



MiChem Dynamics
LEADING CHANGE

FOOD MICROBIOLOGY METHOD VERIFICATION AND UNCERTAINTY OF MEASUREMENT (IMPLEMENTATION OF ISO 16140-3:2021 AND TR28-03) TRAINING

This course aims to give an understanding of the protocol to be implemented for the verification of reference methods and validated alternative methods for implementation in the user laboratory.

It is aligned with the newly revised accreditation requirement (TR28-03) and ISO 16140-3:2021 Microbiology of the food chain – method validation – Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory.

ISO 16140-3:2021 should be implemented, in addition to specific accreditation requirements, by all microbiological laboratories that verify methods used for the analysis (detection and/or quantification, confirmation and typing of microorganisms) in products intended for human consumption; products intended for animal feeding; environmental samples in the area of food and feed production, handling; samples from the primary production stage.



THE COURSE WILL RUN OVER A PERIOD OF 3 DAYS

LEARNING OUTCOMES:

- Understand the underlying theoretical structure of method validation and verification (secondary validation) as described in ISO 16140-3:2021.
- Implement additional method verification requirements.
- Understand the implementation of accreditation requirement TR28-03 Criteria for validation, verification, uncertainty of measurement and quality assurance in Microbiological and Molecular Testing.
- Understand, through practical examples of alternative and reference methods, how data should be applied from the validation study into the verification exercise.

WHO SHOULD ATTEND THIS COURSE:

- Laboratory / Quality managers
- Analysts / technicians
- Technical signatories
- Anyone involved in method development in a microbiology laboratory

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.

COURSE OVERVIEW:

DAY 1

- Introduction
- General principles of verification of qualitative (detection) methods and quantification methods (ISO 16140-3:2021 Clause 4)
 - General
 - Implementation verification
 - (Food) item verification

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COURSE OVERVIEW:

- Requirements for implementation verification and (food) item verification
- Performance characteristics
- Qualitative methods – technical protocol for verification (ISO 16140-3:2021 Clause 5)
 - Estimated LOD50 (eLOD50) determination
 - Experimental design
 - Selection of (food) items
 - Artificial contamination
 - Selection of strains
 - Inoculation of the test portions
 - Evaluation of results
 - Determination of eLOD50 using protocol 1
 - Determination of eLOD50 using protocol 2
 - Acceptability limits
 - Root-cause analysis
 - Practical examples using reference and alternative methods



DAY 2

- Quantitative methods – Technical protocol for verification (ISO 16140-3:2021 Clause 6)
 - Intra-laboratory reproducibility standard deviation determination
 - General
 - Experimental design
 - Selection of the (food) item
 - Natural contamination
 - Artificial contamination
 - Evaluation of results
 - Acceptability limit
 - Root-cause analysis
 - Practical examples using reference and alternative methods
 - Estimated bias (eBias) determination
 - General
 - Experimental design
 - Selection of the (food) item
 - Natural contamination
 - Artificial contamination
 - Evaluation of results
 - Acceptability limit
 - Root-cause analysis
 - Practical examples using reference and alternative methods
- Validated alternative confirmation and typing methods – Technical protocol for verification (ISO 16140-3:2021 Clause 7)
 - General
 - Implementation verification
 - Experimental design
 - General
 - Strain selection
 - Evaluation of results
 - Acceptability limit
 - Root-cause analysis
 - Practical examples using reference and alternative methods

COURSE OVERVIEW:

DAY 3

- Summary of acceptability limits for the verification of validated methods (ISO 16140-3:2021 Clause 8)
- Accreditation requirements: TR28 Version 03
 - Purpose and Scope
 - Definitions and References
 - Method validation and Method verification
 - Quality control and Quality assurance
 - The use of media
 - The use of Reference materials and Reference cultures
 - The use of Polymerase Chain Reaction (PCR) Technology
- Test (assessment)

