

Inspection Management & Closeout Checklist

Use this checklist to help you manage the inspection or audit.

In addition to helping executives succeed with the critical processes that prove effective compliance and reduce risk and cost, Cerulean provides a more formal, one to two-day diagnostic and mock FDA audit 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. Clients can then use Cerulean's report to close these gaps themselves or draw upon the report to issue a request for proposal (RFP) to bring in outside help. If you'd like more information on this private advisory service or other independent compliance expert services, please contact our Managing Director at +1.757.645.2864 or send an email to info@ceruleanllc.com.

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Instructions

Answer each question as you go through the quality system and compliance program inspection or audit. As appropriate, use the comments section to document logic behind skipping sections or replacing items (e.g., if the inspectors refuse to meet with you to review their findings, simply note that along with dates of your request and any reasons the inspectors provide for their refusal).

STATUS	TASKS DURING INSPECTION	ASSIGNED TO	COMMENTS
	Note-takers follow inspectors and take own notes		
	Debrief any interviewed personnel		
	Summarize notes at end of each day <ul style="list-style-type: none"> • Document records requested by inspectors • Document records provided to inspectors 		
	Conduct weekly meeting with inspector(s) <ul style="list-style-type: none"> • Review findings to date • Review note summaries • Raise questions • Review immediate fixes and longer-term gap closure plans (see below) 		
	Conduct weekly meeting with inspection prep team <ul style="list-style-type: none"> • Review findings to date • Review note summaries • Review interview debriefings • Review discussions with inspector(s) • Identify quick “wins” (e.g., fixes can implement immediately) • Identify longer-term gaps to close and initiate draft plans 		
	Verify quick “win” completions		
	Demonstrate completions to inspector(s)		
	Review draft plans to fix longer-term gaps with inspector(s)		
	Conduct inspection closeout review meeting with inspector(s) <ul style="list-style-type: none"> • Identify inconsistencies (if any) based on earlier discussions • Clarify their perception of gaps • Ask for their suggestions in terms of priorities (and possible fixes) 		
	Conduct inspection prep team closeout meeting <ul style="list-style-type: none"> • Review closeout meeting with inspector(s) • Clarify accountabilities for plans and deliverable dates 		
	Other:		