

A background image showing a group of five business professionals in a modern office setting. They are gathered around a table, looking at a laptop and discussing documents. The office has large windows with blinds and a whiteboard in the background.

Cognicert ISO 20387 Bio Banking Lead Implementer Course

Training Overview:

The “ISO 20387 Lead Implementer Course” is designed to equip individuals with the knowledge and skills needed to plan, implement, and manage a biobanking system in accordance with ISO 20387:2018. This course focuses on the specific requirements of ISO 20387 and provides practical guidance on establishing and maintaining a compliant biobanking system. Participants will gain the expertise to lead the implementation of ISO 20387 in biotechnology laboratories and organizations.

Target Audience:

The target audience for the “ISO 20387 Lead Implementer Course” includes:

- **Biotechnology Professionals:** Professionals working in the biotechnology sector responsible for implementing ISO 20387 in their organizations.
- **Laboratory Managers:** Laboratory managers and supervisors in biotechnology facilities seeking to implement ISO 20387.
- **Quality Assurance Specialists:** Quality assurance professionals involved in establishing and managing biobanking systems.
- **Biobank Administrators:** Individuals responsible for the day-to-day operation and compliance of biobanks.

Reference Standards:

The primary reference standard for this course is ISO 20387:2018 – “Biotechnology – Biobanking – General Requirements for Biobanking.” In addition, the training may reference ISO 9001:2015 – “Quality Management Systems” as a general framework for quality management principles and practices.

Objectives:

The objectives of the “ISO 20387 Lead Implementer Course” are:

- **Understanding ISO 20387:** To provide participants with a comprehensive understanding of the ISO 20387 standard and its significance in biotechnology laboratories and biobanking.
- **Implementation Principles:** To familiarize participants with the principles of implementing ISO 20387 effectively.
- **Lead Implementer Competencies:** To develop the competencies required to lead the implementation of ISO 20387 in biotechnology laboratories and organizations.
- **Biobanking Best Practices:** To equip participants with knowledge of best practices for establishing and managing biobanks in compliance with ISO 20387.

Learning Outcomes:

By the end of the course, participants should be able to:

- Interpret and apply the requirements of ISO 20387:2018 to establish and manage a biobanking system.
- Plan and execute the implementation of ISO 20387 in their biotechnology laboratory or organization.
- Establish policies, procedures, and documentation to support compliance with ISO 20387.
- Ensure the effective management of biobanking activities and continuous improvement of the system.
- Demonstrate the skills and knowledge necessary to lead the implementation of ISO 20387 in their biotechnology setting.

Training Content:

The training content should cover various aspects of ISO 20387 implementation. Here’s a breakdown of potential content areas:

- **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

Duration: 5 days

TRAINING METHODOLOGIES

- Case Study
- Individual Exercises
- Role Play
- Group Exercises
- Group Presentation
- Examination