Cerulean's FDA Part 11 Compliance Today Workshop
_____ 2013

Base Agenda

9:00 – 9:15 am	**Introductions and ground rules**	all
9:15 – 10:30 am	**Current Status of FDA's 21 CFR 11** Part 11 up to now FDA's concerns today FDA's special enforcement Interplay with cGCPs, submissions and PAIs Interplay with cGMPs and QSR Forgotten risks with GLPs Leveraging EU's recent Annex 11 Helpful guidance documents to know Example FDA investigator questions you'll be asked Relevant FDA enforcement examples *Interactive exercises:* • Attendees decide if a Part 11-related statement is actually an FDA requirement or not • Attendees identify Part 11 controls at their company versus current FDA expectations	cerulean
10:30-10:45 am	**Break**	
10:45 – 12:00 pm	**Defensible, Lean Part 11 Compliance** Elements of complying with Part 11 today Systematic view and the 3 P's Containing costs with cross-functionality Technique: Narrowing the scope using data and risk Risk-based Part 11 – a simplified approach Levels of validation by risk Technique: e-Compliance Master Plan Dealing with data and systems at critical suppliers Validating hosted IT systems and cloud computing *Interactive exercises:* • Attendees use case studies to rank systems by risk and identify an appropriate level of validation • Attendees use case studies to identify Part 11 controls to put in place with a critical supplier	cerulean
12:00-1:00 pm	**Lunch**	
1:00 – 2:30 pm	**Maintaining Data Integrity – What FDA Looks For** Practical elements of data integrity (ALCOA in practice)	cerulean

	Managing change Qualifying personnel – from CV to training SOPs and policies to consider Conducting a quality audit of Part 11 controls Technique: Part 11-control-responsibility matrix *Interactive exercises:* • Attendees use a checklist to conduct a self-assessment of their company's Part 11 controls	
2:30 – 2:45 pm	**Break**	
2:45 – 3:45 pm	**Modern Validation Protocol** Can we still use a DQ\IQ\OQ\PQ format Sampling and test cases Technique: Data mapping Documents to generate and records to retain *Interactive exercises:* • Using case studies, attendees identify system risk and select sampling sizes • Using case studies, attendees work in teams to draft a data map for a critical system	cerulean
3:45 – 4:00 pm	**Break**	
4:00 – 4:45 pm	**Applying to Your Company** Talking to senior management about Part 11 Quick steps for success – a sample action plan *Interactive Exercise:* • Attendees draft a prioritized action plan to implement modern, simplified, risk-based Part 11 compliance	cerulean
4:45 – 5:00 pm	**Wrap-Up and Final Thoughts**	all