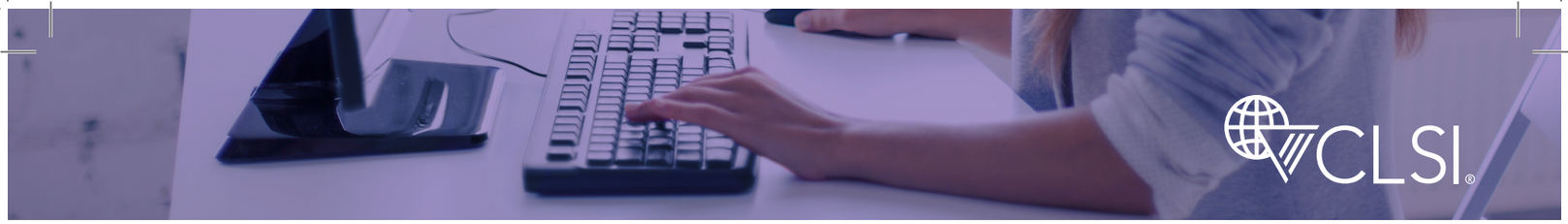
1. Communicate a vision for quality to laboratory personnel.
2. Prepare a rationale for a QMS.
3. Develop your laboratory's quality policy.
4. Describe an organizational structure.
5. Implement a QMS.
6. Prepare an effective quality manual.
7. Support quality planning.
8. Develop a management review process.

Module 2: Customer Focus

1. Identify your laboratory's customers and their expectations.
2. Evaluate your laboratory's capability.
3. Measure customer and user satisfaction.
4. Manage and record complaints.

Module 3: Facilities and Safety Management

1. Describe how facility design and modification affect personnel efficiency and safety.
2. Define access to the laboratory for safety and security.
3. Manage facility use and maintenance.
4. Develop a communications system.
5. Describe a variety of safety programs required for medical laboratories.



Module 4: Personnel Management

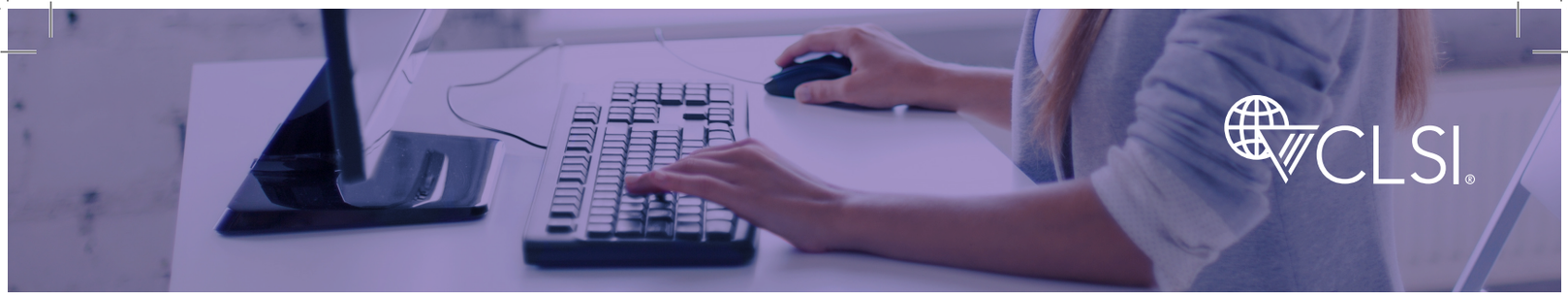
1. Prepare job qualifications and a job description process.
2. Develop an orientation program for the laboratory.
3. Review personnel training.
4. Assess personnel competence.
5. Identify opportunities for continuing education and professional development.
6. Implement a performance evaluation process.
7. Define an end of employment policy, process, and procedure.
8. Organize personnel files.

Module 5: Supplier and Inventory Management

1. Outline processes to select suppliers and identify qualifications.
2. Arrange agreements for materials and services.
3. Provide feedback to suppliers as to whether they meet your laboratory's expectations.
4. Develop a process for inspection and verification of received materials.
5. Classify storage and handling of materials.
6. Identify key factors in maintaining an inventory of laboratory reagents and supplies.
7. Describe the identification and traceability of critical materials.

Module 6: Equipment Management

1. Manage the selection and procurement of new equipment.
2. Describe the requirements for qualifying equipment before initiating its use.
3. Calibrate measurement equipment.
4. Establish an equipment maintenance program.
5. Decommission equipment.
6. Locate equipment files and records.

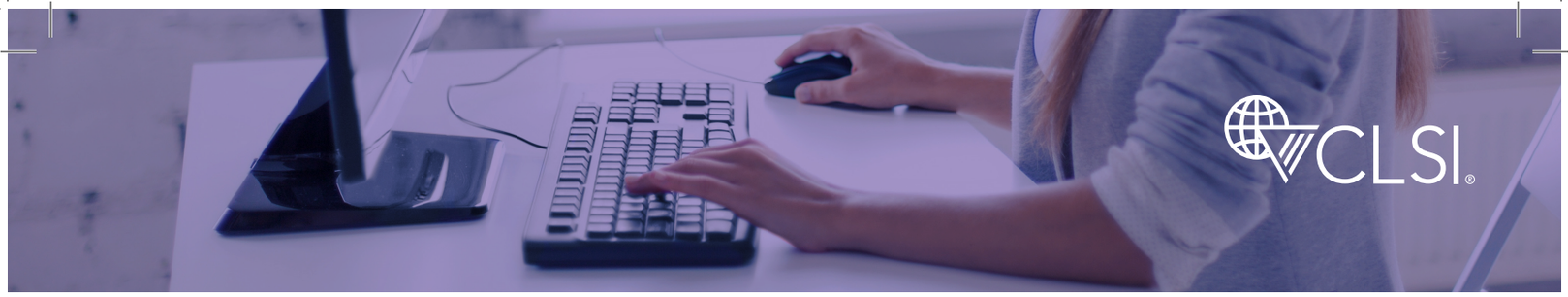


Module 7: Process Management

1. Define process management.
2. Analyze and document the laboratory's QSE activities & path of workflow processes.
3. Review process vs procedure.
4. Implement a process for validation or verification of new and changed QSE and path of workflow processes.
5. Develop a Quality Control Plan (QCP) for each laboratory examination method.
6. Implement a change management plan.
7. Establish a risk management process.

Module 8: Documents and Records Management

1. Distinguish between documents and records.
2. Review the purpose and example process of documents and records management.
3. Apply the four different document types in laboratory work.
4. Recognize document identification and control.
5. Implement a process to create and approve documents.
6. Develop a process to make changes to documents.
7. Define document archival, storage, and retention.
8. Review records creation and identification.
9. Describe records collection and review.
10. Implement a process for making changes to records.
11. Discuss records storage, maintenance, and retention.
12. Develop records security and access.
13. Schedule and process records disposal.

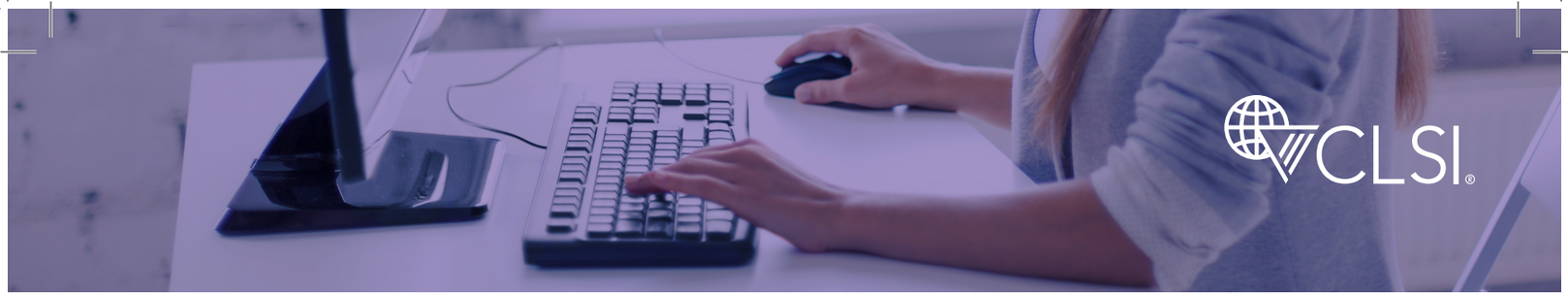


Module 9: Information Management

1. Differentiate between equipment management and information management.
2. Define data and information.
3. Plan for overall information needs.
4. Explain confidentiality of protected information and data.
5. Maintain security needs for data and information access.
6. Describe processes for verifying data integrity after transmissions or transfers.
7. Plan for information availability during downtime.

Module 10: Nonconforming Event Management

1. Review the purpose and examples of Nonconforming Event (NCE) Management.
2. Review just culture behaviors.
3. Describe the parts of a NCE management program.
4. Develop a process to identify, report, and record NCEs.
5. Demonstrate a process to investigate NCEs and complaints.
6. Establish a process for recalls and reporting.
7. Identify processes that manage the classification, analysis, and presentation of data and information.
8. Construct processes that need root cause analysis and improvement.
9. Recognize a process to report NCE information for management review.

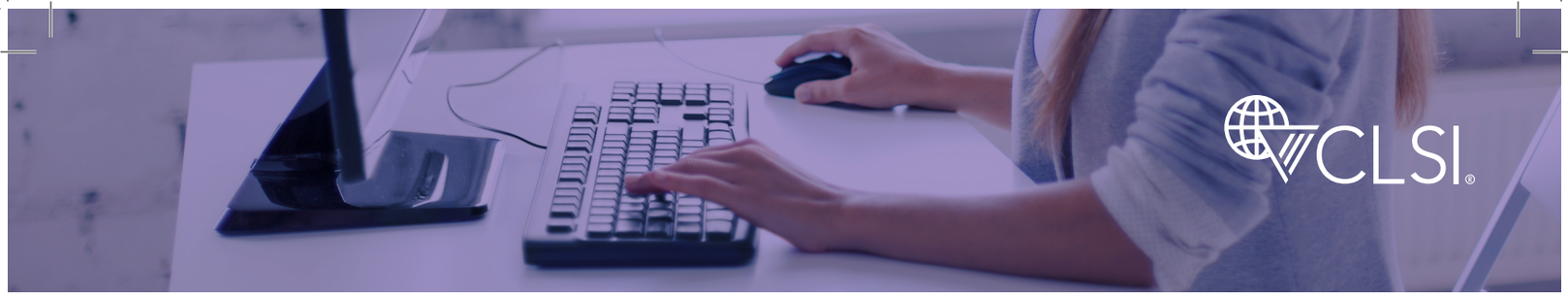


Module 11: Assessments

1. Explore the purpose and types of assessments.
2. Describe the required external and internal assessment processes.
3. Develop your laboratory's process for managing an external accreditation assessment.
4. Develop your laboratory's process for participation in Proficiency Testing (PT) or External Quality Assessment (EQA).
5. Examine alternative assessment processes.
6. Define an internal audit report.
7. Develop, implement, and monitor quality indicators.
8. Identify a laboratory performance comparison.
9. Address blood utilization monitoring, if applicable.
10. Incorporate assessment information into a quality report.

Module 12: Continual Improvement

1. Explain how a laboratory can participate in quality improvement activities at the organizational level.
2. Define a strategy for a continual improvement (CI) program.
3. Identify opportunities for improvement.
4. Select an opportunity to change.
5. Generate solutions.
6. Implement solutions.
7. Evaluate effects of solutions.
8. Integrate and sustain improvements.
9. Identify various definitions, concepts, models, and tools used in an effective CI program.



Summary and Conclusion: CLSI QMS Review

1. Review how the CLSI QMS model was developed.
2. Summarize the structure of the CLSI QMS model.
3. Recognize the laboratory path of workflow.
4. Differentiate between QC, QA, and the QMS.
5. Review the four quality costs.
6. Define key messages from each QSE.
7. Obtain your program certificate after completing the final exam.