

A photograph of a business meeting in a modern office. Five people are gathered around a table, looking at a laptop. The room has large windows with blinds and a whiteboard in the background.

Cognicert ISO 20387 Bio Banking Lead Assessor Course

Training Overview:

The “ISO 20387 Lead Assessor Course” is a comprehensive program designed to equip individuals with the knowledge and skills needed to assess and evaluate biobanking systems in accordance with ISO 20387:2018. This course focuses on the principles of assessment, audit methodologies, and the specific requirements of ISO 20387. Participants will learn how to lead and conduct assessments of biobanking facilities and organizations to ensure compliance with the standard.

Target Audience:

The target audience for the “ISO 20387 Lead Assessor Course” includes professionals and individuals who wish to become proficient in leading assessments and audits of biobanking systems. This may include:

- **Quality Assurance Professionals:** Quality assurance managers, specialists, and professionals responsible for assessing and ensuring compliance with ISO 20387 in biobanking facilities.
- **Biobank Managers:** Managers and administrators of biobanking facilities seeking to assess and improve their compliance with ISO 20387.
- **Biotechnology Industry Professionals:** Professionals working in the biotechnology sector interested in conducting assessments and audits of biobanks.
- **Experienced Auditors:** Individuals with prior experience in auditing quality management systems who wish to expand their auditing expertise to include biobanking.

Reference Standards:

The primary reference standard for this course is ISO 20387:2018 – “Biotechnology – Biobanking – General Requirements for Biobanking.” Additionally, the course may reference ISO 19011:2018 – “Guidelines for Auditing Management Systems” to provide a framework for audit practices and principles.

Objectives:

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

- **Understanding ISO 20387:** To provide participants with a comprehensive understanding of the ISO 20387 standard and its relevance to biobanking.
- **Assessment Principles:** To familiarize participants with the principles of assessment, audit planning, and audit methodologies specific to biobanking.
- **Lead Assessor Competencies:** To develop the competencies required to lead assessments and audits of biobanking facilities effectively.
- **Biobank Assessment Practices:** To equip participants with knowledge of best practices for assessing and auditing biobanks for 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 assess and audit biobanking systems.
- Plan and conduct assessments and audits of biobanking facilities, including preparing assessment schedules and checklists.
- Evaluate and report assessment and audit findings, including nonconformities, and recommend corrective actions.
- Demonstrate the skills and knowledge necessary to lead and manage assessment and audit teams effectively.
- Facilitate the improvement of biobanking systems to ensure compliance with ISO 20387.

Training Content:

The training content should cover various aspects of assessing and auditing biobanking systems in compliance with ISO 20387. 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 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

Duration: 5 days

TRAINING METHODOLOGIES

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