Sanitary Design

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: Pharmaceutical, Dietary Supplement, and Bio industry: Project managers, engineers, quality & production team members and business managers who need to know how to design plants.

Class Length: 8 hours

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:

- Industry Standards
- Facility Design
    - Sources of contamination
    - Distinct Hygienic Zones
    - Site
    - Building Envelope
    - Personnel & Material Flows
    - Interior Spatial Design
    - Building Components & Construction
    - Utility Systems
    - Water Management
    - Room Temperature & Humidity
    - Room Air Quality & Flow
- Equipment Design
    - Cleanable to a microbiological level
    - Made of compatible materials
    - Accessible for inspection, maintenance, cleaning, and sanitation
    - No product or liquid collection
    - Hermetically sealed hollow areas
    - No niches

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

    - Sanitary operational performance
    - Hygienic design of maintenance enclosures
    - Hygienic compatibility with other plant systems
    - Verified cleaning and sanitizing procedures
- Types of water
- Types of Cleaning
    - Clean-in-Place (CIP)
    - Clean-Out-of-Place (COP)
    - Manual
    - Dry
    - Flush