



## **Introduction to Laboratory Current Good Manufacturing Practices (CGMPs): A Systems Based Approach**

### **Course Description**

**“Introduction to Laboratory Current Good Manufacturing Practices (CGMPs): A Systems Based Approach”** is a solid, one-day, introductory level course based on FDA’s quality systems based approach for auditing CGMP facilities. The course materials are based on internal FDA guidance documents and current best practices of the pharmaceutical industry. The course is augmented with real world examples recently encountered by the instructor including references to Form 493 observations and Warning Letters. This is an excellent means to introduce analytical chemists to laboratory CGMPs and the concepts of current good manufacturing practices in general. It’s also an excellent means for laboratory and QA managers to evaluate how their laboratories measure up to current industry standards. Tools and templates, including checklists for assessing your own laboratory’s status of compliance with CGMPs, will be provided on DVD.

### **Target Audience**

Newly hired analytical chemists preparing to work in a CGMP laboratory environment, and QA personnel who review data, reports and audit laboratories, will benefit from this course. Laboratory managers desiring to evaluate the current status of their compliance with CGMPs will also find this course very useful.

### **Course Outline**

1. Introduction to the Systems Based Approach to Laboratory CGMPs.
2. Laboratory Managerial and Administrative Systems (with practical exercise)
3. Laboratory Documentation Practices and Standard Operating Procedures (with practical exercise)
4. Laboratory Equipment Qualification and Calibration (with practical exercise)
5. Laboratory Facilities (with practical exercise)
6. Methods Validation (with practical exercise)
7. Laboratory Computer Systems (with practical exercise)
8. Laboratory Investigations (with practical exercise)
9. General Laboratory Compliance Practices (with practical exercise)
10. Stability Program-An Overview (with practical exercise)
11. Glossary of Common Terms
12. Selected References
13. Selected Vendors
14. Review of Selected References
15. Where to Get Help
16. Questions and Answers