

FDA Pre-Inspection Checklist

Use this checklist to help you prepare for an FDA inspection.

In addition to helping executives with inspection recovery and audit responses, Cerulean provides a more formal, diagnostic and mock FDA audit and gap analysis service for executives, business owners and due diligence teams. Clients receive a formal analysis and set of prioritized recommendations including (where information exists) estimated costs and timelines. If you'd like more information on this private advisory service or other independent compliance expert services, contact us through our website at www.ceruleanllc.com.

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Instructions

Answer each question as you go through the process of preparing your quality system and compliance program for an inspection or audit. As appropriate, use the comments section to document logic behind skipping sections or replacing items (e.g., if you've never been inspected before, substitute "internal audit reports" for "previous inspection reports").

STATUS	TASKS UPON INITIAL NOTIFICATION	ASSIGNED TO	COMMENTS
	Review letter of intent for highlighted issues		
	Review previous inspection reports		
	Review FDA QSIT manual		
	Review FDA guidance for inspecting manufacturers (as appropriate)		
	Review GHTF/IMDRF "Guidelines for Regulatory Auditing of Quality Management Systems" guides		
	Prioritize 5-10 likely areas of inspection		
	Update the Site Inspection Proof Binder as necessary		
	Notify senior management and your Site Inspection Response Team (including backups)		
	Schedule a rapid review and inspection prep session		

STATUS	TASKS PRIOR TO INVESTIGATOR ARRIVAL	ASSIGNED TO	COMMENTS
	Assemble members of the Site Inspection Response Team for the rapid review session		
	Each member identifies interview short list in their respective departments <ul style="list-style-type: none"> • 1 manager • 1-2 staff personnel 		
	Quickly review regulatory inspection handling SOP		
	Conduct a rapid review and inspection expectations overview <ul style="list-style-type: none"> • Review 5-10 likely inspection targets • Discuss process and timelines • Discuss any concerns 		
	Identify investigator tag-along note-taker(s)		
	Schedule debriefings with Site Inspection Response Team members (and backups)		
	Set up meeting room for FDA investigators (and another as your "war room")		