

Cerulean's Modern FDA Supplier Management Workshop

Sample One Day Agenda

9:00 – 9:15 am	Introductions and ground rules	all
9:15 – 10:30 am	<p>Current FDA Supplier Management Requirements Industry – and FDA – challenges in the 21st century Accountability for supplier management compliance – FDA's view GMP and QSR supplier management requirements GCP and GLP supplier management requirements FDASIA's impact and Good Distribution Practices (GDP) Leveraging EU's revised cGMP chapters Helpful harmonized guidance documents to know Example FDA investigator questions you'll be asked Recent relevant FDA enforcement examples</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> Attendees review FDA warning letters to identify hidden supplier management expectations Attendees act as FDA investigators in 3 different case studies 	cerulean
10:30-10:45 am	Break	
10:45 – 12:00 pm	<p>Modern, Lean Supplier Management and Compliance Six stages – from initial evaluation to contract renewal Risk-based supplier management – a simplified approach Levels of supplier control by risk Technique: AVL, CVL and DVL Modern SOPs and policies to consider Records to retain Technique: Vendor dossiers Risks to control with suppliers and recalls Risks to control with suppliers who create/handle your data Managing virtual companies as suppliers Quality agreements – do's and don'ts, and lessons learned Technique: Supplier-responsibility matrix</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> Attendees work in teams to draft a sample supplier-responsibility matrix based on case studies Attendees use a checklist to identify records of supplier oversight their company maintains today v. needs to obtain 	cerulean
12:00-1:00 pm	Lunch	
1:00 – 2:30 pm	<p>Questionnaires, Auditing and Supplier Qualification Practical elements and costs of auditing</p>	cerulean

	<p>Using a basic or initial questionnaire</p> <p>Remote v. onsite auditing</p> <p>Technique: Five threshold questions</p> <p>Auditing suppliers with quality systems</p> <p>Auditing suppliers without a quality system</p> <p>Auditing a virtual company</p> <p>Technique: Rapid red-flag reviews</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> Attendees use 4 case studies determine if a supplier needs an onsite audit, a remote audit, or no audit (and why) Attendees work in teams to conduct a rapid red-flag review of current suppliers (<i>if available</i>) 	
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	<p>Monitoring for Compliance and Liability</p> <p>Ongoing monitoring plans</p> <p>Technique: Supplier compliance certification letter</p> <p>Management review of supplier performance in the QSMR</p> <p>Re-evaluating a supplier at contract's end</p> <p>Technique: Preparing a supplier for a regulatory health inspection</p> <p><i>Interactive hands-on exercise:</i></p> <ul style="list-style-type: none"> Attendees work in teams using a case study to draft a sample monitoring plan 	cerulean
3:45 – 4:00 pm	Break	
4:00 – 4:50 pm	<p>Applying to Your Company</p> <p>Quick steps for success – a sample action plan</p> <p><i>Interactive hands-on exercise:</i></p> <ul style="list-style-type: none"> Attendees draft a prioritized action plan to implement modern, simplified, risk-based supplier management 	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.