

Post-Inspection Response Checklist

Use this checklist to help you rapidly respond to any inspection or audit.

In addition to helping firms with inspection recovery and audit responses, Cerulean provides a more formal, diagnostic and mock FDA audit and compliance gap analysis service. If you'd like information on these confidential services or other independent lean compliance expert services, visit Cerulean's website at www.ceruleanllc.com.

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Instructions

Answer each question as you go through your response to any quality system and compliance program inspection or audit. As appropriate, use the comments section to document your logic behind skipping any steps or activities.

STATUS	15-DAY TASK LIST	ASSIGNED TO	COMMENTS
	Review Form 483 or other summary inspection documents received from investigators		
	Identify issues requiring a response (typically the “inspectional observations”)		
	Update your inspection observation–closure matrix		
	Meet with the Site Inspection Response Team <ul style="list-style-type: none"> • Review inspection summary documents • Review observation-response matrix • Review relevant internal inspection summaries (from note-takers) • Verify everyone understands timelines 		
	Assign accountabilities for response components <ul style="list-style-type: none"> • Timelines and progress to date • Item by item resolutions • Verification of resolutions (or steps you will take to verify if long-term resolution needed) • Additional steps supportive or complementary to each resolution (to go beyond just the specific inspectional observation) 		
	Assemble drafted response and verifications <ul style="list-style-type: none"> • Has each observation been addressed? • Have you done just the minimum or have you taken additional steps? • Have you addressed systemic issues? • Have you addressed potential issues at other sites or with other products? • What proof can you enclose (such as revised SOPs, timelines, validation protocols, etc.)? • Is all proof dated and signed as appropriate? • Is there an overall remediation timeline? • Did you include a list of appendixes or attachments? • Depending on length and format, do you need search or indexing capabilities? 		
	Review draft response and potential verification records with legal counsel		
	Finalize response and verification records, then submit both in paper and electronically, with tracking (retain a complete copy for yourself)		