COURSE OVERVIEW LE0220
Data & Method Validation in Analytical Laboratories

Course Title
Data & Method Validation in Analytical Laboratories

Course Date/Venue
Session 1 : April 06-10, 2025/Boardroom 1, Elite Byblos Hotel Al Barsha, Sheikh Zayed Road, Dubai, UAE
Session 2 : December 14-18, 2025/Al Khobar Meeting Room, Hilton Garden Inn, Al Khobar, KSA

Course Reference
LE0220

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

Course Description

This practical and highly-interactive course includes real-life case studies and exercises where participants will be engaged in a series of interactive small groups and class workshops.

Validation and qualification for analytical methods and equipment are required by many regulations, quality standards and company policies. If executed correctly, they can also help to improve the reliability, consistency and accuracy of analytical data. This course guides analyst, laboratory managers and quality assurance managers through the validation and qualification processes in analytical laboratories.

The course takes into account most national and international regulations and quality standards. Participants of this course will learn how to speed up their validation and qualification process, thereby avoiding troublesome reworking and gaining confidence for audits and inspections.

The validation and qualification procedures presented in this course help to ensure compliance and quality but with minimal extra cost and administrative complexity. The purpose of this course is to answer the key question regarding validation: *How much validation is needed and how much is sufficient?* The recommendations are complementary rather than contradictory to any standards or official guidelines. They are based mainly on common sense and can be used in cases where information from official guidelines and standards is insufficient for day-to-day work.

Course Objectives

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

- Apply and gain an in-depth knowledge on data and method validation in analytical laboratories
- Assess how much validation is needed and how much is sufficient
- Discuss the regulations, quality standards and guidelines pertaining to national and international organizations that includes ISO, EN and US
- Carryout the recommended protocols and steps for the qualifications in design, preinstallation & installations of systems, operations, performance and maintenance
- Recognize parametric statistics and summarizing data as well as statistical analysis of raw data
- Perform T-testing and F-testing and identify linear regression, anova, quality control and charting
- Explain the validation of analytical methods including the validation of standard and non-routine methods, quality control plans, revalidation and parameters for methods validation
- List various examples of method validation and perform proficiency testing for external laboratory qualification
- Describe measurement uncertainty and employ proper auditing

Exclusive Smart Training Kit - H-STK®

*Participants of this course will receive the exclusive "Haward Smart Training Kit" (**H-STK®**). The **H-STK®** 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 data and method validation in analytical laboratories for quality managers, quality professionals, laboratory managers, superintendents, supervisors, chemists, scientists, analysts and other technical staff.

Accommodation

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

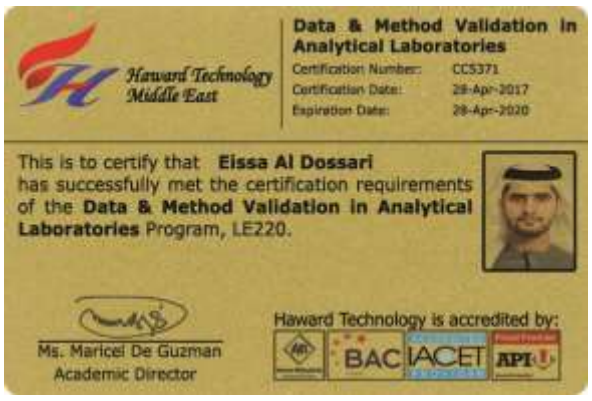
Course Certificate(s)

(1) Internationally recognized Wall Competency Certificates and Plastic Wallet Card Certificates will be issued to participants who completed a minimum of 80% of the total tuition hours and successfully passed the exam at the end of the course. Certificates are valid for 5 years.

Recertification is FOC for a Lifetime.

Sample Certificates

The following are samples of the certificates that will be awarded to course participants: -



(2) Official Transcript of Records will be provided to the successful delegates with the equivalent number of ANSI/IACET accredited Continuing Education Units (CEUs) earned during the course.

Page 1 of 1

Haward Technology Middle East

Continuing Professional Development (HTME-CPD)

CEU Official Transcript of Records

TOR Issuance Date: 28-Apr-17

HTME No. PAR11317

Participant Name: Eissa Al Dossari

Program Ref.	Program Title	Program Date	No. of Contact Hours	CEU's
LE220	**Data & Method Validation in Analytical Laboratories**	April 24-28, 2017	30	3.0

Total No. of CEU's Earned as of TOR Issuance Date **3.0**

TRUE COPY

Maricel De Guzman
Academic Director

Haward Technology has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102, USA. In obtaining this approval, Haward Technology has demonstrated that it complies with the ANSI/IACET 1-2013 Standard which is widely recognized as the standard of good practice internationally. As a result of their Authorized Provider membership status, Haward Technology is authorized to offer IACET CEUs for programs that qualify under the ANSI/IACET 1-2013 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 Association 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 is accredited by

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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:

Dr. Ian Kaloudis, PhD, MSc, PGrad, BSc, is a **Senior Analytical Chemist** with almost **30 years** of extensive experience. His expertise widely covers in the areas of **Chemical Analysis**, **Chemical Laboratory**, **Laboratory** Management, **Laboratory** Supervision & Management, **Analytical Laboratory** Management, **Modern Analytical Laboratory**: Management, **Laboratory Consumables Management**, **Laboratory Instrument Calibrations** & Troubleshooting Techniques, Safety and Quality in **Scientific Laboratory**, **Laboratory** Skills, **Pesticides** Application, **PAH**, **VOC**, Advanced Oxidation Processes (**AOP**), **Phenols**, **Cyanotoxins**, Gas Chromatography (**GC**), Mass Spectrometry (**MS**), **GC/MS** Technology & Problem Solving, High Performance Liquid Chromatography (**HPLC**), **HPLC-ICP-MS/ICP-MS**, **Analytical Instrumentation**, Equipment, Safety & Quality (ISO 17025), **Analytical Instrumentation** for Laboratory, **Analytical Chemistry**, **Analytical Laboratory Quality Management System**, **Waste Water Treatment**, **Elucidation** of Mechanisms, **Statistical Analysis of Data**, Statistical Quality Control (**SQC**), Statistics Methods & Measurement Uncertainty, **ISO 17025:2017**, **Food Safety** and **Environmental** Management Systems. He is currently the **Head of Organic Micropollutants Laboratory** of Athens Water Supply and Sewerage Company wherein he is responsible for the development & validation for the determination of organic pollutants in water, research projects related to water quality and development of cyanotoxins analysis laboratory.

All throughout his career life, Dr. Kaloudis had occupied several challenging positions and dedication as **Quality Manager**, **Head of Industrial Waste Water Control Section**, **Consultant**, **Senior Researcher**, **Collaborating Researcher**, **Research Associate**, **Lecturer**, **Trainer** and **Auditor** for various companies such as the KEK DIASTASI - Hellenic Food Authority Training Programs, University of the West of Scotland, Institute of Nanoscience and Nanotechnology (INN), Hellenic Accreditation System (E.SY.D.), Institute of Physical Chemistry, Food Industrial Research and Technological Development Company and Athens Water Supply and Sewerage Company (EYDAP SA).

Dr. Kaloudis has a **PhD** degree in Chemistry (Honors) from the **National and Kapodistrian University of Athens**, a **Master** degree in **Quality Management** from the **University of the West of Scotland**, a **Postgraduate Programme** in **Production Management & Quality Management** from **Technical Educational Institute (TEI) of Piraeus**, a **Bachelor** degree in **Chemistry** (Honors) from **National and Kapodistrian University of Athens**. Further, he is a **Certified Instructor/Trainer**, a **Certified ISO 17025:2017 Auditor**, a **Registered Food Safety and Hygiene Trainer**, a **Certified ISO 9001 Lead Auditor** from International Register of Certificated Auditors (**IRCA**), a **Certified Environmental Management Systems Auditor** from Institute of Environmental Management and Assessment (**IEMA**), a member of the American Chemical Society (**ACS**), a senior member of the American Society for Quality (**ASQ**), a member of the International Water Association (**IWA**), a member of the European Water Platform, a member of the Hellenic Mass Spectrometry Society (**HMSS**), a member of the Italian Society of Toxicology and a member of the Association of Greek Chemists (**AGC**). He has further published numerous journals/books and delivered various trainings, seminars, conferences, workshops and courses globally.

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$ 5,500 per Delegate + **VAT**. This rate includes H-STK® (Haward Smart Training Kit), buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

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

0730 – 0800	*Registration & Coffee*
0800 – 0815	*Welcome & Introduction*
0815 – 0830	***PRE-TEST***
0830 – 0930	***Regulations, Standards & Guidelines (USA, EN & ISO)*** *Overview • Specific Regulations and Guidelines • Specific Quality Standards and Guidelines • Guidance Documents of National and International Organizations • How to Deal with Multiple Regulations and Quality Standards • Summary Recommendations*
0930 – 0945	*Break*
0945 – 1100	***Installation Qualification & Operational Qualification*** *Preinstallation • Installation • Tests During Installation • The Installation Qualification Protocol • Requalification after Changes to the Systems • Considerations • Documentation • A Practical and Economical Approach for Implementation • System Suitability Testing • Handling of Defective Instruments • Summary Recommendations*
1100 – 1230	***Performance Qualification & Maintenance*** *Logbook • Maintenance • Calibration • Performance Testing*
1230 – 1245	*Break*
1245 – 1420	***Parametric Statistics & Summarising Data*** *Distributions of Data • Standard Deviation • Summarising Data*
1420 - 1430	***Recap*** *Using this Course Overview, the Instructor(s) will Brief Participants about the Topics that were Discussed Today and Advise Them of the Topics to be Discussed Tomorrow*
1430	*Lunch & End of Day One*

Day 2

0730 – 0900	***Statistical Analysis of Raw Data*** *Outlier Testing • Dixon Test • Grubbs Test*
0900 – 0915	*Break*
0915 – 1100	***T-testing & F-testing*** *Hypothesis Testing • The T-test • One Sample T-test • Two Sample T-test • Paired Comparison T-test • The F-test*
1100 – 1230	***Linear Regression & ANOVA*** *The Calibration Process • Correlation Coefficient • Residuals Regression Coefficients*
1230 – 1245	*Break*
1245 – 1420	***Linear Regression & ANOVA (cont'd)*** *Prediction Intervals • Standard Error of Prediction Anova Analysis*
1420 - 1430	***Recap*** *Using this Course Overview, the Instructor(s) will Brief Participants about the Topics that were Discussed Today and Advise Them of the Topics to be Discussed Tomorrow*
1430	*Lunch & End of Day Two*

Day 3

0730 – 0930	***Quality Control & Charting*** *Introduction • QC Sample Types • Shewart Charts*
0930 – 0945	*Break*
0945 – 1100	***Quality Control & Charting (cont'd)*** *Range Charts • Moving Average Charts • Chart Rules and Interpretation*
1100 – 1230	***Validation of Analytical Methods*** *Introduction • Strategy for the Validation of Methods • Validation of Standard Methods • Validation of Nonroutine Methods*
1230 – 1245	*Break*
1245 – 1420	***Validation of Analytical Methods (cont'd)*** *Quality Control Plan • Implementation to Routine Analysis • Revalidation • Parameters for Method Validation • Summary Recommendations*
1420 - 1430	***Recap*** *Using this Course Overview, the Instructor(s) will Brief Participants about the Topics that were Discussed Today and Advise Them of the Topics to be Discussed Tomorrow*
1430	*Lunch & End of Day Three*

Day 4

0730 – 0930	***Example Method Validation*** *Purpose • Scope • Acceptance Criteria*
0930 – 0945	*Break*
0945 – 1100	***Example Method Validation (cont'd)*** *System Suitability • Example Method Validation*
1100 – 1230	***Proficiency Testing for External Laboratory Qualification*** *Procedure • Evaluation of Proficiency Testing • Who Should Participate in Proficiency Testing • Frequency of Tests • Testing Material*
1230 – 1245	*Break*

1245 – 1420	***Proficiency Testing for External Laboratory Qualification (cont'd)*** *Advantages for Laboratories • Performance Improvements • Remaining Issues • Summary Recommendations*
1420 - 1430	***Recap*** *Using this Course Overview, the Instructor(s) will Brief Participants about the Topics that were Discussed Today and Advise Them of the Topics to be Discussed Tomorrow*
1430	*Lunch & End of Day Four*

Day 5

0730 – 0930	***Measurement Uncertainty*** *Introduction to ISO 17025 Requirements • Standard Uncertainty Expanded*
0930 – 0945	*Break*
0945 – 1100	***Measurement Uncertainty (cont'd)*** *Uncertainty Precision and Bias*
1100 – 1200	***Audits*** *Audit Report • Audit Checklist*
1200 – 1215	*Break*
1215 – 1300	***Audits (cont'd)*** *Summary Recommendations*
1300 – 1315	***Course Conclusion*** *Using this Course Overview, the Instructor(s) will Brief Participants about the Course Topics that were Covered During the Course*
1315 – 1415	***COMPETENCY EXAM***
1415 – 1430	*Presentation of Course Certificates*
1430	*Lunch & End of Course*

Practical Sessions

This practical and highly-interactive course includes real-life case studies and exercises:-

Course Coordinator

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