Syllabus

# Certificate Course on

# Laboratory Quality Management System (Technical and Non - Technical)


**ORBITO ASIA DIAGNOSTICS**

737E, Puliyakulam Road
Coimbatore- 641 045 Tamil Nadu, India
Ph. 0422 4030201


Affiliated to


**BHARATHIAR UNIVERSITY**

(A state University, Accredited with "A" Grade by NAAC,
Ranked 13th among Indian Universities by MHRD- NIRF,
World Ranking: Times – 801 – 1000, Shanghai – 901 -1000,
URAP -982)
Coimbatore – 641 046, Tamil Nadu, India


2022 – 2023 Onwards

**About Us:**

Orbito Asia Diagnostics is a comprehensive healthcare facility for imaging and diagnostic facilities, under one roof with NABL, NABH & ISO accreditation. We are one of the largest COVID RT PCR testing laboratory with the capacity of >25000 tests per day with fully automated robotic liquid handling systems. It prides of housing the latest infrastructure, the best possible medical facilities, accompanied with the most competitive prices and thorough individual care so that the customer can have the diagnostic tests done at the most efficient and cost effective means at a single point by our experienced and certified doctors and friendly supportive staff. We strive to provide ultimate diagnostic services to our clients with accurate results, highest quality imaging and comprehensive health check-up services with complete care, courtesy and compassion to our customers. Orbito Asia provides diagnostic solutions that improve patient health and ensure consumer safety. Orbito Asia is determined to continue to play a pioneering role by innovating and designing the diagnostics of the future to address the major challenges for public health. Orbito Asia offers more than 300 different tests and special profiles in pathology and diagnostic and scan services. With more than 20 collection centres across the state, our diagnostic services are unsurpassed. We believe one of the most important facets of being an outstanding reference laboratory is the quality assurance we provide in every result.

**Program Highlights:**

- This certification course of 3 months is designed to fulfil the need for highly trained personnel in Laboratory Quality Management System to maintain an error free environment in diagnosis.
- This practical intensive curriculum is delivered through lectures by the renowned faculty of Bharathiar University and various case studies.
- Regular theory and practical session will be conducted along with seminars carried out by Quality Manager and Deputy Quality Manager.
- Experiential learning at Orbito Asia Diagnostics and case studies conducted by quality coordinators helps the students deepen their knowledge about Quality Control activities carried out in the laboratory.
- The course is associated with department of Biotechnology – Bharathiar University for guest lectures and higher end Practicals using their advanced facility with the help of the distinguished faculty members of the department.

**Eligibility:**

- B.Sc/M.Sc (Molecular biology, Microbiology, Biochemistry and Allied sciences)
- B.Tech/M.Tech (Biotechnology and Allied science)
- MBBS/MD
- Candidates working in a clinical lab, hospital, academic/research institution, Pharmaceutical, Food industry and any health sector with an interest to learn Laboratory Quality Management System with statistical analysis with a minimum graduation degree.

| Year | Subject Code | Title of the course | Hours/ Week |
|---|---|---|---|
| **2022 -2023 onwards** | **22LQMS** | **Laboratory Quality Management System** | **25** |

**Program Educational Objectives (PEOs):**

This programme aims to address the growing need of highly skilled clinical laboratory technologist trained in **Laboratory Quality Management System**. The specific programme objectives are developing professionals with the following competencies.

| | |
|---|---|
| PEO 1 | **To develop Problem solving skills to overcome errors through statistical analysis occurring in clinical laboratories** |
| PEO 2 | **Manage an organization's policies, procedures and processes to promote continual improvement** |
| PEO 3 | **To Ensure importance of quality Control, Customer satisfaction, Satisfy regulatory requirement, and create more efficient processes.** |

**Programme Outcome (POs):**

On completion of the certification course on laboratory Quality management System, the students will be able to :

| | |
|---|---|
| PO 1 | To Conduct Internal Audits. |
| PO 2 | To ensure Good laboratory clinical practices (GLCP). |
| PO 3 | To face the External Audits. |
| PO 4 | To understand statistics to ensure the precision and accuracy of Quality control materials and EQAS. |
| PO 5 | To Prepare Standard operating procedures (SOP). |

**Assessment Criteria:**

| S. No. | Guidelines for Assessment |
|---|---|
| 1. | A combination of theory and practical courses will be offered in this certificate course. Thecourses will be offered with 60% practical and 40% theory. |
| 2. | **Duration :** 3 months |
| 3. | **CREDIT: 20** |
| 4. | **Grade and examination pattern:** Semester pattern (both internal and external) as perthe Bharathiar University Examination norms |
| 5. | **Evaluation:** As per the Bharathiar University Examination norms |
| 6. | **Certificate:** Based on the report of the post – training assessment jointly conducted by Bharathiar University and Orbito Asia Diagnostics |

**Certificate Course on Laboratory Quality Management System**

**Scheme of Examinations**

| S.No | Subject | Hours | | Exam | | Total marks | Credits |
|---|---|---|---|---|---|---|---|
| | | T | P | CIA | ESE | | |
| **Course Duration – 3 months** | | | | | | | |
| **Lecture** | | | | | | | |
| Implementation of quality in laboratory management | | **90** | **-** | **50** | **50** | **100** | **6** |
| 1 | Overview of the quality management system : Facilities and safety overview: Equipment management | | | | | | |
| 2 | Purchasing and Inventory: Sample management: Process Control Quality control for quantitative tests | | | | | | |
| 3 | Quality control for qualitative and semi – quantitative procedures: Assessment: External quality assessment (EQA) : Norms and Accreditation | | | | | | |
| 4 | Personnel management: Customer service: Occurrence management: Process Improvement | | | | | | |
| 5 | Documents and Records : Information management & Statistical Analysis | | | | | | |
| **Practical** | | | | | | | |
| 2. | Biosafety Management | **-** | **90** | **45** | **45** | **90** | **6** |
| | Scenario — Equipment Failure | | | | | | |
| | Scenario — Purchasing and Inventory | | | | | | |
| | Sample Management | | | | | | |
| | Calculation of Mean and Standard Deviation, Levey- Jennings Charts | | | | | | |
| | QC Procedures and QC for serology | | | | | | |
| | Scenario—Organizing an Internal Audit | | | | | | |
| | EQA and Processing Proficiency Testing Samples | | | | | | |
| 3. | Scenario — PreparationsNeeded for a Laboratory Accreditation | | | | | | |
| | Scenario — Overview of Personnel | | | | | | |
| | Restoring Customer Confidence and Planning a Customer Satisfaction Survey | | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Laboratory errors | - | **90** | **45** | **45** | **90** | **6** |
| | Scenario — Improving Laboratory Processes | | | | | | |
| | Differentiating Documents from Records and The Quality Manual | | | | | | |
| | Assessing the Relevancy of a Computerized Laboratory Information System and Developing a System for Assigning | | | | | | |
| | Understanding Planning, Implementation, and Monitoring Processes; Understanding Managerial andStaff Responsibilities | | | | | | |
| 4. | Mini Project | | **30** | **10** | **10** | **20** | **2** |
| **Total** | | **90** | **210** | **140** | **140** | **300** | **20** |

**CIA:** continuous Internal Assessment; **ESE:** End Semester Examination

| Year | Course Code | Title of the paper | L | T | P | C |
|---|---|---|---|---|---|---|
| **2022 -2023 onwards** | **22LQMS01** | Implementation of quality in laboratory management | **5** | **5** | **-** | **6** |

**Course Objectives:**

1. Make students understand the basics of LQMS
2. Make students understand the importance of LQMS
3. Establishment of standardized operating methods
4. To guarantee the quality and reproducibility of study results
5. To make Statistical analysis.

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

| | | |
|---|---|---|
| 1. | Understand the basics of LQMS | K1 & K2 |
| 2. | Understand the importance of LQMS | K1 & K2 |
| 3. | Standardized operating methods | K1 & K2 |
| 4. | Quality and reproducibility of study results | K1 & K2 |
| 5. | Statistical analysis | K3 & K4 |

**K1 –** Remember; **K2 –** Understand; **K3 –** Perform; **K4 –** Analyse

| Subject code | 22LQMS01 | Implementation of quality in laboratory management |
|---|---|---|
| **Unit:1** | **Overview of the quality management system : Facilities and safety overview: Equipment management** | **20 hours** |
| Importance of quality management system; Definition of quality and quality management system; The quality management system model; History of LQM; International Laboratory Standards Importance of safety; Laboratory design; Geographic or spatial organization; Physical aspects of premises and rooms ; Safety management program; Identification of risks; Personal Protective Equipment (PPE); Emergency management and first aid ; Role in quality management system; Selecting and acquiring equipment; Getting equipment ready for service Implementing an equipment maintenance program; Troubleshooting, service, repair and retiring equipment; Equipment maintenance and documentation. | | |
| **Unit:2** | **Purchasing and Inventory: Sample management: Process Control Quality control for quantitative tests** | **20 hours** |
| Role in quality management systems; Purchasing; Implementing an inventory management program; Quantification ; Forms and logs; Receipt and storage of supplies; Monitoring inventory; Role in quality management system; The laboratory handbook; Collection and preservation; Sample processing; Sample storage, retention and disposal; Sample transport; Introduction to quality control; QC for varying methods; Elements of a QC program; Role in quality management system; Control materials; Establishing the value range for the control material; Graphical representation of control ranges ; Interpreting quality control data; Using quality control information. | | |
| **Unit:3** | **Quality control for qualitative and semi – quantitative procedures: Assessment: External quality assessment (EQA) : Norms and Accreditation** | **20 hours** |
| Role in quality management system; Quality control materials; Quality control of stains; QC of microbiological media; Role in quality management system; External audit; Internal audit; Internal audit program; Actions as result of audit; Role in quality management system; Proficiency testing; Other EQA methods; Comparison of EQA methods; Managing EQA in the laboratory; Role in quality management system; International standards and standardization bodies; National Standards and technical guidelines; Certification and accreditation; Process of accreditation; Benefits of accreditation. | | |

| Unit:4 | Personnel management: Customer service: Occurrence management: Process Improvement | 20 hours |
|---|---|---|
| Role in quality management system; Recruitment and orientation; Competency and competency assessment; Training and continuing education; Employee performance appraisal; Personnel records ; Role in quality management system; The laboratory clients – the customers; Assessing and monitoring customer satisfaction; Customer satisfaction surveys; role in quality management system; Sources and consequences of laboratory error; Investigation of occurrences; Rectifying and managing occurrences; Role in quality management system; Tools for process Improvement; Quality Indicators; Selecting Quality indicators; Implementing process improvement. | | |
| **Unit:5** | **Documents and Records : Information management & Statistical Analysis** | **20 hours** |
| Role in quality management system; Overview of documents; The quality manual; Standard operating procedures (SOP); Document control; Overview of records; Storing documents and records; Role in quality management system; Elements of information management; Manual paper-based systems; Computerized laboratory information systems; Role in quality management system; Management role; Organizational structure; Organizational functions: Planning; Organizational functions: Implementation; The laboratory quality manual ; Westgard rules – 12S, 22S,13S,R4S,10X Rules; Mean, Standard Deviation, Coefficient of variation, Standard deviation Index. | | |

**Mapping with program outcomes**

| COs | PO1 | PO2 | PO3 | PO4 | PO5 |
|---|---|---|---|---|---|
| **CO1** | S | S | S | S | S |
| **CO2** | M | S | S | S | S |
| **CO3** | S | S | S | S | S |
| **CO4** | L | M | S | M | S |
| **CO5** | L | M | M | M | S |

**S - Strong; M – Medium; L - Low**

**Reference books**


1. Crosby PB. Quality without tears: the art of hassle-free management. New York, McGraw-Hill, 1995.
2. Deming WE. Out of the crisis. Cambridge, MIT Press, 1982.
3. ISO 9000:2005. Quality management systems –fundamentals and vocabulary. Geneva, International Organization for Standardization, 2005.
4. CDC and NIH. Biosafety in microbiological and biomedical laboratories, 4th ed. United States Government Printing Office, United States Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, 1999.
5. Collins CH, Kennedy DA. Laboratory-acquired infections. In: Laboratory-acquired infections: history, incidence, causes and preventions, 4th ed. Oxford, United Kingdom, Butterworth - Heinemann, 1999:1–37.
6. WHO. Guidelines for health care equipment donations. Geneva, World Health Organization, 2000 (http://www.who.int/hac/techguidance/pht/en/1_equipment %20 donationbuletin82WHO. pdf, accessed 11 April 2011).
7. King B. NIOSH Health Hazard Evaluation Report No. 2004-0081-3002. New York University School of Medicine, New York, 2006:11 (http://www.cdc. gov/niosh/hhe/reports/pdfs/2004-0081-3002.pdf, accessed 11 April 2011).
8. WHO. Guidelines for health care equipment donations. Geneva, World Health Organization, 2000 (http://www.who.int/hac/techguidance/pht/en/ _equipment%20 donationbuletin82WHO. pdf, accessed 11 April 2011).
9. ICAO. Technical instructions for the safe transport of dangerous goods by air, 2007–2008 ed. (Doc 9284). Montreal, Canada, International Civil Aviation Organization, 2006.
10. ISO 15394:2000. Packaging—bar code and two-dimensional symbols for shipping, transport and receiving labels. Geneva, International Organization for Standardization, 2000.
11. ISO 21067:2007. Packaging—vocabulary. Geneva, International Organization for Standardization, 2007.
12. ISO 9000:2005. Quality management systems–fundamentals and vocabulary. Geneva, International Organization for Standardization, 2005.
13. WHO. External quality assessment of health laboratories: report on a WHO Working Group. Geneva, World Health Organization, 1981.

14. CLSI. User protocol for evaluation of qualitative test performance, approved guideline—2nd ed. EP12-A2 (electronic document). Wayne, PA, Clinical and Laboratory Standards Institute, 2008.
15. CLSI. Abbreviated identification of bacteria and yeast, approved guideline—2nd ed. M35-A2. Wayne, PA, Clinical and Laboratory Standards Institute, 2008.
16. CLSI. Performance standards for antimicrobial disk susceptibility tests, approved standards-18th informational supplement. M100-S18. Wayne, PA, Clinical and Laboratory Standards Institute, 2008.
17. Cochran C. The fi ve keys to a successful internal audit program. The Auditor 2:1. Chico, CA, Paton Press, 2007 (http://www.dnvcert.com/DNV/Certifi cation1/Resources1/Articles/ Newsletter Info/Five KeystoaSuccessfulI/).
18. ISO 9000:2005. Quality management systems–fundamentals and vocabulary. Geneva, International Organization for Standardization, 2005.
19. Dawson D, Kim SJ and the Stop Tuberculosis (TB) Unit at the Western Pacific Regional Office (WPRO). Quality assurance of sputum microscopy in DOTS programmes. World Health Organization Regional Office for the Western Pacific, 2003. Deutscher Akkreditierungs Rat (DAR). Acronyms, links, and e-mail addresses (http://www.dar.bam.de/indexe.html).
20. ISO/IEC 17011:2004. Conformity assessment—general requirements for accreditation bodies accrediting conformity assessment bodies. Geneva, International Organization for Standardization, 2004.

| Year | Course Code | Title of the paper | L | T | P | C |
|---|---|---|---|---|---|---|
| **2022 -2023 onwards** | **22LQMSP01** | **Practical - I** | **-** | **-** | **8** | **6** |

**Course Objectives:**

The main objectives of this course are to:

1. Understanding and implementation of Quality Control
2. Documentation of biosafety management
3. Documentation of Levey- Jennings Charts & QC Procedures
4. To conduct the Internal Audit

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

| | | |
|---|---|---|
| 1. | Quality Control implementation | K3 & K4 |
| 2. | Biosafety management | K3 & K4 |
| 3. | Levey- Jennings Charts & QC Procedures | K3 & K4 |
| 4. | Internal Audit | K3 & K4 |

**K1 –** Remember; **K2 –** Understand; **K3 –** Perform; **K4 -** Analyse

| **Subject code** | **22LQMSP01** | **Practical I** |
|---|---|---|
| | | |
| | **Quality Control Management** | **90 hours** |

- Biosafety Management
- Scenario — Equipment Failure
- Scenario — Purchasing and Inventory
- Sample Management
- Calculation of Mean and Standard Deviation, Levey- Jennings Charts
- QC Procedures and QC for serology
- Scenario—Organizing an Internal Audit
- EQA and Processing Proficiency Testing Samples

**Mapping with program outcomes**

| COs | PO1 | PO2 | PO3 | PO4 | PO5 |
|---|---|---|---|---|---|
| **CO1** | S | S | S | S | S |
| **CO2** | M | S | S | S | S |
| **CO3** | S | S | S | S | S |
| **CO4** | L | M | S | M | S |

***S - Strong; M – Medium; L - Low**

**Reference books**


1. Harding AL, Brandt Byers K. Epidemiology of laboratory-associated infections. In: Fleming DO, Hunt DL, eds. Biological safety: principles and practices. Washington, DC, ASM Press, 2000:35–54.
2. Howard Hughes Medical Institute, Office of Laboratory Safety. Laboratory safety study 1993–1997 (http://www.hhmi.org/).
3. Richmond JY, McKinney RW, eds. Primary containment for biohazards: selection, installation and use of biological safety cabinets, 2nd ed. United States Government Printing Offi ce, United States Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health, 2000.
4. Wagar EA et al. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identifi cation errors. Archives of Pathology and Laboratory Medicine, 2006, 130(11):1662–1668 (http://arpa.allenpress.com/pdfserv/ 10.1043%2F1543 2165(2006)130%5 B1662 : PSITCL%5D 2.0.CO%3B2).
5. CLSI. C24-A3—Statistical quality control for quantitative measurement procedures: principles and defi nitions, approved guideline:3rd ed. Wayne, PA, Clinical and Laboratory Standards Institute, 2006.

| Year | Course Code | Title of the paper | L | T | P | C |
|---|---|---|---|---|---|---|
| **2022 -2023 onwards** | **22LQMSP02** | **Practical - II** | **-** | **-** | **8** | **6** |

**Course Objectives:**

The main objectives of this course are to:

1. Understanding and implementation of Quality System Management in all level of a clinical laboratory

**Expected Course Outcomes:**

On the successful completion of the course, student will be able to:

| | | |
|---|---|---|
| 1. | Quality System Management | K3 & K4 |

**K1 –** Remember; **K2 –** Understand; **K3 –** Perform; **K4 -** Analyse

| **Subject code** | **22LQMSP02** | **Practical II** |
|---|---|---|
| | **Quality Control Management** | **90 hours** |
| ➢ Scenario — PreparationsNeeded for a Laboratory Accreditation<br>➢ Scenario — Overview of Personnel<br>➢ Restoring Customer Confidence and Planning a Customer Satisfaction Survey<br>➢ Laboratory errors<br>➢ Scenario — Improving Laboratory Processes<br>➢ Differentiating Documentsfrom Records and The Quality Manual<br>➢ Assessing the Relevancy of aComputerized Laboratory Information System and Developing a System for Assigning<br>➢ Understanding Planning, Implementation, and MonitoringProcesses<br>➢ Understanding Managerial andStaff Responsibilities | | |
| | | |
| **Practicals** | | **90 hours** |

**Mapping with program outcomes**

| COs | PO1 | PO2 | PO3 | PO4 | PO5 |
|---|---|---|---|---|---|
| **CO1** | S | S | S | S | S |

***S - Strong; M – Medium; L - Low**

**Reference Books**


1. ISO 9000:2005. Quality management systems–fundamentals and vocabulary. Geneva, International Organization for Standardization, 2005.
2. WHO. Guidelines for health care equipment donations. Geneva, World Health Organization, 2000 (http://www.who.int/hac/techguidance/pht/en/1_equipment%20donationbuletin82WHO.pdf, accessed 11 April 2011).
3. Cochran C. The fi ve keys to a successful internal audit program. The Auditor 2:1. Chico, CA, Paton Press, 2007 (http://www.dnvcert.com/DNV/Certifi cation1/Resources1/Articles/Newsletter Info/Five KeystoaSuccessfulI/).
4. ISO 9000:2005. Quality management systems–fundamentals and vocabulary. Geneva, International Organization for Standardization, 2005.
5. ISO 19011:2002. Guidelines for quality and/or environmental systems auditing. Geneva, International Organization for Standardization, 2002.


| **MINI PROJECT** | **30 hours** |
|---|---|
| The students should submit a report with the procedure to analyze, conduct and evaluate Internal Audit | |