COBBLESTONE

COURSE ID 0545

Good Laboratory Practices (GLP)

DIRECTED BY

David Long — International Consultant

8 HOUR

ACCREDITED COURSE

Course Topics Include:

- GLP in Safety and Environmental Studies
- Planning / Conducting / Reporting Compliant GLP Studies
- Problem Solving Workshops / Case Studies / Quizzes
- Regulatory Context

about the course

Benjamin Franklin famously said:

"Tell me and I forget, teach me and I may remember, involve me and I learn"

This course has been entirely redesigned with this cogent observation in mind so that each person can get involved in problem-solving and thus learn about Good Laboratory Practice (GLP) Regulations.

Overall, the main intent is to review all the requirements of Good Laboratory Practices (GLP) regulations for facilities engaged in regulated Safety Testing. The learning initiative is achieved through a mixture of short lectures, illustrative answers to FAQs, and by collective problem-solving workshops. The aim is to ensure that each participant is personally faced with real-life situations for which GLP-compliant solutions have to be found.

The participants will also be challenged with the issues of data integrity and the problems of study reconstruction. Participants will be asked to give their own reactions to real-life situations and to solve the issues arising in a way compliant with the regulations.

Involving the participants in GLP decision-making processes means that they will learn and understand rather than just receiving information as they would from a standard course. This 8-hour accredited course will concentrate on existing FDA and OECD Good Laboratory Practices and their application to the workplace including recent developments such as multi-site and short-term studies. Lectures will address how to prepare and react to inspections.

who should attend

This intensive, practical course delivered over two consecutive days will be of value to those professionals in the pharmaceutical, medical device and related industries who are responsible for or involved in any interaction with suppliers, including those working in:

• Scientists	• Regulatory/Compliance Personnel
• Quality Assurance Staff	• Those newly assigned GLP Responsibilities
• More experienced personnel needing to update their knowledge	

learning objectives

Upon completion of this course, you will be able to:

- Define the principles of Good Laboratory Practices intended to assure the quality and integrity of laboratory data
- Develop an insight into procedures for achieving compliance

course outline

Review of Learning Objectives
Introduction and Overview

- Why GLP became necessary
- Scope of GLP
- The Fundamental points of GLP

Planning: Resources

- Personnel: Requirements / Documentation
- Workshop
- Equipment; Requirements / Documentation
- Workshop

Planning: Study Design

- The Master schedule sheet
- Study Director role: The Study Plan / Amendments / Study calendars
- Workshop

Performing: Standard Operating Procedures

- Definition, Characteristics and Value of SOPs
- SOP management
- Workshop

Recording: Data Acquisition

- Raw data
- Workshop

Reporting: Final Study Reports

- Regulatory requirements
- Reporting Results
- Report Statements
- Workshop

Monitoring: Quality Assurance

- Why do we need QA?
- Reporting findings
- QA Statement
- Workshop

Multi-Site Studies

- Definitions
- Roles and Responsibilities
- Communications
- Reporting
- Workshop

National Monitoring of Studies

- The Rules
- Preparation and practice
- Workshop

Review Session and Summing Up

- Case Studies
- FAQs – with commentary by course leaders
- Final Q&A session

Assessment Opportunity

course instructor

David Long worked for Rhône Poulenc Health Division (now Sanofi) in Quality Assurance (QA) for over twenty years where he gained considerable experience in all three Good Practice disciplines, GLP, GCP, and GMP. When he left Rhône-Poulenc he was Senior Director of R&D worldwide for Quality and for Process Improvement. Mr. Long has since worked for CHIMEX, a manufacturing subsidiary of the L'Oreal group, and now runs his own consultancy.
David Long has always shown a keen interest in promoting professional QA activities. He was a founding member and President of the French QA Society and a founding member and President of the European QA Federation. He was also the founder and Chief Editor of the Quality Assurance Journal, an international scientific journal specifically addressing subjects of interest to R&D and QA personnel.

He has lectured and trained widely and has been an active participant in developing training in Good Practices and QA, working with a number of international groups including the OECD and the WHO. His latest contribution through the WHO has been in the co-authoring of a set of guidelines for research performed upstream of the regulatory scene, called "Quality Practices in Basic Biomedical Research".

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 8 contact hours, or .8 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.