



Validation of Non-product Software: Assuring Compliance and Improving Quality

The Regal Sun Resort
Orlando, FL
January 22, 2009

Thursday, January 22nd

- | | |
|----------------------|--|
| 8:00 – 8:30 | REGISTRATION AND CONTINENTAL BREAKFAST |
| 8:30 – 8:40 | Welcome
<i>Dan Olivier, Certified Compliance Solutions, Inc.</i>
<i>Thomas Maeder, Executive Director, MTLI, AdvaMed</i> |
| 8:40 – 8:55 | Groups Develop Discussion Questions |
| 8:55 – 9:40 | Applying Critical Thinking to the Validation of Software for Regulated Processes Using TIR 36
<i>Dan Olivier, Certified Compliance Solutions, Inc.</i> |
| 9:40 – 9:50 | QUESTIONS |
| 9:50 – 10:10 | BREAK |
| 10:10 – 10:50 | Computer System Compliance Based on ITIL
<i>Veronica Lim, Sr. Computer Systems Governance, Genentech</i> |
| 10:50 – 11:00 | QUESTIONS |
| 11:00 – 11:45 | Workshop – ERP System Validation Case Study |
| 11:45 – 12:00 | QUESTIONS |
| 12:00 – 1:00 | LUNCH |
| 1:00 – 1:40 | Lesson Learned in Deploying Large Scale IT Applications
<i>Regina Rohe, Director of Information Quality and Validation North America, bioMerieux</i> |

1:40 – 1:50	QUESTIONS
1:50 – 2:30	Software Validation Compliance Concerns and Part 11 <i>FDA Speaker TBA</i>
2:40 – 3:20	Workshop – Preparing for FDA Inspection of Computer Systems
3:20 – 4:10	Screening, Analysis, and Prevention of Software Defects <i>Vinnie Chopra, Senior Manager, Process, Siemens Medical Solutions</i>
4:10 – 4:20	QUESTIONS
4:20 – 5:00	Pre-submitted Questions <i>All Speakers</i>
4:20 – 4:30	QUESTIONS
4:30 – 5:00	Pre-Submitted Questions <i>All Speakers</i>
5:00	ADJOURNMENT

Important Notice

The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.