



Managing Contract Analytical Outsourcing

Course Description

Managing Contract Analytical Outsourcing is a full-day, introductory level course designed for laboratory managers, quality assurance personnel or other individuals tasked with selecting and partnering with a contract analytical laboratory. One of the little recognized facts is that outsourcing contract analytical work may be one of the most difficult tasks to undertaken by an organization. Many times, the sponsor who is outsourcing work (for the first time) takes an almost casual attitude with respect to choosing a contract laboratory and managing the entire outsourcing process. They often rely on an initial “quality agreement”, which in most cases ends up being no more than a “hiring document”. This is a very risky approach, in that there are numerous companies (some of which whom are no longer in existence) who blindly submitted results generated by a contractor to FDA only to have it rejected as unsatisfactory. The course is designed to help personnel involved with outsourcing avoid these pitfalls by taking a focused and systematic approach to selecting a contract laboratory, monitoring project progress and insuring the quality and integrity of output. Package which is available for download in .zip file format is a complete lesson plan and associated course materials, which include Power Point presentation, student handouts, and checklists which can be used to help select contractors.

Course Outline

1. Introduction: Overview of Outsourced Contract Laboratory Resources
2. Roles and Responsibilities (with practical exercise)
3. The Workflow Plan (with practical exercise)
4. The Communication Plan (with practical exercise)
5. The Technology Transfer Plan (with practical exercise)
6. The Contractor Sourcing Plan (with practical exercise)
7. The Documentation Plan (with practical exercise)
8. The Training Plan (with practical exercise)
9. The Project Management and Monitoring Plan (with practical exercise)
10. Summary