

**Detailed Agenda: Bulletproof Yourself Against FDA Enforcement**

**1. FDA Directions and Priorities through 2010**

- FDA’s new leadership
- Warning letter trends
- Areas of increased focus
- Six top inspection triggers
- Most common inspection findings – domestic versus international
- Top 10 areas of concern (and high priority review by inspectors)
- Hidden risk areas in most companies
- Dealing with the 6 new FDA enforcement policies
- 2010 enforcement trends review checklist

**2. Identifying and Mitigating Your Specific Challenges**

- Integrating risk management – 3 aspects in your firm that FDA inspectors look for
- Maintaining proof of compliance – 4 techniques to keep you in the clear
- CAPAs and non-conformance processes – 4 components you must have to avoid a warning letter
- Quality systems management reviews – what the inspector wants to see
- FDA’s new cross-functional, system compliance expectations – what to do to get the best benefit
- Supply chain / purchasing controls – most common mistakes FDA sees
- Supplier management and qualification – how to handle long-standing supplier problems and minimize your risk of a 483 citation

**3. Preparing for the Inevitable: A SmarterCompliance Strategy for Inspections**

- Preparing – 4 techniques to minimize disruption, lower stress, and increase success rate
- During – 3 techniques to increase your chances of a successful inspection
- Closeout meetings – 10 things the FDA does NOT want to hear
- Responding to 483 observations – 4 techniques to maximize your time, efforts and reduce the chances of a warning letter or other enforcement action
- Responding to 483 observations – 5 steps to encourage a positive “close-out” letter from FDA
- Plus, the 3 secrets to passing an audit/inspection every time (or at least for the past 16 years)

**4. Seven specific steps to take immediately following this webinar**

**5. Checklists and loads of reference material to help you quickly and efficiently implement this advice**

*Excerpt from pre-inspection checklist (just one of 4 checklists) you get in the reference material and toolkit with this seminar*

<b>Instructions</b>			
Answer each question as you go through the process of preparing your quality system a program for inspection or audit. As appropriate, use the comments section to document skipping sections or replacing items (e.g., if you’ve never been inspected before, substitute reports” for “previous inspection reports”).			
STATUS	TASKS UPON NOTIFICATION	ASSIGNED TO	
	Review letter of intent for highlighted issues		
	Review previous inspection reports		
	Review FDA QSIT manual		
	Review FDA guidance for inspecting device manufacturers (as appropriate)		
	Review GHTF “Guidelines for Regulatory Auditing of Quality Management Systems”		
	Prioritize 5-10 likely areas of inspection		
	Assemble “audit package” and send to inspector(s)		