Class Offerings

Technical Training

HPLC 101: Basics of High Performance Liquid Chromatography-Designed for new operators.

***Introduction to Root Cause Analysis and Corrective & Preventive Action*-**Identify the true cause of problems.

***ISO 17025 Internal Audit*-**Comprehensive instructions on auditing quality management.

ISO 9001 Internal Audit Comprehensive instructions on auditing quality management.

***Laboratory Controls in the GMP/GLP Environment*-**Current industry practice for labs.

Lean Six Sigma Basics-Eliminate the waste.

Mock audit or process audit at participant's site (optional add-on to ISO 9001/17025 Internal Audit)-See your operation in action.

Principles of Lean Manufacturing- Origin and main principles of Lean and how they apply in a manufacturing or laboratory settings.

Labtopia

TRAINING SEMINAR INFORMATION

HPLC 101: Basics of High Performance Liquid Chromatography

Overview:

This course provides the student with a solid understanding of the fundamental concepts of High Performance Liquid Chromatography (HPLC). Designed for new operators or those wanting a refresher, this course covers an array of basic HPLC topics. Discussions include types of pumps and detectors and how they work, column selection and mechanisms of separation, solvent selection, choices in sample preparation, considerations in liquid chromatographic method development, fundamental HPLC calculations, basic HPLC system troubleshooting and an open discussion period to address any specific student needs. At the conclusion of this course, the student will have a sound basic understanding of how HPLC components and systems function, how compounds are separated by HPLC and how to make effective daily operational decisions.

Who Should Attend:

New operators or those needing a refresher on HPLC

Trainer

Thomas Hubbell

Labtopia

TRAINING SEMINAR INFORMATION

Introduction to Root Cause Analysis and Corrective & Preventive Action

Overview:

In this introductory course, participants will learn how to effectively perform root cause analysis in order to identify the true cause of problems. Students will develop skills to write effective problem statements, identify the conditions or actions immediately preceding or surrounding the problem, and understand the reasons why these causes occurred. This course will examine some of the most popular methods for root cause analysis including "The 5 Whys", failure mode and effects analysis (FMEA), Pareto Analysis, fault tree analysis, and the Ishikawa diagram (Fishbone diagram or cause and effect).

In addition, the course will review the differences between corrective and preventive action and when each tool is used. At the end of the class, students will have a basic understanding of problem solving techniques and how to apply them in day-to-day business situations.

Lecture will be supplemented with classroom exercises to strengthen the participant's understanding of the methods presented.

Key Session Topics:

- Introduction to Root Cause
- Developing a Problem Statement
- Root Cause Analysis Techniques
- Corrective vs. Preventive Action

Who Should Attend:

Personnel who will be required to perform problem solving investigations.

Trainer:

Gretchen McAuliffe

Labtopia

TRAINING SEMINAR INFORMATION

ISO 9001 / ISO 17025 Internal Audit Training

Overview

This highly participative course provides comprehensive instruction on auditing quality management systems based on the ISO 9001 requirements. The training will teach process based audit skills useful in internal and external audits. Practical workshops, case studies, and simulated assessments are used to practice auditing skills and techniques. Reference is made to the international standards on quality management systems. The first 1.5 days of class will focus on audit principles and common requirements of the ISO 9000 and ISO/IEC 17025 series. Participants may also choose to register for the additional half day session which will focus on unique audit requirements for ISO/IEC 17025 quality management systems.

Prerequisites: Each student shall be required to have studied the current published version of ISO 9001 and/or ISO/IEC 17025 prior to attending the course. Please bring a copy of the standard with you to the course.

Key Session Topics

- Coordinating a quality management system audit
- Constructing an audit program and the preparation of audit checklists
- Learning effective auditing techniques
- Preparing nonconformity statements
- Evaluating the significance of audit findings
- Methods for improving communication skills
- How to report audit findings and conclusions
- Developing and implementing corrective action programs
- Evaluating corrective action responses
- How to effectively follow-up audit findings to recognize if the nonconforming situation has been effectively resolved

ISO 17025 Session Topics

- Overview of ISO/IEC 17025 requirements
- Understanding the difference between quality system registration and accreditation
- Preparing specialized checklists for the laboratory environment
- Identify the evidence needed to demonstrate conformity to the requirements of ISO/IEC 17025.

*A mock audit or process audit at the participant site (2-4 hours) is available for an additional fee.

Who Should Attend:

Personnel who will be required to conduct internal audits or supplier audits.

Trainer

Gretchen McAuliffe

Labtopia

TRAINING SEMINAR INFORMATION

Laboratory Controls in the GMP/GLP Environment

Overview:

What controls should laboratories implement in an FDA regulated environment? This training course provides a thorough review of GMP/GLP requirements and current industry practice for labs which support clinical trials as well as those who provide quality control testing for commercial products. The training includes information on science based management practices, such as:

- Calibration programs
- Analytical method validation
- Equipment qualification
- Control of standards and reagents

In addition, the course emphasizes laboratory quality system elements, as follows:

- SOPs
- Documentation practices,
- Outsourcing,
- Training programs, and
- Change control

The speakers will also cover advanced topics which include out of specification (OOS) investigations, stability testing, and computer systems validation as it pertains to the laboratory.

As is apparent from the multitude of GMP warning letters related to laboratory compliance, laboratory controls is an area the FDA considers vital to drug product safety, quality, and efficacy. The laboratory plays a crucial role in the development and manufacture of drug products from the approval of submission documents to the release of the final product. Whether you work in paper based systems or electronic databases, this course will focus on effective ways to meet the requirements of the standards at any stage in the drug lifecycle.

Who Should Attend:

Managers or Personnel who are required to work in a GMP/GLP Environment.

Trainer

Gretchen McAuliffe

Labtopia

TRAINING SEMINAR INFORMATION

Lean Six Sigma basics

Overview:
This course will teach you how to apply Six Sigma DMAIC (Define, Measure, Analyze, Improve, and Control) and Lean methodologies in your organization. You will learn six sigma team dynamics, and the basic tools and techniques which will allow you identify and run improvement projects to impact the bottom line of your organization.

This training will enable attendees to understand the benefits of Lean Six Sigma deployment in terms cost reduction, improved process efficiencies and customer satisfaction. Attendees will learn about key concepts and methodologies of Lean six Sigma, the six sigma team dynamics, and also the critical roles of individuals at each level of the six sigma team structure

Key Session Topics

- Process standardization
- Variability reduction
- Productivity improvement
- Waste reduction
- Cost saving
- Customer satisfaction

Who Should Attend:
This training is intended for anyone who wants to learn about the basics of Lean Six Sigma and apply it in improvement activities and/or decision making. Excellent for teams members, team leaders, supervisors, or managers.

When:
December 16th

8:00 – 4:00 pm

Trainer:
Mahindra Varma, M.S.

Labtopia

TRAINING SEMINAR INFORMATION

Principles of Lean in the Laboratory

Overview:

The Lean Overview covers the origins of Lean as well as its main principles applied into manufacturing or laboratory settings. By applying Lean tools the company can reap the benefits of lower costs and labor efficiency. Participants will learn more about several Lean tools that can be applied; Value Stream Mapping, 5S (Sort, Set-up, Shine, Standardize, Sustain), Cell/Standard Work, Pull/Kanban, and Set-up Reductions. This presentation will provide a short overview of each of the tools with examples of application in a laboratory. By reviewing workflows, organizing and cleaning the areas, and providing the supplies to the analyst to perform the job; a plant manager/laboratory supervisor can improve the overall cost, resources and space. The participants will participate in simulation exercises to help demonstrate the tools in their own setting. Upon completion, attendees will be prepared to participate in Lean Manufacturing/Lean Lab improvement events under the guidance of knowledgeable Lean Facilitators.

Who Should Attend:

This class is ideal for those that need a basic understanding of Lean Manufacturing terminology and a cursory knowledge of the main tools.

Trainer:

Jeanne Mensingh