ComplianceOnline
The Largest GRC Advisory Network

2 days in-person Seminar

Recordkeeping and Documentation in a GLP Laboratory (US FDA, US EPA and OSHA Focus)

By: **John C. Fetzer, PhD**, Consultant, Fetzpahs Consulting

Location: San Diego, CA | March 15-16, 2018

SPEAKER

John C. Fetzer, PhD, Consultant, Fetzpahs Consulting

Dr. Fetzer has been a method-development analytical chemist for over 3 decades. In that role he developed new methods for GC, HPLC, fluorescence spectroscopy, titrimetry, the use of ion-selective electrodes, and physical properties of aqueous solubility and octanol-water partition coefficient that complied with Good Laboratory practices. As part of his consulting and contracting work he developed GLP-compliant methods for a biopharma startup and for a petrochemical company. In all of these various efforts, numerous SOPs were written, as well as the prototype of a later-approved ASTM method. He supervised and managed a GLP compliant laboratory for over 10 years and helped maintain the documentation necessary for compliance.

LEARNING OBJECTIVES

Upon completing this course, participants should:

- Know the variety of common documentation within a compliant laboratory.
- Understand the requirements for entering information into logbooks and also to know some of the ways that are not compliant.
- Understand the importance of logbooks for: chemicals, instruments, calibration, maintenance and repair, calibrations, training and competence. Know the information suitable in each type.
- Understand the requirements for recordkeeping and archiving.

COURSE DESCRIPTION

GLP requires many types of documents. The seminar covers both the general issues and many specifics that laboratories can receive a non-compliance on. These range from data recording to validation issues to training records to archiving of documents.

An auditor can find numerous common errors and many, many others that are specific to a particular laboratory. This seminar will go through many of the compliance areas and point out some of both of these types. For those implementing GLP or striving to maintain certification, this course should point out many areas to examine that would lessen an unsatisfactory audit.

Most of the focus on a laboratory's compliance with Good Laboratory Practice (GLP) or with the analogous ISO 17025 is on items such as the Standard Operating Procedures (SOPs), training, quality assurance testing, and the statistical assessment of performance and compliance. These, however, are not all that an auditor may delve into. These might the bulk of an audit, yet a laboratory may still fail an audit while doing well on all of these areas. Since laboratories focus on these, other areas might be ignored – the more mundane and simple areas, such as recordkeeping and archiving, basic laboratory operations, and safety.

AGENDA

Day One (8:30 AM - 4:30 PM)

Registration Process - (8:30 am till 9:00 am)

Session 1 (90 Mins)

- Recordkeeping and Archiving – Who, what, when, where, why, and how these are performed – an Overview.

Session 2 (90 Mins)

- Who is responsible – what are the roles?

Session 3 (90 Mins)

- What things must be recorded and archived?
- Why is this important? The Role of Records and Documents in Compliance and Operations

Session 4 (90 Mins)

- Where are specific things recorded and archived?
- The How to keep records, the Logging System, Offsite versus Onsite Archiving.

Day Two (8:30 AM - 4:30 PM)

Session 5 (90 Mins)

- Basic laboratory operations - Facilities maintenance records
- Sample entrance and records, Sample handling and storage, Chain of custody

Session 6 (90 Mins)

- Sample preparation records
- Weighing, volumetric glassware, labeling
- Sample solution handling and records

Session 7 (90 Mins)

- Stability testing! Logbooks for preparation of standards, reagents, and buffers.
- Instrument repair and maintenance logbooks, calibration logbooks

Session 8 (90 Mins)

- Prevention through the Use of Control Charts, Nelson's Rules as a Statistical Basic for such Monitoring
- Troubleshooting and Prevention Efforts
- Safety as a Compliance Issue

WHO WILL BENEFIT

This course is aimed at those working in laboratories that must comply with Good Laboratory Practice or ISO 17025, especially those whose results are to be reported to the US Food and Drug Administration (FDA), the US Environmental Protection Agency (EPA), and the US Occupational Safety and Health Administration (OSHA). The various roles:

- Managers and supervisors of the laboratory
- Quality officers and internal auditors
- Scientists and research associates

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Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Recordkeeping and Documentation in a GLP Laboratory (US FDA, US EPA and OSHA Focus)

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