

# COURSE OVERVIEW LE0560 Advanced Statistical Analysis of Laboratory Data

Method Development, Method Validation, Uncertainty, Calibration, SQC and Data Interpretation

#### **Course Title**

Advanced Statistical Analysis of Laboratory Data: *Method Development, Method Validation, Uncertainty, Calibration, SQC and Data Interpretation* 

#### Course Date/Venue

Session 1: June 22-26, 2025/Meeting Plus 9, City Centre Rotana, Doha, Qatar

Session 2: December 07-11, 2025/Meeting Plus 9, City Centre Rotana, Doha, Qatar



Course Duration/Credits
Five days/3.0 CEUs/30 PDHs

## Course Reference

LE0560

#### **Course Description**







This practical and highly-interactive course includes various practical sessions and exercises. Theory learnt will be applied using our state-of-the-art simulators.

The analytical laboratory has always served an important function by providing data in support of other branches of science and engineering and in helping control product quality or process variables. In recent years, however, the laboratory has in many cases come into its own as a semi-independent entity, geared to the solution of problems by means of the techniques available to it, rather than serving only to provide data for others to interpret.

Whether these problems are solved independently or by co-operative effort is not important. What is important is that the broad capabilities of the laboratory be recognized. Where this is the case, the laboratory can exercise a unique function in developing information essential to the organization of which it is a part, and its staff will enjoy the prestige among its peers that it merits.









Generally, the function of the industrial analytical laboratory is designated as process or product quality control, technical service, or research and development. Often, however, two or more of these functions are exercised in the same laboratory, sometimes by the designation of personnel for a specific type of assignment. It should be emphasized that through the majority of analytical laboratories may be those serving industry and can be placed in one of these four categories, many operations and problems are similar, regardless of the laboratory's affiliation, and can be viewed from the same perspective.

The purpose of any analytical measurement is to get consistent, reliable and accurate data. There is no doubt that incorrect measurement results can lead to tremendous costs. In addition, reporting incorrect analytical results at any particular time leads to loss of a laboratory's confidence in the validity of future results. Therefore, any laboratory should do its outmost to ensure measuring and reporting reliable and accurate data within a known level of confidence. Validation and qualification of processes and equipment will help meet this goal.

The appraisal of quality has a considerable impact on analytical laboratories. Laboratories have to manage the quality of their services and to convince clients that the advocated level of quality is attained and maintained. Increasingly, accreditation is demanded or used as evidence of reliability. Quality control is not meaningful unless the methodology used has been validated properly. Validation of a methodology means the proof of suitability of this methodology to provide useful analytical data. A method is validated when the performance characteristics of the method are adequate and when it has been established that the measurement is under statistical control and produces accurate results.

Despite the fact that a laboratory may have met all qualification and accreditation requirements, its reported data are still subject to verification and challenge. The quality of chemical analysis is usually evaluated on the basis of its uncertainty compared to the requirements of the users of the analysis. If the analytical results are consistent and have small uncertainty compared to the requirements, the analytical data are considered to be of adequate quality. When the results are excessively variable or the uncertainty is larger than the needs, the analytical results are of low or inadequate quality. Thus, the evaluation of the quality of analysis results is a relative determination. What is high quality for one sample could be unacceptable for another. A quantitative measurement is always an estimate of the real value of the measure and involves some level of uncertainty. The limits of the uncertainty must be known within a stated probability, otherwise no use can be made of the measurement. Measurement must be done in such a way that could provide this statistical predictability.

Statistics is an integral part of quality assessment of analytical results. The concept of a frequency distribution, which embodies the behaviour of change fluctuations, is a felicitous one for the description of many pertinent aspects of measurement. If this concept is combined with the principle of least squares, by which the inconsistencies of measurements are compensated, and with the modern ideas underlying "inverse probability," which allow us to make quantitative statements about the causes of observed chance events, we obtain an impressive body of useful knowledge.





Nevertheless, it is by no means certain that a systematic science of data analysis, if and when it finally be developed, will be based exclusively on probabilistic concepts. Undoubtedly probability will always play an important role in data analysis but it is rather likely that principles of a different nature will also be invoked in the final formation of such a science. In the meantime, we must make use of whatever methods are available to us for a meaningful approach to the analysis of experimental data.

This course is designed to provide participants with good knowledge and skills required to perform advanced statistical calculations in modern analytical laboratories. The course starts by reviewing the existing knowledge of participants on the fundamental concepts of statistics. Method development and validation will then be discussed which also include the quality requirements as per the ISO 17025 standard. Participants will then be introduced to the process of measuring uncertainty estimation by identifying uncertainty sources, quantifying and reporting combined uncertainty. The course will then discuss the various calibration functions and the types of statistical quality control charts (SQC) and wrap up with the procedures and methods used to interpret the inter & intra laboratory data. Participants will have the opportunity to apply the principles learned to actual problems through the use of illustrative case studies under the guidance of the instructor. Through a combination of lectures and problem-solving sessions, participants will learn advanced statistical techniques that they can put to immediate use in their laboratory.

#### **Course Objectives**

Upon the successful completion of this course, each participant will be able to: -

- Apply statistical formulas used in QC/QA and illustrate method development & validation
- Identify the proper procedure for analytical measurement & uncertainty including its uncertainty sources, error and uncertainty, method validation and traceability
- Explain the uncertainty evaluation procedure for Quantifying Uncertainty (GUM), and use prior collaborative method development and validation study data
- Calculate the combined uncertainty and analyze the results based on standard and expanded uncertainty reports
- Explain the calibration functions which include the establishment of an analytical range, determination of the calibration function, using of regression lines for comparing analytical methods, verification of linearity & precision and recovery
- Enumerate the types of Statistical Quality Control Charts (SQC), carryout proficiency test program and interpret inter & intra laboratory data

#### **Exclusive Smart Training Kit - H-STK®**



Participants of this course will receive the exclusive "Haward Smart Training Kit" (**H-STK**<sup>®</sup>). The **H-STK**<sup>®</sup> consists of a comprehensive set of technical content which includes **electronic version** of the course materials conveniently saved in a **Tablet PC**.











#### Who Should Attend

This course provides an overview of all significant aspects and considerations of statistical analysis of laboratory data for those who are involved in method development, method validation, uncertainty, calibration, SQC and data interpretation of laboratory data. This includes all degree-holder staff of analytical laboratories, R&D and government statutory employees. Further, QA/QC employees and third-party inspection and certification companies will also benefit from this course.

#### **Course Certificate(s)**

Internationally recognized certificates will be issued to all participants of the course who completed a minimum of 80% of the total tuition hours.

#### **Certificate Accreditations**

Certificates are accredited by the following international accreditation organizations:

BAC

#### British Accreditation Council (BAC)

Haward Technology is accredited by the British Accreditation Council for Independent Further and Higher Education as an International Centre. BAC is the British accrediting body responsible for setting standards within independent further and higher education sector in the UK and overseas. As a BAC-accredited international centre, Haward Technology meets all of the international higher education criteria and standards set by BAC.



The International Accreditors for Continuing Education and Training (IACET - USA)

Haward Technology is an Authorized Training Provider by the International Accreditors for Continuing Education and Training (IACET), 2201 Cooperative Way, Suite 600, Herndon, VA 20171, USA. In obtaining this authority, Haward Technology has demonstrated that it complies with the ANSI/IACET 2018-1 Standard which is widely recognized as the standard of good practice internationally. As a result of our Authorized Provider membership status, Haward Technology is authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET 2018-1 Standard.

Haward Technology's courses meet the professional certification and continuing education requirements for participants seeking Continuing Education Units (CEUs) in accordance with the rules & regulations of the International Accreditors for Continuing Education & Training (IACET). IACET is an international authority that evaluates programs according to strict, research-based criteria and guidelines. The CEU is an internationally accepted uniform unit of measurement in qualified courses of continuing education.

Haward Technology Middle East will award 3.0 CEUs (Continuing Education Units) or 30 PDHs (Professional Development Hours) for participants who completed the total tuition hours of this program. One CEU is equivalent to ten Professional Development Hours (PDHs) or ten contact hours of the participation in and completion of Haward Technology programs. A permanent record of a participant's involvement and awarding of CEU will be maintained by Haward Technology. Haward Technology will provide a copy of the participant's CEU and PDH Transcript of Records upon request.







#### Course Instructor(s)

This course will be conducted by the following instructor(s). However, we have the right to change the course instructor(s) prior to the course date and inform participants accordingly:



Mr. Paul Patsi, MSc, BSc, is a Senior Analytical Chemist and an International Expert in Water & Waste Water Treatment Technology with over 20 years of extensive experience in Analytical Laboratory and Water & Wastewater Treatment Engineering. His expertise covers Laboratory Assessment, Microbiological Quality Assurance, Analytical Chemistry, Statistical Analysis, Laboratory Safety, Equipment & Infrastructure Management, Budgeting & Planning of

Laboratory Consumables, Business Administration, Personnel Management, Laboratory Management, Chemical Analysis, Laboratory Auditing, Risk Assessment, Microbiological Analysis of Water & Waste Water, Waste Water Treatment Analysis, Water Chemistry, HACCP, ISO 22000, ISO 17025, ISO 9001, Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP) and Good Laboratory Practice (GLP). He is also an expert in microbiological indoor air quality, water biology, food sampling and calibration. He is currently the Head of Industrial Analytical Laboratory of PINDOS wherein he is in-charge of the budgeting, auditing, consumables, suppliers, personnel management, equipment and infrastructure management along with waste water treatment and water/environmental legislation.

During his career life, Mr. Paul has held key positions such as the Head of Microbiology & Chemical Laboratory, Head of Quality Control, Technical Consultant, Research Projects Specialist, Scientific Consultant, Biologist-Scientific Expert and Biologist for multi-billion companies like the European Union, Help LTD, Lake Pamvotis Municipality Company, Hellenic Centre for Marine Research, Cargill and Nestle just to name a few.

Mr. Paul has a Master degree in Food Science and Food Technology from the University of Ioannina (Greece) and a Bachelor degree in Biology from the Aristotle University of Thessaloniki (Greece). He is a Certified Instructor/Trainer and a Member of the Society for Applied Microbiology, Society of Biological Scientist and the Global Coalition for Sustained Excellence in Food & Health Protection.

#### Training Methodology

All our Courses are including **Hands-on Practical Sessions** using equipment, State-of-the-Art Simulators, Drawings, Case Studies, Videos and Exercises. The courses include the following training methodologies as a percentage of the total tuition hours:-

30% Lectures

20% Practical Workshops & Work Presentations

30% Hands-on Practical Exercises & Case Studies

20% Simulators (Hardware & Software) & Videos

In an unlikely event, the course instructor may modify the above training methodology before or during the course for technical reasons.









#### **Course Fee**

**US\$ 6,000** per Delegate. This rate includes H-STK® (Haward Smart Training Kit), buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

#### **Accommodation**

Accommodation is not included in the course fees. However, any accommodation required can be arranged at the time of booking.

#### **Course Program**

The following program is planned for this course. However, the course instructor(s) may modify this program before or during the course for technical reasons with no prior notice to participants. Nevertheless, the course objectives will always be met:

Day 1

Registration & Coffee
Welcome & Introduction
PRE-TEST
Fundamental Concepts in Statistics
Review of Basic Statistical Formulas used in QC/QA • Statistical Tests such
as (T&F) Distribution • Probability (One Tail Test & Two Tail Tests) •
Hypothesis Testing
Break
Fundamental Concepts in Statistics (cont'd)
Sampling & Pair Sampling • ANOVA • Normal Distribution • Outliers
Test
Method Development & Validation
Analytical Method Validation • Chemical Method Validation - The Future •
Errors in Instrumental Analysis Regression & Correlation
Break
Method Development & Validation (cont'd)
Laboratory Quality Standards • Design & Analysis of Experiments
Recap
Lunch & End of Day One

#### Day 2

0730 - 0930	Method Development & Validation (cont'd) Statistical Method Validation for Test Laboratories
0020 0045	
0930 - 0945	Break
0945 – 1100	Method Development & Validation (cont'd)
	Method Validation Procedure
1100 - 1230	Measuring Uncertainty
	Analytical Measurement & Uncertainty
1230 – 1245	Break
	Measuring Uncertainty (cont'd)
1245 – 1420	The Process of Measurement Uncertainty Estimation • Specification of the
	Measure • Identifying Uncertainty Sources
1420 - 1430	Recap
1430	Lunch & End of Day Two







Day 3

0730 - 0930	Measuring Uncertainty (cont'd)
	Quantifying Uncertainty (GUM)
0930 - 0945	Break
0945 – 1100	Measuring Uncertainty (cont'd)
	Quantifying Uncertainty (GUM) (cont'd)
1100 – 1230	Measuring Uncertainty (cont'd)
	Calculating the Combined Uncertainty
1230 - 1245	Break
1245 – 1420	Measuring Uncertainty (cont'd)
	Reporting Uncertainty
1420 – 1430	Recap
1430	Lunch & End of Day Three

Day 4

Day 4	
0730 - 0930	<ul> <li>Calibration Functions</li> <li>Calibration of the Analytical Procedure • Establishing of an Analytical Range</li> <li>Determination of the Calibration Function &amp; Process Data • Use of Regression Lines for Comparing Analytical Methods</li> </ul>
0930 - 0945	Break
0945 - 1100	Calibration Functions (cont'd)  Determination for the Linear Calibration Function • Process Data for the Linear Calibration Function • Process Data for the 2-order Calibration Function
1100 – 1230	Calibration Functions (cont'd)  Verification of Linearity & Precision • Recovery Function
1230 – 1245	Break
1245 – 1420	Types of Statistical Quality Control Charts (SQC)  Control Limits • Steps to Construct a Control Chart • SPC, SQC, Shewhart Chart
1420 - 1430	Recap
1430	Lunch & End of Day Four

Day 5

0730 – 0930	Types of Statistical Quality Control Charts (SQC) (cont'd)
	Range Charts • Interpretation Guidelines
0930 - 0945	Break
0945 – 1100	Types of Statistical Quality Control Charts (SQC), Proficiency Test
	Program (PT)
	Cu sum Chart • Proficiency Test Program (PT) • Inter-Laboratory
	Performance test (F-Test / T-Test (Student's t Distribution Test) • Paired Test
	• Q-Test • Z-Score• Box & Whisker Plots • Interpretation & Acceptance
	Criteria of Control Chart used as SQC & International Guideline
1100 – 1230	Interpretation of Inter & Intra Laboratory Data
	Data Generation • Raw Analytical Data Parameters • Signal-to-Noise Ratios
	Final Data   Reporting
1230 - 1245	Break

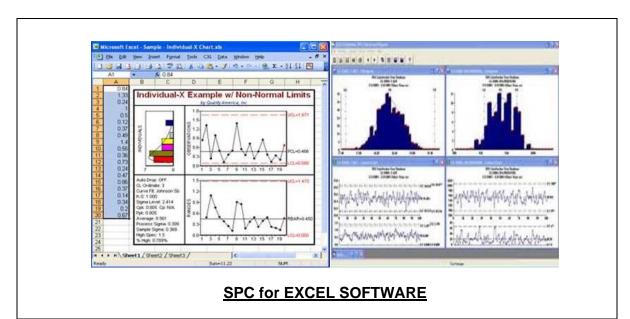




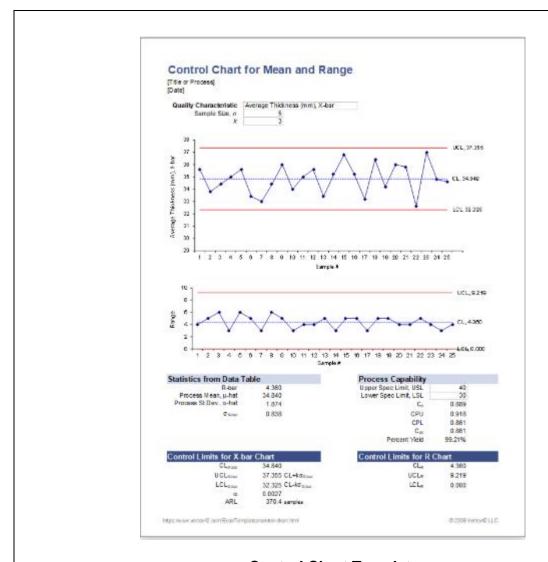
1245 – 1345	Interpretation of Inter & Intra Laboratory Data (cont'd)  Common Mistakes Made in Data Interpretation • Interpreting Numbers Close to or Below Detection Limits • Numbers Close to Guideline Values • Interpretation Using Uncertainty
1345 - 1400	Course Conclusion
1400 – 1415	POST-TEST
1415 – 1430	Presentation of Course Certificates
1430	Lunch & End of Course

## **Simulator (Hands-on Practical Sessions)**

Practical sessions will be organized during the course for delegates to practice the theory learnt. Delegates will be provided with an opportunity to carryout various exercises using our state-of-the-art simulator "SPC for Excel Software", "Control Chart Template", "Box and Whisker Plot Template", "Scatter Diagram Template", "Pareto Chart Template", "Fishbone (Cause-and-Effect) Diagram", "Design of Experiments (DOE)".

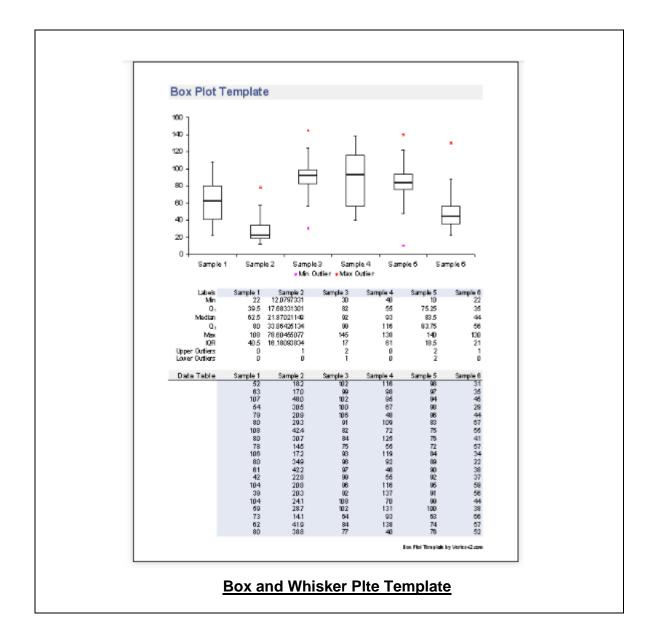




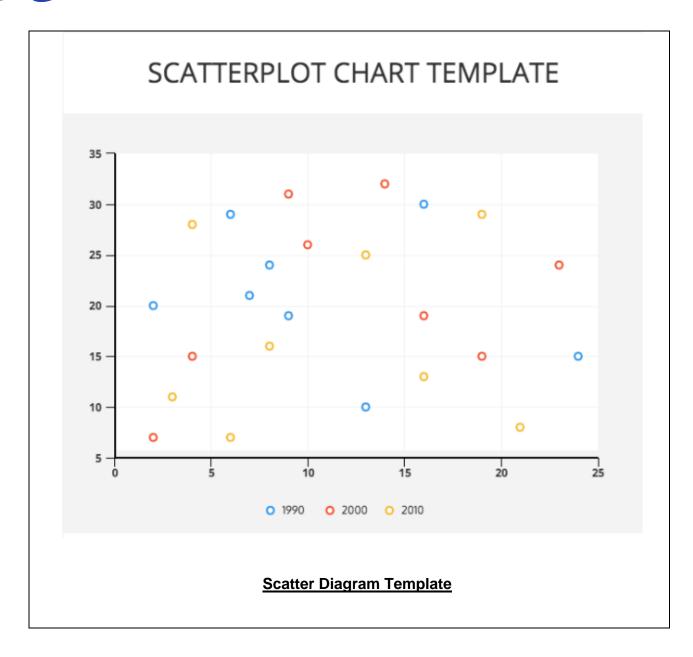


#### **Control Chart Template**

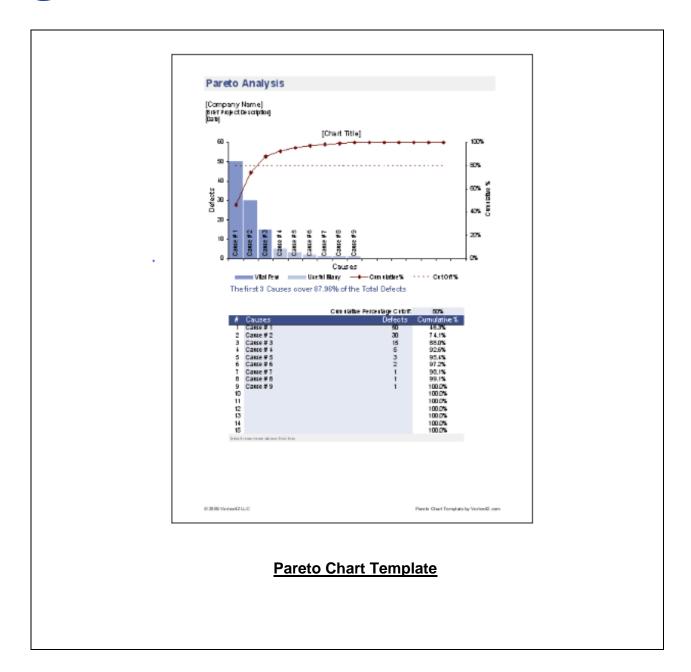






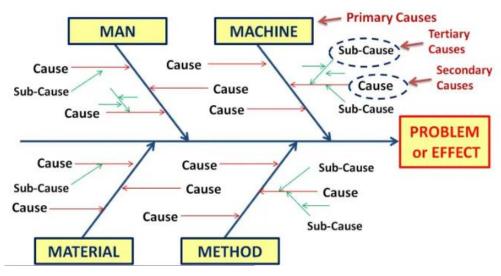




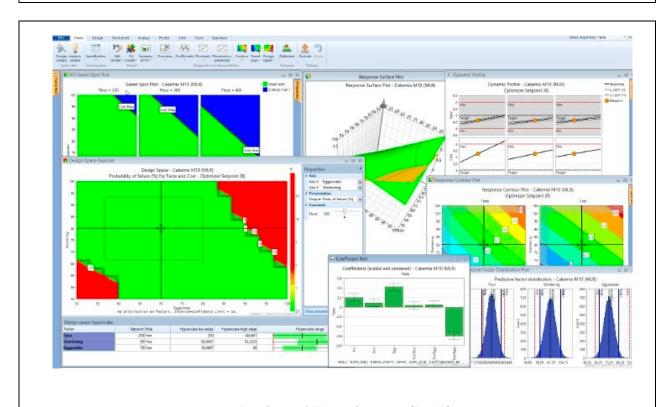




## CAUSE AND EFFECT DIAGRAM



### Fishbone (Cause-and-effect) Diagram)



## **Design of Experiments (DOE)**

## **Course Coordinator**

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