COURSE OVERVIEW LE0290

Advanced GLP: Uncertainty Measurement, Data Validation, Method Validation & Statistical Process Control (SPC) in Analytical Laboratory According to ISO 17025

Course Title

Advanced GLP: Uncertainty Measurement, Data Validation, Method Validation & Statistical Process Control (SPC) in Analytical Laboratory According to ISO 17025

Course Date/Venue

October 13-17, 2025/Ajman Meeting Room, Grand Millennium Al Wahda Hotel, Abu Dhabi, UAE

Course Reference

LE0290

Course Duration/Credits

Five days/3.0 CEUs/30 PDHs

Course Description

This practical and highly-interactive course includes various practical sessions and exercises. Theory learnt will be applied using "MS-Excel" application.

Good laboratory practice means different things to different people. This course covers the advanced topics in Good Laboratory Practice (GLP). All the practices that ensure that laboratory testing is planned, performed, monitored, recorded and reported in an organised and controlled manner, will be discussed in general and the Uncertainty Measurement (GUM) in particular.

The course addresses the requirements of EN ISO / IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories as well as the common requirements of GLP Compliance (OECD, USA, Canada, Europe & Japan) as applicable to QC/QA/Production Control Laboratories. The different GLP standards set out the requirements for technical competence and proper management of the analytical laboratories. The standards usually cover a variety of topics, that will be covered during this course: Laboratory Organization; Personnel; Safety Assurance; Laboratory Facility; Testing and Measuring Equipment; Apparatus and Reagents; Test Methods and Procedures; Calibration; Samples and Test Data Storage, Inspection, Assessment and Uncertainty Measurement (UM). The course will also discuss the requirements to be met by a laboratory supporting its organisations quality system to the ISO 9000 series of standards.

The course provides training of the Good Laboratory Practice (GLP) for personnel of laboratories who wish to produce test results that are fit for the purpose and which would stand up to the scrutiny. Obviously, the primary objective of the GLP is to ensure the generation of high quality data. Statistical tools play an important role in GLP to calculate the Uncertainty Measurement. This course will focus on the latest techniques and standards developed to measure the uncertainty of the data.

The Guideline for Uncertainty Measurement (GUM) will be introduced in a simple way. Every effort is made in this course to eliminate unnecessary complications, to apply the GUM at its simplest level and to take away apparent mystery. Participants who have never drawn up uncertainty budgets before usually develop the required skill well before the end of the course. Others who seek explanations of GUM complexities obtain clarifications expressed in simple terms. Measurement uncertainty problems are solved by brainstorming methods so as to generate interaction by all participants. The course will use the Statistical Process Control (SPC) module as a tool to validate the uncertainty measurement. It covers control charts and their applicability to uncertainty before covering a step-by-step process of calculating uncertainty for a typical application. Methods of reporting uncertainty, the uncertainty budget and applicable standards and guidelines for expressing measurement uncertainty are covered in some detail. Successful completion of this course will enable participants to understand, evaluate and express measurement uncertainty.

Course Objectives

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

- Apply an in-depth knowledge in the Good Laboratory Practice (GLP) in accordance with the international rules and standards
- Practice uncertainty measurement, data validation, method validation and statistical process control in compliance with the latest revision of ISO 17025 standard
- Implement the Good Laboratory Practice (GLP) and gain advanced knowledge in modern laboratories GLP system
- Distinguish the various GLP standards and regulations that set out the requirements for technical competence and proper management of analytical laboratories
- Identify the common requirements of GLP compliance as per OECD, the USA, Canada, Europe and Japan
- Explain the differences between the USA and OECD regulations and identify which system is suitable for your laboratory
- Discuss the critical GLP compliance issues
- Describe the GLP requirements related to organization, personnel, facilities, equipment, operations, testing, control, protocols, records and reports
- Recognize the scope, field of application, components & sources of uncertainty and carry out analytical measurement and experimental studies of method performance
- Review and improve the process of measurement uncertainty estimation and be able to analyze the specification of the measurand
- Identify uncertainty sources and employ the process of quantifying uncertainty
- Carryout the process of calculating the combined uncertainty and be able to review the procedure on reporting uncertainty
- Explain Statistical Process Control (SPC) and identify its applications
- Apply method validation techniques in accordance with ISO17025

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, sample video clips of the instructor's actual lectures & practical sessions during the course conveniently saved in a **Tablet PC**.*

Who Should Attend

This course provides an overview of all significant aspects and considerations of GLP in accordance with the international standards for those involved in laboratory management. This includes laboratory managers, superintendents, supervisors, scientists, doctors, physicians, chemists, researchers, analysts, officers, coordinators and other technical staff. R&D and government statutory employees will benefit from the international standards and regulation part of the course. Further, this course is very important for QA/QC employees and Third-Party Inspection and certification companies.

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 Certificate(s)

(1) Internationally recognized Competency Certificates and Plastic Wallet Cards 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 of 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.

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Haward Technology Middle East

Continuing Professional Development (HTME-CPD)

CEU Official Transcript of Records

TOR Issuance Date: 19-Nov-17

HTME No. PAR11317

Participant Name: Rashed Al Ismail

Program Ref.	Program Title	Program Date	No. of Contact Hours	CEU's
LE290	**Advanced GLP: Uncertainty Measurement, Data Validation, Method Validation & Statistical Process Control (SPC) in Analytical Laboratory According to ISO 17025**	November 15-19, 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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Certificate Accreditations

Certificates are accredited by the following international accreditation organizations: -

- 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.

- 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.

Accommodation

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

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. Yousef Al-Mashni, PhD, MSc, BSc, is an **International Expert** in **Analytical Laboratory** with over **35 years** of extensive experience. He is an **authority** in **Laboratory Equipment**, **Laboratory Quality Management Systems** (**ISO 17025** and **ISO 15189**), **Lab Safety & Health**, Good Laboratory Practice (**GLP**) and **Safety Procedure** in **Laboratories**. His wide expertise also covers **Water Analysis** & **Reporting**, **Water Sampling** & **Testing**, **Water Analyzer**, **Medical Laboratory Auditing**, **ISO 15489**, **Infection Control**, Internal **Quality Control** for **Microbiologists**, **Analytical Techniques**, **Biochemical**, **Hematological**, **Parasitological**, **Biochemical**, **Microbiological** & **Serological Analysis** of **Clinical Specimens**, **Helmith Ova** & **Salmonella** in **Waste Water** & **Sludge**, **Microbiological** Aspects & **Analysis** of **Wastewater**, Microbiology of **Wetlands**, Microbiological **Indoor Air Quality**, **Entrococcus**, **Pseudomonas** & **Aeromonas**, **Sulfate Reducing Bacteria**, **Fluorescense Microscopy**, **Planktology** of **Ambient Environment**, **Oral**, **Medical** & **Diagnostic Microbiology** and **Oral** & **Dental Hygiene**. Further, he is also well-versed in the areas of **Food Hygiene** and **HACCP**, **Food Safety**, **Food Poisoning**, **First Aid & CPR** and **Fire Safety**. He is currently the Deputy **Principal** & **Chief Technical Instructor** of **UNRWA** wherein he is responsible in developing and managing operations at the college/centre including building workshops and laboratories capacity, curriculum development and introducing new courses.

During his long career life, Dr. Yousef worked for many international companies handling key positions such as ICDL Centre **Manager**, **Deputy Principal**, **Chief Technical Instructor**, **Acting Principal**, **Laboratory Supervisor**, **Technical Instructor**, **Technical & Vocational Instructor**, **Senior Medical Laboratory Technician** and **Medical Laboratory Technician**.

Dr. Yousef has a **PhD** degree in **Natural Health Sciences** from the **University of Florida** (**USA**), **Master** degree in **Clinical Microbiology** and **Bachelor** degree **with Honours** in **Microbiology**. Further, he has **Diploma** in Vocational Education (**UNRWA & UNESCO**) and received several **certifications** like **ICDL** and Training of Trainers (**TOT**) in **Cambridge University** (**England**). He is a **Certified Internal Verifier/Assessor/Trainer** by the **Institute of Leadership & Management** (**ILM**), a **Certified Instructor/Trainer** and an active **member** of **Jordan Medical Laboratories Society**, Technical **Accreditation Committee of Medical Laboratories** (**Jordan Institution & Metrology**) and the Technical **Accreditation Committee for Granting ISO 15189 Certificate**. Furthermore, he has also published numerous technical papers and books including **Medical & Diagnostic Microbiology**, **Practical Competencies in Medical Laboratory Technology**, **Safety in Medical Laboratory Science** and **Quality Control in Medical Laboratory Science** just to name a few.

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: ***Monday, 13th of October 2025***

0730 – 0800	*Registration & Coffee*
0800 – 0815	*Welcome & Introduction*
0815 – 0830	***PRE-TEST***
0830 – 0930	***Guide to Good Laboratory Practice*** *Introduction • Quality Assurance in Laboratory • GLP & The Transfer of Technology • The Cost of GLP Non-Compliance • International Regulations Governing GLP • Chronology & Current Regulations (U.S.A, OECD, Canada, Europe & Japan 3.2 Comparison Between US & OECD Regulations)*
0930 – 0945	*Break*
0945 – 1100	***Guide to Good Laboratory Practice (cont'd)*** *Critical GLP Compliance Issues • Organization & Personnel • Facilities • Equipment • Testing Facilities Operation • Test & Control Articles • Protocol for & Conduct of a Study • Records & Reports • Conclusions*
1100 – 1230	***Essential Statistics for Analytical Science*** *Sample • Population • Normal Distribution • Summarizing Data • Confidence Intervals*
1230 – 1245	*Break*
1245 – 1420	***Essential Statistics for Analytical Science (cont'd)*** *Outliers • Errors • Accuracy • Precision • Significant Figures*
1420 - 1430	***Recap***
1430	*Lunch & End of Day One*

Day 2: ***Tuesday, 14th of October 2025***

0730 – 0830	***Scope & Field of Application***
0830 – 0930	***Uncertainty*** *Definition of Uncertainty • Uncertainty Sources • Uncertainty Components • Error & Uncertainty*
0930 – 0945	*Break*
0945 – 1045	***Analytical Measurement & Uncertainty*** *Method Validation • Conduct of Experimental Studies of Method Performance • Traceability*
1045 – 1145	***The Process of Measurement Uncertainty Estimation***
1145 – 1230	***Specification of the Measurand***
1230 – 1245	*Break*
1245 – 1330	***Identifying Uncertainty Sources***
1330 – 1420	***Quantifying Uncertainty (GUM)*** *Introduction • Uncertainty Evaluation Procedure • Relevance of Prior Studies • Evaluating Uncertainty by Quantification of Individual Components • Closely Matched Certified Reference Materials*
1420 - 1430	***Recap***
1430	*Lunch & End of Day Two*

Day 3: Wednesday, 15th of October 2025

0730 – 0930	***Quantifying Uncertainty (GUM) (cont'd)*** *Using Prior Collaborative Method Development & Validation Study Data • Using In-House Development & Validation Studies • Evaluation of Uncertainty for Empirical Methods • Evaluation of Uncertainty for Ad-Hoc Methods • Quantification of Individual Components*
0930 – 0945	*Break*
0945 – 1045	***Quantifying Uncertainty (GUM) (cont'd)*** *Experimental Estimation of Individual Uncertainty Contributions • Estimation Based on other Results or Data • Modelling from Theoretical Principles • Estimation Based on Judgement • Significance of Bias*
1045 – 1230	***Calculating the Combined Uncertainty*** *Standard Uncertainties • Combined Standard Uncertainty • Expanded Uncertainty*
1230 – 1245	*Break*
1245 – 1420	***Reporting Uncertainty*** *General • Information Required • Reporting Standard Uncertainty • Reporting Expanded Uncertainty • Numerical Expression of Results • Compliance Against Limits*
1420 - 1430	***Recap***
1430	*Lunch & End of Day Three*

Day 4: Thursday, 16th of October 2025

0730 – 0930	***Statistical Process Control (SPC)*** *The Measurement Process Model • Setting Up the Statistics • Evaluating the Process • Setting Control Limits • Using Control Limits • Practical Considerations • Rules*
0930 – 0945	*Break*
0945 – 1045	***Statistical Process Control (SPC) (cont'd)*** *Pareto Charts • Fishbone Diagram • Flowcharting • Scatter Plots • Charts*
1045 – 1230	***Method of Validation*** *Scope and Method Specifications • Setting Validation Criteria that will Satisfy the Needs of Customers • Validation Planning • Accuracy by the Analysis of a CRM • Precision/Repeatability • Working range • Linearity*
1230 – 1245	*Break*
1245 – 1420	***Method of Validation (cont'd)*** *Testing for Performance Characteristics • Limit of Detection (LOD) & Quantitation (LOQ) • Quality Control Plan for Routine Analysis*
1420 - 1430	***Recap***
1430	*Lunch & End of Day Four*

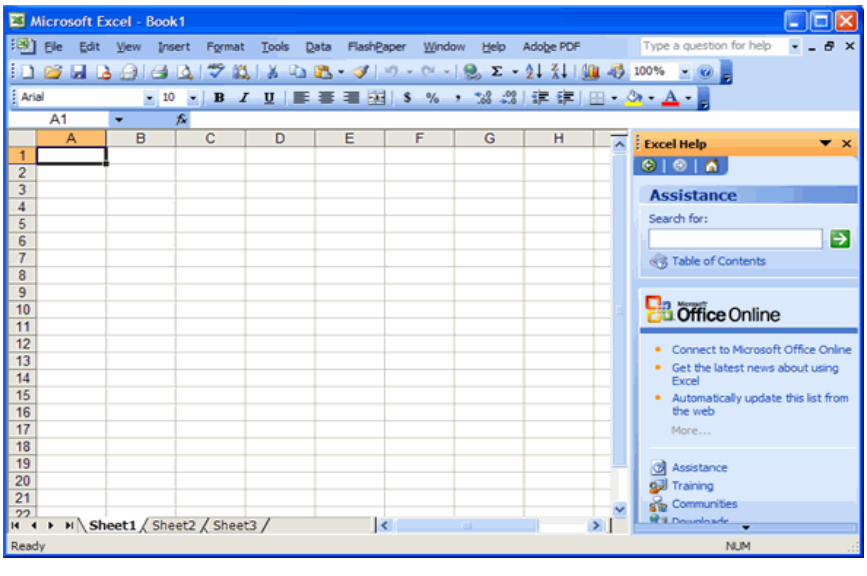
Day 5: Friday, 17th of October 2024

0730 – 0830	***Method of Validation (cont'd)*** *Precision/Ruggedness • Robustness • Stabilities • Validation Report*
0830 – 0930	***Method of Validation (cont'd)*** *Traceability • Proof of the Performance of A Method and/or Assuring the Quality of a Measurement According to ISO 17025 • Analysis of QC Samples • Documentation*
0930 – 0945	*Break*

0945 – 1230	***Method of Validation (cont'd)*** *Analysis of CRM's • Reproducibility Studies Like Proficiency Testing & Interlaboratory Studies • Customer Management*
1230 – 1245	*Break*
1245 – 1300	***Case Study: How to write a Method Validation Document. Students will Work in Groups or Individually to Solve a Case Study***
1300 - 1315	***Course Conclusion***
1315 – 1415	***COMPETENCY EXAM***
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 "MS-Excel" application.



MS-Excel

Course Coordinator

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