

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