

Cognicert - ISO 20387 Bio Banking Lead Implementer 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 ISO 20387 Implementation

- Key principles and concepts of ISO 20387 implementation
- Understanding the Plan-Do-Check-Act (PDCA) cycle

Module 3: ISO 20387 Requirements

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

Module 4: Implementation Planning

- Developing an implementation plan and strategy
- Allocating resources and responsibilities

Module 5: Documentation and Policies

- Developing policies and procedures to support ISO 20387 compliance
- Document control and record-keeping requirements

Module 6: Risk Assessment and Mitigation

- Conducting a risk assessment in the context of biobanking
- Strategies for risk mitigation and management

Module 7: Biobank Infrastructure and Equipment

- Requirements for biobank facilities, storage, and equipment
- Ensuring compliance with infrastructure requirements

Module 8: Personnel and Training

- Staff competencies and training requirements
- Strategies for maintaining a skilled workforce

Module 9: Biobank Operations

- Managing day-to-day biobanking activities in compliance with ISO 20387
- Ensuring the traceability and integrity of collected samples

Module 10: Auditing and Internal Assessment

- Preparing for internal audits and self-assessments
- Best practices for conducting internal assessments

Module 11: Continual Improvement

- The role of continual improvement in ISO 20387 implementation

- Collecting and analyzing data for performance improvement

Module 12: Leading the Implementation Team

- Leading and managing the implementation team effectively
- Team dynamics, communication, and collaboration

Module 13: Certification and Compliance

- Preparing for ISO 20387 certification and audits
- Demonstrating compliance with ISO 20387 requirements

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