	<h1>Training Course Agenda</h1>
<h2>PDA 557 Isolator Technology</h2>	

### DAY 1

#### Welcome and Introductions

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| 8:30 | <ul style="list-style-type: none"> <li>Glove Exercise</li> <li>Your Goals for the Training Course</li> </ul> |
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#### Introduction to RABS and Isolators

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| 9:00 | <ul style="list-style-type: none"> <li>Barrier Technology Justification</li> <li>Isolator Definitions</li> <li>RABS Definitions and Design</li> <li>Comparison of Attributes of Cleanrooms, RABS and Isolators</li> </ul> |
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#### 10:30 Coffee/Tea Break

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| 10:45 | Isolator Decontamination Lab Exercise |
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#### 12:00 Lunch

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| 13:00 | User Requirement Specification (URS) – Group Exercise |
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#### Isolator Design


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| 13:45 | <ul style="list-style-type: none"> <li>Ergonomics and Mock-ups</li> <li>Airflow. Pressure Control, Leak Tightness</li> <li>Aseptic Transfer: Methods and Equipment</li> </ul> |
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#### 14:45 Coffee/Tea Break

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| 15:00 | Biological Indicator Culturing Lab Exercise |
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| 15:45 | Wrap-Up |
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#### 16:00 End of Day 1

	<b>Training Course Agenda</b>
	PDA 557 Isolator Technology

## DAY 2

### 8:30 Recap Day 1

	Isolator Glove and Half Suits
8:45	<ul style="list-style-type: none"> <li>• Design Features</li> <li>• Glove Leak Testing and Maintenance</li> <li>• Room Background/Environmental Monitoring</li> <li>• Isolator Cleaning</li> </ul>

	Bio-Decontamination
9:30	<ul style="list-style-type: none"> <li>• Overview and Definitions</li> <li>• Regulatory Guidance</li> <li>• Biological Indicator Issues</li> <li>• Cycle Development</li> </ul>

### 10:30 Coffee/Tea Break

	Bio-Decontamination Systems
10:45	<ul style="list-style-type: none"> <li>• Mists/Fogs</li> <li>• Gases/Vapors</li> <li>• Open vs. Closed Loop Systems</li> <li>• Hydrogen Peroxide Safety</li> </ul>

11:15	Biological Indicator Results – Lab Exercise Isolator Validation Group Discussion
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### 12:00 Lunch

13:00	Isolator Leak Testing
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	Piping and Instrumentation Diagrams (P&IDs)
13:30	<ul style="list-style-type: none"> <li>• Sterility Test Isolator P&amp;ID Design Group Exercise</li> <li>• Filling Line Isolator P&amp;ID Design Group Exercise</li> <li>• Review of an actual Filling Line P&amp;ID</li> </ul>

### 14:45 Coffee/Tea Break

15:00	Open Group Discussion and Wrap-Up
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### 16:00 End of Training Course