COBBLESTONE

COURSE ID 2564

REVISED!

GLP and Quality Assurance: Developing a GLP Compliant QA Program

DIRECTED BY

David Long — International Consultant

8 HOUR

ACCREDITED COURSE

Course Topics Include:

- How to Develop and Maintain a GLP QA Function
- How to Perform Inspections and Audits

For Live attendees ONLY: Workshops Include:

- SOP audit
- Establishing a QA program
- Protocol audit

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 how to perform the role of Quality Assurance for laboratories undertaking 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 QUALITY ASSURANCE (QA) group auditing and inspecting GLP studies. The important responsibility of setting up, maintaining, and performing a QA program in a laboratory is at the core of this course. The learning initiative is achieved through short lectures, illustrative answers to FAQs, and problem-solving workshops. The aim is to ensure that each participant is personally faced with real-life situations for which a member of a GLP/QA team must find GLP-compliant solutions.

To be efficient in GLP /QA you must understand how studies are planned, performed, and reported, and how a general GLP environment can be assured in the laboratory. Thus, we put great importance on the establishment and application of a GLP/QA audit and inspection program. The participants will also be challenged with the issues of study integrity, the problems of study reconstruction, and the establishment of valid operating procedures. 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 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 directors will also hold an optional, free, hour-long "GLP Quality Assurance - Clinic" after the end of the course for those who have detailed or specific problems that they would like to discuss with them, 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 participants in this course will already know the basics of Good Laboratory Practice either through prior experience or completion of the CfPA Course Good Laboratory Practices #545. The course is designed for those who wish to master how to implement and maintain a GLP QA function. The course explores quality issues within preclinical GLP and provides an opportunity for experienced personnel to update their competencies. Participants may come from:

- Life-Science Industries
- Academia
- Government
- Contract Testing Facilities

The course is designed for people who are considering a career opportunity in GLP/QA or those who are already GLP/QA personnel but who wish to refresh or perfect their QA knowledge and skills.

learning objectives

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

- Effectively implement and maintain a GLP Quality Assurance function in your institution based on acceptable rationale
- Perform inspections and audits of all on-going GLP activities
- Undertake the role of Lead QA in a multi-site situation
- Set up and maintain a QA program
- Perform report reviews using different techniques

course outline

Review of Learning Objectives
Overview of Quality Assurance in GLP

- History
- Fundamental points of GLP
- Principle GLP regulations
- Compliance monitoring
- QA responsibilities

The OECD Approach to Audits/Inspections

- The OECD recommended types of inspections
- Workshop: Determining types of inspection

Performing Inspections

- Workshop: Developing an inspection checklist
- Contribution from Risk analysis
- Quiz/Q&A Session

Auditing Reports

- Report Reviewing Strategies
    - Numerical data
    - Non-numerical data
- Implications of Report Statements
- Workshop: Statistically based report auditing
- Reporting audits in the QA Statement
- Quiz/Q&A Session

Multi-Site Studies

- Regulatory requirements
- Workshop/Quiz/Q&A Session

Monitoring CROs

- Regulatory requirements / What to look for, how to monitor
- Q&A session

Closing Session

- Case Studies
- Final Q&A session

Assessment Opportunity

To Maximize your Learning! Attend this course and its companion
Good Laboratory Practices (GLP)
GLP Study Director

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 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.