



Enhancing Safety Risk Management Lessons Learned from Industry Leaders

The Regal Sun Resort
Orlando, FL
January 20, 2009

Tuesday, January 20th

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| 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 – 9:00 | Groups Develop Discussion Questions |
| 8:40 – 9:40 | How GE Healthcare Implements Safety Risk Management
<i>Tracy Holevas, Quality Assurance Risk Manager, GE Healthcare</i> |
| 9:40 – 9:50 | QUESTIONS |
| 9:50 – 10:10 | BREAK |
| 10:10 – 11:00 | What Recalls Have Taught FDA About Safety Risk Management
<i>FDA Speaker TBA</i> |
| 11:00 – 11:10 | QUESTIONS |
| 11:10 – 11:50 | Workshop – Safety Risk Management Case Studies |
| 11:50 – 12:00 | QUESTIONS |
| 12:00 – 1:00 | LUNCH |
| 1:00 – 1:40 | Lessons Learned in Reducing Safety Risk: What is Acceptable Risk?
<i>Dan Olivier, President, Certified Compliance Solutions, Inc.</i> |

1:40 – 1:50	QUESTIONS
1:50 – 2:30	Integrating Safety Risk Analysis Techniques <i>Todd Hansell, Manger Systems Design Quality Assurance, Covidien</i>
2:30 – 2:50	BREAK
2:50 – 3:30	Workshop – Selecting Risk Control Measures
3:30 – 3:40	QUESTIONS
3:40 – 4:20	Software Safety Risk Management: Lessons Learned in Risk Mitigation <i>Ron Gerner, Manager Software Quality Assurance, Abbott Laboratories</i>
4:20 – 4:30	QUESTIONS
4:30 – 5:00	Response to Questions on Risk Management <i>All Speakers</i>
5:00	ADJOURNMENT
5:00 – 6:00	RECEPTION
6:00 – 7:00	DINNER

Important Notice

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