Introduction to Cleaning Validation

This course provides a basic understanding of cleaning validation. Participants will learn what SOP's and Protocols are required for cleaning validation. They will also learn how to create scientifically sound rationales, validation protocols, and reports.

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

Class Length: One day

Maximum Class Size: 20

Course Prerequisites: A working knowledge of cGMP's, and validation

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

- Why cleaning validation is necessary
    - Product testing can not take enough samples to assure sterility
    - 10% sampling of a batch cannot detect defects at a one in a million standard
- Review of Regulatory Requirements and draft guidelines
- Definition of critical validation parameters / Acceptance Criteria
- Microbiological Considerations
- Equipment Design
- Manual vs. Automated Cleaning
- Design of Cleaning Validation Test Plans
- Review what SOP's must be written and followed during cleaning validation
- Cleaning Agents
- Setting Cleaning and Residue Limits.
- Selection of Suitable Analytical Method for Determination
- Validation of Residue Analysis Procedure for Swab And Rinsate
- Learn to evaluate cleaning practices, limit calculations, and validation documents through internal self-audits to ensure compliance.

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