



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

- 8:45
 - Design Features
 - Glove Leak Testing and Maintenance
 - Room Background/Environmental Monitoring
 - Isolator Cleaning

Bio-Decontamination

- 9:30
 - Overview and Definitions
 - Regulatory Guidance
 - Biological Indicator Issues
 - Cycle Development

10:30 Break

Bio-Decontamination Systems

- 10:45
 - 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