Cerulean's FDA Part 11 Compliance Today Workshop

Sample One Day 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 special enforcement today Accountability for Part 11 compliance – FDA's view Interplay with cGCPs, submissions and PAIs Interplay with cGMPs and QSR Forgotten risks with GLPs Leveraging EU's revised Annex 11 Helpful guidance documents to know Example FDA investigator questions you'll be asked Recent relevant FDA enforcement examples *Interactive hands-on exercises:* • Attendees review FDA warning letters to identify Part 11 references and hidden expectations • Attendees act as FDA investigators in 4 different case studies	cerulean
10:30-10:45 am	Break	
10:45 – 12:00 pm	Defensible, Lean Part 11 Compliance Elements of complying with Part 11 today 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 Validation Master Plan (eVMP) Dealing with data and systems at critical suppliers Validating hosted IT systems and cloud computing Contractual components to address Part 11 risks *Interactive hands-on 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) Managing change – from preapproved to emergency Conducting a quality audit of Part 11 controls	cerulean

	Qualifying personnel – from CV to training Modern SOPs and policies to consider Technique: Part 11 controls-responsibility matrix *Interactive hands-on exercises:* • Attendees review a sample SOP on determining Part 11 applicability against 3 case studies • Attendees match a sample policy on Part 11-relevent electronic security to their company's policy (*if available*)	
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 Example FDA-"approved" test cases for DQ\IQ\OQ\PQ Technique: Data mapping Documents to generate and records to retain Elements to expect in a supplier-provided validation protocol *Interactive hands-on exercise:* • Attendees work in teams to draft a data map for a critical system at their company	cerulean
3:45 – 4:00 pm	Break	
4:00 – 4:50 pm	Applying to Your Company Talking to senior management about Part 11 Quick steps for success – a sample action plan *Interactive hands-on exercise:* • Attendees draft a prioritized action plan to implement modern, simplified, risk-based Part 11 compliance	cerulean
4:50 – 5:00 pm	Wrap-Up and Final Thoughts	all

Cerulean's private in-house corporate workshops are designed to be tailored to your needs. After signing a confidentiality agreement, we work with you to tailor the training – and the tangible deliverables – to you and your organization. You get sample worksheets, checklists, and more to help you rapidly and easily implement the best practices suited to you.

Review some of the hundreds of previous executive testimonials online at our website. And then contact Cerulean today.