



LEVEL 1 BBBEE – 100 % BLACK WOMAN OWNED



METHOD VALIDATION TRAINING AND IMPLEMENTATION

YOUR PILLAR IN CUSTOMER DESIGNED TRAINING SOLUTIONS.



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1. COURSE OVERVIEW

Method Validation (MV) is the process used to **confirm** that the **analytical procedure** employed for a **specific** test is suitable for its **intended use**. This course is intended to enhance the skills of laboratory personnel and provide a systematic and robust approach to conducting method validation. The course begins by introducing personnel to the skill of studying the analytical procedure to identify aspects or areas of the method that needs to be validated based on activity risk assessment. Relevant terminology, accreditation requirements and statistical tools to be employed are defined and practical examples demonstrated. A third section covers method validation parameters: defining their meaning, applicability, laboratory data required for their assessment, application of statistics to data evaluation and discussion of appropriate acceptance criterion for each. The last day of the training is spent on consolidation and practical implementation of method validation based on real laboratory data.

2. COURSE APPROACH

The approach for this course is **PRACTICAL! PRACTICAL! PRACTICAL!** The course changes the traditional approach of theoretical training and focus on enhancing the practical skills of personnel through case studies, class exercises and real method validation. The facilitator(s) will demonstrate how method validation is done for key techniques based on the needs of the majority of attendees. For instance for chemistry the expert facilitator may demonstrate validation for chromatography, spectroscopy, mass spectrometry, calorimetric or spectrophotometric methods. Whilst for biological sciences techniques such as, Colilert or Somatic Coliphages methods may be topics of interest.

3. WHO SHOULD ATTEND?

Laboratory Personnel:

- Analysts
- Supervisors
- Scientists
- Technical Signatories
- Laboratory Manager

Quality Assurance Personnel:

- Quality officer or coordinators
- Quality Manager or Scientist
- Nominated Representatives
- Any other laboratory support staff

4. ABOUT THE FACILITATOR

The facilitator started off his career as a graduate scientist in an accredited laboratory. His role was primarily in method development, optimization and validation for new methods. The approach was always to develop or optimise methods to address an impending problem in the routine laboratory. He successfully validated several methods which were eventually SANAS accredited for the first time or maintained accreditation in the changing accreditation requirements. He was later appointed as a Scientist in the laboratory, leading a team of technicians and technical supervisors in production of accurate test results in good time. This role continued to have a research component where he was involved in troubleshooting, trends analysis, method optimisation for problem solving, maintaining accreditation and increasing scope of accreditation. He boasts with over 10 years' experience in this role. His passion for accreditation grew and was later appointed by SANAS (South African accreditation body) as a SANAS Technical Assessor. This role involves assessment of a number of laboratories in RSA and Africa. He has since gained enormous exposure to method validation and experienced various approaches as he visits laboratories. He has implemented method validation for over 50 different methods which were eventually SANAS accredited. SANAS, noting his passion, got him involved in SANAS Technical Committees for documentation of Technical Requirement Documents. By qualification he holds a BSc Honours in Applied Chemistry and is a Registered Professional Natural Scientist with SACNASP.

5. BENEFITS OF THE COURSE

Benefit to candidate:

- Enhanced practical and applied skills of Method Validation, rather than traditional theoretical knowledge
- Paradigm shift in approach to method validation from the traditional approach of one template fit all
- Improved practical skills in Microsoft Excel Data Analysis on Analysis ToolPak
- Learning from other delegate's experiences and knowledge

Benefits to Company:

- Improved customer satisfaction
- Decreased chances of error leading to decreased client queries
- Improved customer confidence
- Claim for skills levies (for companies registered to claim skills levies)
- Validated Methods

CUSTOMER DESIGNED IN-HOUSE METHOD VALIDATION IMPLEMENTATION

NtsikaTech Solutions subscribes to ensuring value add to the customer rather than selling an incomplete solution. For maximum value add we would like to suggest in-house trainings. In this case the training is designed against the scope of work of the laboratory. The data used is produced from the laboratory. In this approach there will be three outcomes for the laboratory at the end:

(1.) Trained personnel (2.) Fully validated method(s) and (3.) Revised operating procedure.

6. COURSE STRUCTURE AND DAILY SCHEDULE

An overview of the topics covered in each day is listed below. The details of topics to be covered are withheld for intellectual proprietary reasons but will be made available to interested organisations or individual:

DAY 1

Introduction

- Discussion of problem statement covering challenges observed if a method is not validated

Method Validation Terminology

- Discussion of terminologies used in MV in context with training and accreditation requirements

MV Purpose and Accreditation Requirements

- Validation vs Verification
- SANAS accreditation requirements for method validation (SANAS TR 26 and TR 28)

Statistical Tools

- Introduction and definition of various statistical tools
- Tools discussed and briefly demonstrated on Microsoft Excel – Part 1

DAY 2

Statistical Tools

- Tools discussed and briefly demonstrated on Microsoft Excel – Part 2

Disserting the Method

- Approaches of studying the analytical method to identify activities that require validation

Discussion of Method Validation Parameters

- Definitions
- Data Collection required for each parameter
- Data Analysis through application of statistical tools
- Data Interpretation using pre-set criteria

DAY 3

PRACTICAL! PRACTICAL! PRACTICAL!

Method Validation Demonstration For A Chosen Or Relevant Technique(s):

- A "DATA BOOKLET" which has typical data collected from validation of method will be issued
- Method validation conducted from start to finish using data from the booklet
- Demonstration of calculations and various approaches depending on the data available

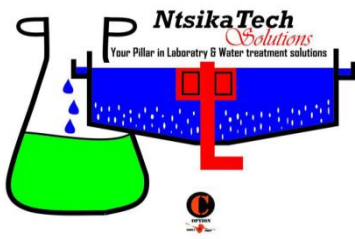
DAY 4 – (In-house Only)

PRACTICAL! PRACTICAL! PRACTICAL!

Method Validation Demonstration For Laboratory Methods:

- If the course is offered in-house this section is done with real data from the laboratory
- The laboratory is allowed a couple of days to collect required data
- Day 4 is done after the data is available
- The laboratory is left with complete method validation report(s) and reviewed method validation procedure





METHOD VALIDATION TRAINING AND IMPLEMENTATION



BOOKING AND REGISTRATION FORM

COMPLETED BOOKING FORMS MUST BE SCANNED AND EMAILED TO: s.s.mbovu@gmail.com

Company Name: _____ VAT No: _____
 Physical Address: _____
 Contact Person: _____
 Telephone No: _____ Email: _____

Training Selection	INHOUSE:	OFF-SITE:	No of Delegates:	No of Methods for MV:
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Delegate 1 Name: _____ Position: _____
 Delegate 2 Name: _____ Position: _____
 Delegate 3 Name: _____ Position: _____
 Delegate 4 Name: _____ Position: _____
 Delegate 5 Name: _____ Position: _____

TRAINING APPROVAL

Name of Approver (Delegated/Authorised): _____
 Position: _____ Employee No: _____
 Telephone No: _____ Email: _____

PAYMENT METHOD

Electronic Funds Transfer to:
 Account Holder: NtsikaTech Solutions Pty Ltd
 Name of Bank: First National Bank
 Account No: 62693358931
 Branch Name: Howick, Pmb

TERMS AND CONDITIONS

- All payments must be made directly to NtsikaTech Solutions Pty Ltd.
- Payment is required in full 7 days from date of invoice
- No seats will be reserved unless and authorised registration form is received.
- Though all efforts will be made not to, however NtsikaTech Solutions (PTY) Ltd. reserves the right to change speakers, program content, date & venue in if circumstances beyond our control prevail
- The signed registration form is a legally binding contract.

COSTING APPROACH

In-house Training: A combination of the minimum number of delegates and/or number of methods requiring validation will be used in costing in-house training (e.g.: in-house training may be done for 1 delegate if a significant number of methods require validation. Whereas a minimum number of delegates may be required where only one method will be validated). Tea and Lunch is not included on costs of an in-house training. **Off Site Training:** The costs exclude travel and accommodation, but include training material and refreshments. If one company registers more than 3 delegates, discounts may be granted.

SUBSTITUTIONS/EVENT RESCHEDULING

Delegates must inform NtsikaTech Solutions (PTY) Ltd in writing of any delegate substitutions. There is no charge for substitutions. NtsikaTech Solutions (PTY) Ltd will not be held liable for incorrect Delegate details on certificates in the event of substitutions being made on the day of the training. In the event of NtsikaTech Solutions (PTY) Ltd having to cancel or postpone an event due to circumstances beyond our control, delegates will be notified in reasonable time and allowed time to adjust to new dates. There will be no refunds or credit vouchers for non-attendance.

REGISTRATION CANCELLATIONS

All cancellations will be subject to approval by the management of NtsikaTech Solutions (PTY) Ltd. All cancellations made 7 working days prior to date of the event will be subject to a 50 % cancellation fee (50 % refund). Cancellations made within 7 days of date of the event, will be subject to a 100 % cancellation fee (no refund). In an event where cancellations results to a significant change on the number of delegates from the same company, NtsikaTech Solutions (PTY) Ltd reserves the right to revise the costs accordingly.

NtsikaTech Solutions Pty Ltd.

Company Registration Details | Reg. No: 2017/145407/07 | Tax No: 9133099235
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