Introduction to Part 11 and Data Integrity

This briefing introduces students to the requirements for data integrity and 21 CFR Part 11, Electronic Records and Electronic Signatures. The boundaries of applicability will be discussed: that a computer system includes all the software and all the hardware; that a system is only considered validated as installed, not on the shelf.

Who Should Attend: Medical Device, Pharmaceutical and Bio industry: Project managers, engineers, quality & production team members and business managers who need a basic introduction to Part 11.

Class Length: 1½ hour

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The Regulatory Requirements and draft guidelines that apply to Part 11 and Data Integrity
- Ability to provide records to FDA
- Protection of records
- Limited system access
- Audit trails
- Operational system checks
- Device checks
- Training
- Signature policy
- Signature control
- System Documentation
- Validation

Validation & Compliance Institute LLC
835 Asa Gray Dr.
Ann Arbor MI 48105
734-274-4680