Introduction

Method validation is the process that provides evidence that a given method, when correctly applied, produces results that are fit for purpose. It is essential to understand method validation if you want to make sure that your microbiological results are accurate.

This course explains the general principles of method validation for microbiological testing and demonstrates some practical techniques that can be applied in the microbiological laboratory.

Objectives

At the end of the course, participants are expected to:

1. Know the need and manner of Validation of microbiological methods for food, water and pharmaceutical products, with particular emphasis on quantitative methods in which the quantitative estimate is based on counting of particles on the basis of growth (multiplication) into colonies or turbidity

2. Be able to apply the necessary statistical tools for the evaluation, interpretation and reporting of validation data

3. Know what primary and secondary validations, the need for quality control and quality assurance, the use of media, reference materials and cultures in validation for methods in microbiology testing methods.

Who Should Attend

This course is suitable for microbiology laboratory personnel who are directly involve in method development and method validation.

Course Contents

Day 1

Introduction & Definitions
Types of microbiology analyses
Types of Validation of Methods for micro-analyses
The need for validation of micro-methods of analysis
Acceptable Methods
Need for QC and QA
Acceptance and Rejection Criteria
Use of Reference materials, & culture for traceability
Guidelines for preparation of method validation
Calculation of z-score

Day 2

Intermediate Precision
Personal Repeatability
Sensibility, Specificity, False positive rate, False negative rate, Efficiency
Apparent Selectivity
Relative recovery rate
Approach to Method Validation
Sources of Uncertainty Measurements
Relationships between Validation Parameters and Methods in microbiology
Drafting Validation Plan
Validation parameters considered in the context of methods of microbiology
Accuracy
Selectivity

Day 3

Limit of Detection
Linearity
Robustness
Repeatability
Reproducibility
Uncertainty of Measurements
Template for Validation/Verification
Template for Evaluation of performances of method
Statement of 'Fitness-for-Purpose'
Preparation of Standard of Culture for use in Spiking
Acceptable Counting Range – Upper Limit and Lower Limit
Detection of Pathogens

Course Presenter

DR. STEPHEN WONG KAM SUN – is a Certified Trainer by the HRD Corp. He is an competent Quality Consultant, trainer and qualified Lead Assessor for both ISO 9000 and ISO/IEC 17025. He is also an effective management trainer. He holds a PhD (Sunway University), MBA degree (University of Wales, UK), Chemistry degree (University Malaya), Diploma in Marketing (CIM, UK) and Certified Diploma in Accounting & Finance (ACCA, UK). He has 36 years of management & training experience, including 26 years in quality training and consultancy.

He was the Hon. Secretary (16 years) for the Institute of Quality Malaysia, an approved Quality Trainer for SIRIM since 1989 and a Quality and Management Consultant to some companies in Malaysia. He was a Council Member of the Malaysian Institute of Management and was also a well recognized trainer for MIM. He was also the Gen. Secretary of Malaysia Register of Certificated Auditors (MRCA) for many years.

He was a member (1991-2002) of the Malaysian National Accreditation Council of the Department of Standards Malaysia and sat on many other national committees on Quality and Environmental in relation to ISO. Dr. Stephen Wong had been a key member of the TC 176 and TC 207 national committees responsible to CASCO for the development of the ISO 9001, ISO/IEC 17025 and ISO 14001 standards and other conformity assessment standards. He was also a member of the IATCA (now IPC) representing MRCA in the development of the ISO 19011 Auditing Standard for the ISO 9001 and the ISO 14001.

Registration Form

Please register the following for the course on "Method Validation for Analytical Laboratory"

Name: _____
Designation: _____

Name: _____
Designation: _____

(please attached extra list if more than two participants)

Name & Address of Company:

_____
_____
_____
_____
_____

Contact Person: _____
Designation: _____
Tel: No: _____ Fax: _____
E-mail: _____

Signature: _____
Date: _____

Method of Payment:
Please made cheque payable to **WKS HOLDINGS SDN BHD** or transfer the payment to our **Public Bank account no: 3078894831** and send us a copy of the transfer slip.

WKS reserves the right to cancel or postpone the course in the event of unforeseen circumstances.

MVLS240324

Registration Guidelines & Procedures

1. Early registration is encouraged. Participants shall be registered on a first-come-first-served basis.
2. Register by completing attached form and return by e-mail to admin@wks-h.com
3. Payment of fee should be made 4 days before course commence.
4. Please made cheque payable to WKS HOLDINGS SDN BHD or transfer the payment to our Public Bank account no: 3078894831 and send us a copy of the transfer slip.
5. Notification of cancellation must be in writing received 4 working days prior to commencement of course (20% of course fee will be retained). Otherwise, full fee will still be charged.
6. WKS reserves the right to cancel or postpone the course in the event of unforeseen circumstances. However, in such an event, participants would be informed as early as it could possibly permit.

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METHOD VALIDATION for MICROBIOLOGICAL Laboratory

Administrative Details

Date: 3 – 5 September 2024
Time: 0900 – 1700
Venue: Plaza Mayang,
Petaling Jaya
Fees: RM 1,350 per participant
HRDCorp Claimable Course

Organized & Management by

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