



MiChem Dynamics
LEADING CHANGE

ISO 20387:2018 – BIOBANKING QUALITY MANAGEMENT SYSTEM IMPLEMENTATION TRAINING

The ISO 20387:2018 Biobanking Quality Management System (QMS) Implementation Training is a comprehensive program designed to equip participants with the knowledge and skills necessary to establish and maintain a robust quality management system in accordance with ISO 20387:2018 standards for biobanking.

This course is ideal for professionals involved in biobanking operations, quality management, regulatory compliance, and anyone seeking to enhance their knowledge of the ISO 20387:2018 standard to elevate the quality and reliability of biobanking processes. Participants will leave the training with a comprehensive understanding of the standard and the practical tools needed for successful QMS implementation in their biobanking facilities.



THE COURSE WILL RUN OVER A PERIOD OF 3 DAYS

LEARNING OUTCOMES:

- Understand the underlying structure of ISO 20387:2018 and all elements associated with the quality management system.
- Write their own management system documents in compliance with ISO 20387:2018.
- Identify relevant performance monitoring approaches.
- Continually improve data quality and effectiveness.
- Understand importance of internal auditing, corrective and risk assessments.

WHO SHOULD ATTEND THIS COURSE:

- Technical / Quality managers
- Supervisors
- Anyone involved in the development, maintenance or improvement of a quality management system

MINIMUM ENTRY REQUIREMENTS:

- Fluency in English writing and reading skills

TUITION:

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

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COURSE OVERVIEW:

DAY 1

- Introduction
- ISO 20387 Clause 4 General requirements
 - General
 - Impartiality
 - Confidentiality
- ISO 20387 Clause 5 Structural requirements
- ISO 20387 Clause 6 Resource requirements
 - General
 - Personnel
 - Facilities/ dedicated areas and environmental conditions
 - Externally provided processes, products and services
 - Equipment

DAY 2

- ISO 20387 Clause 7 Process requirements
 - General
 - Collection of biological material and associated data
 - Reception and distribution of biological material and associated data
 - Transport of biological material and associated data
 - Traceability of biological material and associated data
 - Preparation and preservation of biological material
 - Storage of biological material
 - Quality control of biological material and associated data
 - Validation and verification of methods
 - Management of information and data
 - Nonconforming output
 - Report requirements
 - Complaints

DAY 3

- ISO 20387 Clause 8 Management requirements
 - Options
 - Documented information for the quality management system
 - Control of quality management system documents
 - Control of records
 - Actions to address risks and opportunities
 - Improvement
 - Corrective action for nonconforming output
 - Internal audits
 - Quality management reviews
- Test (assessment)

