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## Introduction

Method validation is the process that provides evidence that a given analytical 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 analytical results are accurate.

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

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## Objectives

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

1. Describe the process of method validation
2. Identify factors that are significant for valid analytical measurements;
3. Select and use the appropriate types of method validation studies
4. Design an analytical method validation study
5. Be able to apply the necessary statistical tools for the evaluation, interpretation and reporting of validation data

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## Who Should Attend

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

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## Course Contents

### Day 1

- What is Method Validation?
- When should methods be validated?
- Regulatory requirement
- Method development
- Statistics for method validation
- Ad-hoc analysis and non-routine analysis
- Analytical Parameters for method validation
  - Selectivity / specificity, Precision, Repeatability, Reproducibility

### Day 2

- Trueness
- Measurement Uncertainty
- Reference material
- Bias Measurement
- Linearity and range
- Detection limit

### Day 3

- Quantitation Limit
- Robustness
- Ruggedness
- Sensitivity
- Using method validation data
- The tools of validation

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## Course Presenter

**STEPHEN WONG** – is a Certified Trainer by the Human Resource Department (HRD) of the Ministry of Human Resource, Malaysia. He is an excellent 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 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 34 years of management & training experience, including 24 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 is a Council Member (since 1989) of the Malaysian Institute of Management and is also a well recognized trainer for MIM. He is also the Gen. Secretary of Malaysia Register of Certificated Auditors (MRCA) since its inception in 1998.

He was a member (1991-2002) of the Malaysian National Accreditation Council of the Department of Standards Malaysia and still sits on three other national committees on Quality and Environmental in relation to ISO. Mr. Stephen Wong has 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 is also a member of the IATCA (now IPC) representing MRCA in the development of the ISO 19011 Auditing Standard for the ISO 9000 and the ISO 14000.

## 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 fax or e-mail.
3. Payment by crossed cheque / postal order made payable to WKS HOLDINGS SDN BHD together with registration form, to be received 4 days before course commence.
4. 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.
5. A registration fee is inclusive of course materials, refreshments and lunch.
6. Closing date is 4 days before commencement of the course.

## 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: \_\_\_\_\_

I/We enclosed a cheque no: \_\_\_\_\_ amount to RM \_\_\_\_\_ made payable to WKS HOLDINGS SDN BHD.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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

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**WKS HOLDINGS SDN BHD** (129630-A)  
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# METHOD VALIDATION for Analytical Laboratory

## Administrative Details

Date: 3 – 5 October 2017  
Time: 0900 – 1715  
Venue: Plaza Mayang, PJ  
Fees: RM 1,250 per participant  
HRDF Claimable

Organized & Management by

**WKS HOLDINGS SDN BHD**

