



## CLASS SCHEDULE

### DAY ONE

#### Classroom

Lecture: Definitions, Aseptic Technique (Needles and Syringes), Documentation, Standard Operating Procedures  
Discussion and video: *Hand Washing and Proper Garbing*

#### Lab

Demonstration and Exercise

- Proper Garbing
- Hand Washing
- Hood Prep

Facility Design and Layout  
Validation and Documentation

- Primary and Secondary Engineering Controls

Discussion and Demonstration

- Supply Selection and Staging
- Needle Size and Syringe Selection
- Hand Position and Material Placement in ISO Class 5

Hands-On Experience  
Work Area Prep  
Manipulations: vials, ampules, bags, etc.

### DAY TWO

#### Classroom

USP 797 Why and How to Use It  
USP 797 Risk Levels and Responsibilities  
Non-viable and Viable Contamination  
Quality Assurance/Quality Control/Quality Improvement

- Personnel: Portfolios or Employee File
- Documentation and Process Validation

Environmental Monitoring and Testing  
Environmental Controls

#### Lab

Personnel Validation

- Media Fills
- Glove Tests

Hands-On Experience:

- Gentamicin Ophth. Solution (from inj)
- Simulated Process: 30 x 0.05 ml PFS

### DAY THREE

#### Classroom

Discussion: Sterilization Methods

- Filtration
  - Filter Types and Applications
- Steam: Autoclave
- Dry Heat: Convection Oven

SOP  
Discussion/Demonstration:  
Validation Methods

- Filters: Bubble Point Test
- Autoclave: Biological Indicators/Steam Indicators
- Convection Oven: Biological Indicators
- Filter Selection : Membrane Compatibility, Features, Benefits

#### Chemicals

Final Check and Testing

#### Lab

Prepare Media for Media Fill  
Prepare High-Risk Formula and Autoclave  
Cleanroom  
Perform Media Fill