

# **GMP Training Systems, Inc.**

Creators of the GMP Ready-to-Use Training System™

## **Understanding and Implementing Good Laboratory Practice (GLP)**

### **Workshop Abstract**

This workshop aims at highlighting the roles, responsibilities and duties of key Management, Supervisors, Scientists, Principal Investigators, Regulatory, QAU and other personnel in GLP facilities, contract laboratories, research institutes, CRO's or other organizations engaged in the conduct of GLP (FDA, FIFRA, OECD, JAPAN, etc) studies and other non-clinical studies related to drug development, safety & toxicity studies and various targeted evaluations. Discussions will include the various aspects of Study Conduct, QAU audits, Protocol development, and the roles of Study Directors, Management, PI's, QAU and other key personnel with real life examples, case histories, group participations and class assignments. The basic tenets of FDA and OECD or other GLP's will be covered with comparison on some key issues. The course is geared towards the development of understanding the basic requirements and key compliance issues with a Risk Assessment and QS based approach at various levels of Management and organization in a compliant GLP Testing Facility.

### **Learning Objectives**

Upon completion of this workshop, participants will be able to:

- Learn about the various significant and highly responsible roles that are played by Management, Study Directors and QAU personnel in a GLP facility.
- Familiarize yourself with some of the delineations and intricacies of responsibilities and accountability in maintaining testing facilities engaged in the conduct of GLP studies.
- Learn to develop protocol, QAU assessment reports, SOP's .and prepare a thorough and comprehensive approach to Regulatory compliance issues.
- Develop strategies in effective implementation of a compliant GLP program with involvement, interactions, case studies and group exercises included in this highly interactive course presentation.

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## **Who should attend**

- Management, Study Directors, Scientists, Principal Investigators, Toxicologists, QA Managers, Study Monitors
- Laboratory Professionals, Regulatory Affairs, Archivists and QAU Personnel
- GLP coordinators, auditors from various Contract Laboratories, CRO's, CMO's and Research Facilities in the conduct and assessment of GLP studies needing compliance to various GLP's

## **Workshop instructor**

The instructor for this workshop is Shib Moorherjea, President of ValQual International. In his career covering three decades, he has held senior scientist and management positions with multinational organizations, including Colgate Palmolive, Johnson & Johnson, Troy Corporation, BASF, and several academic institutions.

## **Workshop approach and style**

Highly interactive and participative. The target levels are mid to higher levels of the organization in the GLP laboratories, CRO's and contract situations and various Study Personnel.

## **GLP Workshop Outline**

This one day course will cover some of the major requirements, definitions and considerations for conducting GLP studies. The conducting of GLP studies has critical importance in the support of product registration in the pharmaceutical, biotechnology as well as other regulated industries.

- Introduction: Quality, Quality Systems
- Global Scenario, Harmonization, ICH
- Requirements of Quality Systems
- Genesis of FDA GLP/OECD GLP
- Basic Definitions and Tenets of the GLP's
- Management: Definition, Scope, Role, Responsibilities
- Study Director: Definition, Scope, Role, Responsibilities
- QAU: Definition, Scope, Role, Responsibilities
- Testing Facility: Definition and Requirement

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- Equipment: Various Equipment, Devices and Instruments
- Protocol and Study Conduct: Role of Study Director
- Study Conduct: Test Systems, Test in Control Articles
- Systems and Procedures: Qualification and Validation
- Computer Systems: Risk Assessment, ERES, Validation
- Records: Storage and Retrieval: Archiving
- Retention, Requirements
- Implementation of GLP in a Testing Facility: Documentation, SOPs
- Case Studies and Group Exercise
- References, Web Addresses, Sources
- Conclusion
- Acknowledgements