Course Code: TLM6

1 Days course (Certificate of completion/attendance)

Laboratory Quality Management System

ISO/IEC 17025:2017

Method Validation for Chemical testing

COURSE AIM

To have a clear understanding of international regulatory authority regulations and gain the background knowledge to effectively plan on method validation for the chemical testing.

ENTRY REQUIREMENT

This course is recommended for those interested in and currently working in chemical testing laboratories, especially for technician / chemist who is performing the method validation for new development testing method, operations manager, professional and technical staff, quality manager, internal auditor, authorized representatives and approved signatory.

LEARNING OUTCOME

Audiences who attend the course could

identify the difference between verification and validation

justify the validation parameters required to evaluate whether the method is fit for intended use.

GENERAL INFORMATION

Venue:	ACI Training Venue
Duration:	1 Day
Language:	Cantonese supplemented with English Material
Methodology:	Presentation and experience sharing
Certificate:	Certificate of successful Completion will be awarded to delegates who have attended full course

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COURSE CONTENT

Method Validation:

Introduction and Essential statistics

- General ISO/IEC 17025 & HOKLAS requirement
- Significance testing (hypothesis testing)
- Analysis of variance
- Type of Quality Control chart

Essential Tools

- Introduction to the concepts of method validation
- Performance parameters I: precision, bias and ruggedness.
- Performance parameters II: selectivity, instrument detection limit, method detection limit, limit of quantitation, linearity and working range.
- Use of precision and accuracy control charts.

Emerging Technologies

Method validation is the essential process and an evidence-based approach for the new developed method to provide the evidence on the "fit for intended use". Several parameters are assessed with different criteria within specific guidance. The method validation report is often to be assessed during the accreditation process.

REMARK

- After completion of all TLM1, TLM3, TLM5 & TLM6, he or she is eligible for applying Professional Certificate of Laboratory Technical Officer.

- After completion of all TLM1, TLM3, TLM4, he or she is eligible for applying Professional Certificate of Laboratory Auditor.

課程編號: TLM6

1天 (證書: 高出席率之學員將獲頒發課程完成證書乙張)

實驗室品質管理系統

ISO/IEC 17025:2017

化學測試方法驗證

培訓目的

清楚了解國際監管機構的法規，掌握相關背景知識，有效規劃化學測試的方法確認

培訓對象

任何有興趣和目前在化學測試實驗室工作的人，特別是執行新開發測試方法的方法驗證的技術員及化學家、營運經理、專業技術人員、品質經理、內部審計師、授權代表和獲批准的簽署人。

學習成果

- 辨識驗證和確認之間的區別
- 證明評估方法是否適合預期用途所需的驗證參數

培訓詳情

地點:	ACI 訓練中心
時間:	一天
課程語言:	廣東話授課輔以英語教材
上課模式:	講解、工作小組討論與練習
證書:	高出席率之學員將獲頒發課程完成證書乙張

培訓內容

方法確認

介紹和基本統計數據

- 一般ISO/IEC 17025 & HOKLAS要求
- 顯著性檢驗(假設檢定)
- 差異分析
- 品質控制圖表類型

基本工具

- 方法驗證概念簡介
- 性能參數 I：精確度、偏差和堅固性
- 性能參數 II：選擇性、儀器檢測限制、方法檢測限制、量化限制、線性和工作範圍
- 使用精確度和準確度控制圖表

新興技術

方法確認是新開發的基本過程和循證方法，提供「適合預期用途」的證據。在特定指導範圍內使用不同的標準評估多個參數。方法確認報告通常在認證過程中進行評估。

備註

- 在完成所有 TLM1、TLM3、TLM5 和 TLM6 後，他/她有資格申請實驗室技術人員專業證書。
- 完成所有TLM1，TLM3，TLM4後，他/她有資格申請實驗室審核員專業證書。

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