IV A 2	346	Please focus on individual system owners here rather than the Quality System.	The focus would be better placed on individual system owners here rather than the Quality System. The management team should own the Quality System not a single senior manager. There may need to be clarification that a Quality System is made up of a number of quality systems (deviations, complaints, training, etc.).
IV A 3	358	What is stated in this document as being included in a quality system is really more what should be included in the SOP. A quality system should contain elements discussed before: defined inputs, outs, controls, value added steps, metrics. The addition of a flow chart would be beneficial.	
IV A. 3	367	Change word from "directives" to "management"	It is unclear as to which directives FDA is referring to. Management makes better sense. If this is incorrect, please clarify.
IVA4	391	Please clarify that objectives should be quality objectives for the site and should be placed within the quality plan.	It is preferable not to review personal objectives as some elements could be outside of the agency's inspectional authority.
IV A 4	395	Please add quality planning can be integrated with the overall plant planning process. There must be sufficient time devoted to the Quality aspects or there should be a separate process integrated as an input to the plant planning process.	This achieves the holistic approach to quality discussed in the introductory sections.
IV A .4	395	This establishes quality planning as a formal documented system. It needs to be clear which elements of quality planning can be subjected to FDA inspections and which are considered internal audit documents.	For a quality planning system to be effective, parts will be outside of inspectional jurisdiction.
	395	Change "identify resources" to "allocate resources"	In order to have an effective quality system, resources must be allocated not just identified
IV A 5	404	Please add in the phrase in italics: ..conduct reviews of the "performance of the quality system.."	It should be made clear that the performance in terms of data from metric should be considered rather than just a review of the design.
	405	Please add the phrase in italics: typically includes both an assessment of the product "and process" as well as the customer needs.	This acknowledges that quality systems should address the process not just the product meeting specifications
IVA5	415	It is unclear how this will be measured. This bullet point should be deleted unless there can be guidance as to clear measurement techniques.	
	417	Please add in a review of quality system indicators such as complaints, deviations, changes, and Annual Product Reviews	A comprehensive review of these indicators assure continuous improvement and communication of the systemic issues to senior management
	419	Please add the phrase in italics: Outside of scheduled reviews, the "key indicators of" the quality systems are typically included as a standing agenda item in general management meetings.	A review of specific items as part of the quality system is imperative for communication and specific areas of improvement