

## Good Clinical Practice

	Start Time	Session - Presenter	
<b>Day 1</b>	9:00 AM	<b>Opening Orientation to Workshop</b>	
	9:15 AM	<b>Introduction to Good Clinical Practice</b>	<b>Tab 1</b>
	9:35 AM	<b>ICH Guidelines</b>	<b>Tab 2</b>
	9:55 AM	<b>Group Exercise</b>	
	10:55 AM	<b>Break</b>	
	11:15 AM	<b>Protocols</b>	<b>Tab 3</b>
	12:00 PM	<b>Group Exercise</b>	
	12:45 PM	<b>Lunch</b>	
	1:45 PM	<b>Informed Consent Documentation</b>	<b>Tab 4</b>
	2:15 PM	<b>Group Exercise</b>	
	3:15 PM	<b>Informed Consent: The Process</b>	<b>Tab 5</b>
	3:45 PM	<b>Break</b>	
	4:05 PM	<b>Group Exercise</b>	
	4:35 PM	<b>Institutional Review Board/Independent Ethics Committees</b>	<b>Tab 6</b>
	5:05 PM	<b>Questions and Answers</b>	
5:20 PM	<b>Adjourn</b>		
<b>Day 2</b>	9:00 AM	<b>Group Exercise</b>	
	10:00 AM	<b>Source Documents</b>	<b>Tab 7</b>
	10:15 AM	<b>Essential Documents</b>	<b>Tab 8</b>
	10:45 AM	<b>Group Exercise</b>	
	11:15 AM	<b>Break</b>	
	11:35 AM	<b>GCP Requirements: Data Management</b>	<b>Tab 9</b>
	12:05 PM	<b>Group Exercise</b>	
	12:35 PM	<b>Monitoring</b>	<b>Tab 10</b>
	12:50 PM	<b>Lunch</b>	
	1:50 PM	<b>Group Exercise</b>	
	2:10 PM	<b>QA/QC</b>	<b>Tab 11</b>
	2:25 PM	<b>Group Exercise</b>	
	3:25 PM	<b>Investigator's Responsibilities</b>	<b>Tab 12</b>
	3:50 PM	<b>Break</b>	
	4:10 PM	<b>Group Exercise</b>	
4:40 PM	<b>Sponsor's Responsibility</b>	<b>Tab 13</b>	
4:55 PM	<b>Questions and Answers</b>		
5:15 PM	<b>Evaluations</b>		
5:30 PM	<b>Adjourn</b>		