cGMP's for Batch Records and Form Completion and Standard Operating Procedures– what does this mean for operations and quality personnel?

This seminar is specially designed to help operators, technicians, engineers, scientists and managers to comply with regulations while filling in records; to understand the reasons behind the regulations for records and procedures. It will provide a practical application of the cGMPs on the operating level. This comprehensive half day training course begins by reviewing the regulations and guidance documents relevant to batch records and standard operating procedures (SOPs).

Who Should Attend: Operators, technicians, quality control and quality assurance personnel, engineers, scientists, supervisors and managers in product development, production, quality, and support groups; anyone who directs the work of others or who works with others in pharmaceutical, medical device, dietary supplements and food.

Class Length: Half day

Maximum Class Size: 25

Course Prerequisites: None

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

- How US FDA regulations apply to employees' own work;
- What records and reports are;
- Why records are kept;
- What the records should contain;
- How the records should be kept;
- How to fill in batch records properly;
- How to comply with regulations while filling in records;
- Why standard operating procedures (sops) are written;
- How to use the sops effectively;
- What the ramifications are when actions are not properly recorded;
- What the ramifications are when procedures are not followed;
- Where to find the batch record source information in the Code of Federal Regulations and Guidance documents;
- Who the FDA is and what power they have;
- Roles and responsibilities of Manufacturing, Quality Assurance, Management and Employees;
- How to avoid getting into trouble by following Standard Operating Procedures as they are written;
- Examples of how manufacturing employees can directly affect their corporation's regulatory compliance;

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