

## **Production and Process Controls**

### **Introduction**

#### **Regulations**

- ◆ Predicate rule

#### **Procedures**

- ◆ Identity, Strength, Quality, Purity
- ◆ Planned Deviations
- ◆ Unplanned Deviations

#### **Materials**

- ◆ Weighing
- ◆ Charge-In
- ◆ Amount of Active
- ◆ Calculation of Yield

#### **Equipment**

- ◆ Identification
- ◆ Process Controls

### **Sampling**

- ◆ Timing
- ◆ Statistical
- ◆ Random
- ◆ Representative

### **Processing**

- ◆ On Line Testing
- ◆ Ranges
- ◆ Control Chart Actions
- ◆ Production Time Limits

### **Contamination**

- ◆ Control

### **Reprocessing**

- ◆ Guidelines

### **Documentation**

- ◆ Batch Records
- ◆ Retention

### **Wrap Up**

**Course Length:** 57 Minutes includes time to take the final exam.

Times are estimates and vary depending on the speed of taking the course assessments. Quiz questions are presented twice, once for the practice quiz and once for the final exam. Quiz times are estimated at 0.75 minutes for each question. Individual student response times may vary.

**Who should take this class?** New employees or those who need a detailed look at all the predicate rule production and process control requirements.

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or,

**Call:** (415) 487-3500 to speak to a training consultant.