



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