



Event Agenda

Design, Validation and Operation of Isolator Systems Training Course (PDA 557)

DAY 1

Welcome and Introductions

8:30

- Glove Exercise
- Your Goals for the Training Course

Introduction to RABS and Isolators

9:00

- Barrier Technology Justification
- Isolator Definitions
- RABS Definitions and Design
- Comparison of Attributes of Cleanrooms, RABS and Isolators

10:30 **Break**

10:45 Isolator Decontamination Lab Exercise

12:00 **Lunch**

13:00 User Requirement Specification (URS) – Group Exercise

Isolator Design

13:45

- Ergonomics and Mock-ups
- Airflow, Pressure Control, Leak Tightness
- Aseptic Transfer: Methods and Equipment

14:45 **Break**

15:00 Biological Indicator Culturing Lab Exercise

15:45 Wrap-Up

16:00 **End of Day 1**



Event Agenda

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DAY 2

8:30 Recap Day 1

Isolator Gloves

- Design Features
- Glove Leak Testing and Maintenance
- Room Background/Environmental Monitoring
- Isolator Cleaning

Bio-Decontamination

- Overview and Definitions
- Regulatory Guidance
- Biological Indicator Issues
- Cycle Development

10:30 Break

Bio-Decontamination Systems

- Mists/Fogs
- Gases/Vapors
- Hydrogen Peroxide Safety

11:15 Biological Indicator Results – Lab Exercise Isolator Validation Group Discussion

12:00 Lunch

13:00 Isolator Leak Testing

13:30 Troubleshooting Positive BI Results

- Group Exercise with Case Study, including P&ID

14:45 Break

15:00 Open Group Discussion and Wrap-Up

16:00 End of Event