

FDA Inspection Handling Checklist

Use this checklist to help you effectively manage and handle an FDA inspection.

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Instructions

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

STATUS	TASKS DURING INSPECTION	ASSIGNED TO	COMMENTS
	Note-takers to follow investigators 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 investigators Document records provided 		
	Conduct weekly meeting with investigators <ul style="list-style-type: none"> Review observations & concerns to date Compare to note-taker summaries Raise questions Review immediate fixes and longer-term gap closure plans (see below) 		
	Conduct debrief meeting with inspection handling team <ul style="list-style-type: none"> Review observations to date Review note-taker summaries Review interview debriefings Review discussions with investigators 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 investigators		
	Review draft plans to fix longer-term gaps with investigator(s)		
	Conduct inspection closeout meeting with investigators <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 handling team closeout meeting <ul style="list-style-type: none"> Review closeout meeting with investigators Clarify accountabilities for plans and deliverable dates 		
	Other:		