



# AL085: Good Laboratory Practice (GLP) & Statistical Process Control (SPC)

## Training Description:

This intensive 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. 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 training course will focus on the latest techniques and standards developed to measure the uncertainty data.

This training 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 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.

## Training Designed for:

This course is intended for all Senior Technician, Chemists Senior Chemists and other Laboratory Personnel.

## Training Requirement:

**“Hand’s on practical sessions, equipment and software will be applied during the course** if required and as per the client’s request.”

**Contents can be adapted to your specific wishes. It is therefore possible to focus on specific modules of the training course as per client’s learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.**

## Training Program:

### FIVE DAYS:

- ❖ **Principles Good Laboratory Practice**
  - Study Director and Principal Investigator
  - Test Facility and Test Site
  - The Study
  - Short-Term Studies
  - Initiation, Starting and Completion Dates
  - Study Plan, Amendments and Deviations
  - Raw Data
  - The Phases of a Study
  - The Master Schedule
  - Test and Reference Item
  - Additional Definitions
- ❖ **Responsibilities in Good Laboratory Practice**
  - Study Director and Principal Investigator
  - Study Personnel
  - The Sponsor

- ❖ **The Quality Assurance Programme**
  - General Considerations
  - Quality Assurance Inspections
  - Quality Assurance Inspection Reports
  - Audits of Raw Data and of Final Reports
  - The Quality Assurance Statement
- ❖ **Facilities**
  - General Requirements
  - Test System Facilities
  - Facilities for Handling Test and Reference Items
  - Archive Facilities
- ❖ **Apparatus, Materials and Reagents**
- ❖ **Computerized Systems**
  - Basic Considerations
  - Data considerations
  - Prospective Validation
  - Retrospective Evaluation
  - Maintenance and Change Control
  - Levels of Complexity
- ❖ **Test Systems**
  - Physical/Chemical Test Systems
  - Biological Test Systems
- ❖ **Test and Reference Items**
  - Handling and Documentation
  - Expiry Dates
  - Sample Retention
- ❖ **Standard Operating Procedures**
  - The Format
  - Issue, Approval and Distribution
  - On-line SOPs
  - The Content
  - Where are SOPs required?
- ❖ **Study Performance and Reporting**
  - The Study Plan
  - Study Conduct
  - The Final Report
  - Re-opening and Amending a Study
  - Discontinued Studies
- ❖ **ISO 17025 Introduction to Accreditation**
- ❖ **Typical Case Studies**
- ❖ **Course Conclusion**
- ❖ **Post-Assessment and Evaluation**

## Training Methodology:

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Gamification, Software & General Discussions
- Pre and Post Test

## Training Certificate(s):

CMCT Internationally recognized certificate will be issued to each participant who completed the course

## Training Fees:

**TBA as per the course location** - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01<sup>st</sup> of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

## Training Timings:

### Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:00	Recess (Prayer Break & Lunch)
13:00 - 14:00	Last Session

### For training registrations or in-house enquiries, please contact:

**Aisha Relativo** - Training & Career Development Manager

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