

## Cerulean's Defensible FDA Recordkeeping Workshop

### Sample One Day Agenda

\*Note: many firms opt to divide the day into a half-day session for management and a half-day session for staff; this agenda assumes a full day for all personnel – half-day agendas are very customized

9:00 – 9:15 am	Introductions and ground rules	all
9:15 – 10:30 am	<p><b>FDA Records &amp; Documents – What's Really Required</b></p> <p>Key provisions in the laws and regulations  Hidden requirements in guidances and warning letters  <b>Who's accountable vs. responsible – FDA's view</b> of liability  Specific records that FDA investigators look for during inspections  Technique: Inspection-records matrix  Example FDA investigator questions <b>you'll be asked</b>  Recent relevant FDA enforcement examples</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> <li>Attendees determine the hidden regulatory recordkeeping requirements in various FDA statements and guidances</li> <li>Attendees act as FDA investigators in 3 different case studies</li> </ul>	cerulean
10:30-10:45 am	Break	
10:45 – 12:00 pm	<p><b>FDA's Hidden Agenda for Record &amp; Data Integrity</b></p> <p>Digital v. paper records  Example record integrity problems FDA looks for  How clinical record integrity triggers pre-approval inspections</p> <p><b>Understanding FDA's A.L.C.O.A acronym</b>  Rapid review of Part 11 today for non-IT personnel</p> <p><b>FDA's special enforcement of data integrity</b>  Long-term archival – digital records as a 100 year experiment</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> <li>Attendees review FDA warning letters to identify examples of FDA data integrity citations</li> <li>Attendees work in teams to draft a good data integrity policy for their company</li> </ul>	cerulean
12:00-1:00 pm	Lunch	
1:00 – 2:00 pm	<p><b>Your Records and Emails – Hidden Risks and Dangers</b></p> <p>Meeting minutes – a step-by-step guide to incrimination  Emails – the informal route to liability and embarrassment  Technique: Email etiquette guide  Technique: Periodic management record reviews</p> <p><i>Interactive hands-on exercises:</i></p> <ul style="list-style-type: none"> <li>Attendees review a sample internal memo to identify potential risks if found by FDA investigators and product liability lawyers</li> </ul>	cerulean

2:00 – 2:15 pm	Break	
2:15 – 3:45 pm	<p>What to Keep, What to Toss &amp; Controls along the Way</p> <p>Good recordkeeping practices for quality systems</p> <p>Recordkeeping SOPs and policies to consider</p> <p>Technique: Records retention schedule</p> <p><b>Understanding what “minimum” retention time really means</b></p> <p>Controlled destruction of old documents – how to prove compliance</p> <p>Conducting a quality audit of recordkeeping controls</p> <p>FDA recordkeeping questions to ask your critical suppliers</p> <p><i>Interactive hands-on exercise:</i></p> <ul style="list-style-type: none"> <li>Attendees review a sample SOP to find the proof an FDA investigator would expect to see if the SOP was followed</li> <li>Attendees work in teams to prepare an FDA records retention schedule</li> </ul>	cerulean
3:45 – 4:00 pm	Break	
4:00 – 4:50 pm	<p>Applying to Your Company</p> <p>Talking to senior management about compliant FDA recordkeeping</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"> <li>Attendees draft a prioritized action plan to implement defensible, good FDA recordkeeping practices</li> </ul>	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.