

DAY 1

8:30 **Welcome and Introductions**

9:00 Introduction to RABS and Isolators

10:30 **Coffee/Tea Break**

10:45 Isolator Decontamination Lab Exercise

12:00 **Lunch**

13:00 User Requirement Specification (URS) Exercise

13:45 Isolator and Equipment Design
 Ergonomics and Mock-ups
 Aseptic Transfer: Methods and Equipment

14:45 **Coffee/Tea Break**

15:00 Biological Indicator Culturing Lab Exercise

15:45 Day 1 Wrap-up

16:00 **End of Day 1**

DAY 2

8:30 **Recap Day 1**

8:45 Glove Systems and Half Suits

9:30 Bio-Decontamination
 Regulatory Guidance
 Cycle Development

10:30 **Coffee/Tea Break**

10:45 Bio-Decontamination Systems

11:15 Reading Biological Indicator Results Lab Exercise

12:00 **Lunch**

13:00 Isolator Leak Testing

13:30 Piping and Instrumentation Diagrams (P&IDs)
 Sterility Test and Filling Line Isolator P&ID Design Exercise

14:45 **Coffee/Tea Break**

15:00 Open Group Discussion and Wrap-up

16:00 **End of Training Course**