

Cognicert - ISO 20387 Bio Banking Lead Assessor Course

Course Outline

Module 1: Introduction to ISO 20387

- Overview of ISO 20387:2018 and its scope
- The importance of ISO 20387 in biotechnology biobanking

Module 2: Principles of Assessment

- Assessment principles and terminology
- Assessment methodologies and planning

Module 3: ISO 20387 Requirements

- In-depth examination of ISO 20387 requirements
- Interpretation and application of ISO 20387 clauses

Module 4: Assessment Planning and Preparation

- Developing assessment objectives and criteria
- Assessment scope, schedule, and checklists

Module 5: Assessment Execution

- Conducting opening meetings and interviews
- Gathering and evaluating evidence during assessments

Module 6: Nonconformities and Reporting

- Identifying nonconformities and opportunities for improvement
- Preparing assessment reports

Module 7: Corrective Action and Follow-up

- Recommending corrective actions and preventive measures
- Ensuring follow-up and closure of nonconformities

Module 8: Leading Assessment Teams

- Leading and managing assessment teams effectively
- Team dynamics and collaboration

Module 9: Assessment Challenges in Biobanking

- Addressing common challenges and issues in biobanking assessments and audits
- Case studies and practical scenarios

Module 10: Assessment Simulation and Role-Playing

- Practical exercises and role-playing to apply assessment principles in biobanking scenarios

Module 11: ISO 20387 Lead Assessor Certification

- Requirements and process for ISO 20387 lead assessor certification

Module 12: Q&A and Course Evaluation

- Opportunity for participants to ask questions and provide feedback on the course

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