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## 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.

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## 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.

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## Who Should Attend

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

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## 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  
Sensitivity, 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

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## Course Presenter

**DR. STEPHEN WONG KAM SUN** – is a HRDC Accredited Trainer and an IQM Certified Expert in ISO/IEC 17025:2017 Standard for Testing, Calibration, and Sampling laboratories. He is a competent Quality Consultant, Trainer and qualified Lead Assessor/Auditor for both ISO 9000 and ISO/IEC 17025.

He is also an effective business management trainer. He holds at least six degrees/professional qualifications, namely, 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 38 years of management & training experience, including 32 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 and a Quality and Management Consultant to many companies in Malaysia. He was a Council Member of the Malaysian Institute of Management and a well-recognized trainer for MIM. He was also the Gen. Secretary of Malaysia Register of Certificated Auditors (MRCA).

He was a member (1991-2002) of the Malaysian National Accreditation Council of the Department of Standards Malaysia and sat on seven other national committees on 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 Microbiology Laboratory"

Name: \_\_\_\_\_  
Designation: \_\_\_\_\_

Name: \_\_\_\_\_  
Designation: \_\_\_\_\_

*(please attached extra list if more than two participants)*

**Reminder: Participants need to bring a laptop and scientific calculator for this course.**

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.

Payment by HRDC grant must be approved before training starts.

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

## 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](mailto: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. Payment by HRDC grant must be approved before training starts.
6. 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 would still be charged.
7. Registration fee is inclusive of course materials, refreshments and lunch.
8. Closing date is 4 days before commencement of the course.
9. 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.

**WKS HOLDINGS SDN BHD** (198401017072)  
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# METHOD VALIDATION for MICROBIOLOGICAL Laboratory

## Administrative Details

Date: 13-15 April 2026  
Time: 0900 – 1700  
Venue: Plaza Mayang,  
Petaling Jaya  
Fees: RM 1,650 per participant  
HRDCorp Claimable Course

Organized & Management by

**WKS HOLDINGS SDN BHD**

