

QUALITY ANALYSIS CONSULTANTS

WORKSHOP OUTLINES

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Please Note: These workshops are one half a day each. They can be combined in any combination to give a full day presentation.

Brief Biographies

The workshops will be presented by Jane Weitzel and Wes Johnson. Jane Weitzel is an American Society for Quality certified Quality Assurance Manager and is presently working in Quality Assurance for Cangene corporation, an ISO 9001 registered company that is licensed under CGMP by Canada, the United States and the United Kingdom. She has helped develop CAN-P-1579, the adaptation of ISO Standard 17025 as a laboratory accreditation standard for the mineral analysis industry, she is a technical assessor for the Standards Council of Canada (SCC) and has many years of experience as an analytical chemist in the mineral analysis and pharmaceutical fields. From this depth of experience Jane will bring many real life examples to help you understand method validation and the measurement of uncertainty in your business.

Dr. Johnson has had many years of experience in commercial, industrial and government laboratories as an analyst, manager and Quality Control/Quality Assurance officer. He is retired from teaching Analytical and Environmental Chemistry at Okanagan University College. He has developed and presented numerous workshops on Quality Control/Quality Assurance, Method Validation, the Estimation of Measurement Uncertainty, Basic Statistics for Validation and Uncertainty Estimation, and aspects of classical and instrumental analysis for industrial clients in Canada and abroad. He was involved in the development of CAN-P-1579 as a member of the Mineral Analysis Working Group set up by the SCC to establish a Standard 17025 accreditation program for laboratories in that industry. Dr. Johnson drafted the CAEAL Policy for the Estimation of Measurement Uncertainty. He has served as an auditor for both private industry and for SCC and CAEAL accreditation visits to numerous laboratories and is an NQI Certified Auditor.

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WORKSHOP ON BASIC STATISTICS FOR VALIDATION AND ESTIMATION OF MEASUREMENT UNCERTAINTY

Introduction

- Definitions
- Basic equations
- Example of Standard Deviation calculation

Normal Data Distribution

- Characteristics
- Example
- Normal error curve
- Z and P factors

Significance Testing

- One-tailed and two-tailed distributions
- Confidence intervals
- Significance tests to compare two means
- Paired t-test
- Comparison of variances – the F-test
- Significance tests for outliers

Regression Methods

- Regression
- Residuals
- Goodness of fit
- Calibration process as a source of measurement uncertainty

Analytical Data Quality

- Method validation as a source of measurement uncertainty information
- Method validation for Standard Methods
- Method validation for in-house methods
- Sampling as a source of variation

Process Capability

Discussion

Workshop conclusion and evaluation, Certificates awarded

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WORKSHOP ON METHOD VALIDATION

Introduction

- What is method validation?
- Why is method validation necessary?
- When should methods be validated?

Method Validation

- Instrument validation
- Computer and software validation
- Validation responsibilities
- Degree of validation
- Analytical requirement
- Validation tools

Breakout

Validation of performance parameters

- Confirmation of identity and selectivity/specificity
- Limits of detection and quantitation
- Working linear range
- Accuracy and trueness
- Precision (repeatability and reproducibility)
- Measurement uncertainty
- Sensitivity
- Ruggedness (or robustness) the Ruggedness test
- Recoveries

Breakout

Discussion

Workshop conclusion and evaluation, Certificates awarded

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WORKSHOP ON LABORATORY ACCREDITATION TO ISO/IEC STANDARD 17025

Overview of Laboratory Accreditation

Industry sectors

Clinical, Agricultural, Food, Environmental, Pharmaceutical, Forensic

An Example of an Accreditation Program (SCC)

PALCAN

PSA Working Groups

Amplification/Application Guides

Accreditation vs. Registration

MRA & Audit of SCC - subsequent training of assessors

Standards

ISO 17025, “old” ISO Guide 25, ISO 9000:1994, ISO 9000:2000, ISO
14000

Industry Specific Standards, eg. aerospace, automotive

Checklists, References

The accreditation process from the lab’s perspective

Develop Quality System

Laboratory Preparation

Assessment

Breakout

Management Systems Audit

Review ISO 17025 Requirements – audit checklist

Technical Assessor Audit

Review ISO 17025 Requirements – audit checklist

Proficiency Testing

Describe Requirement

Describe various Proficiency Testing Schemes

Discussion, Questions and Answers

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WORKSHOP ON THE ESTIMATION OF MEASUREMENT UNCERTAINTY

A Practical Approach to the Estimation of Measurement Uncertainty

Introduction

- Two options to estimate measurement uncertainty
- Rationale for practical approach
- Error discussion

Metrological (Type B) Approach

- Identifying sources of uncertainty - the “Fishbone” diagram
- Quantifying uncertainty

Breakout

- Standard Uncertainty and conversions to it
- Calculating the combined uncertainty

Breakout

Use of Repeat Data (Type A) Approach

- Sample replication as a source of uncertainty information
- Method validation as a source of uncertainty information
- Estimating measurement uncertainty with this approach

Breakout

- Reporting uncertainty

Breakout

Discussion

Workshop conclusion, workshop evaluation, Certificates awarded