COBBLESTONE

COURSE ID 2136

REVISED!

GLP Study Director

How to deal with GLP, Sponsors, QA, and multi-site challenges

DIRECTED BY

David Long — International Consultant

12 HOUR

ACCREDITED COURSE

- Revision of GLP Fundamentals
- The Study Director Responsibilities in Planning,
- Execution and Reporting Studies
- Responding to QA Findings
- The Multi-Site Situation
- Workshops

about the course

Benjamin Franklin famously said:

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

This intensive 12- hour accredited course has been entirely redesigned with Franklin's cogent observation in mind so that each person can get involved in problem-solving and thus learn about how to run regulatory studies that must be performed in compliance with Good Laboratory Practice (GLP) Regulations.

Overall, the main intent is to review the roles and responsibilities of the STUDY DIRECTOR who is in overall control when running GLP studies. The learning initiative is achieved through 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 a study director has to find GLP-compliant solutions.

To understand GLP study direction you must understand how studies are planned, performed, and reported. The course also includes workshops on protocols (study plans), the implementation of procedures, and the importance of the study report within the context of the GLP safety studies.

At every research laboratory, GLP study directors inevitably have problems of GLP implementation. The participants will be challenged 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 accredited training will concentrate on existing OECD and FDA Good Laboratory Practices and their application to the workplace including recent developments such as multi-site studies.

Although there will be ample time for participants to ask questions, the course director will also hold an optional, free, one-hour "GLP Study Director- Clinic" after the end of the course for those who have detailed or specific problems that they would like to discuss, either privately (if your institute considers the issue to be confidential) or openly with all participants if the topic does not require confidential treatment.

who should attend

The course is designed for people who are considering a career opportunity in GLP study direction or those who are already GLP study directors and wish to refresh or perfect their knowledge about running studies in compliance with GLP. The course will benefit the following individuals:

• Existing Study Directors who wish to upgrade their competence in a multi-site situation	• Principal Investigators in the field of Preclinical Regulatory R&D
• The newly appointed Study Director	• Study Monitors
• Study Supervisors who wish to become Study Directors	• Coordinators of multi-site projects

learning objectives

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

- Evaluate risks to study integrity, and develop strategies for dealing with these issues
- Perform preclinical studies to full GLP compliance
- Respond appropriately to Quality Assurance and Monitoring inspectors
- Build adequate communication channels with the aim of successfully dealing with the multi-site situation

course outline

Review of Learning Objectives
Introduction and Overview

- Fundamental points of GLP
- Responsibilities of Study Directors

Planning Studies

- The Master Schedule
- The Study Plan (Protocol)
- Study Calendar
- Workshop on Protocols

Performing Studies

- Standard Operating Procedures
- Workshop on SOPs

Recording Study Data

- Raw Data and responsibilities
- Workshop on Raw Data

Reporting Studies/Archiving Studies

- Study Director and the Final Report
- Archiving responsibilities of the Study Director
- Report Amendments
- GLP Compliance Statements
- Workshop on reports

Monitoring Studies

- Study Director and QA Responsibilities
- Workshop on QA audit inspection reports

Multi-Site Studies

- Regulatory requirements / Role of Study Director
- Workshop

Closing Session

- Case Studies Workshop
- Final Q&A session
- Self-Evaluation 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 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 12 contact hours, or 1.2 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.