



Risk Based Strategies for Design Control and Software Validation

The Regal Sun Resort
Orlando, FL
January 21, 2009

Wednesday, January 21st

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
9:00 – 9:50	Risk Based Approach to Design Validation Using IEC 62304 <i>Dan Olivier, Certified Compliance Solutions, Inc.</i>
9:50 – 10:00	QUESTIONS
10:00 – 10:20	BREAK
10:20 – 11:10	Establishing Design Control Metrics for Global Companies <i>Javad Seyedzadeh, Senior Vice President RA/QA, Gambro</i>
11:10 – 11:20	QUESTIONS
11:20 – 12:00	Workshop 1 – Design and Development and Quality Plans
12:00 – 1:00	LUNCH
1:00 – 1:40	Risk-based Compliance – Negotiating Pathways to Innovation <i>Teresa O’Shea, Director of Strategy Execution, Ethicon Endo-Surgery</i>
1:40 – 1:50	QUESTIONS
1:50 – 2:30	FDA Audit Strategy for Design Control Compliance

FDA Speaker TBA

2:30 – 2:40

QUESTIONS

2:40 – 3:00

BREAK

3:00 – 3:40

Optimizing Design Change Processes to Enhance Customer Satisfaction and Reduce Cost

Brad Blake, Vice President of Instrument Development, Gen-Probe Incorporated

3:40 – 4:20

Reducing Defects Through Effective Requirements Analysis

Robert Kanaley, Quality Systems Advisor, Abbott Vascular

4:20 – 4:30

QUESTIONS

4:30 – 5:00

Pre-Submitted Questions

All Speakers

5:00

ADJOURNMENT

5:00 – 6:00

RECEPTION

Important Notice

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