COURSE TABLE OF CONTENTS

ISO 22367:2026 Risk Management in Medical Laboratories

OEM: ISO • Duration: 2 Days (16 hrs)

COURSE MODULES & TOPICS

Module 1: Risk Management Foundations

- ISO 22367 scope and risk-based thinking
- Hazard, harm, probability, severity and residual risk
- Relationship to ISO 15189 and patient safety

Module 2: Laboratory Process Mapping

- Pre-examination, examination and post-examination processes
- Interfaces, handovers and information flow
- Defining scope, context and risk criteria

Module 3: Risk Identification

- Sources of errors, failures and unsafe conditions
- Personnel, equipment, IT, sample and environmental factors
- Incident data, complaints and near misses

Module 4: Risk Analysis Tools

- Qualitative and semi-quantitative methods
- Risk matrices and limitations of scoring
- FMEA and process-based analysis

Module 5: Risk Evaluation and Prioritization

- Risk acceptability criteria and risk ownership
- Prioritization and escalation
- Documenting evaluation rationale

Module 6: Risk Treatment and Controls

- Avoidance, reduction, sharing and informed retention
- Preventive controls, detection controls and contingency actions
- Action owners, deadlines and residual risk

Module 7: Risk Monitoring and Review

- Control effectiveness and performance indicators
- Review frequency and triggers for reassessment
- Incident learning and risk register updates

Module 8: Integration with ISO 15189

- Embedding risk management in operational processes
- Nonconforming work, corrective action and change management
- Internal audit and management review interfaces

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Module 9: Applied Medical Laboratory Cases

- Patient/sample identification and specimen integrity
- Critical results, reporting delays and IT downtime
- Equipment failures and continuity of service

Module 10: Implementation Workshop and Assessment

- Risk documentation and practical rollout plan
- Review of a completed risk register
- Final case-based knowledge check