



Introduction and Refresher to cGMP (US)

Course Objective: This one day lecture style course will include case studies to give a better understanding of cGMP and their applications. FDA GMP will be covered, and in particular how they apply to operational staff and management of today's Bio-Tech and Pharmaceutical Industry.

Course Description: This course will discuss cGMP through a combination of lectures, case studies, FDA observations and warning letters. The course will explain how cGMP are applicable to operations staff and management. Other topics to be discussed will be cGMP-self audits, how to handle a cGMP inspection and the latest cGMP updates. Also covered in this course will be the history of GMP development, and the key concepts and requirements for properly implementing an effective cGMP program in a Bio-Tech/Pharmaceutical facility

Course Outline:

- . FDA cGMP
- . Case Studies
- . FDA Observations and Warning Letters
- . History and Development of GMP
- . Key concepts and Requirements
- . Recent Changes and Updates