

Cerulean's FDA Supplier Management Today Workshop 2013

Base Agenda

9:00 – 9:15 am	Introductions and ground rules	all
9:15 – 10:30 am	<p>Current FDA Supplier Management Requirements</p> <p>Current industry challenges</p> <p>FDA's cGMP, cGCP, cGLP & QSR supplier requirements</p> <p>Recent FDASIA 2012 requirements</p> <p>Leveraging EMA's 2013 cGMP chapters</p> <p>Helpful guidance documents to use</p> <p>Example FDA investigator questions you'll be asked</p> <p>Relevant enforcement examples</p> <p><i>Interactive exercises:</i></p> <ul style="list-style-type: none"> Attendees decide if a supplier management statement is an FDA requirement or a best practice Attendees identify controls at their company versus current FDA expectations 	cerulean
10:30-10:45 am	Break	
10:45 – 12:00 pm	<p>Modern Supplier Management Program</p> <p>Six phases</p> <p>Technique: AVLs, CVLs, and DVLs</p> <p>Technique: Supplier dossiers</p> <p>Risk-based supplier management – a simplified approach</p> <p>Dealing with virtual companies as suppliers</p> <p><i>Interactive exercises:</i></p> <ul style="list-style-type: none"> Attendees use case studies to rank suppliers by risk Attendees work in teams to draft a sample supplier responsibility table Attendees use a checklist to identify what records of oversight they actually have today vs. need to obtain 	cerulean
12:00-1:00 pm	Lunch	
1:00 – 3:30 pm	<p>Questionnaires, Auditing, and Monitoring</p> <p>Basic questionnaire</p> <p>Remote v. onsite auditing</p> <p>Technique: Five threshold questions</p> <p>Periodic re-evaluations</p> <p>Technique: Preparing a supplier for FDA</p> <p><i>Interactive exercises:</i></p> <ul style="list-style-type: none"> Using case studies, attendees decide which suppliers need to be audited (and why) 	cerulean

	<ul style="list-style-type: none"> Attendees work in teams to draft their modern supplier management workflow 	
3:30 – 3:45 pm	Break	
3:45 – 4:45 pm	<p>Applying to Your Company</p> <p>Talking to senior management about supplier oversight</p> <p>Quick steps for success</p> <p><i>Interactive Exercise:</i></p> <ul style="list-style-type: none"> Attendees draft a prioritized action plan to implement modern, simplified, risk-based supplier management 	cerulean
4:45 – 5:00 pm	Wrap-Up and Final Thoughts	all

Sample agenda only